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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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## I

*(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)*

## REGULATIONS

**REGULATION (EC) No 1221/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 25 November 2009****on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(3)</sup>,

Whereas:

- (1) Article 2 of the Treaty provides that the Community is to have among its tasks the promotion of sustainable growth throughout the Community.
- (2) Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme <sup>(4)</sup> identifies the improvement of collaboration and partnership with enterprises as a strategic approach to meeting environmental objectives. Voluntary commitments are an essential part thereof. Encouraging wider participation in the Community's eco-management and audit scheme (EMAS) and the

development of initiatives to encourage organisations to publish rigorous and independently verified environmental or sustainable development performance reports is regarded as necessary in this context.

- (3) The Commission Communication of 30 April 2007 on the Mid-term review of the Sixth Community Environment Action Programme recognises that there is a need to improve the functioning of the voluntary instruments that have been designed for industry and that those instruments have a great potential but have not been fully developed. It calls upon the Commission to revise the instruments in order to promote their participation and reduce the administrative burden in their management.

- (4) The Commission Communication of 16 July 2008 on the Sustainable Consumption and Production and Sustainable Industrial Policy Action Plan recognises that EMAS helps organisations to optimise their production processes, reducing environmental impacts and making more effective use of resources.

- (5) For the purpose of promoting a coherent approach between the legislative instruments developed at Community level in the field of environmental protection, the Commission and the Member States should consider how registration under EMAS may be taken into account in the development of legislation or used as a tool in the enforcement of legislation. They should also, in order to raise the appeal of EMAS for organisations, take account of EMAS in their procurement policies and, where appropriate, refer to EMAS or equivalent environmental management systems as contract performance conditions for works and service.

<sup>(1)</sup> Opinion of 25 February 2009 (not yet published in the Official Journal).

<sup>(2)</sup> OJ C 120, 28.5.2009, p. 56.

<sup>(3)</sup> Opinion of the European Parliament of 2 April 2009 (not yet published in the Official Journal) and Council Decision of 26 October 2009.

<sup>(4)</sup> OJ L 242, 10.9.2002, p. 1.

- (6) Article 15 of Regulation (EC) No 761/2001 of the European Parliament and of the Council of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) <sup>(1)</sup> provides that the Commission is to review EMAS in the light of the experience gained during its operation and propose appropriate amendments to the European Parliament and the Council.
- (7) Application of environmental management schemes, including EMAS as set out in Regulation (EC) No 761/2001, demonstrated their effectiveness in promoting improvements of the environmental performance of organisations. There is, however, a need to increase the number of organisations participating in the scheme in order to achieve a better overall impact of environmental improvements. To this effect, the experience gathered from the implementation of that Regulation should be used to enhance the ability of EMAS to bring about an improvement in the overall environmental performance of organisations.
- (8) Organisations should be encouraged to participate in EMAS on a voluntary basis and may gain added value in terms of regulatory control, cost savings and public image provided that they are able to demonstrate an improvement of their environmental performance.
- (9) EMAS should be made available to all organisations, in and outside the Community, whose activities have an environmental impact. EMAS should provide a means for those organisations to manage that impact and to improve their overall environmental performance.
- (10) Organisations, in particular small organisations, should be encouraged to participate in EMAS. Their participation should be promoted by facilitating access to information, to existing support funds and to public institutions and by establishing or promoting technical assistance measures.
- (11) Organisations which implement other environmental management systems and want to move to EMAS should be able to do so as easily as possible. Links with other environmental management schemes should be considered.
- (12) Organisations with sites located in one or more Member States should be able to register all or a number of those sites under one single registration.
- (13) The mechanism for establishing an organisation's compliance with all applicable legal requirements relating to the environment should be strengthened in order to enhance the credibility of EMAS and, in particular, to enable Member States to reduce the administrative burden of registered organisations by way of deregulation or regulatory relief.
- (14) The process of implementation of EMAS should include involvement of employees and workers of the organisation as this increases job satisfaction, as well as knowledge of environmental issues which can be replicated in and outside the work environment.
- (15) The EMAS logo should be an appealing communication and marketing tool for organisations, which raises the awareness of buyers and other stakeholders to EMAS. Rules for the use of the EMAS logo should be simplified by the use of one single logo and existing restrictions should be removed save for those relating to the product and packaging. There should be no confusion with environmental product labels.
- (16) Costs and fees for registration under EMAS should be reasonable and proportionate to the size of the organisation and the work to be done by the Competent Bodies. Without prejudice to the rules of the Treaty on State aid, exemptions or reductions of fees should be considered for small organisations.
- (17) Organisations should produce and make publicly available periodic environmental statements providing the public and other interested parties with information on their compliance with applicable legal requirements relating to the environment and their environmental performance.
- (18) In order to ensure relevance and comparability of the information, reporting on the organisations' environmental performance should be on the basis of generic and sector-specific performance indicators focusing on key environmental areas at the process and product level using appropriate benchmarks and scales. This should help organisations compare their environmental performance both over different reporting periods and with the environmental performance of other organisations.

<sup>(1)</sup> OJ L 114, 24.4.2001, p. 1.

- (19) Reference documents including best environmental management practice and environmental performance indicators for specific sectors should be developed through information exchange and collaboration between Member States. Those documents should help organisations better focus on the most important environmental aspects in a given sector.
- (20) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(1)</sup> organises accreditation at the national and European levels and sets the overall framework for accreditation. This Regulation should complement those rules in so far as necessary, while taking into account the specific features of EMAS such as the need to ensure a high level of credibility towards stakeholders, especially Member States and, where appropriate, should set more specific rules. The EMAS provisions should ensure and steadily improve the competence of environmental verifiers by providing for an independent and neutral accreditation or licensing system, training and an appropriate supervision of their activities and thus guarantee the transparency and credibility of organisations participating in EMAS.
- (21) When a Member State decides not to use accreditation for EMAS, Article 5(2) of Regulation (EC) No 765/2008 should apply.
- (22) Promotion and support activities should be undertaken by both the Member States and the Commission.
- (23) Without prejudice to the rules of the Treaty on State aid, incentives should be given by Member States to registered organisations such as access to funding or tax incentives in the framework of schemes supporting environmental performance of industry, provided that organisations are able to demonstrate an improvement of their environmental performance.
- (24) Member States and the Commission should develop and implement specific measures aimed at greater participation in EMAS by organisations, in particular small organisations.
- (25) With the aim of ensuring a harmonised application of this Regulation, the Commission should produce sectoral reference documents in the area covered by this Regulation following a priority programme.
- (26) This Regulation should be revised, if appropriate, within five years of its entry into force in the light of experience gained.
- (27) This Regulation replaces Regulation (EC) No 761/2001 which should therefore be repealed.
- (28) Given that useful elements of Commission Recommendation 2001/680/EC of 7 September 2001 on guidance for the implementation of Regulation (EC) No 761/2001 of the European Parliament and of the Council allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) <sup>(2)</sup> and of Commission Recommendation 2003/532/EC of 10 July 2003 on guidance for the implementation of Regulation (EC) No 761/2001 of the European Parliament and of the Council allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) concerning the selection and use of environmental performance indicators <sup>(3)</sup> are included in this Regulation, those acts should no longer be used as they are superseded by this Regulation.
- (29) Since the objectives of this Regulation, namely to create a single credible scheme and avoid the establishment of different national schemes, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (30) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(4)</sup>.
- (31) In particular the Commission should be empowered to establish procedures for the peer evaluation of Competent Bodies, to develop sectoral reference documents, to recognise existing environmental management systems, or parts thereof, as complying with corresponding requirements of this Regulation and to amend Annexes I to VIII. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (32) Since a period of time is required to ensure that the framework for the proper functioning of this Regulation is in place, Member States should have a period of 12 months following the date of entry into force of this Regulation to modify the procedures followed by Accreditation Bodies and Competent Bodies under the corresponding provisions of this Regulation. Within that 12-month period, Accreditation Bodies and Competent Bodies should be entitled to continue to apply the procedures established under Regulation (EC) No 761/2001,

HAVE ADOPTED THIS REGULATION:

<sup>(1)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(2)</sup> OJ L 247, 17.9.2001, p. 1.

<sup>(3)</sup> OJ L 184, 23.7.2003, p. 19.

<sup>(4)</sup> OJ L 184, 17.7.1999, p. 23.

## CHAPTER I

## GENERAL PROVISIONS

## Article 1

**Objective**

A Community eco-management and audit scheme, hereinafter referred to as 'EMAS', is hereby established, allowing voluntary participation by organisations located inside or outside the Community.

The objective of EMAS, as an important instrument of the Sustainable Consumption and Production and Sustainable Industrial Policy Action Plan, is to promote continuous improvements in the environmental performance of organisations by the establishment and implementation of environmental management systems by organisations, the systematic, objective and periodic evaluation of the performance of such systems, the provision of information on environmental performance, an open dialogue with the public and other interested parties and the active involvement of employees in organisations and appropriate training.

## Article 2

**Definitions**

For the purposes of this Regulation the following definitions shall apply:

1. 'environmental policy' means the overall intentions and direction of an organisation relating to its environmental performance as formally expressed by top management including compliance with all applicable legal requirements relating to the environment and also a commitment to continuous improvement of environmental performance. It provides a framework for action and for the setting of environmental objectives and targets;
2. 'environmental performance' means the measurable results of an organisation's management of its environmental aspects;
3. 'legal compliance' means full implementation of applicable legal requirements, including permit conditions, relating to the environment;
4. 'environmental aspect' means an element of an organisation's activities, products or services that has or can have an impact on the environment;
5. 'significant environmental aspect' means an environmental aspect that has or can have a significant environmental impact;
6. 'direct environmental aspect' means an environmental aspect associated with activities, products and services of the organisation itself over which it has direct management control;
7. 'indirect environmental aspect' means an environmental aspect which can result from the interaction of an organisation with third parties and which can to a reasonable degree be influenced by an organisation;
8. 'environmental impact' means any change to the environment, whether adverse or beneficial, wholly or partially resulting from an organisation's activities, products or services;
9. 'environmental review' means an initial comprehensive analysis of environmental aspects, environmental impacts and environmental performance related to an organisation's activities, products and services;
10. 'environmental programme' means a description of the measures, responsibilities and means taken or envisaged to achieve environmental objectives and targets and the deadlines for achieving the environmental objectives and targets;
11. 'environmental objective' means an overall environmental goal, arising from the environmental policy, that an organisation sets itself to achieve, and which is quantified where practicable;
12. 'environmental target' means a detailed performance requirement, arising from the environmental objectives, applicable to an organisation or parts thereof, and that needs to be set and met in order to achieve those objectives;
13. 'environmental management system' means the part of the overall management system that includes the organisational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing and maintaining the environmental policy and managing the environmental aspects;
14. 'best environmental management practice' means the most effective way to implement the environmental management system by organisations in a relevant sector and that can result in best environmental performance under given economic and technical conditions;
15. 'substantial change' means any change in an organisation's operation, structure, administration, processes, activities, products or services that has or can have a significant impact on an organisation's environmental management system, the environment or human health;
16. 'internal environmental audit' means a systematic, documented, periodic and objective evaluation of the environmental performance of an organisation, management system and processes designed to protect the environment;
17. 'auditor' means an individual or group of individuals, belonging to an organisation itself or a natural or legal person external to that organisation, acting on behalf of that organisation, carrying out an assessment of, in particular, the environmental management system in place and determining conformity with the organisation's environmental policy and programme, including compliance with the applicable legal requirements relating to the environment;



18. 'environmental statement' means the comprehensive information to the public and other interested parties regarding an organisation's:
- (a) structure and activities;
  - (b) environmental policy and environmental management system;
  - (c) environmental aspects and impacts;
  - (d) environmental programme, objectives and targets;
  - (e) environmental performance and compliance with applicable legal obligations relating to the environment as set out in Annex IV;
19. 'updated environmental statement' means the comprehensive information to the public and other interested parties containing updates of the last validated environmental statement, only with regard to an organisation's environmental performance and compliance with applicable legal obligations relating to the environment as set out in Annex IV;
20. 'environmental verifier' means:
- (a) a conformity assessment body as defined in Regulation (EC) No 765/2008 or any association or group of such bodies, which has obtained accreditation in accordance with this Regulation; or
  - (b) any natural or legal person, or any association or group of such persons, which has obtained a licence to carry out verification and validation in accordance with this Regulation;
21. 'organisation' means a company, corporation, firm, enterprise, authority or institution, located inside or outside the Community, or part or combination thereof, whether incorporated or not, public or private, which has its own functions and administration;
22. 'site' means a distinct geographic location under the management control of an organisation covering activities, products and services, including all infrastructure, equipment and materials; a site is the smallest entity to be considered for registration;
23. 'cluster' means a group of independent organisations related to each other by geographical proximity or business activities jointly implementing the environmental management system;
24. 'verification' means the conformity assessment process carried out by an environmental verifier to demonstrate whether an organisation's environmental review, environmental policy, environmental management system and internal environmental audit and its implementation fulfils the requirements of this Regulation;
25. 'validation' means the confirmation by the environmental verifier who carried out the verification, that the information and data in an organisation's environmental statement and updated environmental statement are reliable, credible and correct and meet the requirements of this Regulation;
26. 'enforcement authorities' means the relevant competent authorities as identified by the Member States to detect, prevent and investigate breaches of applicable legal requirements relating to the environment and, where required, take enforcement action;
27. 'environmental performance indicator' means a specific expression that allows measurement of an organisation's environmental performance;
28. 'small organisations' means:
- (a) micro, small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises <sup>(1)</sup>; or
  - (b) local authorities governing less than 10 000 inhabitants or other public authorities employing fewer than 250 persons and having an annual budget not exceeding EUR 50 million, or an annual balance sheet not exceeding EUR 43 million, including all of the following:
    - (i) government or other public administrations, or public advisory bodies at national, regional or local level;
    - (ii) natural or legal persons performing public administrative functions under national law, including specific duties, activities or services in relation to the environment; and
    - (iii) natural or legal persons having public responsibilities or functions, or providing public services, relating to the environment under the control of a body or person referred to in point (b);
29. 'corporate registration' means a single registration of all or some sites of an organisation with sites located in one or more Member States or third countries;
30. 'Accreditation Body' means a national accreditation body appointed pursuant to Article 4 of Regulation (EC) No 765/2008 which is responsible for the accreditation and supervision of environmental verifiers;

<sup>(1)</sup> OJ L 124, 20.5.2003, p. 36.

31. 'Licensing Body' means a body appointed in accordance with Article 5(2) of Regulation (EC) No 765/2008 which is responsible for issuing licences to, and for supervising, environmental verifiers.

## CHAPTER II

### REGISTRATION OF ORGANISATIONS

#### Article 3

##### Determination of the Competent Body

1. Applications for registration from organisations in a Member State shall be made to a Competent Body in that Member State.
2. An organisation with sites located in one or more Member States or third countries may apply for one single corporate registration of all or some of those sites.

Applications for a single corporate registration shall be made to a Competent Body of the Member State where the organisation's headquarters or management centre designated for the purpose of this paragraph is located.

3. Applications for registration from organisations outside the Community, including corporate registration consisting only of sites located outside the Community, shall be made to any Competent Body in those Member States that provide for the registration of organisations from outside the Community in accordance with the second subparagraph of Article 11(1).

Those organisations shall ensure that the environmental verifier which will carry out the verification and validate the environmental management system of the organisation is accredited or licensed in the Member State where the organisation applies for registration.

#### Article 4

##### Preparation for registration

1. Organisations wishing to be registered for the first time shall:
  - (a) carry out an environmental review of all environmental aspects of the organisation in accordance with the requirements set out in Annex I and in point A.3.1 of Annex II;
  - (b) in the light of the results of the environmental review, develop and implement an environmental management system covering all the requirements referred to in Annex II, and, where available, taking into account the best environmental management practice for the relevant sector referred to in Article 46(1)(a);
  - (c) carry out an internal audit in accordance with the requirements set out in point A.5.5 of Annex II and Annex III;
  - (d) prepare an environmental statement, in accordance with Annex IV. Where sectoral reference documents as referred to in Article 46 are available for the specific sector, the assessment of the organisation's environmental performance shall take into account the relevant document.

2. Organisations may use the assistance referred to in Article 32 that is available in the Member State where the organisation applies for registration.

3. Organisations which have a certified environmental management system, recognised in accordance with Article 45(4), shall not be obliged to carry out those parts which have been recognised as equivalent to this Regulation.

4. Organisations shall provide material or documentary evidence showing that the organisation complies with all applicable legal requirements relating to the environment.

Organisations may request information from the competent enforcement authority or authorities in accordance with Article 32 or the environmental verifier.

Organisations outside the Community shall also make reference to the legal requirements relating to the environment applicable to similar organisations in the Member States where they intend to submit an application.

Where sectoral reference documents as referred to in Article 46 are available for the specific sector, the assessment of the organisation's environmental performance shall be made with reference to the relevant document.

5. The initial environmental review, the environment management system, the audit procedure and its implementation shall be verified by an accredited or licensed environmental verifier and the environmental statement shall be validated by that verifier.

#### Article 5

##### Application for registration

1. Any organisation meeting requirements set out in Article 4 may apply for registration.
2. The application for registration shall be made to the Competent Body determined in accordance with Article 3 and shall include the following:
  - (a) the validated environmental statement in electronic or printed form;
  - (b) the declaration as referred to in Article 25(9), signed by the environmental verifier which validated the environmental statement;
  - (c) a completed form, which includes at least the minimum information on as set out in Annex VI;
  - (d) evidence of payment of applicable fees, if applicable.



3. The application shall be written in (one of) the official language(s) of the Member State in which the organisation applies for registration.

### CHAPTER III

#### OBLIGATIONS OF REGISTERED ORGANISATIONS

##### Article 6

##### Renewal of EMAS registration

1. A registered organisation shall at least on a three-yearly basis:
  - (a) have the full environmental management system and audit programme and its implementation verified;
  - (b) prepare the environmental statement in accordance with the requirements set out in Annex IV and have it validated by an environmental verifier;
  - (c) forward the validated environmental statement to the Competent Body;
  - (d) forward to the Competent Body a completed form, which includes at least the minimum information set out in Annex VI;
  - (e) pay a fee for the renewal of the registration to the Competent Body, if applicable.
2. Without prejudice to paragraph 1, in the intervening years, a registered organisation shall:
  - (a) in accordance with the audit programme, carry out an internal audit of its environmental performance and compliance with applicable legal requirements relating to the environment in accordance with Annex III;
  - (b) prepare an updated environmental statement in accordance with the requirements laid down in Annex IV, and have it validated by an environmental verifier;
  - (c) forward the validated updated environmental statement to the Competent Body;
  - (d) forward to the Competent Body a completed form, which includes at least the minimum information set out in Annex VI;
  - (e) pay a fee for the maintenance of the registration to the Competent Body, if applicable.
3. Registered organisations shall make their environmental statement and updated environmental statement accessible to the public within one month of registration and one month after the renewal of the registration is completed.

Registered organisations may satisfy that requirement by providing access to the environmental statement and the updated environmental statement upon request or by creating links to Internet sites where those statements can be accessed.

Registered organisations shall specify the way in which they provide public access in the form set out in Annex VI.

##### Article 7

##### Derogation for small organisations

1. Competent Bodies shall, upon request of a small organisation, extend for that organisation the three-yearly frequency referred to in Article 6(1) up to four years or the annual frequency referred to in Article 6(2) up to two years, provided that the environmental verifier that has verified the organisation confirms that all the following conditions are met:
  - (a) no significant environmental risks are present;
  - (b) the organisation has no substantial changes planned as defined in Article 8, and
  - (c) there exist no significant local environmental problems that the organisation contributes to.

To submit the request referred to in the first subparagraph, the organisation may use the form set out in Annex VI.

2. The Competent Body shall refuse the request if the conditions set out in paragraph 1 are not met. It shall communicate a reasoned justification to the organisation.

3. Organisations benefiting from an extension of up to two years, as referred to in paragraph 1, shall forward the non-validated updated environmental statement to the Competent Body each year that they are exempt from the obligation to have a validated updated environmental statement.

##### Article 8

##### Substantial changes

1. Where a registered organisation plans to introduce substantial changes, the organisation shall carry out an environmental review of these changes, including their environmental aspects and impacts.

2. Following the environmental review of changes, the organisation shall update the initial environmental review, modify the environmental policy, the environmental programme and the environmental management system and revise and update the entire environmental statement accordingly.

3. All documents modified and updated pursuant to paragraph 2 shall be verified and validated within six months.

4. After validation, the organisation shall submit changes to the Competent Body using the form set out in Annex VI and make the changes publicly available.

*Article 9***Internal environmental audit**

1. A registered organisation shall establish an audit programme that ensures that over a period of time, not exceeding three years or four years if the derogation provided for in Article 7 applies, all activities in the organisation are subject to an internal environmental audit in accordance with the requirements set out in Annex III.

2. The audit shall be carried out by auditors who possess, individually or collectively, the competence necessary for carrying out these tasks and are sufficiently independent of the activities they audit to make an objective judgment.

3. The organisation's environmental auditing programme shall define the objectives of each audit or audit cycle including the audit frequency for each activity.

4. A written audit report shall be prepared by the auditors at the end of each audit and audit cycle.

5. The auditor shall communicate the findings and conclusions of the audit to the organisation.

6. Following the audit process, the organisation shall prepare and implement an appropriate action plan.

7. The organisation shall put in place appropriate mechanisms that ensure that the audit results are followed up.

*Article 10***Use of the EMAS logo**

1. Without prejudice to Article 35(2), the EMAS logo set out in Annex V may be used only by registered organisations and only as long as their registration is valid.

The logo shall always bear the registration number of the organisation.

2. The EMAS logo shall only be used in accordance with the technical specifications set out in Annex V.

3. In case an organisation chooses, in accordance with Article 3(2), not to include all its sites in the corporate registration, it shall ensure that in its communications with the public and in its use of the EMAS logo it is clear which sites are covered by the registration.

4. The EMAS logo shall not be used:

- (a) on products or their packaging; or
- (b) in conjunction with comparative claims concerning other activities and services or in a way that may create confusion with environmental product labels.

5. Any environmental information published by a registered organisation may bear the EMAS logo provided such information makes reference to the organisation's latest environmental statement or updated environmental statement from which it was drawn and it has been validated by an environmental verifier as being:

- (a) accurate;
- (b) substantiated and verifiable;
- (c) relevant and used in an appropriate context or setting;
- (d) representative of the overall environmental performance of the organisation;
- (e) unlikely to result in misinterpretation; and
- (f) significant in relation to the overall environmental impact.

## CHAPTER IV

**RULES APPLICABLE TO COMPETENT BODIES***Article 11***Designation and role of Competent Bodies**

1. Member States shall designate Competent Bodies, which shall be responsible for the registration of organisations located in the Community in accordance with this Regulation.

Member States may provide that the Competent Bodies they designate provide for and shall be responsible for the registration of organisations located outside the Community in accordance with this Regulation.

The Competent Bodies shall control the entry and maintenance of organisations on the register, including suspension and deletion.

2. The Competent Bodies may be national, regional or local.

3. The composition of the Competent Bodies shall guarantee their independence and neutrality.

4. The Competent Bodies shall have the appropriate resources, both financial and in terms of personnel, for the proper performance of their tasks.

5. The Competent Bodies shall apply this Regulation in a consistent manner and shall participate in regular peer evaluation as set out in Article 17.

#### Article 12

##### **Obligations concerning the registration process**

1. Competent Bodies shall establish procedures for the registration of organisations. They shall in particular establish rules for:

- (a) considering observations from interested parties, including Accreditation and Licensing Bodies and competent enforcement authorities and the organisations' representative bodies, concerning applicant or registered organisations;
- (b) refusal of registration, suspension or deletion of organisations, and
- (c) resolution of appeals and complaints made against their decisions.

2. Competent Bodies shall establish and maintain a register of organisations registered in their Member States, including information as to how their environmental statement or updated environmental statement can be obtained, and, in the case of changes, update that register on a monthly basis.

The register shall be publicly available on a website.

3. Competent Bodies shall each month, directly or via the national authorities as decided by the Member States concerned, communicate changes in the register referred to in paragraph 2 to the Commission.

#### Article 13

##### **Registration of organisations**

1. Competent Bodies shall consider applications for registration of organisations in accordance with the procedures established to this end.

2. Where an organisation applies for registration, the Competent Body shall register that organisation and give it a registration number if all the following conditions are fulfilled:

- (a) the Competent Body has received an application for registration, which includes all the documents referred to in Article 5(2)(a) to (d);
- (b) the Competent Body has checked that the verification and validation have been carried out in accordance with Articles 25, 26 and 27;
- (c) the Competent Body is satisfied on the basis of material evidence received, for example through a written report from the competent enforcement authority that there is no evidence of breach of applicable legal requirements relating to the environment;

(d) there are no relevant complaints from interested parties or complaints have been positively solved;

(e) the Competent Body is satisfied on the basis of evidence received that the organisation meets all the requirements of this Regulation; and

(f) the Competent Body has received a registration fee, if applicable.

3. The Competent Body shall inform the organisation that it has been registered and provide the organisation with its registration number and the EMAS logo.

4. If a Competent Body concludes that an applicant organisation does not comply with the requirements set out in paragraph 2, it shall refuse to register that organisation and communicate a reasoned justification to the organisation.

5. If a Competent Body receives a written supervision report from the Accreditation or Licensing Body which provides evidence that the activities of the environmental verifier were not performed adequately enough to ensure that the requirements of this Regulation are met by the applicant organisation, it shall refuse to register that organisation. The Competent Body shall invite the organisation to submit a new application for registration.

6. In order to obtain the necessary evidence for taking a decision on refusal of registration of organisations, the Competent Body shall consult the concerned parties including the organisation.

#### Article 14

##### **Renewal of the organisation's registration**

1. A Competent Body shall renew the registration of the organisation if all the following conditions are fulfilled:

- (a) the Competent Body has received a validated environmental statement as referred to in Article 6(1)(c), a validated updated environmental statement as referred to in Article 6(2)(c) or a non-validated updated environmental statement as referred to in Article 7(3);
- (b) the Competent Body has received a completed form, which includes at least the minimum information set out in Annex VI, as referred to in Article 6(1)(d) and in Article 6(2)(d);
- (c) the Competent Body has no evidence that the verification and validation have not been carried out in accordance with Articles 25, 26 and 27;
- (d) the Competent Body has no evidence of non-compliance by the organisation with applicable legal requirements relating to the environment;

- (e) there are no relevant complaints from interested parties or complaints have been positively solved;
  - (f) the Competent Body is satisfied on the basis of evidence received that the organisation meets all the requirements of this Regulation; and
  - (g) the Competent Body has received a fee for renewal of the registration, if applicable.
2. The Competent Body shall inform the organisation that its registration has been renewed.

#### Article 15

##### **Suspension or deletion of organisations from the register**

1. Where a Competent Body believes that a registered organisation does not comply with this Regulation, it shall give the organisation the opportunity to submit its views on the matter. Should the organisation fail to provide a satisfactory response it shall be deleted or suspended from the register.
2. Where a Competent Body receives a written supervision report from the Accreditation or Licensing Body which provides evidence that the activities of the environmental verifier were not performed adequately enough to ensure that the requirements of this Regulation are met by the registered organisation, registration shall be suspended.
3. A registered organisation shall be suspended or deleted from the register, as appropriate, if it fails to submit to a Competent Body, within two months of being required to do so, any of the following:
- (a) the validated environmental statement, an updated environmental statement or the signed declaration referred to in Article 25(9);
  - (b) a form which includes at least the minimum information set out in Annex VI from the organisation.
4. If a Competent Body is informed through a written report by the competent enforcement authority of a breach by the organisation of any applicable legal requirements relating to the environment, it shall suspend or delete the reference to that organisation from the register as appropriate.
5. In case a Competent Body decides to suspend or delete a registration it shall take into account at least the following:
- (a) the environmental effect of the non-compliance by the organisation with the requirements of this Regulation;
  - (b) the foreseeability of the non-compliance by the organisation with the requirements of this Regulation or the circumstances leading to it;
  - (c) previous instances of non-compliance with the requirements of this Regulation by the organisation; and
  - (d) the specific circumstances of the organisation.

6. In order to obtain the necessary evidence for taking its decision on suspension or deletion of organisations from the register, the Competent Body shall consult the concerned parties including the organisation.

7. Where the Competent Body has received evidence, other than by means of a written supervision report of the Accreditation or Licensing Body, that activities of the environmental verifier were not performed adequately enough to ensure that the requirements of this Regulation are met by the organisation, it shall consult the Accreditation or Licensing Body supervising the environmental verifier.

8. The Competent Body shall give reasons for any measures taken.

9. The Competent Body shall provide appropriate information to the organisation concerning the consultations with the concerned parties.

10. Suspension of an organisation from the register shall be lifted if the Competent Body has received satisfactory information that the organisation is in compliance with the requirements of this Regulation.

#### Article 16

##### **Forum of Competent Bodies**

1. A Forum of Competent Bodies from all Member States, hereinafter referred to as 'the Forum of Competent Bodies', shall be set up by the Competent Bodies and meet at least once per year in the presence of a representative of the Commission.

The Forum of Competent Bodies shall adopt its rules of procedure.

2. Competent Bodies of each Member State shall participate in the Forum of Competent Bodies. Where several Competent Bodies are established within one Member State, appropriate measures shall be taken to ensure that all of them are informed about the activities of the Forum of Competent Bodies.

3. The Forum of Competent Bodies shall develop guidance to ensure the consistency of procedures relating to the registration of organisations in accordance with this Regulation, including renewal of registration and suspension and deletion of organisations from the register both inside and outside the Community.

The Forum of Competent Bodies shall transmit to the Commission the guidance documents and documents referring to the peer evaluation.

4. Guidance documents referring to harmonisation procedures approved by the Forum of Competent Bodies shall be proposed as appropriate by the Commission for adoption in accordance with the regulatory procedure with scrutiny referred to in Article 49(3).

Those documents shall be made publicly available.

## Article 17

**Peer evaluation of Competent Bodies**

1. A peer evaluation shall be organised by the Forum of Competent Bodies to assess conformity of the registration system of every Competent Body with this Regulation and to develop a harmonised approach to the application of the rules relating to registration.

2. The peer evaluation shall be carried out on a regular basis and at least every four years, and shall include an assessment of the rules and procedures set out in Articles 12, 13 and 15. All Competent Bodies shall participate in the peer evaluation.

3. The Commission shall establish procedures for carrying out the peer evaluation, including appropriate appeals procedures against decisions taken as a result of the peer evaluation.

Those measures, designed to amend non-essential elements of this Regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 49(3).

4. Procedures referred to in paragraph 3 shall be established before the first peer evaluation takes place.

5. The Forum of Competent Bodies shall transmit a regular report of the peer evaluation to the Commission and the Committee established under Article 49(1).

That report shall be made publicly available after approval by the Forum of Competent Bodies and the Committee referred to in the first subparagraph.

## CHAPTER V

**ENVIRONMENTAL VERIFIERS**

## Article 18

**Tasks of Environmental verifiers**

1. Environmental verifiers shall assess whether an organisation's environmental review, environmental policy, management system, audit procedures and their implementation comply with the requirements of this Regulation.

2. Environmental verifiers shall verify the following:

- (a) compliance of the organisation with all the requirements of this Regulation with respect to the initial environmental review, environmental management system, environmental audit and its results and the environmental statement or updated environmental statement;
- (b) compliance of the organisation with applicable Community, national, regional and local legal requirements relating to the environment;

(c) the organisation's continuous improvement of environmental performance; and

(d) the reliability, credibility and correctness of the data and information in the following documents:

- (i) the environmental statement;
- (ii) the updated environmental statement;
- (iii) any environmental information to be validated.

3. Environmental verifiers shall, in particular, verify the appropriateness of the initial environmental review, or audit or other procedures carried out by the organisation, without unnecessarily duplicating those procedures.

4. Environmental verifiers shall verify whether the results of the internal audit are reliable. Where appropriate, they shall use spot-checks for that purpose.

5. At the time of the verification for the preparation for registration of an organisation, the environmental verifier shall check that at least the following requirements are met by that organisation:

- (a) a fully operational environmental management system in accordance with Annex II is in place;
- (b) a fully planned audit programme is in place and has begun in accordance with Annex III so that at least the most significant environmental impacts have been covered;
- (c) the management review referred to in Part A of Annex II is completed; and
- (d) an environmental statement is prepared in accordance with Annex IV and sectoral reference documents were taken into account, where available.

6. For the purposes of the verification for the renewal of registration referred to in Article 6(1), the environmental verifier shall check that the following requirements are met by the organisation:

- (a) the organisation has a fully operational environmental management system in accordance with Annex II;
- (b) the organisation has a fully operational planned audit programme, with at least one audit cycle completed in accordance with Annex III;
- (c) the organisation has completed one management review; and
- (d) the organisation has prepared an environmental statement in accordance with Annex IV and sectoral reference documents were taken into account, where available.



7. For the purposes of the verification for renewal of registration referred to in Article 6(2), the environmental verifier shall check that at least the following requirements are met by the organisation:

- (a) the organisation has carried out an internal audit of the environmental performance and the compliance with applicable legal requirements relating to the environment in accordance with Annex III;
- (b) the organisation demonstrates ongoing compliance with applicable legal requirements relating to the environment and continuous improvement of its environmental performance; and
- (c) the organisation has prepared an updated environmental statement in accordance with Annex IV and, where available, sectoral reference documents were taken into account.

#### Article 19

##### Frequency of verification

1. The environmental verifier shall design, in consultation with the organisation, a programme that ensures that all elements required for registration and renewal of registration referred to in Articles 4, 5 and 6 are verified.

2. The environmental verifier shall at intervals not exceeding 12 months validate any updated information in the environmental statement or updated environmental statement.

Where relevant, the derogation provided for in Article 7 shall apply.

#### Article 20

##### Requirements for environmental verifiers

1. In order to obtain accreditation or a licence in accordance with this Regulation, a candidate environmental verifier shall introduce a request with the Accreditation or Licensing Body from which it seeks accreditation or a licence.

That request shall specify the scope of the requested accreditation or licence by reference to the classification of economic activities as set out in Regulation (EC) No 1893/2006 <sup>(1)</sup>.

2. The environmental verifier shall provide to the Accreditation or Licensing Body appropriate evidence of its competence, including knowledge, relevant experience and technical capacities relevant to the scope of the requested accreditation or licence in the following fields:

- (a) this Regulation;

- (b) the general functioning of environmental management systems;
- (c) relevant sectoral reference documents issued by the Commission, under Article 46, for the application of this Regulation;
- (d) the legislative, regulatory and administrative requirements relevant to the activity subject to verification and validation;
- (e) environmental aspects and impacts including the environmental dimension of sustainable development;
- (f) the technical aspects, relevant to environmental issues, of the activity subject to verification and validation;
- (g) the general functioning of the activity subject to verification and validation in order to assess the appropriateness of the management system, in relation to the interaction of the organisation and its products, services and operations with the environment including at least the following:
  - (i) technologies employed by the organisation;
  - (ii) terminology and tools deployed in the activities;
  - (iii) operational activities and characteristics of their interaction with the environment;
  - (iv) methodologies for the evaluation of significant environmental aspects;
  - (v) pollution control and mitigation technologies;
- (h) environmental auditing requirements and methodology including the ability to undertake effective verification audits of an environmental management system, identification of appropriate audit findings and conclusions and preparation and presentation of audits reports, in oral and written forms, to provide a clear record of the verification audit;
- (i) information audit, the environmental statement and the updated environmental statement in relation to data management, data storage and manipulation, presentation of data in written and graphical format for the appreciation of potential data errors, use of assumptions and estimates;
- (j) the environmental dimension of products and services including the environmental aspects and environmental performance during the usage and post-use, and the integrity of data provided for environmental decision making.

3. The environmental verifier shall be required to demonstrate a continuing professional development in the fields of competence set out in paragraph 2 and to maintain such development for assessment by the Accreditation or Licensing Body.

<sup>(1)</sup> Regulation (EC) No 1893/2006 of the European Parliament and of the Council of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 (OJ L 393, 30.12.2006, p. 1).



4. The environmental verifier shall be an external third party, independent, in particular of the organisation's auditor or consultant, impartial and objective in performing its activities.

5. The environmental verifier shall ensure that it is free from any commercial, financial or other pressures which might influence its judgment or endanger trust in its independence of judgment and integrity in relation to the verification activities. The environmental verifier shall ensure compliance with any rules applicable in this respect.

6. The environmental verifier shall have documented methods and procedures, including quality control mechanisms and confidentiality provisions, to comply with the verification and validation requirements of this Regulation.

7. Where an organisation acts as environmental verifier, it shall keep an organisation chart detailing structures and responsibilities within the organisation and a statement of legal status, ownership and funding sources.

That organisation chart shall be made available on request.

8. Compliance with these requirements shall be ensured through the assessment carried out prior to the accreditation or licensing and through the supervision by the Accreditation or Licensing Body.

#### Article 21

##### **Additional requirements for environmental verifiers which are natural persons and performing verification and validation activities individually**

Natural persons acting as environmental verifiers and performing verification and validation individually shall have, in addition to complying with the requirements set out in Article 20:

- (a) all the necessary competence to perform verification and validation activities in their licensed fields;
- (b) a limited scope of the licence dependent on their personal competence.

#### Article 22

##### **Additional requirements for environmental verifiers active in third countries**

1. Where an environmental verifier intends to carry out verification and validation activities in third countries, it shall seek accreditation or licence for specific third countries.

2. In order to obtain accreditation or a licence for a third country, the environmental verifier shall meet, in addition to the requirements set out in Articles 20 and 21, the following requirements:

- (a) knowledge and understanding of the legislative, regulatory and administrative requirements relating to the environment in the third country for which accreditation or a licence is sought;

- (b) knowledge and understanding of the official language of the third country for which accreditation or a licence is sought.

3. The requirements set out in paragraph 2 shall be deemed to be met where the environmental verifier demonstrates the existence of a contractual relationship between itself and a qualified person or organisation fulfilling those requirements.

That person or organisation shall be independent of the organisation to be verified.

#### Article 23

##### **Supervision of environmental verifiers**

1. Supervision of verification and validation activities carried out by environmental verifiers in:

- (a) the Member State where they are accredited or licensed shall be carried out by the Accreditation or Licensing Body that granted the accreditation or licence;
- (b) a third country shall be carried out by the Accreditation or Licensing Body that granted the accreditation or licence to the environmental verifier for those activities;
- (c) a Member State other than where the accreditation or licence was granted shall be carried out by the Accreditation or Licensing Body of the Member State where the verification takes place.

2. At least four weeks in advance of each verification in a Member State, the environmental verifier shall notify its accreditation or licence details and the time and place of the verification to the Accreditation or Licensing Body responsible for the supervision of the environmental verifier concerned.

3. The environmental verifier shall immediately inform the Accreditation or Licensing Body of any changes which have a bearing on the accreditation or licence or their scope.

4. Provision shall be made by the Accreditation or Licensing Body, at regular intervals not exceeding 24 months, to ensure that the environmental verifier continues to comply with the accreditation or licence requirements and to monitor the quality of the verification and validation activities undertaken.

5. Supervision may consist of an office audit, on-the-spot supervision in organisations, questionnaires, a review of environmental statements or updated environmental statements validated by the environmental verifiers and review of the verification report.

Supervision shall be proportionate to the activity undertaken by the environmental verifier.

6. Organisations must allow the Accreditation or Licensing Bodies to supervise the environmental verifier during the verification and validation process.

7. Any decision taken by the Accreditation or Licensing Body to terminate or suspend the accreditation or licence or restrict the scope of the accreditation or licence shall be taken only after the environmental verifier has had the possibility of a hearing.

8. If the supervising Accreditation or Licensing Body is of the opinion that the quality of the work of an environmental verifier does not meet the requirements of this Regulation, a written supervision report shall be transmitted to the environmental verifier concerned and to the Competent Body to which the organisation concerned intends to apply for registration or which registered the organisation concerned.

In the case of any further dispute, the supervision report shall be transmitted to the Forum of Accreditation and Licensing Bodies referred to in Article 30.

#### Article 24

##### **Additional requirements for supervision of environmental verifiers active in a Member State other than that where the accreditation or licence was granted**

1. An environmental verifier accredited or licensed in one Member State shall, at least four weeks before performing verification and validation activities in another Member State, notify to the Accreditation or Licensing Body of the latter Member State the following information:

- (a) its accreditation or licence details, competences, in particular knowledge of legal requirements relating to the environment and official language of the other Member State, and team composition if appropriate;
- (b) the time and place of the verification and validation;
- (c) the address and contact details of the organisation.

That notification shall be provided before each verification and validation activity.

2. The Accreditation or Licensing Body may request clarification of the verifier's knowledge of the necessary applicable legal requirements relating to the environment.

3. The Accreditation or Licensing Body may require conditions other than those referred to in paragraph 1 only where those other conditions do not prejudice the right of the environmental verifier to provide services in a Member State other than the one where the accreditation or licence was granted.

4. The Accreditation or Licensing Body shall not use the procedure referred to in paragraph 1 to delay the arrival of

the environmental verifier. Where the Accreditation or Licensing Body is not able to fulfil its tasks in accordance with paragraphs 2 and 3 before the time for verification and validation as notified by the verifier in accordance with paragraph 1(b), it shall communicate a reasoned justification to the verifier.

5. No discriminatory fees for notification and supervision shall be charged by the Accreditation or Licensing Bodies.

6. Where the supervising Accreditation or Licensing Body is of the opinion that the quality of the work of the environmental verifier does not meet the requirements of this Regulation, a written supervision report shall be transmitted to the environmental verifier concerned, the Accreditation or Licensing Body which granted the accreditation or licence, and the Competent Body to which the organisation concerned intends to apply for registration or which registered the organisation concerned. In the case of any further dispute the supervision report shall be transmitted to the Forum of Accreditation and Licensing Bodies referred to in Article 30.

#### Article 25

##### **Conditions for performing verification and validation**

1. The environmental verifier shall operate within the scope of its accreditation or licence, and on the basis of a written agreement with the organisation.

That agreement shall:

- (a) specify the scope of the activity;
- (b) specify conditions aimed at enabling the environmental verifier to operate in an independent professional manner; and
- (c) commit the organisation to providing the necessary cooperation.

2. The environmental verifier shall ensure that the components of the organisation are unambiguously defined and correspond to a real division of the activities.

The environmental statement shall clearly specify the different parts of the organisation that are subject to verification or validation.

3. The environmental verifier shall carry out an assessment of the elements set out in Article 18.

4. As part of the verification and validation activities the environmental verifier shall examine documentation, visit the organisation, carry out spot-checks and conduct interviews with personnel.

5. Prior to a visit by the environmental verifier, the organisation shall provide it with basic information about the organisation and its activities, the environmental policy and programme, the description of the environmental management system in operation in the organisation, details of the environmental review or audit carried out, the report on that review or audit and on any corrective action taken afterwards, and the draft environmental statement or updated environmental statement.

6. The environmental verifier shall prepare a written report for the organisation, on the outcome of the verification, which shall specify:

- (a) all issues relevant to the activity carried out by the environmental verifier;
- (b) a description of conformity with all requirements of this Regulation including supporting evidence, findings and conclusions;
- (c) the comparison of the achievements and targets with the previous environmental statements and the environmental performance assessment and assessment of the continuous environmental performance improvement of the organisation;
- (d) if applicable, technical defects in the environmental review, audit method, environmental management system, or any other relevant process.

7. In cases of non-conformity with the provisions of this Regulation, the report shall specify in addition:

- (a) findings and conclusions on the non-conformity by the organisation and evidence on which those findings and conclusion are based;
- (b) points of disagreement with the draft environmental statement or updated environmental statement, and details of the amendments or additions that should be made to the environmental statement or updated environmental statement.

8. After verification, the environmental verifier shall validate the organisation's environmental statement or updated environmental statement and confirm that it meets the requirements of this Regulation provided that the outcome of the verification and validation confirms that:

- (a) the information and data in the organisation's environmental statement or updated environmental statement are reliable and correct and meet the requirements of this Regulation; and
- (b) there is no evidence that the organisation does not fulfil applicable legal requirements relating to the environment.

9. Upon validation, the environmental verifier shall issue a signed declaration as referred to in Annex VII declaring that the verification and validation were carried out in accordance with this Regulation.

10. Environmental verifiers accredited or licensed in one Member State may perform verification and validation activities in any other Member State in accordance with the requirements set out in this Regulation.

The verification or validation activity shall be subject to supervision by the Accreditation or Licensing Body of the Member State where the activity is to be performed. The start of the activity shall be notified to that Accreditation or Licensing Body in accordance with the timing set out in Article 24(1).

#### Article 26

##### **Verification and validation of small organisations**

1. When carrying out verification and validation activities, the environmental verifier shall take into account specific characteristics of small organisations, including the following:

- (a) short reporting lines;
- (b) multifunctional staff;
- (c) on-the-job training;
- (d) the ability to adapt rapidly to change; and
- (e) limited documentation of procedures.

2. The environmental verifier shall conduct verification or validation in a way that does not impose unnecessary burdens on small organisations.

3. The environmental verifier shall take into account objective evidence that a system is effective, including the existence of procedures within the organisation that are proportionate to the size and complexity of the operation, the nature of the associated environmental impacts and the competence of the operators.

#### Article 27

##### **Conditions for verification and validation in third countries**

1. Environmental verifiers accredited or licensed in a Member State may perform verification and validation activities for an organisation located in a third country in accordance with the requirements set out in this Regulation.

2. At least six weeks before verification or validation in a third country, the environmental verifier shall notify its accreditation or licence details and the time and place of the verification or validation to the Accreditation or Licensing Body of the Member State in which the organisation concerned intends to apply for registration or is registered.

3. The verification and validation activities shall be subject to supervision by the Accreditation or Licensing Body of the Member State in which the environmental verifier is accredited or licensed. The start of the activity shall be notified to that Accreditation or Licensing Body in accordance with the timing set out in paragraph 2.

## CHAPTER VI

## ACCREDITATION AND LICENSING BODIES

## Article 28

## Operation of Accreditation and Licensing

1. Accreditation Bodies appointed by the Member States pursuant to Article 4 of Regulation (EC) No 765/2008 shall be responsible for the accreditation of environmental verifiers and the supervision of the activities carried out by environmental verifiers in accordance with this Regulation.

2. Member States may appoint a Licensing Body, in accordance with Article 5(2) of Regulation (EC) No 765/2008, which shall be responsible for issuing licences to and supervising environmental verifiers.

3. Member States may decide not to allow the accreditation or licensing of natural persons as environmental verifiers.

4. Accreditation and Licensing Bodies shall assess an environmental verifier's competence in the light of the elements set out in Articles 20, 21 and 22 relevant to the scope of the requested accreditation or licence.

5. The scope of accreditation or the licence of environmental verifiers shall be determined according to the classification of economic activities as set out in Regulation (EC) No 1893/2006. That scope shall be limited by the competence of the environmental verifier and, where appropriate, it shall take into account the size and complexity of the activity.

6. Accreditation and Licensing Bodies shall establish appropriate procedures on accreditation or licensing, refusal of accreditation or a licence, suspension and withdrawal of accreditation or a licence of environmental verifiers and on supervision of environmental verifiers.

Those procedures shall include mechanisms for considering observations from concerned parties, including Competent Bodies and the representative bodies of organisations, concerning applicants and accredited or licensed environmental verifiers.

7. In the case of a refusal of accreditation or licence, the Accreditation or Licensing Body shall inform the environmental verifier of the reasons for the decision.

8. Accreditation or Licensing Bodies shall establish, revise and update a list of environmental verifiers and their scope of accreditation or licence in their Member States and shall communicate each month, directly or via the national authorities as decided by the Member State concerned, changes in that list to the Commission and to the Competent Body of the Member State where the Accreditation or Licensing Body is located.

9. Within the framework of the rules and procedures regarding monitoring of activities as laid down in Article 5(3) of Regulation (EC) No 765/2008, Accreditation and Licensing Bodies shall draw up a supervision report where they decide, after consultation with the environmental verifier concerned, either of the following:

- (a) that the activities of the environmental verifier were not performed adequately enough to ensure that the requirements of this Regulation are met by the organisation;
- (b) that the verification and the validation by the environmental verifier were carried out in violation of one or more of the requirements of this Regulation.

This report shall be transmitted to the Competent Body in the Member State where the organisation is registered or applies for registration and, if applicable, to the Accreditation or Licensing Body that granted the accreditation or licence.

## Article 29

## Suspension and withdrawal of accreditation or licence

1. Suspension or withdrawal of the accreditation or licence shall require the consultation of concerned parties including the environmental verifier, in order to provide the Accreditation or Licensing Body with the necessary evidence for taking its decision.

2. The Accreditation or Licensing Body shall inform the environmental verifier of the reasons for the measures taken and, if applicable, of the process of discussion with the competent enforcement authority.

3. The accreditation or licence shall be suspended or withdrawn until assurance of the environmental verifier's compliance with this Regulation is obtained, as appropriate, depending on the nature and scope of the failure or violation of legal requirements.

4. Suspension of the accreditation or licence shall be lifted where the Accreditation or Licensing Body has received satisfactory information that the environmental verifier complies with this Regulation.

## Article 30

## Forum of the Accreditation and Licensing Bodies

1. A forum constituted of all the Accreditation and Licensing Bodies from all Member States, hereinafter referred to as 'the Forum of the Accreditation and Licensing Bodies', shall be set up and meet at least once per year in the presence of a representative of the Commission.

2. The task of the Forum of the Accreditation and Licensing Bodies shall be to ensure the consistency of procedures relating to the following:

- (a) the accreditation or licensing of environmental verifiers under this Regulation, including refusal, suspension and withdrawal of accreditation or licence;
- (b) the supervision of activities carried out by accredited or licensed environmental verifiers.

3. The Forum of the Accreditation and Licensing Bodies shall develop guidance on issues in the field of the competence of Accreditation and Licensing Bodies.

4. The Forum of the Accreditation and Licensing Bodies shall adopt its rules of procedure.

5. The guidance documents referred to in paragraph 3 and the rules of procedure referred to in paragraph 4 shall be transmitted to the Commission.

6. Guidance documents referring to harmonisation procedures approved by the Forum of the Accreditation and Licensing Bodies shall be proposed as appropriate by the Commission for adoption in accordance with the regulatory procedure with scrutiny referred to in Article 49(3).

These documents shall be made publicly available.

#### Article 31

##### Peer evaluation of Accreditation and Licensing Bodies

1. The peer evaluation with regard to accreditation and licensing of environmental verifiers under this Regulation to be organised by the Forum of Accreditation and Licensing Bodies, shall be carried out on a regular basis, at least every four years, and shall include an assessment of the rules and procedures set out in Articles 28 and 29.

All Accreditation and Licensing Bodies shall participate in the peer evaluation.

2. The Forum of Accreditation and Licensing Bodies shall transmit a regular report of the peer evaluation to the Commission and the Committee established under Article 49(1).

That report shall be made publicly available after approval by the Forum of Accreditation and Licensing Bodies and the Committee referred to in the first subparagraph.

#### CHAPTER VII

##### RULES APPLICABLE TO MEMBER STATES

#### Article 32

##### Assistance to organisations relating to compliance with legal requirements relating to the environment

1. Member States shall ensure that organisations get access to information and assistance possibilities regarding legal requirements relating to the environment in that Member State.

2. The assistance shall include the following:

(a) information regarding the applicable legal requirements relating to the environment;

(b) identification of the competent enforcement authorities for specific legal requirements relating to the environment that have been identified as being applicable.

3. Member States may confer the tasks referred to in paragraphs 1 and 2 to the Competent Bodies or to any other body having the necessary expertise and the appropriate resources to fulfil the task.

4. Member States shall ensure that enforcement authorities reply to requests, at least from small organisations, on the applicable legal requirements relating to the environment that fall within their competence, and provide information to the organisations on the means of showing how the organisations meet relevant legal requirements.

5. Member States shall ensure that competent enforcement authorities communicate a failure by registered organisations to comply with applicable legal requirements relating to the environment to the Competent Body which has registered the organisation.

The competent enforcement authority shall inform that Competent Body as soon as possible and in any case within one month after it has become aware of the failure.

#### Article 33

##### Promotion of EMAS

1. Member States shall, in conjunction with Competent Bodies, enforcement authorities and other relevant stakeholders, promote the EMAS scheme taking into account activities referred to in Articles 34 to 38.

2. To that end, Member States may establish a promotion strategy which shall be revised on a regular basis.

#### Article 34

##### Information

1. Member States shall take appropriate measures to provide information to:

(a) the public about the objectives and principal components of EMAS;

(b) organisations about the contents of this Regulation.

2. Member States shall, where appropriate, use professional publications, local journals, promotion campaigns or any other functional means to increase general awareness of EMAS.

Member States may cooperate, in particular, with industrial associations, consumer organisations, environmental organisations, trade unions, local institutions and other relevant stakeholders.



*Article 35***Promotion activities**

1. Member States shall carry out promotion activities for EMAS. These activities may include:

- (a) the promotion of the exchange of knowledge and best practices on EMAS among all concerned parties;
- (b) the development of effective tools for EMAS promotion and to share them with organisations;
- (c) the provision of technical support to organisations in the definition and implementation of their EMAS-related marketing activities;
- (d) the encouragement of partnerships among organisations for EMAS promotion.

2. The EMAS logo without a registration number may be used by Competent Bodies, Accreditation and Licensing Bodies, national authorities and other stakeholders for EMAS-related marketing and promotional purposes. In such cases, use of the EMAS logo set out in Annex V shall not suggest that the user is registered where this is not the case.

*Article 36***Promotion of participation of small organisations**

Member States shall take adequate measures to encourage the participation of small organisations, *inter alia*, by:

- (a) facilitating access to information and support funds specially adapted to them;
- (b) ensuring that reasonable registration fees encourage their participation;
- (c) promoting technical assistance measures.

*Article 37***Cluster and step-by-step approach**

1. Member States shall encourage local authorities to provide, in participation with industrial associations, chambers of commerce and other concerned parties, specific assistance to clusters of organisations to meet the requirements for registration as referred to in Articles 4, 5 and 6.

Each organisation from the cluster shall be registered separately.

2. Member States shall encourage organisations to implement an environment management system. They shall in particular encourage a step-by-step approach leading to EMAS registration.

3. Systems established pursuant to paragraphs 1 and 2 shall operate with the objective of avoiding unnecessary costs for participants, in particular for small organisations.

*Article 38***EMAS and other policies and instruments in the Community**

1. Without prejudice to Community legislation, Member States shall consider how registration under EMAS in accordance with this Regulation can be:

- (a) taken into account in the development of new legislation;
- (b) used as a tool in the application and enforcement of legislation;
- (c) taken into account in public procurement and purchasing.

2. Without prejudice to Community legislation, notably competition, taxation and State aid legislation, Member States shall, where appropriate, take measures facilitating organisations to become or remain EMAS registered.

Those measures may include, *inter alia*, the following:

- (a) regulatory relief, so that a registered organisation is considered as being compliant with certain legal requirements relating to the environment laid down in other legal instruments, identified by the competent authorities;
- (b) better regulation, whereby other legal instruments are modified so that burdens on organisations participating in EMAS are removed, reduced or simplified with a view to encouraging the efficient operation of markets and raising the level of competitiveness.

*Article 39***Fees**

1. Member States may charge fees taking into account the following:

- (a) the costs incurred in connection with the provision of information and assistance to organisations by the bodies designated or set up to that end by Member States pursuant to Article 32;
- (b) the costs incurred in connection with the accreditation, licensing and supervision of environmental verifiers;
- (c) the costs for registration, renewal of registration, suspension and deletion by Competent Bodies as well as the additional costs of administering those processes for organisations outside the Community.



Those fees shall not exceed a reasonable amount and shall be proportionate to the size of the organisation and to the work to be done.

2. Member States shall ensure that organisations are informed about all applicable fees.

#### Article 40

##### Non-compliance

1. Member States shall take appropriate legal or administrative measures in case of non-compliance with this Regulation.

2. Member States shall put in place effective provisions against the use of the EMAS logo in violation of this Regulation.

Provisions put in place in accordance with Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market <sup>(1)</sup> may be used.

#### Article 41

##### Information and reporting to the Commission

1. Member States shall inform the Commission of the structure and procedures relating to the functioning of the Competent Bodies and Accreditation and Licensing Bodies and shall update that information, where appropriate.

2. Every two years, Member States shall report to the Commission updated information on the measures taken pursuant to this Regulation.

In those reports, Member States shall take account of the latest report presented by the Commission to the European Parliament and to the Council pursuant to Article 47.

#### CHAPTER VIII

##### RULES APPLICABLE TO THE COMMISSION

#### Article 42

##### Information

1. The Commission shall provide information to:

- (a) the public on the objectives and principal components of EMAS;
- (b) organisations on the content of this Regulation.

2. The Commission shall maintain and make publicly available:

- (a) a register of environmental verifiers and registered organisations;
- (b) a database of environmental statements in electronic format;
- (c) a database of best practices on EMAS, including, inter alia, effective tools for EMAS promotion and examples of technical support to organisations;
- (d) a list of Community resources for the funding of EMAS implementation and related projects and activities.

#### Article 43

##### Collaboration and coordination

1. The Commission shall promote, as appropriate, collaboration between Member States in order, in particular, to achieve a uniform and consistent application of the rules throughout the Community relating to the following:

- (a) registration of organisations;
- (b) environmental verifiers;
- (c) the information and assistance referred to in Article 32.

2. Without prejudice to Community legislation on public procurement, the Commission and other Community institutions and bodies shall, where appropriate, refer to EMAS or other environmental management systems recognised in accordance with Article 45, or equivalent, as contract performance conditions for works and service contracts.

#### Article 44

##### Integration of EMAS into other policies and instruments in the Community

The Commission shall consider how registration under EMAS in accordance with this Regulation can be:

- 1. taken into account in the development of new legislation and revision of existing legislation, in particular in the form of regulatory relief and better regulation as described in Article 38(2);
- 2. used as a tool in the context of application and enforcement of legislation.

<sup>(1)</sup> OJ L 149, 11.6.2005, p. 22.

*Article 45***Relationship with other environmental management systems**

1. Member States may submit to the Commission a written request for recognition of existing environmental management systems, or parts thereof, that are certified in accordance with appropriate certification procedures recognised at national or regional level as complying with corresponding requirements of this Regulation.

2. Member States shall specify in their request the relevant parts of the environmental management systems and the corresponding requirements of this Regulation.

3. Member States shall provide evidence of the equivalence with this Regulation of all relevant parts of the environmental management system concerned.

4. The Commission shall, after examination of the request referred to in paragraph 1, and acting in accordance with the advisory procedure referred to in Article 49(2), recognise the relevant parts of the environmental management systems and recognise the accreditation or licensing requirements for the certification bodies if it is of the opinion that a Member State has:

- (a) specified sufficiently clearly in the request the relevant parts of the environmental management systems and the corresponding requirements of this Regulation;
- (b) provided sufficient evidence of the equivalence with this Regulation of all relevant parts of the environmental management system at stake.

5. The Commission shall publish the references of the recognised environmental management systems, including the relevant sections of EMAS referred to in Annex I to which those references apply, and the recognised accreditation or licensing requirements in the *Official Journal of the European Union*.

*Article 46***Development of reference documents and guides**

1. The Commission shall, in consultation with Member States and other stakeholders, develop sectoral reference documents that shall include:

- (a) best environmental management practice;
- (b) environmental performance indicators for specific sectors;
- (c) where appropriate, benchmarks of excellence and rating systems identifying environmental performance levels.

The Commission may also develop reference documents for cross-sectoral use.

2. The Commission shall take into account existing reference documents and environmental performance indicators developed in accordance with other environmental policies and instruments in the Community or international standards.

3. The Commission shall establish, by the end of 2010, a working plan setting out an indicative list of sectors, which will be considered priorities for the adoption of sectoral and cross-sectoral reference documents.

The working plan shall be made publicly available and regularly updated.

4. The Commission shall, in cooperation with the Forum of Competent Bodies, develop a guide on registration of organisations outside the Community.

5. The Commission shall publish a user's guide setting out the steps needed to participate in EMAS.

That guide shall be available in all official languages of the institutions of the European Union and online.

6. Documents developed in accordance with paragraphs 1 and 4 shall be submitted for adoption. Those measures, designed to amend non-essential elements of this Regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 49(3).

*Article 47***Reporting**

Every five years, the Commission shall submit to the European Parliament and to the Council a report containing information on the actions and measures taken under this Chapter and information received from the Member States pursuant to Article 41.

The report shall include an assessment of the impact of the scheme on the environment and the trend in terms of number of participants.

## CHAPTER IX

**FINAL PROVISIONS***Article 48***Amendment of Annexes**

1. The Commission may amend the Annexes if necessary or appropriate, in the light of experience gained in the operation of EMAS, in response to identified needs for guidance on EMAS requirements and in the light of any changes in international standards or new standards which are of relevance to the effectiveness of this Regulation.

2. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 49(3).

*Article 49***Committee procedure**

1. The Commission shall be assisted by a Committee.
2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 50***Review**

The Commission shall review EMAS in the light of the experience gained during its operation and international developments by 11 January 2015. It shall take into account the reports transmitted to the European Parliament and to the Council in accordance with Article 47.

*Article 51***Repeal and transitional provisions**

1. The following legal acts shall be repealed:
  - (a) Regulation (EC) No 761/2001;
  - (b) Commission Decision 2001/681/EC of 7 September 2001 on guidance for the implementation of Regulation (EC) No 761/2001 of the European Parliament and of the Council allowing voluntary participation by organisations in a Community Eco-management and audit scheme (EMAS) <sup>(1)</sup>;

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 25 November 2009.

*For the European Parliament*  
*The President*  
 J. BUZEK

*For the Council*  
*The President*  
 Å. TORSTENSSON

- (c) Commission Decision 2006/193/EC of 1 March 2006 laying down rules, under Regulation (EC) No 761/2001 of the European Parliament and of the Council, on the use of the EMAS logo in the exceptional cases of transport packaging and tertiary packaging <sup>(2)</sup>.
2. By way of derogation from paragraph 1:
  - (a) national Accreditation Bodies and Competent Bodies set up pursuant to Regulation (EC) No 761/2001 shall continue their activities. Member States shall modify the procedures followed by Accreditation Bodies and Competent Bodies in accordance with this Regulation. Member States shall ensure that the systems implementing the modified procedures are fully operational by 11 January 2011;
  - (b) organisations registered in accordance with Regulation (EC) No 761/2001 shall remain on the EMAS register. At the time of the next verification of an organisation the environmental verifier shall check its compliance with the new requirements of this Regulation. If the next verification is to be carried out before 11 July 2010, the date of the next verification may be extended by six months in agreement with the environmental verifier and the Competent Bodies;
  - (c) environmental verifiers accredited in accordance with Regulation (EC) No 761/2001 may continue to perform their activities in accordance with the requirements established by this Regulation.
3. References to Regulation (EC) No 761/2001 shall be construed as references to this Regulation and be read in accordance with the correlation table set out in Annex VIII.

*Article 52***Entry into force**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

<sup>(1)</sup> OJ L 247, 17.9.2001, p. 24.

<sup>(2)</sup> OJ L 70, 9.3.2006, p. 63.

## ANNEX I

**ENVIRONMENTAL REVIEW**

The environmental review shall cover the following areas:

**1. Identification of the applicable legal requirements relating to the environment.**

In addition to the establishment of a list of applicable legal requirements, the organisation shall also indicate how evidence that it is complying with the different requirements can be provided.

**2. Identification of all direct and indirect environmental aspects with a significant impact on the environment, qualified and quantified as appropriate and compiling a register of those identified as significant;**

An organisation shall consider the following issues in assessing the significance of an environmental aspect:

- (i) potential to cause environmental harm;
- (ii) fragility of the local, regional or global environment;
- (iii) size, number, frequency and reversibility of the aspect or impact;
- (iv) existence and requirements of relevant environmental legislation;
- (v) importance to the stakeholders and employees of the organisation.

**(a) Direct environmental aspects**

Direct environmental aspects are associated with activities, products and services of the organisation itself over which it has direct management control.

All organisations have to consider the direct aspects of their operations.

Direct environmental aspects relate to, but are not limited to:

- (i) legal requirements and permit limits;
- (ii) emissions to air;
- (iii) releases to water;
- (iv) production, recycling, reuse, transportation and disposal of solid and other wastes, particularly hazardous wastes;
- (v) use and contamination of land;
- (vi) use of natural resources and raw materials (including energy);
- (vii) use of additives and auxiliaries as well as semi-manufactured goods;
- (viii) local issues (noise, vibration, odour, dust, visual appearance, etc.);
- (ix) transport issues (both for goods and services);
- (x) risks of environmental accidents and impacts arising, or likely to arise, as consequences of incidents, accidents and potential emergency situations;
- (xi) effects on biodiversity.

**(b) Indirect environmental aspects**

Indirect environmental aspects can result from the interaction of an organisation with third parties which can to a reasonable degree be influenced by the organisation seeking EMAS-registration.

For non-industrial organisations, such as local authorities or financial institutions, it is essential that they also consider the environmental aspects associated with their core business. An inventory limited to the environmental aspects of an organisation's site and facilities is insufficient.

These include, but are not limited to:

- (i) product life cycle related issues (design, development, packaging, transportation, use and waste recovery/disposal);
- (ii) capital investments, granting loans and insurance services;
- (iii) new markets;
- (iv) choice and composition of services (e.g. transport or the catering trade);
- (v) administrative and planning decisions;
- (vi) product range compositions;
- (vii) the environmental performance and practices of contractors, subcontractors and suppliers.

Organisations must be able to demonstrate that the significant environmental aspects associated with their procurement procedures have been identified and that significant environmental impacts associated with these aspects are addressed within the management system. The organisation should endeavour to ensure that the suppliers and those acting on the organisation's behalf comply with the organisation's environmental policy within the remit of the activities carried out for the contract.

In the case of these indirect environmental aspects, an organisation shall consider how much influence it can have over these aspects, and what measures can be taken to reduce the environmental impact.

### 3. Description of the criteria for assessing the significance of the environmental impact

An organisation shall define the criteria for assessing the significance of the environmental aspects of its activities, products and services, to determine which have a significant environmental impact.

The criteria developed by an organisation shall take into account Community legislation and shall be comprehensive, capable of independent checking, reproducible and made publicly available.

Considerations in establishing the criteria for assessing the significance of an organisation's environmental aspects may include, but are not limited to:

- (a) information about the condition of the environment to identify activities, products and services of the organisation that may have an environmental impact;
- (b) the organisation's existing data on material and energy inputs, discharges, wastes and emissions in terms of risk;
- (c) views of interested parties;
- (d) environmental activities of the organisation that are regulated;
- (e) procurement activities;
- (f) design, development, manufacturing, distribution, servicing, use, re-use, recycling and disposal of the organisation's products;
- (g) those activities of the organisation with the most significant environmental costs, and environmental benefits.

In assessing the significance of the environmental impacts of the organisation's activities the organisation shall think not only of normal operating conditions but also of start-up and shutdown conditions and of reasonably foreseeable emergency conditions. Account shall be taken of past, present and planned activities.

- 4. Examination of all existing environmental management practices and procedures.
  - 5. Evaluation of feedback from the investigation of previous incidents.
-

## ANNEX II

**Environmental management system requirements and additional issues to be addressed by organisations implementing EMAS**

The environmental management system requirements under EMAS are those laid down in Section 4 of the EN ISO 14001:2004 standard. These requirements are reproduced in the left column of the table below, which constitutes Part A of this Annex.

In addition, registered organisations are required to address a number of additional issues that have a direct link to a number of elements of Section 4 of the EN ISO 14001:2004 standard. These additional requirements are listed in the right column below, which constitutes Part B of this Annex.

PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>Organisations participating in the eco-management and audit scheme (EMAS) shall implement the requirements of EN ISO 14001:2004, which are described in Section 4 of the European Standard <sup>(1)</sup> and are fully reproduced below:</p> <p>A. Environmental management system requirements</p> <p>A.1. General requirements</p> <p>The organisation shall establish, document, implement, maintain and continually improve an environmental management system in accordance with the requirements of this International Standard and determine how it will fulfill these requirements.</p> <p>The organisation shall define and document the scope of its environmental management system.</p> <p>A.2. Environmental policy</p> <p>Top management shall define the organisation's environmental policy and ensure that, within the defined scope of its environmental management system, it:</p> <ul style="list-style-type: none"> <li>(a) is appropriate to the nature, scale and environmental impacts of its activities, products and services;</li> <li>(b) includes a commitment to continual improvement and prevention of pollution;</li> <li>(c) includes a commitment to comply with applicable legal requirements and with other requirements to which the organisation subscribes which relate to its environmental aspects;</li> <li>(d) provides the framework for setting and reviewing environmental objectives and targets;</li> <li>(e) is documented, implemented and maintained;</li> <li>(f) is communicated to all persons working for or on behalf of the organisation; and</li> <li>(g) is available to the public.</li> </ul>	

<sup>(1)</sup> The use of the text reproduced in this Annex is made with the permission of the European Committee for Standardisation (CEN). The full text can be purchased from the national standard bodies, the list of which is given in this Annex. Any reproduction of this Annex for commercial reasons is not permitted.



PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>A.3. Planning</p> <p>A.3.1. Environmental aspects</p> <p>The organisation shall establish, implement and maintain a procedure(s):</p> <ul style="list-style-type: none"> <li>(a) to identify the environmental aspects of its activities, products and services within the defined scope of the environmental management system that it can control and those that it can influence taking into account planned or new developments, or new or modified activities, products and services; and</li> <li>(b) to determine those aspects that have or can have significant impact(s) on the environment (i.e. significant environmental aspects).</li> </ul> <p>The organisation shall document this information and keep it up to date.</p> <p>The organisation shall ensure that the significant environmental aspects are taken into account in establishing, implementing and maintaining its environmental management system.</p> <p>A.3.2. Legal and other requirements</p> <p>The organisation shall establish, implement and maintain a procedure(s):</p> <ul style="list-style-type: none"> <li>(a) to identify and have access to the applicable legal requirements and other requirements to which the organisation subscribes related to its environmental aspects; and</li> <li>(b) to determine how these requirements apply to its environmental aspects.</li> </ul> <p>The organisation shall ensure that these applicable legal requirements and other requirements to which the organisation subscribes are taken into account in establishing, implementing and maintaining its environmental management system.</p>	<p>B.1. Environmental review</p> <p>Organisations shall carry out an initial environmental review as set out in Annex I in order to identify and evaluate their environmental aspects and identify applicable legal requirements relating to the environment.</p> <p>Organisations outside the Community shall also make reference to the legal requirements relating to the environment applicable to similar organisations in the Member States where they intend to submit an application.</p> <p>B.2. Legal compliance</p> <p>Organisations wishing to register with EMAS shall be able to demonstrate that they:</p> <ul style="list-style-type: none"> <li>(1) have identified, and know the implications to the organisation of all applicable legal requirements relating to the environment, identified during the environmental review according to Annex I.</li> <li>(2) provide for legal compliance with environmental legislation, including permits and permit limits; and</li> <li>(3) have procedures in place that enable the organisation to meet these requirements on an ongoing basis.</li> </ul>

PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>A.3.3. Objectives, targets and programme(s)</p> <p>The organisation shall establish, implement and maintain documented environmental objectives and targets, at relevant functions and levels within the organisation.</p> <p>The objectives and targets shall be measurable, where practicable, and consistent with the environmental policy, including the commitments to prevention of pollution, to compliance with applicable legal requirements and with other requirements to which the organisation subscribes, and to continual improvement.</p> <p>When establishing and reviewing its objectives and targets, an organisation shall take into account the legal requirements and other requirements to which the organisation subscribes, and its significant environmental aspects. It shall also consider its technological options, its financial, operational and business requirements, and the views of interested parties.</p> <p>The organisation shall establish, implement and maintain a programme(s) for achieving its objectives and targets. Programme(s) shall include:</p> <ul style="list-style-type: none"> <li>(a) designation of responsibility for achieving objectives and targets at relevant functions and levels of the organisation; and</li> <li>(b) the means and time-frame by which they are to be achieved.</li> </ul>	<p>B.3. Environmental performance</p> <ul style="list-style-type: none"> <li>(1) Organisations shall be able to demonstrate that the management system and the audit procedures address the actual environmental performance of the organisation with respect to the direct and indirect aspects identified in the environmental review under Annex I.</li> <li>(2) The environmental performance of the organisation against its objectives and targets shall be evaluated as part of the management review process. The organisation shall also commit itself to the continual improvement of its environmental performance. In doing so, the organisation may base its action on local, regional and national environmental programmes.</li> <li>(3) The means to achieve the objectives and targets cannot be environmental objectives. If the organisation comprises one or more sites, each of the sites to which EMAS applies shall comply with all the requirements of EMAS including the continual improvement of environmental performance as defined in Article 2(2).</li> </ul>
<p>A.4. Implementation and operation</p> <p>A.4.1. Resources, roles, responsibility and authority</p> <p>Management shall ensure the availability of resources essential to establish, implement, maintain and improve the environmental management system. Resources include human resources and specialised skills, organisational infrastructure, technology and financial resources.</p>	

PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>Roles, responsibilities and authorities shall be defined, documented and communicated in order to facilitate effective environmental management.</p> <p>The organisation's top management shall appoint a specific management representative(s) who, irrespective of other responsibilities, shall have defined roles, responsibilities and authority for:</p> <ul style="list-style-type: none"> <li>(a) ensuring that an environmental management system is established, implemented and maintained in accordance with the requirements of this International Standard;</li> <li>(b) reporting to top management on the performance of the environmental management system for review, including recommendations for improvement.</li> </ul>	
A.4.2. Competence, training and awareness	B.4. Employee involvement
	<ul style="list-style-type: none"> <li>(1) The organisation should acknowledge that active employee involvement is a driving force and a prerequisite for continuous and successful environmental improvements as well as being a key resource in the improvement of environmental performance as well as the right method to anchor the environmental management and audit system in the organisation in a successful way.</li> <li>(2) The term 'employee participation' includes both participation of, and information to the individual employee and his representatives. Therefore, there should be an employee participation scheme at all levels. The organisation should acknowledge that commitment, responsiveness and active support from the side of the management is a prerequisite for the success of those processes. In this context the necessity of feedback from the management to the employees must be stressed.</li> </ul>
<p>The organisation shall ensure that any person(s) performing tasks for it or on its behalf that have the potential to cause a significant environmental impact(s) identified by the organisation is (are) competent on the basis of appropriate education, training or experience, and shall retain associated records.</p>	
<p>The organisation shall identify training needs associated with its environmental aspects and its environmental management system. It shall provide training or take other action to meet these needs, and shall retain associated records.</p>	
<p>The organisation shall establish, implement and maintain a procedure(s) to make persons working for it or on its behalf aware of:</p>	
<ul style="list-style-type: none"> <li>(a) the importance of conformity with the environmental policy and procedures and with the requirements of the environmental management system;</li> </ul>	

PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>(b) the significant environmental aspects and related actual or potential impacts associated with their work, and the environmental benefits of improved personal performance;</p> <p>(c) their roles and responsibilities in achieving conformity with the requirements of the environmental management system; and</p> <p>(d) the potential consequences of departure from specified procedures.</p>	<p>(3) In addition to the these requirements, employees shall be involved in the process aimed at continually improving the organisation's environmental performance through:</p> <p>(a) the initial environmental review, the analysis of the status quo and in collecting and verifying information,</p> <p>(b) the establishment and implementation of an environmental management and audit system improving environmental performance,</p> <p>(c) environmental committees to gather information and to ensure the participation of environmental officer/management representatives and employees and their representatives,</p> <p>(d) joint working groups for the environmental action programme and environmental auditing,</p> <p>(e) the elaboration of the environmental statements.</p> <p>(4) Appropriate forms of participation such as the suggestion-book system or project-based group works or environmental committees should be used for this purpose. Organisations shall take note of Commission guidance on best practice in this field. Where they so request, any employee representatives shall also be involved.</p>
<p>A.4.3. Communication</p> <p>With regard to its environmental aspects and environmental management system, the organisation shall establish, implement and maintain a procedure(s) for:</p> <p>(a) internal communication among the various levels and functions of the organisation;</p> <p>(b) receiving, documenting and responding to relevant communication from external interested parties.</p> <p>The organisation shall decide whether to communicate externally about its significant environmental aspects, and shall document its decision. If the decision is to communicate, the organisation shall establish and implement a method(s) for this external communication.</p>	
	<p>B.5. Communication</p> <p>(1) Organisations shall be able to demonstrate an open dialogue with the public and other interested parties including local communities and customers with regard to the environmental impact of their activities, products and services in order to identify the public's and other interested parties' concerns.</p>

PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>A.4.4. Documentation</p> <p>The environmental management system documentation shall include:</p> <ul style="list-style-type: none"> <li>(a) the environmental policy, objectives and targets;</li> <li>(b) description of the scope of the environmental management system;</li> <li>(c) description of the main elements of the environmental management system and their interaction, and reference to related documents;</li> <li>(d) documents, including records, required by this International Standard; and</li> <li>(e) documents, including records, determined by the organisation to be necessary to ensure the effective planning, operation and control of processes that relate to its significant environmental aspects.</li> </ul> <p>A.4.5. Control of documents</p> <p>Documents required by the environmental management system and by this International Standard shall be controlled. Records are a special type of document and shall be controlled in accordance with the requirements given in point A.5.4.</p> <p>The organisation shall establish, implement and maintain a procedure(s) to:</p> <ul style="list-style-type: none"> <li>(a) approve documents for adequacy prior to issue;</li> <li>(b) review and update as necessary and re-approve documents,</li> <li>(c) ensure that changes and the current revision status of documents are identified;</li> <li>(d) ensure that relevant versions of applicable documents are available at points of use;</li> <li>(e) ensure that documents remain legible and readily identifiable;</li> <li>(f) ensure that documents of external origin determined by the organisation to be necessary for the planning and operation of the environmental management system are identified and their distribution controlled; and</li> <li>(g) prevent the unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose.</li> </ul>	<ul style="list-style-type: none"> <li>(2) Openness, transparency and periodic provision of environmental information are key factors in differentiating EMAS from other schemes. Those factors are also important for the organisation in building confidence with interested parties.</li> <li>(3) EMAS provides flexibility to allow organisations to target relevant information to specific audiences while ensuring that all information is available to those who require it.</li> </ul>

PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>A.4.6. Operational control</p> <p>The organisation shall identify and plan those operations that are associated with the identified significant environmental aspects consistent with its environmental policy, objectives and targets, in order to ensure that they are carried out under specified conditions, by:</p> <ul style="list-style-type: none"> <li>(a) establishing, implementing and maintaining a documented procedure(s) to control situations where their absence could lead to deviation from the environmental policy, objectives and targets; and</li> <li>(b) stipulating the operating criteria in the procedure(s); and</li> <li>(c) establishing, implementing and maintaining procedures related to the identified significant environmental aspects of goods and services used by the organisation and communicating applicable procedures and requirements to suppliers, including contractors.</li> </ul> <p>A.4.7. Emergency preparedness and response</p> <p>The organisation shall establish, implement and maintain a procedure(s) to identify potential emergency situations and potential accidents that can have an impact(s) on the environment and how it will respond to them.</p> <p>The organisation shall respond to actual emergency situations and accidents and prevent or mitigate associated adverse environmental impacts.</p> <p>The organisation shall periodically review and, where necessary, revise its emergency preparedness and response procedures, in particular, after the occurrence of accidents or emergency situations.</p> <p>The organisation shall also periodically test such procedures where practicable.</p> <p>A.5. Checking</p> <p>A.5.1. Monitoring and measurement</p> <p>The organisation shall establish, implement and maintain a procedure(s) to monitor and measure, on a regular basis, the key characteristics of its operations that can have a significant environmental impact. The procedure(s) shall include the documenting of information to monitor performance, applicable operational controls and conformity with the organisation's environmental objectives and targets.</p> <p>The organisation shall ensure that calibrated or verified monitoring and measurement equipment is used and maintained and shall retain associated records.</p> <p>A.5.2. Evaluation of compliance</p> <p>A.5.2.1. Consistent with its commitment to compliance, the organisation shall establish, implement and maintain a procedure(s) for periodically evaluating compliance with applicable legal requirements.</p>	



PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>The organisation shall keep records of the results of the periodic evaluations.</p> <p>A.5.2.2. The organisation shall evaluate compliance with other requirements to which it subscribes. The organisation may wish to combine this evaluation with the evaluation of legal compliance referred to in A.5.2.1 or to establish a separate procedure(s).</p> <p>The organisation shall keep records of the results of the periodic evaluations.</p> <p>A.5.3. Non-conformity, corrective action and preventive action</p> <p>The organisation shall establish, implement and maintain a procedure(s) for dealing with actual and potential non-conformity(ies) and for taking corrective action and preventive action. The procedure(s) shall define requirements for:</p> <ul style="list-style-type: none"> <li>(a) identifying and correcting non-conformity(ies) and taking action(s) to mitigate their environmental impacts;</li> <li>(b) investigating non-conformity(ies), determining their cause(s) and taking actions in order to avoid their recurrence;</li> <li>(c) evaluating the need for action(s) to prevent non-conformity(ies) and implementing appropriate actions designed to avoid their occurrence;</li> <li>(d) recording the results of corrective action(s) and preventive action(s) taken; and</li> <li>(e) reviewing the effectiveness of corrective action(s) and preventive action(s) taken. Actions taken shall be appropriate to the magnitude of the problems and the environmental impacts encountered.</li> </ul> <p>The organisation shall ensure that any necessary changes are made to environmental management system documentation.</p> <p>A.5.4. Control of records</p> <p>The organisation shall establish and maintain records as necessary to demonstrate conformity to the requirements of its environmental management system and of this International Standard, and the results achieved.</p> <p>The organisation shall establish, implement and maintain a procedure(s) for the identification, storage, protection, retrieval, retention and disposal of records.</p> <p>Records shall be and remain legible, identifiable and traceable.</p>	

PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>A.5.5. Internal audit</p> <p>The organisation shall ensure that internal audits of the environmental management system are conducted at planned intervals to:</p> <ul style="list-style-type: none"> <li>(a) determine whether the environmental management system: <ul style="list-style-type: none"> <li>— conforms to planned arrangements for environmental management including the requirements of this International Standard, and</li> <li>— has been properly implemented and is maintained; and</li> </ul> </li> <li>(b) provide information on the results of audits to management.</li> </ul> <p>Audit programme(s) shall be planned, established, implemented and maintained by the organisation, taking into consideration the environmental importance of the operation(s) concerned and the results of previous audits.</p> <p>Audit procedure(s) shall be established, implemented and maintained that address:</p> <ul style="list-style-type: none"> <li>— the responsibilities and requirements for planning and conducting audits, reporting results and retaining associated records,</li> <li>— the determination of audit criteria, scope, frequency and methods.</li> </ul> <p>Selection of auditors and conduct of audits shall ensure objectivity and the impartiality of the audit process.</p> <p>A.6. Management review</p> <p>Top management shall review the organisation's environmental management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. Reviews shall include assessing opportunities for improvement and the need for changes to the environmental management system, including the environmental policy and environmental objectives and targets.</p> <p>Records of the management reviews shall be retained.</p> <p>Input to management reviews shall include:</p> <ul style="list-style-type: none"> <li>(a) results of internal audits and evaluations of compliance with legal requirements and with other requirements to which the organisation subscribes;</li> <li>(b) communication(s) from external interested parties, including complaints;</li> <li>(c) the environmental performance of the organisation;</li> <li>(d) the extent to which objectives and targets have been met;</li> <li>(e) status of corrective and preventive actions;</li> <li>(f) follow-up actions from previous management reviews;</li> </ul>	

PART A environmental management systems requirements under EN ISO 14001:2004	PART B additional issues to be addressed by organisations implementing EMAS
<p>(g) changing circumstances, including developments in legal and other requirements related to its environmental aspects; and</p> <p>(h) recommendations for improvement.</p> <p>The outputs from management reviews shall include any decisions and actions related to possible changes to environmental policy, objectives, targets and other elements of the environmental management system, consistent with the commitment to continual improvement.</p> <p>List of national standard bodies</p> <p>BE: IBN/BIN (Institut Belge de Normalisation/Belgisch Instituut voor Normalisatie)</p> <p>CZ: ČNI (Český normalizační institut)</p> <p>DK: DS (Dansk Standard)</p> <p>DE: DIN (Deutsches Institut für Normung e.V.)</p> <p>EE: EVS (Eesti Standardikeskus)</p> <p>EL: ELOT (Ελληνικός Οργανισμός Τυποποίησης)</p> <p>ES: AENOR (Asociación Española de Normalización y Certificación)</p> <p>FR: AFNOR (Association Française de Normalisation)</p> <p>IE: NSAI (National Standards Authority of Ireland)</p> <p>IT: UNI (Ente Nazionale Italiano di Unificazione)</p> <p>CY: Κυπριακός Οργανισμός Προώθησης Ποιότητας</p> <p>LV: LVS (Latvijas Standarts)</p> <p>LT: LST (Lietuvos standartizacijos departamentas)</p> <p>LU: SEE (Service de l'Energie de l'Etat) (Luxembourg)</p> <p>HU: MSZT (Magyar Szabványügyi Testület)</p> <p>MT: MSA (Awtorità Maltija dwar l-Istandards/Malta Standards Authority)</p> <p>NL: NEN (Nederlands Normalisatie-Instituut)</p> <p>AT: ON (Österreichisches Normungsinstitut)</p> <p>PL: PKN (Polski Komitet Normalizacyjny)</p> <p>PT: IPQ (Instituto Português da Qualidade)</p> <p>SI: SIST (Slovenski inštitut za standardizacijo)</p> <p>SK: SÚTN (Slovenský ústav technickej normalizácie)</p> <p>FI: SFS (Suomen Standardisoimisliitto r.y)</p> <p>SE: SIS (Swedish Standards Institute)</p> <p>UK: BSI (British Standards Institution).</p>	<p>Complementary list of national standard bodies</p> <p>National standard bodies in Member States not covered by EN ISO 14001:2004:</p> <p>BG: BDS (Български институт за стандартизация);</p> <p>RO: ASRO (Asociația de Standardizare din România).</p> <p>National standard bodies in Member States, where a national standard body listed in EN ISO 14001:2004 has been replaced:</p> <p>CZ: ÚNMZ (Ústav pro technickou normalizaci, metrologii a státní zkušebnictví).</p>

## ANNEX III

## INTERNAL ENVIRONMENTAL AUDIT

A. **Audit programme and audit frequency**1. *Audit programme*

The audit programme shall guarantee that the management of the organisation is provided with the information it needs to review the organisation's environmental performance and the effectiveness of the environmental management system, and be able to demonstrate that they are under control.

2. *Objectives of the audit programme*

The objectives shall include, in particular, assessing the management systems in place, and determining conformity with the organisation's policy and programme, which shall include compliance with relevant environmental regulatory requirements.

3. *Scope of the audit programme*

The overall scope of the individual audits, or of each stage of an audit cycle where appropriate, shall be clearly defined and shall explicitly specify the:

- (a) subject areas covered;
- (b) activities to be audited;
- (c) environmental criteria to be considered;
- (d) period covered by the audit.

Environmental audit includes assessment of the factual data necessary to evaluate environmental performance.

4. *Audit frequency*

The audit or audit cycle which covers all activities of the organisation shall be completed, as appropriate, at intervals of no longer than three years or four years if the derogation provided for in Article 7 applies. The frequency with which any activity is audited will vary depending on the:

- (a) nature, scale and complexity of the activities;
- (b) significance of associated environmental impacts;
- (c) importance and urgency of the problems detected by previous audits;
- (d) history of environmental problems.

More complex activities with a more significant environmental impact shall be audited more frequently.

The organisation shall carry out audits at least on an annual basis, as this will help to demonstrate to the organisation's management and the environmental verifier that it is in control of its significant environmental aspects.

The organisation shall carry out audits regarding:

- (a) the environmental performance of the organisation; and
- (b) the organisation's compliance with applicable legal obligations relating to the environment.

**B. Audit activities**

Audit activities shall include discussions with personnel, inspection of operating conditions and equipment and reviewing of records, written procedures and other relevant documentation, with the objective of evaluating the environmental performance of the activity being audited to determine whether it meets the applicable standards, regulations or environmental objectives and targets set and whether the system in place to manage environmental responsibilities is effective and appropriate, inter alia, spot-checking of compliance with these criteria should be used to determine the effectiveness of the entire management system.

The following steps, in particular, shall be included in the audit process:

- (a) understanding of the management systems;
- (b) assessing strengths and weaknesses of the management systems;
- (c) gathering relevant evidence;
- (d) evaluating audit findings;
- (e) preparing audit conclusions;
- (f) reporting audit findings and conclusions.

**C. Reporting audit findings and conclusions**

The fundamental objectives of a written audit report are:

- (a) to document the scope of the audit;
  - (b) to provide the management with information on the state of compliance with the organisations' environmental policy and the environmental progress of the organisation;
  - (c) to provide the management with information on the effectiveness and reliability of the arrangements for monitoring environmental impacts of the organisation;
  - (d) to demonstrate the need for corrective action, where appropriate.
-



## ANNEX IV

**ENVIRONMENTAL REPORTING****A. Introduction**

Environmental information shall be presented in a clear and coherent manner in electronic form or in printed form.

**B. Environmental statement**

The environmental statement shall contain at least the elements and shall meet the minimum requirements as set out below:

- (a) a clear and unambiguous description of the organisation registering under EMAS and a summary of its activities, products and services and its relationship to any parent organisations as appropriate;
- (b) the environmental policy and a brief description of the environmental management system of the organisation;
- (c) a description of all the significant direct and indirect environmental aspects which result in significant environmental impacts of the organisation and an explanation of the nature of the impacts as related to these aspects (Annex I.2);
- (d) a description of the environmental objectives and targets in relation to the significant environmental aspects and impacts;
- (e) a summary of the data available on the performance of the organisation against its environmental objectives and targets with respect to its significant environmental impacts. Reporting shall be on the core indicators and on other relevant existing environmental performance indicators as set out in Section C;
- (f) other factors regarding environmental performance including performance against legal provisions with respect to their significant environmental impacts;
- (g) a reference to the applicable legal requirements relating to the environment;
- (h) the name and accreditation or licence number of the environmental verifier and the date of validation.

The updated environmental statement shall contain at least the elements and shall meet the minimum requirements as set out in points (e) to (h).

**C. Core indicators and other relevant existing environmental performance indicators****1. Introduction**

Organisations shall report, both in the environmental statement and the updated environmental statement, on the core indicators insofar as these relate to the direct environmental aspects of the organisation and other relevant existing environmental performance indicators as set out below.

The reporting shall provide data on actual input/impact. If disclosure would adversely affect the confidentiality of commercial or industrial information of the organisation where such confidentiality is provided for by national or Community law to protect a legitimate economic interest, the organisation may be permitted to index this information in its reporting, e.g. by establishing a base line year (with the index number 100) from which the development of the actual input/impact would appear.

The indicators shall:

- (a) give an accurate appraisal of the organisation's environmental performance;
- (b) be understandable and unambiguous;

- (c) allow for a year on year comparison to assess the development of the environmental performance of the organisation;
- (d) allow for comparison with sector, national or regional benchmarks as appropriate;
- (e) allow for comparison with regulatory requirements as appropriate.

## 2. Core indicators

- (a) Core indicators shall apply to all types of organisations. They focus on performance in the following key environmental areas:
  - (i) Energy efficiency;
  - (ii) Material efficiency;
  - (iii) Water;
  - (iv) Waste;
  - (v) Biodiversity; and
  - (vi) Emissions.

Where an organisation concludes that one or more core indicators are not relevant to its significant direct environmental aspects, that organisation may not report on those core indicators. The organisation shall provide justification to that effect with reference to its environmental review.

- (b) Each core indicator is composed of:
  - (i) a figure A indicating the total annual input/impact in the given field;
  - (ii) a figure B indicating the overall annual output of the organisation; and
  - (iii) a figure R indicating the ratio A/B.

Each organisation shall report on all 3 elements for each indicator.

- (c) The indication of the total annual input/impact in the given field, figure A, shall be reported as follows:
  - (i) on Energy efficiency
    - concerning the 'total direct energy use', the total annual energy consumption, expressed in MWh or GJ,
    - concerning the 'total renewable energy use', the percentage of total annual consumption of energy (electricity and heat) produced by the organisation from renewable energy sources,
  - (ii) on Material efficiency
    - concerning the 'annual mass-flow of different materials used' (excluding energy carriers and water), expressed in tonnes,
  - (iii) on Water
    - concerning the 'total annual water consumption', expressed in m<sup>3</sup>,
  - (iv) on Waste
    - concerning the 'total annual generation of waste', broken down by type, expressed in tonnes,
    - concerning the 'total annual generation of hazardous waste' expressed in kilograms or tonnes,

(v) on Biodiversity

- concerning the 'use of land', expressed in m<sup>2</sup> of built-up area,

(vi) on Emissions

- concerning the 'total annual emission of greenhouse gases', including at least emissions of CO<sub>2</sub>, CH<sub>4</sub>, N<sub>2</sub>O, HFCs, PFCs and SF<sub>6</sub>, expressed in tonnes of CO<sub>2</sub> equivalent,
- concerning the 'total annual air emission', including at least emissions of SO<sub>2</sub>, NO<sub>x</sub> and PM, expressed in kilograms or tonnes,

In addition to the indicators defined above, an organisation may use also other indicators to express the total annual input/impact in the given field;

(d) The indication of the overall annual output of the organisation, figure B, is the same for all fields, but is adapted to the different types of organisations, depending on their type of activity, and shall be reported as follows:

- (i) for organisations working in the production sector (industry), it shall indicate the total annual gross value-added expressed in million euro (EUR Mio) or total annual physical output expressed in tonnes or, in the case of small organisations the total annual turnover or number of employees;
- (ii) for organisations in the non-production sectors (administration/services), it shall relate to the size of the organisation expressed in number of employees.

In addition to the indicators defined above, an organisation may use also other indicators to express its overall annual output.

3. *Other relevant environmental performance indicators*

Each organisation shall also report annually on its performance relating to the more specific environmental aspects as identified in its environmental statement and, where available, take account of sectoral reference documents as referred to in Article 46.

**D. Public availability**

The organisation shall be able to demonstrate to the environmental verifier that anybody interested in the organisation's environmental performance can easily and freely be given access to the information required above under points B and C.

The organisation shall ensure that this information is available in (one of) the official language(s) of the Member State, in which the organisation is registered, and if applicable in (one of) the official language(s) of those Member States, in which sites covered by the corporate registration are located.

**E. Local accountability**

Organisations registering under EMAS may wish to produce one corporate environmental statement, covering a number of different geographic locations.

As the intention of EMAS is to ensure local accountability, organisations shall ensure that the significant environmental impacts of each site are clearly identified and reported within the corporate environmental statement.

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## ANNEX V

## EMAS LOGO



1. The logo may be used in any of the 23 languages provided the following wording is used:

Bulgarian:	‘Проверено управление по околна среда’
Czech:	‘Ověřený systém environmentálního řízení’
Danish:	‘Verificeret miljøledelse’
Dutch:	‘Geverifieerd milieuzorgsysteem’
English:	‘Verified environmental management’
Estonian:	‘Tõendatud keskkonnajuhtimine’
Finnish:	‘Todennettu ympäristöasioiden hallinta’
French:	‘Management environnemental vérifié’
German:	‘Geprüftes Umweltmanagement’
Greek:	‘επιθεωρημένη περιβαλλοντική διαχείριση’
Hungarian:	‘Hitelesített környezetvédelmi vezetési rendszer’
Italian:	‘Gestione ambientale verificata’
Irish:	‘Bainistíocht comhshaoil fíoraithe’
Latvian:	‘Verificēta vides pārvaldība’
Lithuanian:	‘Įvertinta aplinkosaugos vadyba’
Maltese:	‘Immaniggar Ambjentali Verifikat’
Polish:	‘Zweryfikowany system zarządzania środowiskowego’
Portuguese:	‘Gestão ambiental verificada’
Romanian:	‘Management de mediu verificat’
Slovak:	‘Overené environmentálne manažérstvo’
Slovenian:	‘Preverjen sistem ravnanja z okoljem’
Spanish:	‘Gestión medioambiental verificada’
Swedish:	‘Verifierat miljöledningssystem’

2. The logo shall be used either:

- in three colours (Pantone No 355 Green; Pantone No 109 Yellow; Pantone No 286 Blue),
- in black,
- in white, or,
- in a grey scale,

## ANNEX VI

## INFORMATION REQUIREMENTS FOR REGISTRATION

(information to be provided when applicable)

## 1. ORGANISATION

Name	.....
Address	.....
Town	.....
Postal Code	.....
Country/land/region/Autonomous Community	.....
Contact person	.....
Telephone	.....
FAX	.....
E-mail	.....
Website	.....
Public access to the environmental statement or the updated environmental statement	
(a) printed form	.....
(b) electronic form	.....
Registration number	.....
Registration date	.....
Suspension date of registration	.....
Deletion date of registration	.....
Date of the next environmental statement	.....
Date of the next updated environmental state- ment	.....
Request for derogation pursuant to Article 7 YES – NO	.....
NACE Code of activities	.....
Number of employees	.....
Turnover or annual balance sheet	.....

## 2. SITE

Name	.....
Address	.....
Postal Code	.....
Town	.....
Country land/region/Autonomous Community	.....
Contact person	.....
Telephone	.....
FAX	.....
E-mail	.....
Website	.....



Public access to the environmental statement  
or the updated environmental statement

(a) printed form .....

(b) electronic form .....

Registration number .....

Date of registration .....

Suspension date of registration .....

Deletion date of registration .....

Date of the next environmental statement .....

Date of the next updated environmental state-  
ment .....

Request for derogation pursuant to Article 7  
YES – NO .....

NACE Code of activities .....

Number of Employees .....

Turnover/or annual balance sheet .....

### 3. ENVIRONMENTAL VERIFIER

Name of environmental verifier .....

Address .....

Postal Code .....

Town .....

Country/land/region/Autonomous Community .....

Telephone .....

FAX .....

E-mail .....

Registration number of accreditation or licence .....

Scope of accreditation or licence (NACE  
Codes) .....

Accreditation or Licensing Body .....

Done at ... on .../.../20 .....

Signature of the representative of the organisa-  
tion .....

\_\_\_\_\_

## ANNEX VII

**ENVIRONMENTAL VERIFIER'S DECLARATION ON VERIFICATION AND VALIDATION ACTIVITIES**

..... (name).

with EMAS environmental verifier registration number .....

accredited or licensed for the scope ..... (NACE Code)

declares to have verified whether the site(s) or the whole organisation as indicated in the environmental statement/updated environmental statement (\*) of the organisation ..... (name)

with registration number (if available) .....

meet all requirements of Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS).

By signing this declaration, I declare that:

- the verification and validation has been carried out in full compliance with the requirements of Regulation (EC) No 1221/2009,
- the outcome of the verification and validation confirms that there is no evidence of non-compliance with applicable legal requirements relating to the environment,
- the data and information of the environmental statement/the updated environmental statement (\*) of the organisation/site (\*) reflect a reliable, credible and correct image of all the organisations/sites (\*) activities, within the scope mentioned in the environmental statement.

This document is not equivalent to EMAS registration. EMAS registration can only be granted by a Competent Body under Regulation (EC) No 1221/2009. This document shall not be used as a stand-alone piece of public communication.

Done at ... on .../.../20....

Signature

.....  
(\*) cross when non-applicable.

\_\_\_\_\_

## ANNEX VIII

## CORRELATION TABLE

Regulation (EC) No 761/2001	this Regulation
Article 1(1)	Article 1
Article 1(2)(a)	—
Article 1(2)(b)	—
Article 1(2)(c)	—
Article 1(2)(d)	—
Article 2(a)	Article 2(1)
Article 2(b)	—
Article 2(c)	Article 2(2)
Article 2(d)	—
Article 2(e)	Article 2(9)
Article 2(f)	Article 2(4)
Article 2(g)	Article 2(8)
Article 2(h)	Article 2(10)
Article 2(i)	Article 2(11)
Article 2(j)	Article 2(12)
Article 2(k)	Article 2(13)
Article 2(l)	Article 2(16)
Article 2(l)(i)	—
Article 2(l)(ii)	—
Article 2(m)	—
Article 2(n)	Article 2(17)
Article 2(o)	Article 2(18)
Article 2(p)	—
Article 2(q)	Article 2(20)
Article 2(r)	—
Article 2(s) first subparagraph	Article 2(21)
Article 2(s) second subparagraph	—
Article 2(t)	Article 2(22)
Article 2(u)	—
Article 3(1)	—
Article 3(2)(a) first subparagraph	Article 4(1)(a) and (b)
Article 3(2)(a) second subparagraph	Article 4(3)
Article 3(2)(b)	Article 4(1)(c)
Article 3(2)(c)	Article 4(1)(d)
Article 3(2)(d)	Article 4(5)
Article 3(2)(e)	Article 5(2) first subparagraph; Article 6(3)
Article 3(3)(a)	Article 6(1)(a)
Article 3(3)(b) first sentence	Article 6(1)(b) and (c)
Article 3(3)(b) second sentence	Article 7(1)
Article 4(1)	—
Article 4(2)	Article 51(2)
Article 4(3)	—
Article 4(4)	—

Regulation (EC) No 761/2001	this Regulation
Article 4(5) first sentence	Article 25(10) first subparagraph
Article 4(5) second sentence	Article 25(10) second subparagraph, second sentence
Article 4(6)	Article 41
Article 4(7)	—
Article 4(8) first subparagraph	Article 30(1)
Article 4(8) second subparagraph	Article 30(3) and (5)
Article 4(8) third subparagraph, first and second sentence	Article 31(1)
Article 4(8) third subparagraph, last sentence	Article 31(2)
Article 5(1)	Article 11(1) first subparagraph
Article 5(2)	Article 11(3)
Article 5(3) first sentence	Article 12(1)
Article 5(3) second sentence, first indent	Article 12(1)(a)
Article 5(3) second sentence, second indent	Article 12(1)(b)
Article 5(4)	Article 11(1) second and third subparagraph
Article 5(5) first sentence	Article 16(1)
Article 5(5) second sentence	Article 16(3) first sentence
Article 5(5) third sentence	Article 17(1)
Article 5(5) fourth sentence	Article 16(3) second subparagraph and Article 16(4) second subparagraph
Article 6(1)	Article 13(1)
Article 6(1), first indent	Article 13(2)(a) and Article 5(2)(a)
Article 6(1), second indent	Article 13(2)(a) and Article 5(2)(c)
Article 6(1), third indent	Article 13(2)(f) and Article 5(2)(d)
Article 6(1), fourth indent	Article 13(2)(c)
Article 6(1), second subparagraph	Article 13(2) first sentence
Article 6(2)	Article 15(3)
Article 6(3), first indent	Article 15(3)(a)
Article 6(3), second indent	Article 15(3)(b)
Article 6(3), third indent	—
Article 6(3), last sentence	Article 15(8)
Article 6(4), first paragraph	Article 15(2)
Article 6(4), second subparagraph	Article 15(4)
Article 6(5), first sentence	Article 15(6)
Article 6(5), second sentence	Article 15(8) and (9)
Article 6(6)	Article 15(10)
Article 7(1)	Article 28(8)
Article 7(2), first sentence	Article 12(2)
Article 7(2), second sentence	Article 12(3)
Article 7(3)	Article 42(2)(a)
Article 8(1), first sentence	Article 10(1)
Article 8(1), second sentence	Article 10(2)
Article 8(2)	—
Article 8(3) first subparagraph	Article 10(4)
Article 8(3) second subparagraph	—
Article 9(1) introductory sentence	Article 4(3)

Regulation (EC) No 761/2001	this Regulation
Article 9(1)(a)	Article 45(4)
Article 9(1)(b)	Article 45(4)
Article 9(1) second subparagraph	Article 45(5)
Article 9(2)	—
Article 10(1)	—
Article 10(2), first subparagraph	Article 38(1) and (2)
Article 10(2), second subparagraph, first sentence	Article 41
Article 10(2), second subparagraph, second sentence	Article 47
Article 11(1), first subparagraph	Article 36
Article 11(1), first indent	Article 36(a)
Article 11(1), second indent	Article 36(c)
Article 11(1), third indent	Article 36(b)
Article 11(1), second subparagraph, first sentence	Article 37(1)
Article 11(1), second subparagraph, second sentence	—
Article 11(1), second subparagraph, third sentence	Article 37(2)
Article 11(1), second subparagraph, fourth sentence	Article 37(3)
Article 11(2)	Article 43(2)
Article 11(3), first sentence	Article 41(2)
Article 11(3), second sentence	Article 47
Article 12(1)(a)	—
Article 12(1)(b)	Article 35(1)
Article 12(1) second subparagraph	—
Article 12(2)	Article 41(2)
Article 12(3)	—
Article 13	Article 40(1)
Article 14(1)	Article 49(1)
Article 14(2)	—
Article 14(3)	—
Article 15(1)	Article 50
Article 15(2)	Article 48
Article 15(3)	—
Article 16(1)	Article 39(1)
Article 16(2)	Article 42(2)
Article 17(1)	—
Article 17(2), (3) and (4)	Article 51(2)
Article 17(5)	—
Article 18	Article 52

**REGULATION (EC) No 1222/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 25 November 2009**  
**on the labelling of tyres with respect to fuel efficiency and other essential parameters**  
**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(2)</sup>,

Whereas:

- (1) Sustainable mobility is a major challenge facing the Community in the light of climate change and the need to support European competitiveness, as emphasised in the Commission Communication of 8 July 2008 entitled 'Greening Transport'.
- (2) The Commission Communication of 19 October 2006 entitled 'Action Plan for Energy Efficiency – Realising the Potential' highlighted the potential for reducing the total energy consumption by 20 % by 2020 by means of a list of targeted actions including the labelling of tyres.
- (3) The Commission Communication of 7 February 2007 entitled 'Results of the review of the Community strategy to reduce CO<sub>2</sub> emissions from passenger cars and light-commercial vehicles' highlighted the potential for reducing CO<sub>2</sub> emissions by means of complementary measures for car components with the highest impact on fuel consumption, such as tyres.
- (4) Tyres, mainly because of their rolling resistance, account for 20 % to 30 % of the fuel consumption of vehicles. A reduction of the rolling resistance of tyres may therefore contribute significantly to the energy efficiency of road transport and thus to the reduction of emissions.

- (5) Tyres are characterised by a number of parameters which are interrelated. Improving one parameter such as rolling resistance may have an adverse impact on other parameters such as wet grip, while improving wet grip may have an adverse impact on external rolling noise. Tyre manufacturers should be encouraged to optimise all parameters beyond the standards already achieved.

- (6) Fuel-efficient tyres are cost-effective since fuel savings more than compensate for the increased purchase price of tyres stemming from higher production costs.

- (7) Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor <sup>(3)</sup> sets out minimum requirements for the rolling resistance of tyres. Technological developments make it possible to significantly decrease energy losses due to tyre rolling resistance beyond those minimum requirements. To reduce the environmental impact of road transport, it is therefore appropriate to lay down provisions to encourage end-users to purchase more fuel-efficient tyres by providing harmonised information on that parameter.

- (8) Traffic noise is a significant nuisance and has a harmful effect on health. Regulation (EC) No 661/2009 sets out minimum requirements for the external rolling noise of tyres. Technological developments make it possible to significantly reduce external rolling noise beyond those minimum requirements. To reduce traffic noise, it is therefore appropriate to lay down provisions to encourage end-users to purchase tyres with low external rolling noise by providing harmonised information on that parameter.

- (9) The provision of harmonised information on external rolling noise would also facilitate the implementation of measures against traffic noise and contribute to increased awareness of the effect of tyres on traffic noise within the framework of Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise <sup>(4)</sup>.

<sup>(1)</sup> OJ C 228, 22.9.2009, p. 81.

<sup>(2)</sup> Opinion of the European Parliament of 22 April 2009 (not yet published in the Official Journal), Council Common Position of 20 November 2009 (not yet published in the Official Journal) and Position of the European Parliament of 24 November 2009 (not yet published in the Official Journal).

<sup>(3)</sup> OJ L 200, 31.7.2009, p. 1.

<sup>(4)</sup> OJ L 189, 18.7.2002, p. 12.



- (10) Regulation (EC) No 661/2009 sets out minimum requirements for the wet grip performance of tyres. Technological developments make it possible to significantly improve wet grip beyond those minimum requirements, and thus to reduce wet braking distances. To improve road safety, it is therefore appropriate to lay down provisions to encourage end-users to purchase tyres with high wet grip performance by providing harmonised information about that parameter.
- (11) The provision of information on wet grip may not reflect the primary performance of tyres specifically designed for snow and ice conditions. Taking into account the fact that harmonised testing methods are not yet available in respect of such tyres, it is appropriate to provide for the possibility of adapting their grip grading at a later stage.
- (12) The provision of information on tyre parameters in the form of a standard label is likely to influence purchasing decisions by end-users in favour of safer, quieter and more fuel-efficient tyres. This, in turn, is likely to encourage tyre manufacturers to optimise those tyre parameters, which would pave the way for more sustainable consumption and production.
- (13) A multiplicity of rules concerning the labelling of tyres across Member States would create barriers to intra-Community trade and increase the administrative burden and testing costs for tyre manufacturers.
- (14) Replacement tyres account for 78 % of the tyre market. It is therefore appropriate to inform the end-user about the parameters of replacement tyres as well as tyres fitted on new vehicles.
- (15) The need for greater information on tyre fuel efficiency and other parameters is relevant for consumers, as well as fleet managers and transport undertakings, which cannot easily compare the parameters of different tyre brands in the absence of a labelling and harmonised testing regime. It is therefore appropriate to include C1, C2 and C3 tyres within the scope of this Regulation.
- (16) The energy label which ranks products on a scale from 'A' to 'G', as applied to household appliances pursuant to Council Directive 92/75/EEC of 22 September 1992 on the indication by labelling and standard product information of the consumption of energy and other resources by household appliances <sup>(1)</sup>, is well known by consumers and has proven to be successful in promoting more efficient appliances. The same design should be used for the labelling of tyre fuel efficiency.
- (17) The display of a label on tyres at the point of sale, as well as in technical promotional material, should ensure that distributors as well as potential end-users receive harmonised information on tyre fuel efficiency, wet grip performance and external rolling noise at the time and place of the purchasing decision.
- (18) Some end-users choose tyres before arriving at the point of sale, or purchase tyres by mail order. To ensure that those end-users can also make an informed choice on the basis of harmonised information on tyre fuel efficiency, wet grip performance and external rolling noise, labels should be displayed in all technical promotional material, including where such material is made available on the Internet. Technical promotional material does not include advertisements in billboards, newspapers, magazines, radio broadcasting, television and similar online formats.
- (19) Potential end-users should be provided with information explaining each component of the label and its relevance. This information should be provided in technical promotional material, for instance on suppliers' websites.
- (20) Information should be provided in accordance with harmonised testing methods that should be reliable, accurate and reproducible, in order to enable end-users to compare different tyres and so as to limit testing costs for manufacturers.
- (21) In order to reduce greenhouse gas emissions and increase the safety of road transport, Member States may put in place incentives in favour of fuel-efficient, safer and low noise tyres. It is appropriate that minimum fuel efficiency and wet grip classes be determined below which such incentives may not be granted in order to avoid fragmentation of the internal market. Such incentives may constitute State aid. This Regulation should be without prejudice to the outcome of any future State aid procedure which may be undertaken in accordance with Articles 87 and 88 of the Treaty with respect to such incentives and should not cover taxation and fiscal matters.
- (22) Compliance with the provisions on labelling by suppliers and distributors is essential in order to achieve the aims of those provisions and to ensure a level playing field within the Community. Member States should therefore monitor such compliance through market surveillance and regular ex-post controls, in particular in line with Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(2)</sup>.
- (23) Member States should refrain, when implementing the relevant provisions of this Regulation, from implementing measures that impose unjustified, bureaucratic and unwieldy obligations on small and medium-sized enterprises.

<sup>(1)</sup> OJ L 297, 13.10.1992, p. 16.

<sup>(2)</sup> OJ L 218, 13.8.2008, p. 30.

- (24) Tyre suppliers and distributors should be encouraged to comply with the provisions of this Regulation before 2012 to speed up the recognition of the label and the realisation of its benefits.
- (25) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(1)</sup>.
- (26) In particular, the Commission should be empowered to introduce requirements with respect to wet grip grading of C2 and C3 tyres, to adapt the grip grading of tyres specifically designed for snow and ice conditions and to adapt the Annexes, including the testing methods and related allowances, to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (27) A review of this Regulation should be undertaken to determine end-users' understanding of the label and the ability of this Regulation to achieve market transformation,
- (c) tyres designed to be fitted only to vehicles registered for the first time before 1 October 1990;
- (d) T-type temporary-use spare tyres;
- (e) tyres whose speed rating is less than 80 km/h;
- (f) tyres whose nominal rim diameter does not exceed 254 mm or is 635 mm or more;
- (g) tyres fitted with additional devices to improve traction properties, such as studded tyres;
- (h) tyres designed only to be fitted on vehicles intended exclusively for racing.

### Article 3

#### Definitions

For the purpose of this Regulation:

1. 'C1, C2 and C3 tyres' means the tyre classes defined in Article 8 of Regulation (EC) No 661/2009;
2. 'T-type temporary-use spare tyre' means a temporary-use spare tyre designed for use at inflation pressures higher than those established for standard and reinforced tyres;
3. 'point of sale' means a location where tyres are displayed or stored and offered for sale to end-users, including car show rooms in relation to tyres offered for sale to end-users which are not fitted on the vehicles;
4. 'technical promotional material' means technical manuals, brochures, leaflets and catalogues (whether these appear in printed, electronic or online form), as well as websites, the purpose of which is to market tyres to end-users or distributors and that describe the specific technical parameters of a tyre;
5. 'technical documentation' means information relating to tyres, including the manufacturer and brand of the tyre; description of the tyre type or the grouping of tyres determined for the declaration of the fuel efficiency class, wet grip class and external rolling noise class and measured value; test reports and testing accuracy;
6. 'manufacturer' means any natural or legal person who manufactures a product, or has a product designed or manufactured and markets that product under his name or trademark;
7. 'importer' means any natural or legal person established within the Community who places a product from a third country on the Community market;
8. 'authorised representative' means any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

HAVE ADOPTED THIS REGULATION:

### Article 1

#### Aim and subject matter

1. The aim of this Regulation is to increase the safety, and the economic and environmental efficiency of road transport by promoting fuel-efficient and safe tyres with low noise levels.
2. This Regulation establishes a framework for the provision of harmonised information on tyre parameters through labelling, allowing end-users to make an informed choice when purchasing tyres.

### Article 2

#### Scope

1. This Regulation shall apply to C1, C2 and C3 tyres.
2. This Regulation shall not apply to:
  - (a) re-treaded tyres;
  - (b) off-road professional tyres;

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

9. 'supplier' means the manufacturer or its authorised representative in the Community or the importer;
10. 'distributor' means any natural or legal person in the supply chain, other than the supplier or the importer, who makes a tyre available on the market;
11. 'making available on the market' means any supply of a product for distribution or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;
12. 'end-user' means a consumer, as well as a fleet manager or road transport undertaking, that buys or is expected to buy a tyre;
13. 'essential parameter' means a tyre parameter such as rolling resistance, wet grip or external rolling noise that has a notable impact on the environment, road safety or health during use.

#### Article 4

##### Responsibilities of tyre suppliers

1. Suppliers shall ensure that C1 and C2 tyres, which are delivered to distributors or end-users, are:
  - (a) equipped with a sticker on the tyre tread displaying a label indicating the fuel efficiency class as set out in Annex I, Part A, the external rolling noise class and measured value as set out in Annex I, Part C and, where applicable, the wet grip class as set out in Annex I, Part B,
  - or
  - (b) for each batch of one or more identical tyres delivered, accompanied by a label in printed format indicating the fuel efficiency class as set out in Annex I, Part A, the external rolling noise class and measured value as set out in Annex I, Part C and, where applicable, the wet grip class as set out in Annex I, Part B.
2. The format of the sticker and the label referred to in paragraph 1 shall be as prescribed in Annex II.
3. Suppliers shall state the fuel efficiency class, the external rolling noise class and measured value and, where applicable, the wet grip class, of C1, C2 and C3 tyres in technical promotional material, including on their websites, as set out in Annex I, in the order specified in Annex III.
4. Suppliers shall make technical documentation available to the authorities of Member States on request, for a period ending five years after the last tyre of a given tyre type has been made available on the market. The technical documentation shall be sufficiently detailed as to allow the authorities to verify the accuracy of information provided on the label with regard to fuel efficiency, wet grip and external rolling noise.

#### Article 5

##### Responsibilities of tyre distributors

1. Distributors shall ensure that:
  - (a) tyres, at the point of sale, bear the sticker provided by suppliers in accordance with Article 4(1)(a) in a clearly visible position,
  - or
  - (b) before the sale of the tyre, the label referred to in Article 4(1)(b) is shown to the end-user and is clearly displayed in the immediate proximity of the tyre at the point of sale.
2. Where tyres offered for sale are not visible to the end-user, distributors shall provide end-users with information on the fuel efficiency class, wet grip class and external rolling noise class and measured value of those tyres.
3. For C1, C2 and C3 tyres, distributors shall state the fuel efficiency class, the external rolling noise measured value and, where applicable, the wet grip class, as set out in Annex I, on or with the bills delivered to end-users when they purchase tyres.

#### Article 6

##### Responsibilities of vehicle suppliers and vehicle distributors

Where end users are offered a choice at the point of sale between different tyres to be fitted on a new vehicle which they are intending to acquire, vehicle suppliers and distributors shall, before the sale, provide them with information, for each of the tyres offered, on the fuel efficiency class, the external rolling noise class and measured value, and, where applicable, the wet grip class of C1, C2 and C3 tyres, as set out in Annex I and in the order specified in Annex III. That information shall be included at least in the technical promotional material.

#### Article 7

##### Harmonised testing methods

The information to be provided under Articles 4, 5 and 6 on the fuel efficiency class, the external rolling noise class and measured value, and the wet grip class of tyres shall be obtained by applying the harmonised testing methods referred to in Annex I.

#### Article 8

##### Verification procedure

Member States shall assess the conformity of the declared fuel efficiency and wet grip classes, within the meaning of Annex I, Parts A and B, and the declared external rolling noise class and measured value within the meaning of Annex I, Part C, in accordance with the procedure set out in Annex IV.

*Article 9***Internal market**

1. Where the requirements of this Regulation are complied with, Member States shall neither prohibit nor restrict the making available on the market of the tyres referred to in Article 2 on grounds of product information.
2. Unless they have evidence to the contrary, Member States shall consider that labels and product information comply with this Regulation. They may require suppliers to provide technical documentation, in accordance with Article 4(4), in order to assess the accuracy of the declared values and classes.

*Article 10***Incentives**

Member States shall not provide incentives with regard to tyres below class C with respect to either fuel efficiency or wet grip within the meaning of Annex I, Parts A and B respectively. Taxation and fiscal measures do not constitute incentives for the purpose of this Regulation.

*Article 11***Amendments and adaptations to technical progress**

The following measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(2):

- (a) introduction of information requirements with respect to wet grip grading of C2 and C3 tyres, provided that suitable harmonised testing methods are available;
- (b) adaptation, where relevant, of grip grading to the technical specificities of tyres primarily designed to perform better in ice and/or snow conditions than a normal tyre with regard to their ability to initiate, maintain, or stop vehicle motion;
- (c) adaptation of Annexes I to IV to technical progress.

*Article 12***Enforcement**

In accordance with Regulation (EC) No 765/2008 Member States shall ensure that the authorities responsible for market surveillance verify compliance with Articles 4, 5 and 6 of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 25 November 2009.

For the European Parliament  
The President  
J. BUZEK

*Article 13***Committee procedure**

1. The Commission shall be assisted by a committee.
2. Where reference is made to this paragraph, Articles 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 14***Review**

1. The Commission shall assess the need to review this Regulation, taking into account, *inter alia*:
  - (a) the effectiveness of the label in terms of end-user awareness, in particular whether the provisions of Article 4(1)(b) are as effective as those of Article 4(1)(a) in contributing to the objectives of this Regulation;
  - (b) whether the labelling scheme should be extended to include retreaded tyres;
  - (c) whether new tyre parameters, such as mileage, should be introduced;
  - (d) the information on tyre parameters provided by vehicle suppliers and distributors to end-users.
2. The Commission shall present the result of this assessment to the European Parliament and the Council no later than 1 March 2016, and, if appropriate, submit proposals to the European Parliament and to the Council.

*Article 15***Transitional provision**

Articles 4 and 5 shall not apply to tyres produced before 1 July 2012.

*Article 16***Entry into force**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall apply from 1 November 2012.

For the Council  
The President  
Å. TORSTENSSON

## ANNEX I

## GRADING OF TYRE PARAMETERS

**Part A: Fuel efficiency classes**

The fuel efficiency class must be determined on the basis of the rolling resistance coefficient (RRC) according to the 'A' to 'G' scale specified below and measured in accordance with UNECE Regulation No 117 and its subsequent amendments.

If a tyre type is approved for more than one tyre class (e.g. C1 and C2), the grading scale used to determine the fuel efficiency class of this tyre type should be that which is applicable to the highest tyre class (e.g. C2, not C1).

C1 tyres		C2 tyres		C3 tyres	
RRC in kg/t	Energy efficiency class	RRC in kg/t	Energy efficiency class	RRC in kg/t	Energy efficiency class
$RRC \leq 6,5$	A	$RRC \leq 5,5$	A	$RRC \leq 4,0$	A
$6,6 \leq RRC \leq 7,7$	B	$5,6 \leq RRC \leq 6,7$	B	$4,1 \leq RRC \leq 5,0$	B
$7,8 \leq RRC \leq 9,0$	C	$6,8 \leq RRC \leq 8,0$	C	$5,1 \leq RRC \leq 6,0$	C
Empty	D	Empty	D	$6,1 \leq RRC \leq 7,0$	D
$9,1 \leq RRC \leq 10,5$	E	$8,1 \leq RRC \leq 9,2$	E	$7,1 \leq RRC \leq 8,0$	E
$10,6 \leq RRC \leq 12,0$	F	$9,3 \leq RRC \leq 10,5$	F	$RRC \geq 8,1$	F
$RRC \geq 12,1$	G	$RRC \geq 10,6$	G	Empty	G

**Part B: Wet grip classes**

The wet grip class of C1 tyres must be determined on the basis of the wet grip index (G) according to the 'A' to 'G' scale specified below and measured in accordance with UNECE Regulation No 117 and its subsequent amendments.

G	Wet grip class
$1,55 \leq G$	A
$1,40 \leq G \leq 1,54$	B
$1,25 \leq G \leq 1,39$	C
Empty	D
$1,10 \leq G \leq 1,24$	E
$G \leq 1,09$	F
Empty	G

**Part C: External rolling noise classes and measured value**

The external rolling noise measured value (N) must be declared in decibels and calculated in accordance with UNECE Regulation No 117 and its subsequent amendments.

The external rolling noise class must be determined on the basis of the limit values ( $LV$ ) set out in Part C of Annex II of Regulation (EC) No 661/2009 as follows.

$N$  in dB

External rolling noise class



$N \leq LV - 3$



$LV - 3 < N \leq LV$



$N > LV$

\_\_\_\_\_

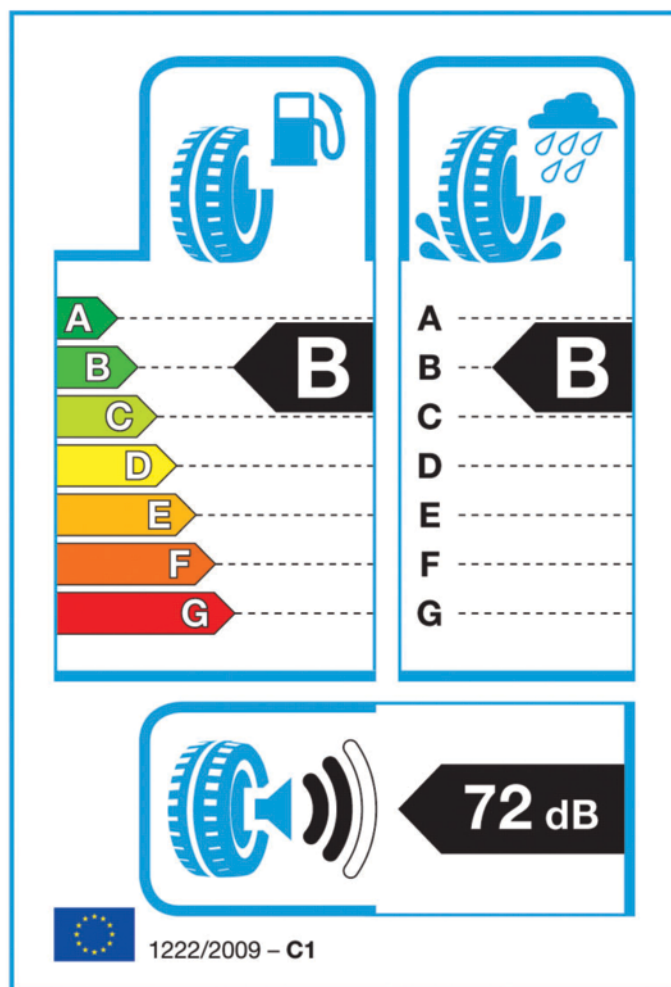


## ANNEX II

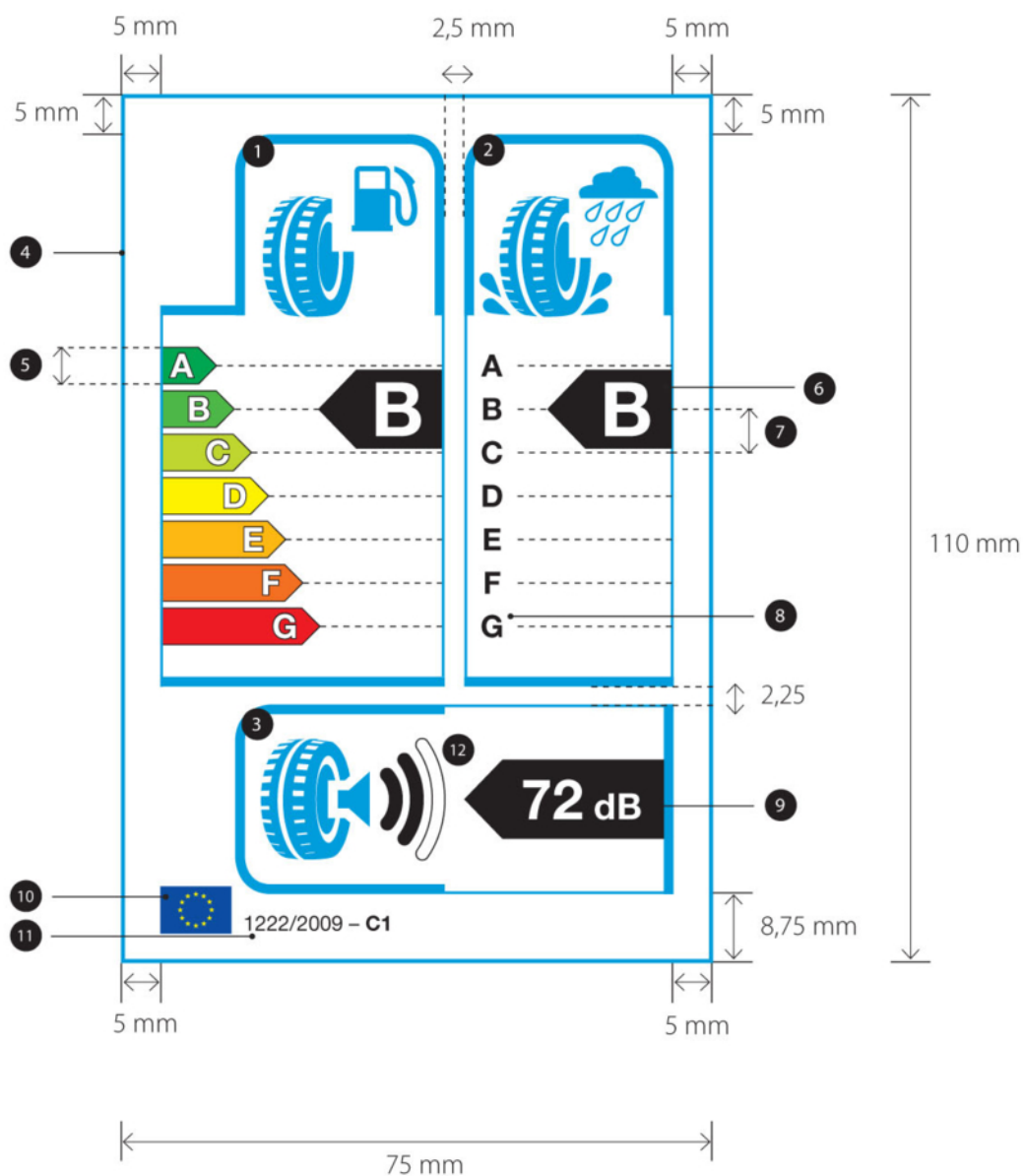
## FORMAT OF THE LABEL

## 1. Label design

1.1. The label referred to in Articles 4(1) and 5(1) must be in accordance with the illustration below:



1.2. The following provides specifications for the label:



1.3. The label must be at least 75 mm wide and 110 mm high. Where the label is printed in a larger format, its content must nevertheless remain proportionate to the specifications above.

1.4. The label must conform to the following requirements:

- (a) Colours are CMYK – cyan, magenta, yellow and black – and are given following this example: 00-70-X-00: 0 % cyan, 70 % magenta, 100 % yellow, 0 % black;
- (b) The numbers listed below refer to the legends indicated in point 1.2:

**1 Fuel efficiency**

Pictogram as supplied: width: 19,5 mm, height: 18,5 mm – Frame for pictogram: stroke: 3,5 pt, width: 26 mm, height: 23 mm – Frame for grading: stroke: 1 pt – Frame end: stroke: 3,5 pt, width: 36 mm – Colour: X-10-00-05;

**2 Wet grip**

Pictogram as supplied: width: 19 mm, height: 19 mm – Frame for pictogram: stroke: 3,5 pt, width: 26 mm, height: 23 mm – Frame for grading: stroke: 1 pt – Frame end: stroke: 3,5 pt, width: 26 mm – Colour: X-10-00-05;

**3** *External rolling noise*

Pictogram as supplied: width: 14 mm, height: 15 mm – Frame for pictogram: stroke: 3,5 pt, width: 26 mm, height: 24 mm – Frame for value: stroke: 1 pt – Frame end: stroke: 3,5 pt, height: 24 mm – Colour: X-10-00-05;

**4** *Label border: stroke: 1,5 pt – Colour: X-10-00-05;***5** *'A' to 'G' scale*

Arrows: height: 4,75 mm, gap: 0,75 mm, black stroke: 0,5 pt – colours:

— A: X-00-X-00;

— B: 70-00-X-00;

— C: 30-00-X-00

— D: 00-00-X-00;

— E: 00-30-X-00

— F: 00-70-X-00;

— G: 00-X-X-00.

Text: Helvetica Bold 12 pt, 100 % white, black outline: 0,5 pt;

**6** *Grading*

Arrow: width: 16 mm, height: 10 mm, 100 % black;

Text: Helvetica Bold 27 pt, 100 % white;

**7** *Lines in scale: stroke: 0,5 pt, dashed line interval: 5,5 mm, 100 % black;***8** *Scale text: Helvetica Bold 11 pt, 100 % black;***9** *External rolling noise measured value*

Arrow: width: 25,25 mm, height: 10 mm, 100 % black;

Text: Helvetica Bold 20 pt, 100 % white;

Unit text: Helvetica Bold 13 pt, 100 % white;

**10** *EU logo: width: 9 mm, height: 6 mm;***11** *Regulation reference: Helvetica Regular 7,5 pt, 100 % black;*

Tyre class reference: Helvetica Bold 7,5 pt, 100 % black;

**12** *External rolling noise class as supplied in part C of Annex I: width: 8,25 mm, height: 15,5 mm – 100 % black*

(c) The background must be white.

1.5. The tyre class (C1 or C2) must be indicated on the label in the format prescribed in the illustration in point 1.2.

**2. Sticker**

- 2.1. The sticker referred to in Articles 4(1) and 5(1) consists of two parts: (i) a label printed in the format described in point 1 of this Annex and (ii) a brand space printed in accordance with the specifications described in point 2.2 of this Annex.
  - 2.2. Brand space: Suppliers must add their trade name or trade mark, the tyre line, tyre dimension, load index, speed rating and other technical specifications on the sticker along with the label, in any colour, format and design, provided that this does not detract from or disrupt the message on the label defined in point 1 of this Annex. The total surface of the sticker shall not exceed 250 cm<sup>2</sup> and the total height of the sticker shall not exceed 220 mm.
-

## ANNEX III

**Information provided in technical promotional material**

1. Information on tyres must be provided in the order specified as follows:
    - (i) the fuel efficiency class (letter 'A' to 'G');
    - (ii) the wet grip class (letter 'A' to 'G');
    - (iii) the external rolling noise class and measured value (dB).
  2. The information provided in point 1 must meet the following requirements:
    - (i) be easy to read;
    - (ii) be easy to understand;
    - (iii) if different grading is available for a given tyre type depending on dimension or other parameters, the range between the least and best performing tyre is stated.
  3. Suppliers must also make the following available on their websites:
    - (i) a link to the relevant Commission webpage dedicated to this Regulation;
    - (ii) an explanation of the pictograms printed on the label;
    - (iii) a statement highlighting the fact that actual fuel savings and road safety depend heavily on the behaviour of drivers, and in particular the following:
      - eco-driving can significantly reduce fuel consumption,
      - tyre pressure should be regularly checked to optimise wet grip and fuel efficiency performance,
      - stopping distances should always be strictly respected,
-

## ANNEX IV

**Verification procedure**

The conformity of the declared fuel efficiency and wet grip classes as well as the declared external rolling noise class and measured value must be assessed for each tyre type or each grouping of tyres as determined by the supplier, according to one of the following procedures:

- (a) (i) a single tyre is tested first. If the measured value meets the declared class or external rolling noise measured value, the test is passed;

and

- (ii) if the measured value does not meet the declared class or external rolling noise measured value, three more tyres are tested. The average measurement value stemming from the four tyres tested are used to assess conformity with the declared information;

or

- (b) where the labelled classes or values are derived from type approval test results obtained in accordance with Directive 2001/43/EC, Regulation (EC) No 661/2009, or UNECE Regulation No 117 and its subsequent amendments, Member States may make use of the tyre conformity of production data from these type approvals.

Assessment of conformity of production data must take into account allowances as specified in section 8 of UNECE Regulation No 117 and its subsequent amendments.

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**REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 30 November 2009**  
**on cosmetic products**  
**(recast)**  
**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(2)</sup>,

Whereas:

- (1) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products <sup>(3)</sup> has been significantly amended on several occasions. Since further amendments are to be made, in this particular case it should be recast as one single text in the interests of clarity.
- (2) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Community.
- (3) This Regulation aims at simplifying procedures and streamlining terminology, thereby reducing administrative burden and ambiguities. Moreover, it strengthens certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health.
- (4) This Regulation comprehensively harmonises the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health.

(5) The environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency <sup>(4)</sup>, which enables the assessment of environmental safety in a cross-sectoral manner.

(6) This Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products. The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use.

(7) The assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment, taking into account all characteristics of the product. Cosmetic products may include creams, emulsions, lotions, gels and oils for the skin, face masks, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and anti-perspirants, hair colorants, products for waving, straightening and fixing hair, hair-setting products, hair-cleansing products (lotions, powders, shampoos), hair-conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers, brilliantines), shaving products (creams, foams, lotions), make-up and products removing make-up, products intended for application to the lips, products for care of the teeth and the mouth, products for nail care and make-up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products.

(8) The Commission should define the categories of cosmetic products which are relevant for the application of this Regulation.

(9) Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health.

<sup>(1)</sup> OJ C 27, 3.2.2009, p. 34.

<sup>(2)</sup> Opinion of the European Parliament of 24 March 2009 (not yet published in the Official Journal) and Council Decision of 20 November 2009.

<sup>(3)</sup> OJ L 262, 27.9.1976, p. 169.

<sup>(4)</sup> OJ L 396, 30.12.2006, p. 1.



- (10) The presentation of a cosmetic product and in particular its form, odour, colour, appearance, packaging, labelling, volume or size should not endanger health and safety of consumers due to confusion with foodstuffs, in accordance with Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers <sup>(1)</sup>.
- (11) In order to establish clear responsibilities, each cosmetic product should be linked to a responsible person established within the Community.
- (12) Ensuring traceability of a cosmetic product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators.
- (13) It is necessary to determine under which conditions a distributor is to be considered as the responsible person.
- (14) All legal or natural persons in the wholesale trade as well as retailers selling directly to the consumer are covered by reference to the distributor. The obligations of the distributor should therefore be adapted to the respective role and part of the activity of each of these operators.
- (15) The European cosmetics sector is one of the industrial activities affected by counterfeiting, which may increase risks to human health. Member States should pay particular attention to the implementation of horizontal Community legislation and measures regarding counterfeit products in the field of cosmetic products, for example Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights <sup>(2)</sup> and Directive 2004/48/EC of the European parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights <sup>(3)</sup>. In-market controls represent a powerful means of identifying products that do not comply with the requirements of this Regulation.
- (16) To ensure their safety, cosmetic products placed on the market should be produced according to good manufacturing practice.
- (17) For the purpose of effective market surveillance, a product information file should be made readily accessible, at one single address within the Community, to the competent authority of the Member State where the file is located.
- (18) In order to be comparable and of high quality, the results of the non-clinical safety studies carried out for the purposes of assessing the safety of a cosmetic product should comply with the relevant Community legislation.
- (19) It should be made clear which information is to be made available to the competent authorities. That information should include all the necessary particulars relating to identity, quality, safety for human health and the effects claimed for the cosmetic product. In particular, this product information should include a cosmetic product safety report documenting that a safety assessment has been conducted.
- (20) To ensure the uniform application and control of the restrictions for substances, sampling and analysis should be carried out in a reproducible and standardised manner.
- (21) The term 'mixture' as defined in this Regulation should have the same meaning as the term 'preparation' previously used in Community legislation.
- (22) For reasons of effective market surveillance, the competent authorities should be notified of certain information about the cosmetic product placed on the market.
- (23) In order to allow for rapid and appropriate medical treatment in the event of difficulties, the necessary information about the product formulation should be submitted to poison control centres and assimilated entities, where such centres have been established by Member States to that end.
- (24) In order to keep administrative burdens to a minimum, the notified information for competent authorities, poison control centres and assimilated entities should be submitted centrally for the Community by way of an electronic interface.
- (25) In order to ensure a smooth transition to the new electronic interface, economic operators should be allowed to notify the information required in accordance with this Regulation before its date of application.
- (26) The general principle of the responsibility of the manufacturer or importer for the safety of the product should be supported by restrictions of some substances in Annexes II and III. Moreover, substances which are intended to be used as colorants, preservatives and UV-filters should be listed in the Annexes IV, V and VI respectively in order to be allowed for these uses.

<sup>(1)</sup> OJ L 192, 11.7.1987, p. 49.

<sup>(2)</sup> OJ L 196, 2.8.2003, p. 7.

<sup>(3)</sup> OJ L 157, 30.4.2004, p. 45.

- (27) To avoid ambiguities, it should be clarified that the list of allowed colorants contained in Annex IV includes only substances which colour through absorption and reflection and not substances which colour through photoluminescence, interference, or chemical reaction.
- (28) To address safety concerns raised, Annex IV, which is currently restricted to skin colorants, should also include hair colorants once the risk assessment of these substances by the Scientific Committee for Consumer Safety (SCCS) set up by Commission Decision 2008/721/EC of 5 September 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment <sup>(1)</sup> has been finalised. To this end, the Commission should have the possibility to include hair colorants in the scope of that Annex by the comitology procedure.
- (29) The use of nanomaterials in cosmetic products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Community should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly.
- (30) At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the SCCS should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials.
- (31) The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.
- (32) Given the hazardous properties of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2, pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures <sup>(2)</sup>, their use in cosmetic products should be prohibited. However, as a hazardous property of a substance does not necessarily always entail a risk, there should be a possibility to allow the use of substances classified as CMR 2 substances where, in view of exposure and concentration, they have been found safe for use in cosmetic products by the SCCS and are regulated by the Commission in the Annexes to this Regulation. With regard to substances which are classified as CMR 1A or 1B substances, there should be a possibility, in the exceptional case that these substances comply with food safety requirements, inter alia as a result of their naturally occurring in food, and that no suitable alternative substances exist, to use such substances in cosmetic products on the condition that such use has been found safe by the SCCS. Where such conditions are met, the Commission should amend the relevant Annexes to this Regulation within 15 months of classification of substances as CMR 1A or 1B substances under Regulation (EC) No 1272/2008. Such substances should be continuously reviewed by the SCCS.
- (33) A safety assessment of substances, particularly those classified as CMR 1A or 1B substances, should consider the overall exposure to such substances stemming from all sources. At the same time, for those involved in producing safety assessments, it is essential that there be a harmonised approach to the development and use of such overall exposure estimates. In consequence, the Commission, in close cooperation with the SCCS, the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and other relevant stakeholders, should, as a matter of urgency, carry out a review and develop guidance regarding the production and use of overall exposure estimates for these substances.
- (34) The assessment by the SCCS of the use of substances classified as CMR 1A and 1B in cosmetic products should also take into account the exposure to those substances of vulnerable population groups, such as children under three years of age, elderly people, pregnant and breast-feeding women and persons with compromised immune responses.
- (35) The SCCS should give opinions where appropriate on the safety of use of nanomaterials in cosmetic products. These opinions should be based on full information being made available by the responsible person.
- (36) Action by the Commission and Member States relating to the protection of human health should be based on the precautionary principle.
- (37) In order to ensure product safety, prohibited substances should be acceptable at trace levels only if they are technologically inevitable with correct manufacturing processes and provided that the product is safe.
- (38) The Protocol on protection and welfare of animals annexed to the Treaty provides that the Community and the Member States are to pay full regard to the welfare requirements of animals in the implementation of Community policies, in particular with regard to the internal market.

<sup>(1)</sup> OJ L 241, 10.9.2008, p. 21.

<sup>(2)</sup> OJ L 353, 31.12.2008, p. 1.

- (39) Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes <sup>(1)</sup> established common rules for the use of animals for experimental purposes within the Community and laid down the conditions under which such experiments must be carried out in the territory of the Member States. In particular, Article 7 of that Directive requires that animal experiments be replaced by alternative methods, where such methods exist and are scientifically satisfactory.
- (40) The safety of cosmetic products and their ingredients may be ensured through the use of alternative methods which are not necessarily applicable to all uses of chemical ingredients. Therefore, the use of such methods by the whole cosmetic industry should be promoted and their adoption at Community level ensured, where such methods offer an equivalent level of protection to consumers.
- (41) The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. Provisions prohibiting animal testing of finished cosmetic products should therefore be laid down. The application, in particular by small and medium-sized enterprises, of both test methods and assessment procedures for relevant available data, including the use of read-across and weight-of-evidence approaches, which do not involve the use of animals for assessing the safety of finished cosmetic products could be facilitated by Commission guidelines.
- (42) It will gradually become possible to ensure the safety of ingredients used in cosmetic products by using non-animal alternative methods validated at Community level, or approved as being scientifically validated, by the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the Organisation for Economic Cooperation and Development (OECD). After consulting the SCCS as regards the applicability of the validated alternative methods to the field of cosmetic products, the Commission should immediately publish the validated or approved methods recognised as being applicable to such ingredients. In order to achieve the highest possible degree of animal protection, a deadline should be set for the introduction of a definitive prohibition.
- (43) The Commission established timetables of deadlines up to 11 March 2009 for prohibiting the marketing of cosmetic products, the final formulation, ingredients or combinations of ingredients which have been tested on animals, and for prohibiting each test currently carried out using animals. In view, however, of tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, it is appropriate for the final deadline for prohibiting the marketing of cosmetic products for which those tests are used to be 11 March 2013. On the basis of annual reports, the Commission should be authorised to adapt the timetables within the abovementioned maximum time limit.
- (44) Better coordination of resources at Community level will contribute to increasing the scientific knowledge indispensable for the development of alternative methods. It is essential, for this purpose, that the Community continue and increase its efforts and take the measures necessary for the promotion of research and the development of new non-animal alternative methods, in particular within its Framework Programmes for research.
- (45) The recognition by third countries of alternative methods developed in the Community should be encouraged. In order to achieve this objective, the Commission and the Member States should take all appropriate steps to facilitate acceptance of such methods by the OECD. The Commission should also endeavour, within the framework of European Community cooperation agreements, to obtain recognition of the results of safety tests carried out in the Community using alternative methods so as to ensure that the export of cosmetic products for which such methods have been used is not hindered and to prevent or avoid third countries requiring the repetition of such tests using animals.
- (46) Transparency is needed regarding the ingredients used in cosmetic products. Such transparency should be achieved by indication of the ingredients used in a cosmetic product on its packaging. Where for practical reasons it is impossible to indicate the ingredients on the packaging, such information should be enclosed so that the consumer has access to this information.
- (47) A glossary of common ingredient names should be compiled by the Commission to ensure uniform labelling and to facilitate identification of cosmetics ingredients. This glossary should not be intended to constitute a limitative list of substances used in cosmetic products.
- (48) In order to inform consumers, cosmetic products should bear precise and easily understandable indications concerning their durability for use. Given that consumers should be informed of the date until which the cosmetic product will continue to fulfil its initial function and remain safe, it is important to know the date of minimum durability, i.e. the date by which it is best to use the product. Where the minimum durability is more than 30 months, the consumer should be informed of the period of time after opening that the cosmetic product may be used without any harm to the consumer. However, this requirement should not apply where the concept of the durability after opening is not relevant, that is to say for single-use products, products not at risk of deterioration or products which do not open.

<sup>(1)</sup> OJ L 358, 18.12.1986, p. 1.

- (49) A number of substances have been identified by the SCCS as likely to cause allergic reactions and it will be necessary to restrict their use and/or impose certain conditions concerning them. In order to ensure that consumers are adequately informed, the presence of these substances should be mentioned in the list of ingredients and consumers' attention should be drawn to the presence of these ingredients. This information should improve the diagnosis of contact allergies among consumers and should enable them to avoid the use of cosmetic products which they do not tolerate. For substances which are likely to cause allergy to a significant part of the population, other restrictive measures such as a ban or a restriction of concentration should be considered.
- (50) In the safety assessment of a cosmetic product it should be possible to take into account results of risk assessments that have been carried out in other relevant areas. The use of such data should be duly substantiated and justified.
- (51) The consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products. In particular Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market <sup>(1)</sup> is applicable. Furthermore, the Commission, in cooperation with Member States, should define common criteria in relation to specific claims for cosmetic products.
- (52) It should be possible to claim on a cosmetic product that no animal testing was carried out in relation to its development. The Commission, in consultation with the Member States, has developed guidelines to ensure that common criteria are applied in the use of claims and that an aligned understanding of the claims is reached, and in particular that such claims do not mislead the consumer. In developing such guidelines, the Commission has also taken into account the views of the many small and medium-sized enterprises which make up the majority of the 'non-animal testing' producers, relevant non-governmental organisations, and the need for consumers to be able to make practical distinctions between products on the basis of animal testing criteria.
- (53) In addition to the labelled information, consumers should be given the possibility to request certain product-related information from the responsible person in order to make informed product choices.
- (54) Effective market surveillance is necessary in order to ensure that the provisions of this Regulation are respected. To this end, serious undesirable effects should be notified and competent authorities should have a possibility to request from the responsible person a list of cosmetic products containing substances which have raised serious doubts in terms of safety.
- (55) This Regulation is without prejudice to the possibility for Member States to regulate, in compliance with Community law, the notification by health professionals or consumers of serious undesirable effects to the competent authorities of Member States.
- (56) This Regulation is without prejudice to the possibility for Member States to regulate, in compliance with Community law, the establishment of economic operators in the area of cosmetic products.
- (57) In case of non-compliance with this Regulation, a clear and efficient procedure for the withdrawal and recall of products may be necessary. This procedure should, where possible, build upon existing Community rules for unsafe goods.
- (58) In order to address cosmetic products which, despite complying with the provisions of this Regulation, might endanger human health, a safeguard procedure should be introduced.
- (59) The Commission should provide indications for the uniform interpretation and application of the concept of serious risks in order to facilitate the consistent implementation of this Regulation.
- (60) In order to comply with principles of good administrative practices, any decision by a competent authority in the framework of market surveillance should be duly substantiated.
- (61) In order to ensure effective in-market control, a high degree of administrative cooperation amongst the competent authorities is necessary. This concerns in particular mutual assistance in the verification of product information files located in another Member State.
- (62) The Commission should be assisted by the SCCS, an independent risk assessment body.
- (63) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(2)</sup>.
- (64) In particular, power should be conferred on the Commission to adapt the Annexes to this Regulation to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

<sup>(1)</sup> OJ L 149, 11.6.2005, p. 22.

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.



(65) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of certain measures relating to CMRs, nanomaterials and potential risks to human health.

(66) Member States should lay down provisions on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(67) Economic operators as well as Member States and the Commission need sufficient time to adapt to the changes introduced by this Regulation. Therefore it is appropriate to provide for a sufficient transitional period for that adaptation. However, in order to ensure a smooth transition, economic operators should be allowed to place on the market cosmetic products which comply with this Regulation before the expiry of that transitional period.

(68) In order to enhance the safety of cosmetic products and strengthen the market surveillance, cosmetic products placed on the market after the date of application of this Regulation should comply with its obligations regarding safety assessment, the product information file and notification, even if similar obligations have already been fulfilled under Directive 76/768/EEC.

(69) Directive 76/768/EEC should be repealed. However, in order to ensure appropriate medical treatment in the event of difficulties and to ensure market surveillance, the information received pursuant to Article 7(3) and Article 7a(4) of Directive 76/768/EEC concerning cosmetic products should be kept by the competent authorities for a certain period of time and the information kept by the responsible person should remain available for the same period of time.

(70) This Regulation should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Part B of Annex IX.

(71) Since the objective of this Regulation, namely the achievement of the internal market and a high level of protection of human health through the compliance of cosmetic products with the requirements laid down in this Regulation, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

## CHAPTER I

### SCOPE, DEFINITIONS

#### Article 1

#### Scope and objective

This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.

#### Article 2

#### Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;

(b) 'substance' means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(c) 'mixture' means a mixture or solution composed of two or more substances;

(d) 'manufacturer' means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark;

(e) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community market;

(f) 'end user' means either a consumer or professional using the cosmetic product;

(g) 'making available on the market' means any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

(h) 'placing on the market' means the first making available of a cosmetic product on the Community market;

- (i) 'importer' means any natural or legal person established within the Community, who places a cosmetic product from a third country on the Community market;
- (j) 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services <sup>(1)</sup> on the basis of a request made by the Commission in accordance with Article 6 of that Directive;
- (k) 'nanomaterial' means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm;
- (l) 'preservatives' means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product;
- (m) 'colorants' means substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants;
- (n) 'UV-filters' means substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation;
- (o) 'undesirable effect' means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product;
- (p) 'serious undesirable effect' means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death;
- (q) 'withdrawal' means any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain;
- (r) 'recall' means any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user;
- (s) 'frame formulation' means a formulation which lists the category or function of ingredients and their maximum concentration in the cosmetic product or gives relevant quantitative and qualitative information whenever a cosmetic product is not covered or only partially covered by such a formulation. The Commission shall provide indications for the establishment of the frame formulation and adapt them regularly to technical and scientific progress.

2. For the purposes of point (a) of paragraph 1, a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product.

3. In view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (k) of paragraph 1 to technical and scientific progress and to definitions subsequently agreed at international level. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

## CHAPTER II

### SAFETY, RESPONSIBILITY, FREE MOVEMENT

#### Article 3

##### Safety

A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

- (a) presentation including conformity with Directive 87/357/EEC;
- (b) labelling;
- (c) instructions for use and disposal;
- (d) any other indication or information provided by the responsible person defined in Article 4.

The provision of warnings shall not exempt persons defined in Articles 2 and 4 from compliance with the other requirements laid down in this Regulation.

#### Article 4

##### Responsible person

1. Only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market.

2. For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation.

3. For a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer established within the Community shall be the responsible person.

<sup>(1)</sup> OJ L 204, 21.7.1998, p. 37.

The manufacturer may designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

4. Where, for a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer is established outside the Community, he shall designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

5. For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market.

The importer may, by written mandate, designate a person established within the Community as the responsible person who shall accept in writing.

6. The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trade-mark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.

The translation of information relating to a cosmetic product already placed on the market shall not be considered as a modification of that product of such a nature that compliance with the applicable requirements of this Regulation may be affected.

#### Article 5

##### Obligations of responsible persons

1. Responsible persons shall ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, Article 19(1),(2) and (5), as well as Articles 20, 21, 23 and 24.

2. Responsible persons who consider or have reason to believe that a cosmetic product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate.

Furthermore, where the cosmetic product presents a risk to human health, responsible persons shall immediately inform the competent national authorities of the Member States in which they made the product available and of the Member State in which the product information file is readily accessible, giving details, in particular, of the non-compliance and of the corrective measures taken.

3. Responsible persons shall cooperate with these authorities, at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular, responsible persons shall, further to a reasoned request from a competent national authority, provide it

with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in a language which can be easily understood by that authority.

#### Article 6

##### Obligations of distributors

1. In the context of their activities, when making a cosmetic product available on the market, distributors shall act with due care in relation to applicable requirements.

2. Before making a cosmetic product available on the market distributors shall verify that:

- the labelling information provided for in Article 19(1)(a), (e) and (g) and Article 19(3) and (4) is present,
- the language requirements provided for in Article 19(5) are fulfilled,
- the date of minimum durability specified, where applicable under Article 19(1), has not passed.

3. Where distributors consider or have reason to believe that:

- a cosmetic product is not in conformity with the requirements laid down in this Regulation, they shall not make the product available on the market until it has been brought into conformity with the applicable requirements,
- a cosmetic product which they have made available on the market is not in conformity with this Regulation, they shall make sure that the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate, are taken.

Furthermore, where the cosmetic product presents a risk to human health, distributors shall immediately inform the responsible person and the competent national authorities of the Member States in which they made the product available, giving details, in particular, of the non-compliance and of the corrective measures taken.

4. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in this Regulation.

5. Distributors shall cooperate with competent authorities, at the request of the latter, on any action to eliminate the risks posed by products which they have made available on the market. In particular, distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2, in a language which can be easily understood by that authority.



## Article 7

**Identification within the supply chain**

At the request of a competent authority:

- responsible persons shall identify the distributors to whom they supply the cosmetic product,
- the distributor shall identify the distributor or the responsible person from whom, and the distributors to whom, the cosmetic product was supplied.

This obligation shall apply for a period of three years following the date on which the batch of the cosmetic product was made available to the distributor.

## Article 8

**Good manufacturing practice**

1. The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensuring the objectives of Article 1.
2. Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*.

## Article 9

**Free movement**

Member States shall not, for reasons related to the requirements laid down in this Regulation, refuse, prohibit or restrict the making available on the market of cosmetic products which comply with the requirements of this Regulation.

## CHAPTER III

**SAFETY ASSESSMENT, PRODUCT INFORMATION FILE, NOTIFICATION**

## Article 10

**Safety assessment**

1. In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.

The responsible person shall ensure that:

- (a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;

- (b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;

- (c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

The first subparagraph shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.

The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable undertakings, in particular small and medium-sized enterprises, to comply with the requirements laid down in Annex I. Those guidelines shall be adopted in accordance with the regulatory procedure referred to in Article 32(2).

2. The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State.

3. Non-clinical safety studies referred to in the safety assessment according to paragraph 1 and carried out after 30 June 1988 for the purpose of assessing the safety of a cosmetic product shall comply with Community legislation on the principles of good laboratory practice, as applicable at the time of performance of the study, or with other international standards recognised as being equivalent by the Commission or the ECHA.

## Article 11

**Product information file**

1. When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

2. The product information file shall contain the following information and data which shall be updated as necessary:

- (a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;

- (b) the cosmetic product safety report referred to in Article 10(1);

- (c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;

- (d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;
  - (e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.
3. The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.
- (f) the presence of substances in the form of nanomaterials and:
    - (i) their identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI to this Regulation;
    - (ii) the reasonably foreseeable exposure conditions;
  - (g) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008;
  - (h) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The information contained in the product information file shall be available in a language which can be easily understood by the competent authorities of the Member State.

4. The requirements provided in paragraphs 1 to 3 of this Article shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.

The first subparagraph shall also apply to cosmetic products notified under Directive 76/768/EEC.

2. When the cosmetic product is placed on the market, the responsible person shall notify to the Commission the original labelling, and, where reasonably legible, a photograph of the corresponding packaging.

3. As from 11 July 2013, a distributor who makes available in a Member State a cosmetic product already placed on the market in another Member State and translates, on his own initiative, any element of the labelling of that product in order to comply with national law, shall submit, by electronic means, the following information to the Commission:

- (a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;
- (b) the Member State in which the cosmetic product is made available;
- (c) his name and address;
- (d) the name and address of the responsible person where the product information file is made readily accessible..

4. Where a cosmetic product has been placed on the market before 11 July 2013 but is no longer placed on the market as from that date, and a distributor introduces that product in a Member State after that date, that distributor shall communicate the following to the responsible person:

- (a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;
- (b) the Member State in which the cosmetic product is made available;

#### Article 12

##### Sampling and analysis

1. Sampling and analysis of cosmetic products shall be performed in a reliable and reproducible manner.

2. In the absence of any applicable Community legislation, reliability and reproducibility shall be presumed if the method used is in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*.

#### Article 13

##### Notification

1. Prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, the following information to the Commission:

- (a) the category of cosmetic product and its name or names, enabling its specific identification;
- (b) the name and address of the responsible person where the product information file is made readily accessible;
- (c) the country of origin in the case of import;
- (d) the Member State in which the cosmetic product is to be placed on the market;
- (e) the contact details of a physical person to contact in the case of necessity;

(c) his name and address.

On the basis of that communication, the responsible person shall submit to the Commission, by electronic means, the information referred to in paragraph 1 of this Article, where notifications according to Article 7(3) and Article 7a (4) of Directive 76/768/EEC have not been carried out in the Member State in which the cosmetic product is made available.

5. The Commission shall, without delay, make the information referred to in points (a) to (g) of paragraph 1, and in paragraphs 2 and 3 available electronically to all competent authorities.

That information may be used by competent authorities only for the purposes of market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

6. The Commission shall, without delay, make the information referred to in paragraphs 1, 2 and 3 available electronically to poison centres or similar bodies, where such centres or bodies have been established by Member States.

That information may be used by those bodies only for the purposes of medical treatment.

7. Where any of the information set out in paragraphs 1, 3 and 4 changes, the responsible person or the distributor shall provide an update without delay.

8. The Commission may, taking into account technical and scientific progress and specific needs related to market surveillance, amend paragraphs 1 to 7 by adding requirements.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

#### CHAPTER IV

#### RESTRICTIONS FOR CERTAIN SUBSTANCES

##### Article 14

#### Restrictions for substances listed in the Annexes

1. Without prejudice to Article 3, cosmetic products shall not contain any of the following:

(a) prohibited substances

— prohibited substances listed in Annex II;

(b) restricted substances

— restricted substances which are not used in accordance with the restrictions laid down in Annex III;

(c) colorants

(i) colorants other than those listed in Annex IV and colorants which are listed there but not used in accordance with the conditions laid down in that Annex, except for hair colouring products referred to in paragraph 2;

(ii) without prejudice to points (b), (d)(i) and (e)(i), substances which are listed in Annex IV but which are not intended to be used as colorants, and which are not used in accordance with the conditions laid down in that Annex;

(d) preservatives

(i) preservatives other than those listed in Annex V and preservatives which are listed there but not used in accordance with the conditions laid down in that Annex;

(ii) without prejudice to points (b), (c)(i) and (e)(i), substances listed in Annex V but which are not intended to be used as preservatives, and which are not used in accordance with the conditions laid down in that Annex;

(e) UV-filters

(i) UV-filters other than those listed in Annex VI and UV-filters which are listed there but not used in accordance with the conditions laid down in that Annex;

(ii) without prejudice to points (b), (c)(i) and (d)(i), substances listed in Annex VI but which are not intended to be used as UV-filters and which are not used in accordance with the conditions laid down in that Annex.

2. Subject to a decision of the Commission to extend the scope of Annex IV to hair colouring products, such products shall not contain colorants intended to colour the hair, other than those listed in Annex IV and colorants intended to colour the hair which are listed there but not used in accordance with the conditions laid down in that Annex.

The decision of the Commission referred to in the first subparagraph, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

##### Article 15

#### Substances classified as CMR substances

1. The use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. To these ends the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation.

2. The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

However, such substances may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, all of the following conditions are fulfilled:

- (a) they comply with the food safety requirements as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>(1)</sup>;
- (b) there are no suitable alternative substances available, as documented in an analysis of alternatives;
- (c) the application is made for a particular use of the product category with a known exposure; and
- (d) they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups.

Specific labelling in order to avoid misuse of the cosmetic product shall be provided in accordance with Article 3 of this Regulation, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure.

In order to implement this paragraph, the Commission shall amend the Annexes to this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation within 15 months of the inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 32(4) of this Regulation.

The Commission shall mandate the SCCS to re-evaluate those substances as soon as safety concerns arise, and at the latest five years after their inclusion in Annexes III to VI to this Regulation, and at least every subsequent five years.

3. By 11 January 2012, the Commission shall ensure that appropriate guidance is developed with the aim of enabling a harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances. This guidance shall be developed in consultation with the SCCS, the

ECHA, the EFSA and other relevant stakeholders, drawing, as appropriate, on relevant best practice.

4. When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.

#### Article 16

#### Nanomaterials

1. For every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured.

2. The provisions of this Article do not apply to nanomaterials used as colorants, UV-filters or preservatives regulated under Article 14, unless expressly specified.

3. In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market, except where they have already been placed on the market by the same responsible person before 11 January 2013.

In the latter case, cosmetic products containing nanomaterials placed on the market shall be notified to the Commission by the responsible person between 11 January 2013 and 11 July 2013 by electronic means, in addition to the notification in Article 13.

The first and the second subparagraphs shall not apply to cosmetic products containing nanomaterials that are in conformity with the requirements set out in Annex III.

The information notified to the Commission shall contain at least the following:

- (a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;
- (b) the specification of the nanomaterial including size of particles, physical and chemical properties;
- (c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;
- (d) the toxicological profile of the nanomaterial;
- (e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;
- (f) the reasonably foreseeable exposure conditions.

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1.

The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Commission thereof.

The Commission shall provide a reference number for the submission of the toxicological profile, which may substitute the information to be notified under point (d).

4. In the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions. The Commission shall make this information public. The SCCS shall deliver its opinion within six months of the Commission's request. Where the SCCS finds that any necessary data is lacking, the Commission shall request the responsible person to provide such data within an explicitly stated reasonable time, which shall not be extended. The SCCS shall deliver its final opinion within six months of submission of additional data. The opinion of the SCCS shall be made publicly available.

5. The Commission may, at any time, invoke the procedure in paragraph 4 where it has any safety concerns, for example due to new information supplied by a third party.

6. Taking into account the opinion of the SCCS, and where there is a potential risk to human health, including when there is insufficient data, the Commission may amend Annexes II and III.

7. The Commission may, taking into account technical and scientific progress, amend paragraph 3 by adding requirements.

8. The measures, referred to in paragraphs 6 and 7, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

9. On imperative grounds of urgency the Commission may use the procedure referred to in Article 32(4).

10. The following information shall be made available by the Commission:

- (a) By 11 January 2014, the Commission shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated thereafter and be made publicly available.
- (b) The Commission shall submit to the European Parliament and the Council an annual status report, which will give information on developments in the use of nanomaterials in

cosmetic products within the Community, including those used as colorants, UV-filters and preservatives in a separate section. The first report shall be presented by 11 July 2014. The report update shall summarise, in particular, the new nanomaterials in new categories of cosmetic products, the number of notifications, the progress made in developing nano-specific assessment methods and safety assessment guides, and information on international cooperation programmes.

11. The Commission shall regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress and shall, where necessary, propose suitable amendments to those provisions.

The first review shall be undertaken by 11 July 2018.

#### Article 17

### Traces of prohibited substances

The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.

#### CHAPTER V

### ANIMAL TESTING

#### Article 18

### Animal testing

1. Without prejudice to the general obligations deriving from Article 3, the following shall be prohibited:

- (a) the placing on the market of cosmetic products where the final formulation, in order to meet the requirements of this Regulation, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;
- (b) the placing on the market of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Regulation, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;
- (c) the performance within the Community of animal testing of finished cosmetic products in order to meet the requirements of this Regulation;



(d) the performance within the Community of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Regulation, after the date on which such tests are required to be replaced by one or more validated alternative methods listed in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) <sup>(1)</sup> or in Annex VIII to this Regulation.

2. The Commission, after consulting the SCCS and the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, has established timetables for the implementation of the provisions under points (a), (b) and (d) of paragraph 1, including deadlines for the phasing-out of the various tests. The timetables were made available to the public on 1 October 2004 and sent to the European Parliament and the Council. The period for implementation was limited to 11 March 2009 in relation to points (a), (b) and (d) of paragraph 1.

In relation to the tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of paragraph 1(a) and (b) shall be limited to 11 March 2013.

The Commission shall study possible technical difficulties in complying with the ban in relation to tests, in particular those concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration. Information about the provisional and final results of these studies forms part of the yearly reports presented pursuant to Article 35.

On the basis of these annual reports, the timetables established as referred to in the first subparagraph, could be adapted up to 11 March 2009 in relation to the first subparagraph and may be adapted up to 11 March 2013 in relation to the second subparagraph and after consultation of the entities referred to in the first subparagraph.

The Commission shall study progress and compliance with the deadlines as well as possible technical difficulties in complying with the ban. Information about the provisional and final results of the Commission studies forms part of the yearly reports presented pursuant to Article 35. If these studies conclude, at the latest two years prior to the end of the maximum period referred to in the second subparagraph, that for technical reasons one or more tests referred to in that subparagraph will not be developed and validated before the expiry of the period referred to therein it shall inform the European Parliament and the Council and shall put forward a legislative proposal in accordance with Article 251 of the Treaty.

In exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic ingredient, a Member State may request the Commission to grant a derogation from

paragraph 1. The request shall contain an evaluation of the situation and indicate the measures necessary. On this basis, the Commission may, after consulting the SCCS and by means of a reasoned decision, authorise the derogation. That authorisation shall lay down the conditions associated with this derogation in terms of specific objectives, duration and reporting of the results.

A derogation shall be granted only where:

- (a) the ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function;
- (b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.

The decision on the authorisation, the conditions associated with it and the final result achieved shall be part of the annual report presented by the Commission in accordance with Article 35.

The measures referred to in the sixth subparagraph, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

3. For the purposes of this Article and Article 20:

- (a) 'finished cosmetic product' means the cosmetic product in its final formulation, as placed on the market and made available to the end user, or its prototype;
- (b) 'prototype' means a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed.

## CHAPTER VI

### CONSUMER INFORMATION

#### Article 19

##### Labelling

1. Without prejudice to other provisions in this Article, cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering:

- (a) the name or registered name and the address of the responsible person. Such information may be abbreviated in so far as the abbreviation makes it possible to identify that person and his address. If several addresses are indicated, the one where the responsible person makes readily available the product information file shall be highlighted. The country of origin shall be specified for imported cosmetic products;

<sup>(1)</sup> OJ L 142, 31.5.2008, p. 1.

- (b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;
- (c) the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function and, in particular, will remain in conformity with Article 3 ('date of minimum durability').

The date itself or details of where it appears on the packaging shall be preceded by the symbol shown in point 3 of Annex VII or the words: 'best used before the end of'.

The date of minimum durability shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer. This information shall be indicated, except where the concept of durability after opening is not relevant, by the symbol shown in point 2 of Annex VII followed by the period (in months and/or years);

- (d) particular precautions to be observed in use, and at least those listed in Annexes III to VI and any special precautionary information on cosmetic products for professional use;
- (e) the batch number of manufacture or the reference for identifying the cosmetic product. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging;
- (f) the function of the cosmetic product, unless it is clear from its presentation;
- (g) a list of ingredients. This information may be indicated on the packaging alone. The list shall be preceded by the term 'ingredients'.

For the purpose of this Article, an ingredient means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing. The following shall not, however, be regarded as ingredients:

- (i) impurities in the raw materials used;
- (ii) subsidiary technical materials used in the mixture but not present in the final product.

Perfume and aromatic compositions and their raw materials shall be referred to by the terms 'parfum' or 'aroma'. Moreover, the presence of substances, the mention of which is required under the column 'Other' in Annex III, shall be indicated in the list of ingredients in addition to the terms parfum or aroma.

The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.

All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

Colorants other than colorants intended to colour the hair may be listed in any order after the other cosmetic ingredients. For decorative cosmetic products marketed in several colour shades, all colorants other than colorants intended to colour the hair used in the range may be listed, provided that the words 'may contain' or the symbol '+/-' are added. The CI (Colour Index) nomenclature shall be used, where applicable.

2. Where it is impossible for practical reasons to label the information mentioned in points (d) and (g) of paragraph 1 as provided, the following applies:

- the information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card;
- unless impracticable, this information shall be referred to by abbreviated information or the symbol given in point 1 of Annex VII, which must appear on the container or packaging for the information referred in point (d) of paragraph 1 and on packaging for the information referred in point (g) of paragraph 1.

3. In the case of soap, bath balls and other small products where it is impossible for practical reasons for the information referred to in point (g) of paragraph 1 to appear on a label, tag, tape or card or in an enclosed leaflet, this information shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.



4. For cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, Member States shall adopt detailed rules for indication of the information referred to in paragraph 1.

5. The language of the information mentioned in points (b), (c), (d) and (f) of paragraph 1 and in paragraphs (2), (3) and (4) shall be determined by the law of the Member States in which the product is made available to the end user.

6. The information mentioned in point (g) of paragraph 1 shall be expressed by using the common ingredient name set out in the glossary provided for in Article 33. In the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.

#### *Article 20*

##### **Product claims**

1. In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

2. The Commission shall, in cooperation with Member States, establish an action plan regarding claims used and fix priorities for determining common criteria justifying the use of a claim.

After consulting the SCCS or other relevant authorities, the Commission shall adopt a list of common criteria for claims which may be used in respect of cosmetic products, in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation, taking into account the provisions of Directive 2005/29/EC.

By 11 July 2016, the Commission shall submit to the European Parliament and the Council a report regarding the use of claims on the basis of the common criteria adopted under the second subparagraph. If the report concludes that claims used in respect of cosmetic products are not in conformity with the common criteria, the Commission shall take appropriate measures to ensure compliance in cooperation with the Member States.

3. The responsible person may refer, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the cosmetic product, to the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished cosmetic product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products.

#### *Article 21*

##### **Access to information for the public**

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier, as well as existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product are made easily accessible to the public by any appropriate means.

The quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances in accordance with Article 3 of Regulation (EC) No 1272/2008.

#### CHAPTER VII

##### **MARKET SURVEILLANCE**

#### *Article 22*

##### **In-market control**

Member States shall monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples.

Member States shall also monitor compliance with the principles of good manufacturing practices.

Member States shall entrust to market surveillance authorities the necessary powers, resources and knowledge in order for those authorities to properly perform their tasks.

Member States shall periodically review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means.

#### *Article 23*

##### **Communication of serious undesirable effects**

1. In the event of serious undesirable effects, the responsible person and distributors shall without delay notify the following to the competent authority of the Member State where the serious undesirable effect occurred:

- (a) all serious undesirable effects which are known to him or which may reasonably be expected to be known to him;

(b) the name of the cosmetic product concerned, enabling its specific identification;

(c) the corrective measures taken by him, if any.

2. Where the responsible person reports serious undesirable effects to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information referred to in paragraph 1 to the competent authorities of the other Member States.

3. Where distributors report serious undesirable effects to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information referred to in paragraph 1 to the competent authorities of the other Member States and to the responsible person.

4. Where end users or health professionals report serious undesirable effects to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information on the cosmetic product concerned to the competent authorities of the other Member States and to the responsible person.

5. Competent authorities may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

#### Article 24

##### Information on substances

In the event of serious doubt regarding the safety of any substance contained in cosmetic products, the competent authority of a Member State in which a product containing such a substance is made available on the market may by reasoned request require the responsible person to submit a list of all cosmetic products for which he is responsible and which contain this substance. The list shall indicate the concentration of this substance in the cosmetic products.

Competent authorities may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

#### CHAPTER VIII

##### NON-COMPLIANCE, SAFEGUARD CLAUSE

#### Article 25

##### Non-compliance by the responsible person

1. Without prejudice to paragraph 4, competent authorities shall require the responsible person to take all appropriate measures, including corrective actions bringing the cosmetic product

into conformity, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit, commensurate with the nature of the risk, where there is non-compliance with any of the following:

(a) the good manufacturing practice referred to in Article 8;

(b) the safety assessment referred to in Article 10;

(c) the requirements for the product information file referred to in Article 11;

(d) the provisions on sampling and analysis referred to in Article 12;

(e) the notification requirements referred to in Articles 13 and 16;

(f) the restrictions for substances referred to in Articles 14, 15 and 17;

(g) the animal testing requirements referred to in Article 18;

(h) the labelling requirements referred to in Article 19(1), (2), (5) and (6);

(i) the requirements related to product claims set out in Article 20;

(j) the access to information for the public referred to in Article 21;

(k) the communication of serious undesirable effects referred to in Article 23;

(l) the information requirements on substances referred to in Article 24.

2. Where applicable, a competent authority shall inform the competent authority of the Member State in which the responsible person is established of the measures which it has required the responsible person to take.

3. The responsible person shall ensure that the measures referred to in paragraph 1 are taken in respect of all the products concerned which are made available on the market throughout the Community.

4. In the case of serious risks to human health, where the competent authority considers that the non-compliance is not limited to the territory of the Member State in which the cosmetic product is made available on the market, it shall inform the Commission and the competent authorities of the other Member States of the measures which it has required the responsible person to take.

5. The competent authority shall take all appropriate measures to prohibit or restrict the making available on the market of the cosmetic product or to withdraw the product from the market or to recall it in the following cases:

(a) where an immediate action is necessary in the event of serious risk to human health; or

- (b) where the responsible person does not take all appropriate measures within the time limit referred to in paragraph 1.

In the event of serious risks to human health, that competent authority shall inform the Commission and the competent authorities of the other Member States, without delay, of the measures taken.

6. In the absence of a serious risk to human health, in the event that the responsible person does not take all appropriate measures, the competent authority shall without delay inform the competent authority of the Member State in which the responsible person is established of the measures taken.

7. For the purposes of paragraphs 4 and 5 of this Article, the information exchange system provided for in Article 12(1) of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety <sup>(1)</sup> shall be used.

Article 12(2), (3) and (4) of Directive 2001/95/EC and Article 23 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(2)</sup> shall also apply.

#### Article 26

##### **Non-compliance by distributors**

Competent authorities shall require distributors to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within a given reasonable time limit, commensurate with the nature of the risk, where there is non-compliance with obligations laid down in Article 6.

#### Article 27

##### **Safeguard clause**

1. In the case of products meeting the requirements listed in Article 25(1), where a competent authority ascertains, or has reasonable grounds for concern, that a cosmetic product or products made available on the market present or could present a serious risk to human health, it shall take all appropriate provisional measures in order to ensure that the product or products concerned are withdrawn, recalled or their availability is otherwise restricted.

2. The competent authority shall immediately communicate to the Commission and the competent authorities of the other Member States the measures taken and any supporting data.

For the purposes of the first subparagraph, the information exchange system provided for in Article 12(1) of Directive 2001/95/EC shall be used.

Article 12(2), (3) and (4) of Directive 2001/95/EC shall apply.

3. The Commission shall determine, as soon as possible, whether the provisional measures referred to in paragraph 1 are justified or not. For that purpose it shall, whenever possible, consult the interested parties, the Member States and the SCCS.

4. Where the provisional measures are justified, Article 31(1) shall apply.

5. Where the provisional measures are not justified the Commission shall inform the Member States thereof and the competent authority concerned shall repeal the provisional measures in question.

#### Article 28

##### **Good administrative practices**

1. Any decision taken pursuant to Articles 25 and 27 shall state the exact grounds on which it is based. It shall be notified by the competent authority without delay to the responsible person, who shall at the same time be informed of the remedies available to him under the law of the Member State concerned and of the time limits to which remedies are subject.

2. Except in the case where immediate action is necessary for reasons of serious risk to human health, the responsible person shall have the opportunity to put forward his viewpoint before any decision is taken.

3. Where applicable, the provisions mentioned in paragraphs 1 and 2 shall apply with regard to the distributor for any decisions taken pursuant to Articles 26 and 27.

#### CHAPTER IX

##### **ADMINISTRATIVE COOPERATION**

#### Article 29

##### **Cooperation between competent authorities**

1. The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the proper application and due enforcement of this Regulation and shall transmit to each other all information necessary with a view to applying this Regulation uniformly.

2. The Commission shall provide for the organisation of an exchange of experience between the competent authorities in order to coordinate the uniform application of this Regulation.

3. Cooperation may be part of initiatives developed at international level.

<sup>(1)</sup> OJ L 11, 15.1.2002, p. 4.

<sup>(2)</sup> OJ L 218, 13.8.2008, p. 30.

*Article 30***Cooperation regarding verification of product information files**

The competent authority of any Member State where the cosmetic product is made available may request the competent authority of the Member State where the product information file is made readily accessible to verify whether the product information file satisfies the requirements referred to in Article 11(2) and whether the information set out therein provides evidence of the safety of the cosmetic product.

The requesting competent authority shall provide a motivation for the request.

Upon that request, the competent authority requested shall, without undue delay and taking into account the degree of urgency, carry out the verification and shall inform the requesting competent authority of its findings.

## CHAPTER X

**IMPLEMENTING MEASURES, FINAL PROVISIONS***Article 31***Amendment of the Annexes**

1. Where there is a potential risk to human health, arising from the use of substances in cosmetic products, which needs to be addressed on a Community-wide basis, the Commission may, after consulting the SCCS, amend Annexes II to VI accordingly.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 32(4).

2. The Commission may, after consulting the SCCS, amend Annexes III to VI and VIII for the purposes of adapting them to technical and scientific progress.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

3. Where it appears necessary, in order to ensure the safety of cosmetic products placed on the market, the Commission may, after consulting the SCCS, amend Annex I.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

*Article 32***Committee procedure**

1. The Commission shall be assisted by the Standing Committee on Cosmetic Products.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply having regard to the provisions of Article 8 thereof.

*Article 33***Glossary of common ingredient names**

The Commission shall compile and update a glossary of common ingredient names. To this end, the Commission shall take account of internationally recognised nomenclatures including the International Nomenclature of Cosmetic Ingredients (INCI). That glossary shall not constitute a list of the substances authorised for use in cosmetic products.

The common ingredient name shall be applied for the purpose of labelling cosmetic products placed on the market at the latest twelve months after publication of the glossary in the *Official Journal of the European Union*.

*Article 34***Competent authorities, poison control centres or assimilated entities**

1. Member States shall designate their national competent authorities.

2. Member States shall communicate the details of authorities referred to in paragraph 1 and of the poison centres and similar bodies referred to in Article 13(6) to the Commission. They shall communicate an update of these details as necessary.

3. The Commission shall compile and update a list of the authorities and bodies referred to in paragraph 2 and make it available to the public.

*Article 35***Annual report on animal testing**

Every year the Commission shall present a report to the European Parliament and the Council on:

(1) progress made in the development, validation and legal acceptance of alternative methods. The report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by Directive 86/609/EEC. The Commission shall in particular ensure the development, validation and legal acceptance of alternative test methods which do not use live animals;

- (2) progress made by the Commission in its efforts to obtain acceptance by the OECD of alternative methods validated at Community level and recognition by third countries of the results of the safety tests carried out in the Community using alternative methods, in particular within the framework of cooperation agreements between the Community and these countries;
- (3) the manner in which the specific needs of small and medium-sized enterprises have been taken into account.

#### Article 36

##### Formal objection against harmonised standards

1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements set out in the relevant provisions of this Regulation, the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall deliver its opinion without delay.
2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the *Official Journal of the European Union*.
3. The Commission shall inform the Member States and the European standardisation body concerned. It shall, if necessary, request the revision of the harmonised standards concerned.

#### Article 37

##### Penalties

Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 11 July 2013 and shall notify it without delay of any subsequent amendment affecting them.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 November 2009.

For the European Parliament  
The President  
J. BUZEK

#### Article 38

##### Repeal

Directive 76/768/EEC is repealed with effect from 11 July 2013, with the exception of Article 4b which is repealed with effect from 1 December 2010.

References to the repealed Directive shall be understood as references to this Regulation.

This Regulation shall be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Part B of Annex IX.

However, the competent authorities shall continue to keep available the information received pursuant to Article 7(3) and Article 7a(4) of Directive 76/768/EEC and responsible persons shall continue to keep readily accessible the information collected pursuant to Article 7a of that Directive until 11 July 2020.

#### Article 39

##### Transitional provisions

By way of derogation from Directive 76/768/EEC, cosmetic products which comply with this Regulation may be placed on the market before 11 July 2013.

As from 11 January 2012, by way of derogation from Directive 76/768/EEC, notification carried out in accordance with Article 13 of this Regulation shall be considered to comply with Article 7(3) and Article 7a(4) of that Directive.

#### Article 40

##### Entry into force and date of application

1. This Regulation shall enter into force on the [twentieth day after its publication in the *Official Journal of the European Union*
2. It shall apply from 11 July 2013, with the exception of:
  - Article 15(1) and (2) which shall apply from 1 December 2010, as well as Articles 14, 31 and 32 to the extent that they are necessary to apply Article 15(1) and (2); and
  - Article 16(3) second subparagraph, which shall apply from 11 January 2013.

For the Council  
The President  
B. ASK



## ANNEX I

**COSMETIC PRODUCT SAFETY REPORT**

The cosmetic product safety report shall, as a minimum, contain the following:

**PART A – Cosmetic product safety information****1. Quantitative and qualitative composition of the cosmetic product**

The qualitative and quantitative composition of the cosmetic product, including chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS, where possible) and their intended function. In the case of perfume and aromatic compositions, description of the name and code number of the composition and the identity of the supplier.

**2. Physical/chemical characteristics and stability of the cosmetic product**

The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product.

The stability of the cosmetics product under reasonably foreseeable storage conditions.

**3. Microbiological quality**

The microbiological specifications of the substance or mixture and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people and persons showing compromised immune responses.

Results of preservation challenge test.

**4. Impurities, traces, information about the packaging material**

The purity of the substances and mixtures.

In the case of traces of prohibited substances, evidence for their technical unavoidability.

The relevant characteristics of packaging material, in particular purity and stability.

**5. Normal and reasonably foreseeable use**

The normal and reasonably foreseeable use of the product. The reasoning shall be justified in particular in the light of warnings and other explanations in the product labelling.

**6. Exposure to the cosmetic product**

Data on the exposure to cosmetic product taking into consideration the findings under Section 5 in relation to

- 1) The site(s) of application;
- 2) The surface area(s) of application;
- 3) The amount of product applied;
- 4) The duration and frequency of use;
- 5) The normal and reasonably foreseeable exposure route(s);
- 6) The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account.

The calculation of the exposure shall also take into consideration the toxicological effects to be considered (e.g. exposure might need to be calculated per unit area of skin or per unit of body weight). The possibility of secondary exposure by routes other than those resulting from direct application should also be considered (e.g. non-intended inhalation of sprays, non-intended ingestion of lip products, etc.).

Particular consideration shall be given to any possible impacts on exposure due to particle sizes.

#### **7. Exposure to the substances**

Data on the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under Section 6.

#### **8. Toxicological profile of the substances**

Without prejudice to Article 18, the toxicological profile of substance contained in the cosmetic product for all relevant toxicological endpoints. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity shall be made.

All significant toxicological routes of absorption shall be considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL) shall be calculated. The absence of these considerations shall be duly justified.

Particular consideration shall be given to any possible impacts on the toxicological profile due to

- particle sizes, including nanomaterials,
- impurities of the substances and raw material used, and
- interaction of substances.

Any read-across shall be duly substantiated and justified.

The source of information shall be clearly identified.

#### **9. Undesirable effects and serious undesirable effects**

All available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data.

#### **10. Information on the cosmetic product**

Other relevant information, e.g. existing studies from human volunteers or the duly confirmed and substantiated findings of risk assessments carried out in other relevant areas.

### **PART B – Cosmetic product safety assessment**

#### **1. Assessment conclusion**

Statement on the safety of the cosmetic product in relation to Article 3.

#### **2. Labelled warnings and instructions of use**

Statement on the need to label any particular warnings and instructions of use in accordance with Article 19(1)(d).

#### **3. Reasoning**

Explanation of the scientific reasoning leading to the assessment conclusion set out under Section 1 and the statement set out under Section 2. This explanation shall be based on the descriptions set out under Part A. Where relevant, margins of safety shall be assessed and discussed.



There shall be inter alia a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

Possible interactions of the substances contained in the cosmetic product shall be assessed.

The consideration and non-consideration of the different toxicological profiles shall be duly justified.

Impacts of the stability on the safety of the cosmetic product shall be duly considered.

#### 4. Assessor's credentials and approval of part B

Name and address of the safety assessor.

### Proof of qualification of safety assessor.

Date and signature of safety assessor.

*Preamble to Annexes II to VI*

- (1) For the purposes of the Annexes II to VI:
- (a) 'Rinse-off product' means a cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes;
  - (b) 'Leave-on product' means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes;
  - (c) 'Hair product' means a cosmetic product which is intended to be applied on the hair of head or face, except eye lashes;
  - (d) 'Skin product' means a cosmetic product which is intended to be applied on the skin;
  - (e) 'Lip product' means a cosmetic product which is intended to be applied on the lips;
  - (f) 'Face product' means a cosmetic product which is intended to be applied on the skin of the face;
  - (g) 'Nail product' means a cosmetic product which is intended to be applied on nails;
  - (h) 'Oral product' means a cosmetic product which is intended to be applied on teeth or the mucous membranes of the oral cavity;
  - (i) 'Product applied on mucous membranes' means a cosmetic product which is intended to be applied on the mucous membranes
    - of the oral cavity,
    - on the rim of the eyes,
    - or of the external genital organs;
  - (j) 'Eye product' means a cosmetic product which is intended to be applied in the vicinity of the eyes;
  - (k) 'Professional use' means the application and use of cosmetic products by persons in the exercise of their professional activity.
- (2) In order to facilitate substance identification, the following descriptors are used:
- The Non-proprietary Names (INN) for pharmaceutical products, WHO, Geneva, August 1975;
  - The Chemical Abstracts Service numbers (CAS);
  - The EC number which correspond to either the European Inventory of Existing Commercial chemical Substances (EINECS) numbers or the European List of Notified Chemical Substances (ELINCS) numbers or the registration number given under Regulation (EC) No 1907/2006;
  - The XAN which is the name approved by specific country (X), e.g. USAN which correspond to the United State approved name;
  - The name in the glossary of common ingredient names referred to in Article 33 of this Regulation.
- (3) Substances listed in Annexes III to VI do not cover nanomaterials, except where specifically mentioned.
-

## ANNEX II

## LIST OF SUBSTANCES PROHIBITED IN COSMETIC PRODUCTS

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1	N-(5-Chlorobenzoxazol-2-yl)acetamide	35783-57-4	
2	(2-Acetoxyethyl)trimethylammonium hydroxide (Acetylcholine) and its salts	51-84-3	200-128-9
3	Deanol aceglumate (INN)	3342-61-8	222-085-5
4	Spironolactone (INN)	52-01-7	200-133-6
5	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid (Tiratricol (INN)) and its salts	51-24-1	200-086-1
6	Methotrexate (INN)	59-05-2	200-413-8
7	Aminocaproic acid (INN) and its salts	60-32-2	200-469-3
8	Cinchophen (INN), its salts, derivatives and salts of these derivatives	132-60-5	205-067-1
9	Thyropropic acid (INN) and its salts	51-26-3	
10	Trichloroacetic acid	76-03-9	200-927-2
11	<i>Aconitum napellus</i> L. (leaves, roots and galenical preparations)	84603-50-9	283-252-6
12	Aconitine (principal alkaloid of <i>Aconitum napellus</i> L.) and its salts	302-27-2	206-121-7
13	<i>Adonis vernalis</i> L. and its preparations	84649-73-0	283-458-6
14	Epinephrine (INN)	51-43-4	200-098-7
15	<i>Rauwolfia serpentina</i> L., alkaloids and their salts	90106-13-1	290-234-1
16	Alkyne alcohols, their esters, ethers and salts		
17	Isoprenaline (INN)	7683-59-2	231-687-7
18	Allyl isothiocyanate	57-06-7	200-309-2
19	Alloclamide (INN) and its salts	5486-77-1	
20	Nalorphine (INN), its salts and ethers	62-67-9	200-546-1
21	Sympathomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution AP (69) 2 of the Council of Europe	300-62-9	206-096-2
22	Aniline, its salts and its halogenated and sulphonated derivatives	62-53-3	200-539-3
23	Betoxycaine (INN) and its salts	3818-62-0	
24	Zoxazolamine (INN)	61-80-3	200-519-4
25	Procainamide (INN), its salts and derivatives	51-06-9	200-078-8
26	Benzidine	92-87-5	202-199-1
27	Tuaminoheptane (INN), its isomers and salts	123-82-0	204-655-5
28	Octodrine (INN) and its salts	543-82-8	208-851-1
29	2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts	530-34-7	
30	1,3-Dimethylpentylamine and its salts	105-41-9	203-296-1
31	4-Aminosalicylic acid and its salts	65-49-6	200-613-5
32	Toluidines, their isomers, salts and halogenated and sulphonated derivatives	26915-12-8	248-105-2

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
33	Xylidines, their isomers, salts and halogenated and sulphonated derivatives	1300-73-8	215-091-4
34	Imperatorin (9-(3-methylbut-2-enyloxy)furo[3,2-g]chromen-7-one)	482-44-0	207-581-1
35	<i>Ammi majus</i> L. and its galenical preparations	90320-46-0	291-072-4
36	2,3-Dichloro-2-methylbutane	507-45-9	
37	Substances with androgenic effect		
38	Anthracene oil	120-12-7	204-371-1
39	Antibiotics		
40	Antimony and its compounds	7440-36-0	231-146-5
41	<i>Apocynum cannabinum</i> L. and its preparations	84603-51-0	283-253-1
42	Apomorphine ((R) 5,6,6a,7-tetrahydro-6-methyl-4H-dibenzo[de,g]quinoline-10,11-diol) and its salts	58-00-4	200-360-0
43	Arsenic and its compounds	7440-38-2	231-148-6
44	<i>Atropa belladonna</i> L. and its preparations	8007-93-0	232-365-9
45	Atropine, its salts and derivatives	51-55-8	200-104-8
46	Barium salts, with the exception of barium sulphide under the conditions laid down in Annex III, and of barium sulfate, lakes, salts and pigments prepared from colouring agents when listed in Annex IV		
47	Benzene	71-43-2	200-753-7
48	Benzimidazol-2(3H)-one	615-16-7	210-412-4
49	Benzazepines and benzodiazepines	12794-10-4	
50	1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts	644-26-8	211-411-1
51	2,2,6-Trimethyl-4-piperidyl benzoate (eucaine) and its salts	500-34-5	
52	Isocarboxazid (INN)	59-63-2	200-438-4
53	Bendroflumethiazide (INN) and its derivatives	73-48-3	200-800-1
54	Beryllium and its compounds	7440-41-7	231-150-7
55	Bromine, elemental	7726-95-6	231-778-1
56	Bretylium tosilate (INN)	61-75-6	200-516-8
57	Carbromal (INN)	77-65-6	201-046-6
58	Bromisoval (INN)	496-67-3	207-825-7
59	Brompheniramine (INN) and its salts	86-22-6	201-657-8
60	Benzilonium bromide (INN)	1050-48-2	213-885-5
61	Tetrylammonium bromide (INN)	71-91-0	200-769-4
62	Brucine	357-57-3	206-614-7
63	Tetracaine (INN) and its salts	94-24-6	202-316-6
64	Mofebutazone (INN)	2210-63-1	218-641-1
65	Tolbutamide (INN)	64-77-7	200-594-3
66	Carbutamide (INN)	339-43-5	206-424-4
67	Phenylbutazone (INN)	50-33-9	200-029-0
68	Cadmium and its compounds	7440-43-9	231-152-8
69	Cantharides, <i>Cantharis vesicatoria</i>	92457-17-5	296-298-7
70	Cantharidine	56-25-7	200-263-3

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
71	Phenprobamate (INN)	673-31-4	211-606-1
72	Nitroderivatives of carbazole		
73	Carbon disulphide	75-15-0	200-843-6
74	Catalase	9001-05-2	232-577-1
75	Cephaeline and its salts	483-17-0	207-591-6
76	<i>Chenopodium ambrosioides</i> L. (essential oil)	8006-99-3	
77	2,2,2-Trichloroethane-1,1-diol	302-17-0	206-117-5
78	Chlorine	7782-50-5	231-959-5
79	Chlorpropamide (INN)	94-20-2	202-314-5
80	Moved or deleted		
81	4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)	5909-04-6	
82	Chlorzoxazone (INN)	95-25-0	202-403-9
83	2-Chloro-6-methylpyrimidin-4-yl dimethylamine (crimidine-ISO)	535-89-7	208-622-6
84	Chlorprothixene (INN) and its salts	113-59-7	204-032-8
85	Clofenamide (INN)	671-95-4	211-588-5
86	N,N-bis(2-chloroethyl)methylamine N-oxide and its salts	126-85-2	
87	Chlormethine (INN) and its salts	51-75-2	200-120-5
88	Cyclophosphamide (INN) and its salts	50-18-0	200-015-4
89	Mannomustine (INN) and its salts	576-68-1	209-404-3
90	Butanilicaine (INN) and its salts	3785-21-5	
91	Chlormezanone (INN)	80-77-3	201-307-4
92	Triparanol (INN)	78-41-1	201-115-0
93	2-[2(4-Chlorophenyl)-2-phenylacetyl]indane-1,3-dione (chlorophacinone-ISO)	3691-35-8	223-003-0
94	Chlorphenoxamine (INN)	77-38-3	
95	Phenaglycodol (INN)	79-93-6	201-235-3
96	Chloroethane	75-00-3	200-830-5
97	Chromium; chromic acid and its salts	7440-47-3	231-157-5
98	<i>Claviceps purpurea</i> Tul., its alkaloids and galenical preparations	84775-56-4	283-885-8
99	<i>Conium maculatum</i> L. (fruit, powder, galenical preparations)	85116-75-2	285-527-6
100	Glycyclamide (INN)	664-95-9	211-557-6
101	Cobalt benzenesulphonate	23384-69-2	
102	Colchicine, its salts and derivatives	64-86-8	200-598-5
103	Colchicoside and its derivatives	477-29-2	207-513-0
104	<i>Colchicum autumnale</i> L. and its galenical preparations	84696-03-7	283-623-2
105	Convallatoxin	508-75-8	208-086-3
106	<i>Anamirta cocculus</i> L. (fruit)		
107	<i>Croton tiglium</i> L. (oil)	8001-28-3	
108	1-Butyl-3-(N-crotonoylsulphanilyl)urea	52964-42-8	

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
109	Curare and curarine	8063-06-7/ 22260-42-0	232-511-1/ 244-880-6
110	Synthetic curarizants		
111	Hydrogen cyanide and its salts	74-90-8	200-821-6
112	Feclamine (INN); 2-( $\alpha$ -Cyclohexylbenzyl)-N,N,N',N'-tetraethyl-1,3-propanediamine	3590-16-7	
113	Cyclomenol (INN) and its salts	5591-47-9	227-002-6
114	Sodium hexacyclonate (INN)	7009-49-6	
115	Hexapropymate (INN)	358-52-1	206-618-9
116	Moved or deleted		
117	O,O'-Diacetyl-N-allyl-N-normorphine	2748-74-5	
118	Pipazetate (INN) and its salts	2167-85-3	218-508-8
119	5-( $\alpha,\beta$ -Dibromophenethyl)-5-methylhydantoin	511-75-1	208-133-8
120	N,N'-Pentamethylenebis(trimethylammonium) salts, e. g. pentamethonium bromide (INN)	541-20-8	208-771-7
121	N,N'-[(Methylimino)diethylene]bis(ethyltrimethylammonium) salts, e. g. azamethonium bromide (INN)	306-53-6	206-186-1
122	Cyclarbamate (INN)	5779-54-4	227-302-7
123	Clofenotane (INN); DDT (ISO)	50-29-3	200-024-3
124	N,N'-Hexamethylenebis(trimethylammonium) salts, e. g. hexamethonium bromide (INN)	55-97-0	200-249-7
125	Dichloroethanes (ethylene chlorides) e.g. 1,2-Dichloroethane	107-06-2	203-458-1
126	Dichloroethylenes (acetylene chlorides) e.g. Vinylidene chloride (1,1-Dichloroethylene)	75-35-4	200-864-0
127	Lysergide (INN) (LSD) and its salts	50-37-3	200-033-2
128	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts	3572-52-9	222-686-2
129	Cinchocaine (INN) and its salts	85-79-0	201-632-1
130	3-Diethylaminopropyl cinnamate	538-66-9	
131	O,O'-Diethyl-O-4-nitrophenyl phosphorothioate (Parathion - ISO)	56-38-2	200-271-7
132	[Oxalylbis(iminoethylene)]bis[(o-chlorobenzyl)diethylammonium] salts, e. g. ambenonium chloride (INN)	115-79-7	204-107-5
133	Methypylon (INN) and its salts	125-64-4	204-745-4
134	Digitaline and all heterosides of <i>Digitalis purpurea</i> L.	752-61-4	212-036-6
135	7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propyl]theophylline (xanthinol)	2530-97-4	
136	Dioxethedrin (INN) and its salts	497-75-6	207-849-8
137	Piprocuarium iodide (INN)	3562-55-8	222-627-0
138	Propyphenazone (INN)	479-92-5	207-539-2
139	Tetrabenazine (INN) and its salts	58-46-8	200-383-6
140	Captodiamine (INN)	486-17-9	207-629-1
141	Mefeclozazine (INN) and its salts	1243-33-0	
142	Dimethylamine	124-40-3	204-697-4
143	1,1-Bis(dimethylaminomethyl)propyl benzoate (amydracaine, alypine) and its salts	963-07-5	213-512-6
144	Methapyrilene (INN) and its salts	91-80-5	202-099-8

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
145	Metamfepramone (INN) and its salts	15351-09-4	239-384-1
146	Amitriptyline (INN) and its salts	50-48-6	200-041-6
147	Metformin (INN) and its salts	657-24-9	211-517-8
148	Isosorbide dinitrate (INN)	87-33-2	201-740-9
149	Malononitrile	109-77-3	203-703-2
150	Succinonitrile	110-61-2	203-783-9
151	Dinitrophenol isomers	51-28-5/ 329-71-5/ 573-56-8/ 25550-58-7	200-087-7/ 206-348-1/ 209-357-9/ 247-096-2
152	Inproquone (INN)	436-40-8	
153	Dimevamide (INN) and its salts	60-46-8	200-479-8
154	Diphenylpyraline (INN) and its salts	147-20-6	205-686-7
155	Sulfinpyrazone (INN)	57-96-5	200-357-4
156	N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethylammonium salts, e. g. isopropamide iodide (INN)	71-81-8	200-766-8
157	Benactyzine (INN)	302-40-9	206-123-8
158	Benzatropine (INN) and its salts	86-13-5	
159	Cyclizine (INN) and its salts	82-92-8	201-445-5
160	5,5-Diphenyl-4-imidazolidone (Doxenitoin (INN))	3254-93-1	221-851-6
161	Probenecid (INN)	57-66-9	200-344-3
162	Disulfiram (INN); thiram (INN)	97-77-8/ 137-26-8	202-607-8/ 205-286-2
163	Emetine, its salts and derivatives	483-18-1	207-592-1
164	Ephedrine and its salts	299-42-3	206-080-5
165	Oxanamide (INN) and its derivatives	126-93-2	
166	Eserine or physostigmine and its salts	57-47-6	200-332-8
167	Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in Annex VI		
168	Choline salts and their esters, e. g. choline chloride (INN)	67-48-1	200-655-4
169	Caramiphen (INN) and its salts	77-22-5	201-013-6
170	Diethyl 4-nitrophenyl phosphate (Paraoxon - ISO)	311-45-5	206-221-0
171	Metethoheptazine (INN) and its salts	509-84-2	
172	Oxpheneridine (INN) and its salts	546-32-7	
173	Ethoheptazine (INN) and its salts	77-15-6	201-007-3
174	Metheptazine (INN) and its salts	469-78-3	
175	Methylphenidate (INN) and its salts	113-45-1	204-028-6
176	Doxylamine (INN) and its salts	469-21-6	207-414-2
177	Tolboxane (INN)	2430-46-8	
178	4-Benzyloxyphenol and 4-ethoxyphenol	103-16-2/ 622-62-8	203-083-3/ 210-748-1
179	Parethoxycaine (INN) and its salts	94-23-5	205-246-4
180	Fenozolone (INN)	15302-16-6	239-339-6
181	Glutethimide (INN) and its salts	77-21-4	201-012-0



Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
182	Ethylene oxide	75-21-8	200-849-9
183	Bemegride (INN) and its salts	64-65-3	200-588-0
184	Valnoctamide (INN)	4171-13-5	224-033-7
185	Haloperidol (INN)	52-86-8	200-155-6
186	Paramethasone (INN)	53-33-8	200-169-2
187	Fluanisone (INN)	1480-19-9	216-038-8
188	Trifluoperidol (INN)	749-13-3	
189	Fluoresone (INN)	2924-67-6	220-889-0
190	Fluorouracil (INN)	51-21-8	200-085-6
191	Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Annex III	7664-39-3	231-634-8
192	Furfuryltrimethylammonium salts, e. g. furtrethonium iodide (INN)	541-64-0	208-789-5
193	Galantamine (INN)	357-70-0	
194	Progestogens		
195	1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO)	58-89-9	200-401-2
196	(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethano-naphthalene (endrin-ISO)	72-20-8	200-775-7
197	Hexachloroethane	67-72-1	200-666-4
198	(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethanonaphthalene (isodrin-ISO)	465-73-6	207-366-2
199	Hydrastine, hydrastinine and their salts	118-08-1/ 6592-85-4	204-233-0/ 229-533-9
200	Hydrazides and their salts e.g. Isoniazid (INN)	54-85-3	200-214-6
201	Hydrazine, its derivatives and their salts	302-01-2	206-114-9
202	Octamoxin (INN) and its salts	4684-87-1	
203	Warfarin (INN) and its salts	81-81-2	201-377-6
204	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl)acetate and salts of the acid	548-00-5	208-940-5
205	Methocarbamol (INN)	532-03-6	208-524-3
206	Propatynitrate (INN)	2921-92-8	220-866-5
207	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin		
208	Fenadiazole (INN)	1008-65-7	
209	Nitroxoline (INN) and its salts	4008-48-4	223-662-4
210	Hyoscyamine, its salts and derivatives	101-31-5	202-933-0
211	<i>Hyoscyamus niger</i> L. (leaves, seeds, powder and galenical preparations)	84603-65-6	283-265-7
212	Pemoline (INN) and its salts	2152-34-3	218-438-8
213	Iodine	7553-56-2	231-442-4
214	Decamethylenebis(trimethylammonium) salts, e. g. decamethonium bromide (INN)	541-22-0	208-772-2
215	Ipecacuanha ( <i>Cephaelis ipecacuanha</i> Brot. and related species) (roots, powder and galenical preparations)	8012-96-2	232-385-8
216	(2-Isopropylpent4-enoyl)urea (apronalide)	528-92-7	208-443-3
217	$\alpha$ -Santonin [(3S,5aR,9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphtho[1,2-b]furan-2,8-dione]	481-06-1	207-560-7
218	<i>Lobelia inflata</i> L. and its galenical preparations	84696-23-1	283-642-6

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
219	Lobeline (INN) and its salts	90-69-7	202-012-3
220	Barbiturates		
221	Mercury and its compounds, except those special cases included in Annex V	7439-97-6	231-106-7
222	3,4,5-Trimethoxyphenethylamine (Mescaline) and its salts	54-04-6	200-190-7
223	Metalddehyde	9002-91-9	
224	2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide and its salts	305-13-5	
225	Coumetarol (INN)	4366-18-1	224-455-1
226	Dextromethorphan (INN) and its salts	125-71-3	204-752-2
227	2-Methylheptylamine and its salts	540-43-2	
228	Isometheptene (INN) and its salts	503-01-5	207-959-6
229	Mecamylamine (INN)	60-40-2	200-476-1
230	Guaifenesin (INN)	93-14-1	202-222-5
231	Dicoumarol (INN)	66-76-2	200-632-9
232	Phenmetrazine (INN), its derivatives and salts	134-49-6	205-143-4
233	Thiamazole (INN)	60-56-0	200-482-4
234	3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H-pyrano [3,2-c]-[1] benzopyran-5-one (cyclocoumarol)	518-20-7	208-248-3
235	Carisoprodol (INN)	78-44-4	201-118-7
236	Meprobamate (INN)	57-53-4	200-337-5
237	Tefazoline (INN) and its salts	1082-56-0	
238	Arecoline	63-75-2	200-565-5
239	Poldine metilsulfate (INN)	545-80-2	208-894-6
240	Hydroxyzine (INN)	68-88-2	200-693-1
241	2-Naphthol	135-19-3	205-182-7
242	1-and 2-Naphthylamines and their salts	134-32-7/ 91-59-8	205-138-7/ 202-080-4
243	3-(1-Naphthyl)-4-hydroxycoumarin	39923-41-6	
244	Naphazoline (INN) and its salts	835-31-4	212-641-5
245	Neostigmine and its salts e. g. neostigmine bromide (INN)	114-80-7	204-054-8
246	Nicotine and its salts	54-11-5	200-193-3
247	Amyl nitrites	110-46-3	203-770-8
248	Inorganic nitrites, with the exception of sodium nitrite	14797-65-0	
249	Nitrobenzene	98-95-3	202-716-0
250	Nitrocresols and their alkali metal salts	12167-20-3	
251	Nitrofurantoin (INN)	67-20-9	200-646-5
252	Furazolidone (INN)	67-45-8	200-653-3
253	Nitroglycerin; Propane-1,2,3-triyl trinitrate	55-63-0	200-240-8
254	Acenocoumarol (INN)	152-72-7	205-807-3
255	Alkali pentacyanonitrosylferrate (2-) e.g.	14402-89-2/ 13755-38-9	238-373-9 / -
256	Nitrostilbenes, their homologues and their derivatives		
257	Noradrenaline and its salts	51-41-2	200-096-6

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
258	Noscapine (INN) and its salts	128-62-1	204-899-2
259	Guanethidine (INN) and its salts	55-65-2	200-241-3
260	Oestrogens		
261	Oleandrin	465-16-7	207-361-5
262	Chlortalidone (INN)	77-36-1	201-022-5
263	Pelletierine and its salts	2858-66-4/ 4396-01-4	220-673-6/ 224-523-0
264	Pentachloroethane	76-01-7	200-925-1
265	Pentaerithrityl tetranitrate (INN)	78-11-5	201-084-3
266	Petrichloral (INN)	78-12-6	
267	Octamylamine (INN) and its salts	502-59-0	207-947-0
268	Picric acid	88-89-1	201-865-9
269	Phenacemide (INN)	63-98-9	200-570-2
270	Difenclozazine (INN)	5617-26-5	
271	2-Phenylindan-1,3-dione (phenindione (INN))	83-12-5	201-454-4
272	Ethylphenacemide (pheneturide (INN))	90-49-3	201-998-2
273	Phenprocoumon (INN)	435-97-2	207-108-9
274	Fenylramidol (INN)	553-69-5	209-044-7
275	Triamterene (INN) and its salts	396-01-0	206-904-3
276	Tetraethyl pyrophosphate (TEPP - ISO)	107-49-3	203-495-3
277	Tritolyl phosphate	1330-78-5	215-548-8
278	Psilocybine (INN)	520-52-5	208-294-4
279	Phosphorus and metal phosphides	7723-14-0	231-768-7
280	Thalidomide (INN) and its salts	50-35-1	200-031-1
281	<i>Physostigma venenosum</i> Balf.	89958-15-6	289-638-0
282	Picrotoxin	124-87-8	204-716-6
283	Pilocarpine and its salts	92-13-7	202-128-4
284	$\alpha$ -Piperidin-2-ylbenzyl acetate, laevorotatory threoform (levofacetoperane (INN)) and its salts	24558-01-8	
285	Pipradrol (INN) and its salts	467-60-7	207-394-5
286	Azacyclonol (INN) and its salts	115-46-8	204-092-5
287	Bietamiverine (INN)	479-81-2	207-538-7
288	Butopiprine (INN) and its salts	55837-15-5	259-848-7
289	Lead and its compounds	7439-92-1	231-100-4
290	Coniine	458-88-8	207-282-6
291	<i>Prunus laurocerasus</i> L. ('cherry laurel water')	89997-54-6	289-689-9
292	Metyrapone (INN)	54-36-4	200-206-2
293	Radioactive substances, as defined by Directive 96/29/Euratom <sup>(1)</sup> laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation		
294	<i>Juniperus sabina</i> L. (leaves, essential oil and galenical preparations)	90046-04-1	289-971-1

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
295	Hyoscine, its salts and derivatives	51-34-3	200-090-3
296	Gold salts		
297	Selenium and its compounds with the exception of selenium disulphide under the conditions set out under reference No 49 in Annex III	7782-49-2	231-957-4
298	<i>Solanum nigrum</i> L. and its galenical preparations	84929-77-1	284-555-6
299	Sparteine (INN) and its salts	90-39-1	201-988-8
300	Glucocorticoids (Corticosteroids)		
301	<i>Datura stramonium</i> L. and its galenical preparations	84696-08-2	283-627-4
302	Strophantines, their aglucones and their respective derivatives	11005-63-3	234-239-9
303	<i>Strophantus</i> species and their galenical preparations		
304	Strychnine and its salts	57-24-9	200-319-7
305	<i>Strychnos</i> species and their galenical preparations		
306	Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961		
307	Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH <sub>2</sub> groups) and their salts		
308	Sultiame (INN)	61-56-3	200-511-0
309	Neodymium and its salts	7440-00-8	231-109-3
310	Thiotepa (INN)	52-24-4	200-135-7
311	<i>Pilocarpus jaborandi</i> Holmes and its galenical preparations	84696-42-4	283-649-4
312	Tellurium and its compounds	13494-80-9	236-813-4
313	Xylometazoline (INN) and its salts	526-36-3	208-390-6
314	Tetrachloroethylene	127-18-4	204-825-9
315	Carbon tetrachloride	56-23-5	200-262-8
316	Hexaethyl tetraphosphate	757-58-4	212-057-0
317	Thallium and its compounds	7440-28-0	231-138-1
318	<i>Thevetia nerifolia</i> Juss., glycoside extract	90147-54-9	290-446-4
319	Ethionamide (INN)	536-33-4	208-628-9
320	Phenothiazine (INN) and its compounds	92-84-2	202-196-5
321	Thiourea and its derivatives, with the exception of the one listed in Annex III	62-56-6	200-543-5
322	Mephenesin (INN) and its esters	59-47-2	200-427-4
323	Vaccines, toxins or serums defined as immunological medicinal products pursuant to Article 1(4) of Directive 2001/83/EC		
324	Tranlycypromine (INN) and its salts	155-09-9	205-841-9
325	Trichloronitromethane (chloropicrine)	76-06-2	200-930-9
326	2,2,2-Tribromoethanol (tribromoethyl alcohol)	75-80-9	200-903-1
327	Trichlormethine (INN) and its salts	817-09-4	212-442-3
328	Tretamine (INN)	51-18-3	200-083-5
329	Gallamine triethiodide (INN)	65-29-2	200-605-1
330	<i>Urginea scilla</i> Steinh. and its galenical preparations	84650-62-4	283-520-2
331	Veratrine, its salts and galenical preparations	8051-02-3	613-062-00-4
332	<i>Schoenocaulon officinale</i> Lind (seeds and galenical preparations)	84604-18-2	283-296-6

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
333	<i>Veratrum</i> spp. and their preparations	90131-91-2	290-407-1
334	Vinyl chloride monomer	75-01-4	200-831-0
335	Ergocalciferol (INN) and cholecalciferol (vitamins D <sub>2</sub> and D <sub>3</sub> )	50-14-6/ 67-97-0	200-014-9/ 200-673-2
336	Salts of O-alkyldithiocarbonic acids (xanthates)		
337	Yohimbine and its salts	146-48-5	205-672-0
338	Dimethyl sulfoxide (INN)	67-68-5	200-664-3
339	Diphenhydramine (INN) and its salts	58-73-1	200-396-7
340	4-tert-Butylphenol	98-54-4	202-679-0
341	4-tert-Butylpyrocatechol	98-29-3	202-653-9
342	Dihydrotachysterol (INN)	67-96-9	200-672-7
343	Dioxane	123-91-1	204-661-8
344	Morpholine and its salts	110-91-8	203-815-1
345.	<i>Pyrethrum album</i> L. and its galenical preparations		
346	2-[4-Methoxybenzyl-N-(2-pyridyl)amino]ethyl dimethylamine maleate (Mepyramine maleate; pyrilamine maleate)	59-33-6	200-422-7
347	Tripeleminamine (INN)	91-81-6	202-100-1
348	Tetrachlorosalicylanilides	7426-07-5	
349	Dichlorosalicylanilides	1147-98-4	
350	Tetrabromosalicylanilides		
351	Dibromosalicylanilides		
352	Bithionol (INN)	97-18-7	202-565-0
353	Thiuram monosulphides	97-74-5	202-605-7
354	Moved or deleted		
355	Dimethylformamide (N,N-Dimethylformamide)	68-12-2	200-679-5
356	4-Phenylbut-3-en-2-one (Benzylidene acetone)	122-57-6	204-555-1
357	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol (coniferyl alcohol) except for normal content in natural essences used		
358	Furocoumarines (e. g. trioxsalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used.  In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg	3902-71-4/ 298-81-7/ 484-20-8	223-459-0/ 206-066-9/ 207-604-5
359	Oil from the seeds of <i>Laurus nobilis</i> L.	84603-73-6	283-272-5
360	Safrole except for normal content in the natural essences used and provided the concentration does not exceed:  100 ppm in the finished product, 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children	94-59-7	202-345-4
361	5,5'-Diisopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypoidite (thymol iodide)	552-22-7	209-007-5
362	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonaphthone or 7-acetyl-6-ethyl-1,1,4,4-tetramethyl-1,2,3,4-tetrahydronaphthalen (AETT; Versalide)	88-29-9	201-817-7
363	o-Phenylenediamine and its salts	95-54-5	202-430-6

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
364	4-Methyl- <i>m</i> -phenylenediamine (Toluene-2,4-diamine) and its salts	95-80-7	202-453-1
365	Aristolochic acid and its salts; <i>Aristolochia</i> spp. and their preparations	475-80-9/ 313-67-7/ 15918-62-4	202-499-6/ 206-238-3/-
366	Chloroform	67-66-3	200-663-8
367	2,3,7,8-Tetrachlorodibenzo- <i>p</i> -dioxin (TCDD)	1746-01-6	217-122-7
368	2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)	828-00-2	212-579-9
369	Pyrithione sodium (INNM) (2)	3811-73-2	223-296-5
370	<i>N</i> -(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide (Captan - ISO)	133-06-2	205-087-0
371	2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (Hexachlorophene (INN))	70-30-4	200-733-8
372	6-(Piperidinyl)-2,4-pyrimidinediamine 3-oxide (Minoxidil (INN)) and its salts	38304-91-5	253-874-2
373	3,4',5-Tribromosalicylanilide (Tribromsalan (INN))	87-10-5	201-723-6
374	<i>Phytolacca</i> spp. and their preparations	65497-07-6/ 60820-94-2	
375	Tretinoin (INN) (retinoic acid and its salts)	302-79-4	206-129-0
376	1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole - CI 76050) and its salts	615-05-4	210-406-1
377	1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) and its salts	5307-02-8	226-161-9
378	Colouring agent CI 12140	3118-97-6	221-490-4
379	Colouring agent CI 26105 (Solvent Red 24)	85-83-6	201-635-8
380	Colouring agent CI 42555 (Basic Violet 3)	548-62-9	208-953-6
	Colouring agent CI 42555:1	467-63-0	207-396-6
	Colouring agent CI 42555:2		
381	Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))	14779-78-3	238-849-6
383	2-Amino-4-nitrophenol	99-57-0	202-767-9
384	2-Amino-5-nitrophenol	121-88-0	204-503-8
385	11- $\alpha$ -Hydroxypregn-4-ene-3,20-dione and its esters	80-75-1	201-306-9
386	Colouring agent CI 42640 ([4-[[4-(Dimethylamino)phenyl][4-[ethyl(3-sulphonatobenzyl)amino]phenyl]methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt)	1694-09-3	216-901-9
387	Colouring agent CI 13065	587-98-4	209-608-2
388	Colouring agent CI 42535 (Basic Violet 1)	8004-87-3	
389	Colouring agent CI 61554 (Solvent Blue 35)	17354-14-2	241-379-4
390	Anti-androgens of steroidal structure		
391	Zirconium and its compounds, with the exception of the substances listed under reference number 50 in Annex III, and the zirconium lakes, pigments or salts of the colouring agents when listed in Annex IV	7440-67-7	231-176-9
392	Moved or deleted		
393	Acetonitrile	75-05-8	200-835-2
394	Tetrahydrozoline (Tetryzoline (INN)) and its salts	84-22-0	201-522-3



Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
395	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in No 51 in Annex III	148-24-3/ 134-31-6	205-711-1/ 205-137-1
396	Dithio-2,2-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) - (pyrithione disulphide + magnesium sulphate)	43143-11-9	256-115-3
397	Colouring agent CI 12075 (Pigment Orange 5) and its lakes, pigments and salts	3468-63-1	222-429-4
398	Colouring agent CI 45170 and CI 45170:1 (Basic Violet 10)	81-88-9/ 509-34-2	201-383-9/ 208-096-8
399	Lidocaine (INN)	137-58-6	205-302-8
400	1,2-Epoxybutane	106-88-7	203-438-2
401	Colouring agent CI 15585	5160-02-1/ 2092-56-0	225-935-3/ 218-248-5
402	Strontium lactate	29870-99-3	249-915-9
403	Strontium nitrate	10042-76-9	233-131-9
404	Strontium polycarboxylate		
405	Pramocaine (INN)	140-65-8	205-425-7
406	4-Ethoxy-m-phenylenediamine and its salts	5862-77-1	
407	2,4-Diaminophenylethanol and its salts	14572-93-1	
408	Pyrocatechol (Catechol)	120-80-9	204-427-5
409	Pyrogallol	87-66-1	201-762-9
410	Nitrosamines e.g. Dimethylnitrosoamine; Nitrosodipropylamine; 2,2'-Nitrosoimino)bisethanol	62-75-9/ 621-64-7/ 1116-54-7	200-549-8/ 210-698-0/ 214-237-4
411	Secondary alkyl- and alkanolamines and their salts		
412	4-Amino-2-nitrophenol	119-34-6	204-316-1
413	2-Methyl-m-phenylenediamine (Toluene-2,6-diamine)	823-40-5	212-513-9
414	4-tert.-Butyl-3-methoxy-2,6-dinitrotoluene (Musk Ambrette)	83-66-9	201-493-7
415	Moved or deleted		
416	Cells, tissues or products of human origin		
417	3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein (INN))	77-09-8	201-004-7
418	3-Imidazol-4-ylacrylic acid (Urocanic acid) and its ethyl ester	104-98-3/ 27538-35-8	203-258-4/ 248-515-1
419	Category 1 material and Category 2 material as defined in Articles 4 and 5 respectively of Regulation (EC) No 1774/2002 of the European Parliament and of the Council <sup>(3)</sup> , and ingredients derived therefrom		
420	Crude and refined coal tars	8007-45-2	232-361-7
421	1,1,3,3,5-Pentamethyl-4,6-dinitroindane (Moskene)	116-66-5	204-149-4
422	5-tert.-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (Musk Tibetene)	145-39-1	205-651-6
423	Alanroot oil ( <i>Inula helenium</i> L.), when used as a fragrance ingredient	97676-35-2	
424	Benzyl cyanide, when used as a fragrance ingredient	140-29-4	205-410-5
425	Cyclamen alcohol, when used as a fragrance ingredient	4756-19-8	225-289-2
426	Diethyl maleate, when used as a fragrance ingredient	141-05-9	205-451-9
427	3,4-Dihydrocoumarin, when used as a fragrance ingredient	119-84-6	204-354-9
428	2,4-Dihydroxy-3-methylbenzaldehyde, when used as a fragrance ingredient	6248-20-0	228-369-5

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
429	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol), when used as a fragrance ingredient	40607-48-5	254-999-5
430	4,6-Dimethyl-8- <i>tert</i> -butylcoumarin, when used as a fragrance ingredient	17874-34-9	241-827-9
431	Dimethyl citraconate, when used as a fragrance ingredient	617-54-9	
432	7,11-Dimethyl-4,6,10-dodecatrien-3-one (Pseudomethylionone), when used as a fragrance ingredient	26651-96-7	247-878-3
433	6,10-Dimethyl-3,5,9-undecatrien-2-one (Pseudoionone)(, when used as a fragrance ingredient	141-10-6	205-457-1
434	Diphenylamine, when used as a fragrance ingredient	122-39-4	204-539-4
435	Ethyl acrylate, when used as a fragrance ingredient	140-88-5	205-438-8
436	Fig leaf absolute ( <i>Ficus carica</i> L.), when used as a fragrance ingredient	68916-52-9	
437	<i>trans</i> -2-Heptenal, when used as a fragrance ingredient	18829-55-5	242-608-0
438	<i>trans</i> -2-Hexenal diethyl acetal, when used as a fragrance ingredient	67746-30-9	266-989-8
439	<i>trans</i> -2-Hexenal dimethyl acetal, when used as a fragrance ingredient	18318-83-7	242-204-4
440	Hydroabietyl alcohol, when used as a fragrance ingredient	13393-93-6	236-476-3
441	6-Isopropyl-2-decahydronaphthalenol, when used as a fragrance ingredient	34131-99-2	251-841-7
442	7-Methoxycoumarin, when used as a fragrance ingredient	531-59-9	208-513-3
443	4-(4-Methoxyphenyl)-3-butene-2-one (Anisylidene acetone), when used as a fragrance ingredient	943-88-4	213-404-9
444	1-(4-Methoxyphenyl)-1-penten-3-one (alpha-Methylanisylideneacetone), when used as a fragrance ingredient	104-27-8	203-190-5
445	Methyl <i>trans</i> -2-butenolate, when used as a fragrance ingredient	623-43-8	210-793-7
446	7-Methylcoumarin, when used as a fragrance ingredient	2445-83-2	219-499-3
447	5-Methyl-2,3-hexanedione (Acetyl isovaleryl), when used as a fragrance ingredient	13706-86-0	237-241-8
448	2-Pentylidenecyclohexanone, when used as a fragrance ingredient	25677-40-1	247-178-8
449	3,6,10-Trimethyl-3,5,9-undecatrien-2-one (Pseudo-Isomethyl ionone), when used as a fragrance ingredient	1117-41-5	214-245-8
450	Verbena oil ( <i>Lippia citriodora</i> Kunth.), when used as a fragrance ingredient	8024-12-2	
451	Moved or deleted		
452	6-(2-Chloroethyl)-6-(2-methoxyethoxy)-2,5,7,10-tetraoxa-6-silaundecane	37894-46-5	253-704-7
453	Cobalt dichloride	7646-79-9	231-589-4
454	Cobalt sulphate	10124-43-3	233-334-2
455	Nickel monoxide	1313-99-1	215-215-7
456	Dinickel trioxide	1314-06-3	215-217-8
457	Nickel dioxide	12035-36-8	234-823-3
458	Trinickel disulphide	12035-72-2	234-829-6
459	Tetracarbonylnickel	13463-39-3	236-669-2
460	Nickel sulphide	16812-54-7	240-841-2
461	Potassium bromate	7758-01-2	231-829-8
462	Carbon monoxide	630-08-0	211-128-3
463	Buta-1,3-diene, see also entries 464-611	106-99-0	203-450-8

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
464	Isobutane, if it contains $\geq 0,1$ % w/w Butadiene	75-28-5	200-857-2
465	Butane, if it contains $\geq 0,1$ % w/w Butadiene	106-97-8	203-448-7
466	Gases (petroleum), C <sub>3-4</sub> , if they contain $> 0,1$ % w/w Butadiene	68131-75-9	268-629-5
467	Tail gas (petroleum), catalytic cracked distillate and catalytic cracked naphtha fractionation absorber, if it contains $> 0,1$ % w/w Butadiene	68307-98-2	269-617-2
468	Tail gas (petroleum), catalytic polymn. naphtha fractionation stabiliser, if it contains $> 0,1$ % w/w Butadiene	68307-99-3	269-618-8
469	Tail gas (petroleum), catalytic reformed naphtha fractionation stabiliser, hydrogen sulfide-free, if it contains $> 0,1$ % w/w Butadiene	68308-00-9	269-619-3
470	Tail gas (petroleum), cracked distillate hydrotreater stripper, if it contains $> 0,1$ % w/w Butadiene	68308-01-0	269-620-9
471	Tail gas (petroleum), gas oil catalytic cracking absorber, if it contains $> 0,1$ % w/w Butadiene	68308-03-2	269-623-5
472	Tail gas (petroleum), gas recovery plant, if it contains $> 0,1$ % w/w Butadiene	68308-04-3	269-624-0
473	Tail gas (petroleum), gas recovery plant deethaniser, if it contains $> 0,1$ % w/w Butadiene	68308-05-4	269-625-6
474	Tail gas (petroleum), hydrodesulfurised distillate and hydrodesulfurised naphtha fractionator, acid-free, if it contains $> 0,1$ % w/w Butadiene	68308-06-5	269-626-1
475	Tail gas (petroleum), hydrodesulfurised vacuum gas oil stripper, hydrogen sulfide-free, if it contains $> 0,1$ % w/w Butadiene	68308-07-6	269-627-7
476	Tail gas (petroleum), isomerised naphtha fractionation stabiliser, if it contains $> 0,1$ % w/w Butadiene	68308-08-7	269-628-2
477	Tail gas (petroleum), light straight-run naphtha stabiliser, hydrogen sulfide-free, if it contains $> 0,1$ % w/w Butadiene	68308-09-8	269-629-8
478	Tail gas (petroleum), straight-run distillate hydrodesulfurised, hydrogen sulfide-free, if it contains $> 0,1$ % w/w Butadiene	68308-10-1	269-630-3
479	Tail gas (petroleum), propane-propylene alkylation feed prep deethaniser, if it contains $> 0,1$ % w/w Butadiene	68308-11-2	269-631-9
480	Tail gas (petroleum), vacuum gas oil hydrodesulfurised, hydrogen sulfide-free, if it contains $> 0,1$ % w/w Butadiene	68308-12-3	269-632-4
481	Gases (petroleum), catalytic cracked overheads, if they contain $> 0,1$ % w/w Butadiene	68409-99-4	270-071-2
482	Alkanes, C <sub>1-2</sub> , if they contain $> 0,1$ % w/w Butadiene	68475-57-0	270-651-5
483	Alkanes, C <sub>2-3</sub> , if they contain $> 0,1$ % w/w Butadiene	68475-58-1	270-652-0
484	Alkanes, C <sub>3-4</sub> , if they contain $> 0,1$ % w/w Butadiene	68475-59-2	270-653-6
485	Alkanes, C <sub>4-5</sub> , if they contain $> 0,1$ % w/w Butadiene	68475-60-5	270-654-1
486	Fuel-gases, if they contain $> 0,1$ % w/w Butadiene	68476-26-6	270-667-2
487	Fuel gases, crude oil distillates, if they contain $> 0,1$ % w/w Butadiene	68476-29-9	270-670-9
488	Hydrocarbons, C <sub>3-4</sub> , if they contain $> 0,1$ % w/w Butadiene	68476-40-4	270-681-9
489	Hydrocarbons, C <sub>4-5</sub> , if they contain $> 0,1$ % w/w Butadiene	68476-42-6	270-682-4
490	Hydrocarbons, C <sub>2-4</sub> , C <sub>3</sub> -rich, if they contain $> 0,1$ % w/w Butadiene	68476-49-3	270-689-2

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
491	Petroleum gases, liquefied, if they contain > 0,1 % w/w Butadiene	68476-85-7	270-704-2
492	Petroleum gases, liquefied, sweetened, if they contain > 0,1 % w/w Butadiene	68476-86-8	270-705-8
493	Gases (petroleum), C <sub>3-4</sub> , isobutane-rich if they contain > 0,1 % w/w Butadiene	68477-33-8	270-724-1
494	Distillates (petroleum), C <sub>3-6</sub> , piperylene-rich, if they contain > 0,1 % w/w Butadiene	68477-35-0	270-726-2
495	Gases (petroleum), amine system feed, if they contain > 0,1 % w/w Butadiene	68477-65-6	270-746-1
496	Gases (petroleum), benzene unit hydrodesulfurised off, if they contain > 0,1 % w/w Butadiene	68477-66-7	270-747-7
497	Gases (petroleum), benzene unit recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-67-8	270-748-2
498	Gases (petroleum), blend oil, hydrogen-nitrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-68-9	270-749-8
499	Gases (petroleum), butane splitter overheads, if they contain > 0,1 % w/w Butadiene	68477-69-0	270-750-3
500	Gases (petroleum), C <sub>2-3</sub> , if they contain > 0,1 % w/w Butadiene	68477-70-3	270-751-9
501	Gases (petroleum), catalytic-cracked gas oil depropaniser bottoms, C <sub>4</sub> -rich acid-free, if they contain > 0,1 % w/w Butadiene	68477-71-4	270-752-4
502	Gases (petroleum), catalytic-cracked naphtha debutaniser bottoms, C <sub>3-5</sub> -rich, if they contain > 0,1 % w/w Butadiene	68477-72-5	270-754-5
503	Gases (petroleum), catalytic cracked naphtha depropaniser overhead, C <sub>3</sub> -rich acid-free, if they contain > 0,1 % w/w Butadiene	68477-73-6	270-755-0
504	Gases (petroleum), catalytic cracker, if they contain > 0,1 % w/w Butadiene	68477-74-7	270-756-6
505	Gases (petroleum), catalytic cracker, C <sub>1-5</sub> -rich, if they contain > 0,1 % w/w Butadiene	68477-75-8	270-757-1
506	Gases (petroleum), catalytic polymd. naphtha stabiliser overhead, C <sub>2-4</sub> -rich, if they contain > 0,1 % w/w Butadiene	68477-76-9	270-758-7
507	Gases (petroleum), catalytic reformed naphtha stripper overheads, if they contain > 0,1 % w/w Butadiene	68477-77-0	270-759-2
508	Gases (petroleum), catalytic reformer, C <sub>1-4</sub> -rich, if they contain > 0,1 % w/w Butadiene	68477-79-2	270-760-8
509	Gases (petroleum), C <sub>6-8</sub> catalytic reformer recycle, if they contain > 0,1 % w/w Butadiene	68477-80-5	270-761-3
510	Gases (petroleum), C <sub>6-8</sub> catalytic reformer, if they contain > 0,1 % w/w Butadiene	68477-81-6	270-762-9
511	Gases (petroleum), C <sub>6-8</sub> catalytic reformer recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-82-7	270-763-4
512	Gases (petroleum), C <sub>3-5</sub> olefinic-paraffinic alkylation feed, if they contain > 0,1 % w/w Butadiene	68477-83-8	270-765-5
513	Gases (petroleum), C <sub>2</sub> -return stream, if they contain > 0,1 % w/w Butadiene	68477-84-9	270-766-0
514	Gases (petroleum), C <sub>4</sub> -rich, if they contain > 0,1 % w/w Butadiene	68477-85-0	270-767-6
515	Gases (petroleum), deethaniser overheads, if they contain > 0,1 % w/w Butadiene	68477-86-1	270-768-1
516	Gases (petroleum), deisobutaniser tower overheads, if they contain > 0,1 % w/w Butadiene	68477-87-2	270-769-7
517	Gases (petroleum), depropaniser dry, propene-rich, if they contain > 0,1 % w/w Butadiene	68477-90-7	270-772-3

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
518	Gases (petroleum), depropaniser overheads, if they contain > 0,1 % w/w Butadiene	68477-91-8	270-773-9
519	Gases (petroleum), dry sour, gas-concn. -unit-off, if they contain > 0,1 % w/w Butadiene	68477-92-9	270-774-4
520	Gases (petroleum), gas concn. reabsorber distn., if they contain > 0,1 % w/w Butadiene	68477-93-0	270-776-5
521	Gases (petroleum), gas recovery plant depropaniser overheads, if they contain > 0,1 % w/w Butadiene	68477-94-1	270-777-0
522	Gases (petroleum), Girbatol unit feed, if they contain > 0,1 % w/w Butadiene	68477-95-2	270-778-6
523	Gases (petroleum), hydrogen absorber off, if they contain > 0,1 % w/w Butadiene	68477-96-3	270-779-1
524	Gases (petroleum), hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-97-4	270-780-7
525	Gases (petroleum), hydrotreater blend oil recycle, hydrogen-nitrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-98-5	270-781-2
526	Gases (petroleum), isomerised naphtha fractionator, C <sub>4</sub> -rich, hydrogen sulfide-free, if they contain > 0,1 % w/w Butadiene	68477-99-6	270-782-8
527	Gases (petroleum), recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68478-00-2	270-783-3
528	Gases (petroleum), reformer make-up, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68478-01-3	270-784-9
529	Gases (petroleum), reforming hydrotreater, if they contain > 0,1 % w/w Butadiene	68478-02-4	270-785-4
530	Gases (petroleum), reforming hydrotreater, hydrogen-methane-rich, if they contain > 0,1 % w/w Butadiene	68478-03-5	270-787-5
531	Gases (petroleum), reforming hydrotreater make-up, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68478-04-6	270-788-0
532	Gases (petroleum), thermal cracking distn., if they contain > 0,1 % w/w Butadiene	68478-05-7	270-789-6
533	Tail gas (petroleum), catalytic cracked clarified oil and thermal cracked vacuum residue fractionation reflux drum, if it contains > 0,1 % w/w Butadiene	68478-21-7	270-802-5
534	Tail gas (petroleum), catalytic cracked naphtha stabilisation absorber, if it contains > 0,1 % w/w Butadiene	68478-22-8	270-803-0
535	Tail gas (petroleum), catalytic cracker, catalytic reformer and hydrodesulfurised combined fractionator, if it contains > 0,1 % w/w Butadiene	68478-24-0	270-804-6
536	Tail gas (petroleum), catalytic cracker refractionation absorber, if it contains > 0,1 % w/w Butadiene	68478-25-1	270-805-1
537	Tail gas (petroleum), catalytic reformed naphtha fractionation stabiliser, if it contains > 0,1 % w/w Butadiene	68478-26-2	270-806-7
538	Tail gas (petroleum), catalytic reformed naphtha separator, if it contains > 0,1 % w/w Butadiene	68478-27-3	270-807-2
539	Tail gas (petroleum), catalytic reformed naphtha stabiliser, if it contains > 0,1 % w/w Butadiene	68478-28-4	270-808-8
540	Tail gas (petroleum), cracked distillate hydrotreater separator, if it contains > 0,1 % w/w Butadiene	68478-29-5	270-809-3
541	Tail gas (petroleum), hydrodesulfurised straight-run naphtha separator, if it contains > 0,1 % w/w Butadiene	68478-30-8	270-810-9

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
542	Tail gas (petroleum), saturate gas plant mixed stream, C <sub>4</sub> -rich, if it contains > 0,1 % w/w Butadiene	68478-32-0	270-813-5
543	Tail gas (petroleum), saturate gas recovery plant, C <sub>1-2</sub> -rich, if it contains > 0,1 % w/w Butadiene	68478-33-1	270-814-0
544	Tail gas (petroleum), vacuum residues thermal cracker, if it contains > 0,1 % w/w Butadiene	68478-34-2	270-815-6
545	Hydrocarbons, C <sub>3-4</sub> -rich, petroleum distillate, if they contain > 0,1 % w/w Butadiene	68512-91-4	270-990-9
546	Gases (petroleum), catalytic reformed straight-run naphtha stabiliser overheads, if they contain > 0,1 % w/w Butadiene	68513-14-4	270-999-8
547	Gases (petroleum), full-range straight-run naphtha dehexaniser off, if they contain > 0,1 % w/w Butadiene	68513-15-5	271-000-8
548	Gases (petroleum), hydrocracking depropaniser off, hydrocarbon-rich, if they contain > 0,1 % w/w Butadiene	68513-16-6	271-001-3
549	Gases (petroleum), light straight-run naphtha stabiliser off, if they contain > 0,1 % w/w Butadiene	68513-17-7	271-002-9
550	Gases (petroleum), reformer effluent high-pressure flash drum off, if they contain > 0,1 % w/w Butadiene	68513-18-8	271-003-4
551	Gases (petroleum), reformer effluent low-pressure flash drum off, if they contain > 0,1 % w/w Butadiene	68513-19-9	271-005-5
552	Residues (petroleum), alkylation splitter, C <sub>4</sub> -rich, if they contain > 0,1 % w/w Butadiene	68513-66-6	271-010-2
553	Hydrocarbons, C <sub>1-4</sub> , if they contain > 0,1 % w/w Butadiene	68514-31-8	271-032-2
554	Hydrocarbons, C <sub>1-4</sub> , sweetened, if they contain > 0,1 % w/w Butadiene	68514-36-3	271-038-5
555	Gases (petroleum), oil refinery gas distn. off, if they contain > 0,1 % w/w Butadiene	68527-15-1	271-258-1
556	Hydrocarbons, C <sub>1-3</sub> , if they contain > 0,1 % w/w Butadiene	68527-16-2	271-259-7
557	Hydrocarbons, C <sub>1-4</sub> , debutaniser fraction, if they contain > 0,1 % w/w Butadiene	68527-19-5	271-261-8
558	Gases (petroleum), benzene unit hydrotreater depentaniser overheads, if they contain > 0,1 % w/w Butadiene	68602-82-4	271-623-5
559	Gases (petroleum), C <sub>1-5</sub> , wet, if they contain > 0,1 % w/w Butadiene	68602-83-5	271-624-0
560	Gases (petroleum), secondary absorber off, fluidised catalytic cracker overheads fractionator, if they contain > 0,1 % w/w Butadiene	68602-84-6	271-625-6
561	Hydrocarbons, C <sub>2-4</sub> , if they contain > 0,1 % w/w Butadiene	68606-25-7	271-734-9
562	Hydrocarbons, C <sub>3</sub> , if they contain > 0,1 % w/w Butadiene	68606-26-8	271-735-4
563	Gases (petroleum), alkylation feed, if they contain > 0,1 % w/w Butadiene	68606-27-9	271-737-5
564	Gases (petroleum), depropaniser bottoms fractionation off, if they contain > 0,1 % w/w Butadiene	68606-34-8	271-742-2
565	Petroleum products, refinery gases, if they contain > 0,1 % w/w Butadiene	68607-11-4	271-750-6
566	Gases (petroleum), hydrocracking low-pressure separator, if they contain > 0,1 % w/w Butadiene	68783-06-2	272-182-1
567	Gases (petroleum), refinery blend, if they contain > 0,1 % w/w Butadiene	68783-07-3	272-183-7
568	Gases (petroleum), catalytic cracking, if they contain > 0,1 % w/w Butadiene	68783-64-2	272-203-4



Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
569	Gases (petroleum), C <sub>2-4</sub> , sweetened, if they contain > 0,1 % w/w Butadiene	68783-65-3	272-205-5
570	Gases (petroleum), refinery, if they contain > 0,1 % w/w Butadiene	68814-67-5	272-338-9
571	Gases (petroleum), platformer products separator off, if they contain > 0,1 % w/w Butadiene	68814-90-4	272-343-6
572	Gases (petroleum), hydrotreated sour kerosine depentaniser stabiliser off, if they contain > 0,1 % w/w Butadiene	68911-58-0	272-775-5
573	Gases (petroleum), hydrotreated sour kerosine flash drum, if they contain > 0,1 % w/w Butadiene	68911-59-1	272-776-0
574	Gases (petroleum), crude oil fractionation off, if they contain > 0,1 % w/w Butadiene	68918-99-0	272-871-7
575	Gases (petroleum), dehexaniser off, if they contain > 0,1 % w/w Butadiene	68919-00-6	272-872-2
576	Gases (petroleum), distillate unifier desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene	68919-01-7	272-873-8
577	Gases (petroleum), fluidised catalytic cracker fractionation off if they contain > 0,1 % w/w Butadiene	68919-02-8	272-874-3
578	Gases (petroleum), fluidised catalytic cracker scrubbing secondary absorber off, if they contain > 0,1 % w/w Butadiene	68919-03-9	272-875-9
579	Gases (petroleum), heavy distillate hydrotreater desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene	68919-04-0	272-876-4
580	Gases (petroleum), light straight run gasoline fractionation stabiliser off, if they contain > 0,1 % w/w Butadiene	68919-05-1	272-878-5
581	Gases (petroleum), naphtha unifier desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene	68919-06-2	272-879-0
582	Gases (petroleum), platformer stabiliser off, light ends fractionation, if they contain > 0,1 % w/w Butadiene	68919-07-3	272-880-6
583	Gases (petroleum), preflash tower off, crude distn., if they contain > 0,1 % w/w Butadiene	68919-08-4	272-881-1
584	Gases (petroleum), straight-run naphtha catalytic reforming off, if they contain > 0,1 % w/w Butadiene	68919-09-5	272-882-7
585	Gases (petroleum), straight-run stabiliser off, if they contain > 0,1 % w/w Butadiene	68919-10-8	272-883-2
586	Gases (petroleum), tar stripper off, if they contain > 0,1 % w/w Butadiene	68919-11-9	272-884-8
587	Gases (petroleum), unifier stripper off, if they contain > 0,1 % w/w Butadiene	68919-12-0	272-885-3
588	Gases (petroleum), fluidised catalytic cracker splitter overheads, if they contain > 0,1 % w/w Butadiene	68919-20-0	272-893-7
589	Gases (petroleum), catalytic cracked naphtha debutaniser, if they contain > 0,1 % w/w Butadiene	68952-76-1	273-169-3
590	Tail gas (petroleum), catalytic cracked distillate and naphtha stabiliser, if it contains > 0,1 % w/w Butadiene	68952-77-2	273-170-9
591	Tail gas (petroleum), catalytic hydrodesulfurised naphtha separator, if it contains > 0,1 % w/w Butadiene	68952-79-4	273-173-5
592	Tail gas (petroleum), straight-run naphtha hydrodesulfurised, if it contains > 0,1 % w/w Butadiene	68952-80-7	273-174-0
593	Tail gas (petroleum), thermal-cracked distillate, gas oil and naphtha absorber, if it contains > 0,1 % w/w Butadiene	68952-81-8	273-175-6

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
594	Tail gas (petroleum), thermal cracked hydrocarbon fractionation stabiliser, petroleum coking, if it contains > 0,1 % w/w Butadiene	68952-82-9	273-176-1
595	Gases (petroleum), light steam-cracked, butadiene conc., if they contain > 0,1 % w/w Butadiene	68955-28-2	273-265-5
596	Gases (petroleum), sponge absorber off, fluidised catalytic cracker and gas oil desulfuriser overhead fractionation, if they contain > 0,1 % w/w Butadiene	68955-33-9	273-269-7
597	Gases (petroleum), straight-run naphtha catalytic reformer stabiliser overhead, if they contain > 0,1 % w/w Butadiene	68955-34-0	273-270-2
598	Gases (petroleum), crude distn. and catalytic cracking, if they contain > 0,1 % w/w Butadiene	68989-88-8	273-563-5
599	Hydrocarbons, C <sub>4</sub> , if they contain > 0,1 % w/w Butadiene	87741-01-3	289-339-5
600	Alkanes, C <sub>1-4</sub> , C <sub>3</sub> -rich, if they contain > 0,1 % w/w Butadiene	90622-55-2	292-456-4
601	Gases (petroleum), gas oil diethanolamine scrubber off, if they contain > 0,1 % w/w Butadiene	92045-15-3	295-397-2
602	Gases (petroleum), gas oil hydrodesulfurisation effluent, if they contain > 0,1 % w/w Butadiene	92045-16-4	295-398-8
603	Gases (petroleum), gas oil hydrodesulfurisation purge, if they contain > 0,1 % w/w Butadiene	92045-17-5	295-399-3
604	Gases (petroleum), hydrogenator effluent flash drum off, if they contain > 0,1 % w/w Butadiene	92045-18-6	295-400-7
605	Gases (petroleum), naphtha steam cracking high-pressure residual, if they contain > 0,1 % w/w Butadiene	92045-19-7	295-401-2
606	Gases (petroleum), residue visbreaking off, if they contain > 0,1 % w/w Butadiene	92045-20-0	295-402-8
607	Gases (petroleum), steam-cracker C <sub>3</sub> -rich, if they contain > 0,1 % w/w Butadiene	92045-22-2	295-404-9
608	Hydrocarbons, C <sub>4</sub> , steam-cracker distillate, if they contain > 0,1 % w/w Butadiene	92045-23-3	295-405-4
609	Petroleum gases, liquefied, sweetened, C <sub>4</sub> fraction, if they contain > 0,1 % w/w Butadiene	92045-80-2	295-463-0
610	Hydrocarbons, C <sub>4</sub> , 1,3-butadiene- and isobutene-free, if they contain > 0,1 % w/w Butadiene	95465-89-7	306-004-1
611	Raffinates (petroleum), steam-cracked C <sub>4</sub> fraction cuprous ammonium acetate extn., C <sub>3-5</sub> and C <sub>3-5</sub> unsatd., butadiene-free, if they contain > 0,1 % w/w Butadiene	97722-19-5	307-769-4
612	Benzo[def]chrysene (benzo[a]pyrene)	50-32-8	200-028-5
613	Pitch, coal tar-petroleum, if it contains > 0,005 % w/w benzo[a]pyrene	68187-57-5	269-109-0
614	Distillates (coal-petroleum), condensed-ring arom., if they contain > 0,005 % w/w benzo[a]pyrene	68188-48-7	269-159-3
615	Moved or deleted		
616	Moved or deleted		
617	Creosote oil, acenaphthene fraction, acenaphthene-free, if it contains > 0,005 % w/w benzo[a]pyrene	90640-85-0	292-606-9
618	Pitch, coal tar, low-temp., if it contains > 0,005 % w/w benzo[a]pyrene	90669-57-1	292-651-4
619	Pitch, coal tar, low-temp., heat-treated, if it contains > 0,005 % w/w benzo[a]pyrene	90669-58-2	292-653-5

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
620	Pitch, coal tar, low-temp., oxidised, if it contains > 0,005 % w/w benzo[a]pyrene	90669-59-3	292-654-0
621	Extract residues (coal), brown, if they contain > 0,005 % w/w benzo[a]pyrene	91697-23-3	294-285-0
622	Paraffin waxes (coal), brown-coal high-temp. tar, if they contain > 0,005 % w/w benzo[a]pyrene	92045-71-1	295-454-1
623	Paraffin waxes (coal), brown-coal high-temp. tar, hydrotreated, if they contain > 0,005 % w/w benzo[a]pyrene	92045-72-2	295-455-7
624	Waste solids, coal-tar pitch coking, if they contain > 0,005 % w/w benzo[a]pyrene	92062-34-5	295-549-8
625	Pitch, coal tar, high-temp., secondary, if it contains > 0,005 % w/w benzo[a]pyrene	94114-13-3	302-650-3
626	Residues (coal), liq. solvent extn., if they contain > 0,005 % w/w benzo[a]pyrene	94114-46-2	302-681-2
627	Coal liquids, liq. solvent extn. soln., if they contain > 0,005 % w/w benzo[a]pyrene	94114-47-3	302-682-8
628	Coal liquids, liq. solvent extn., if they contain > 0,005 % w/w benzo[a]pyrene	94114-48-4	302-683-3
629	Paraffin waxes (coal), brown-coal high-temp. tar, carbon-treated, if they contain > 0,005 % w/w benzo[a]pyrene	97926-76-6	308-296-6
630	Paraffin waxes (coal), brown-coal high-temp tar, clay-treated, if they contain > 0,005 % w/w benzo[a]pyrene	97926-77-7	308-297-1
631	Paraffin waxes (coal), brown-coal high-temp tar, silicic acid-treated, if they contain > 0,005 % w/w benzo[a]pyrene	97926-78-8	308-298-7
632	Absorption oils, bicyclo arom. and heterocyclic hydrocarbon fraction, if they contain > 0,005 % w/w benzo[a]pyrene	101316-45-4	309-851-5
633	Aromatic hydrocarbons, C <sub>20-28</sub> , polycyclic, mixed coal-tar pitch-polyethylene polypropylene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene	101794-74-5	309-956-6
634	Aromatic hydrocarbons, C <sub>20-28</sub> , polycyclic, mixed coal-tar pitch-polyethylene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene	101794-75-6	309-957-1
635	Aromatic hydrocarbons, C <sub>20-28</sub> , polycyclic, mixed coal-tar pitch-polystyrene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene	101794-76-7	309-958-7
636	Pitch, coal tar, high-temp., heat-treated, if it contains > 0,005 % w/w benzo[a]pyrene	121575-60-8	310-162-7
637	Dibenz[a,h]anthracene	53-70-3	200-181-8
638	Benz[a]anthracene	56-55-3	200-280-6
639	Benzo[e]pyrene	192-97-2	205-892-7
640	Benzo[j]fluoranthene	205-82-3	205-910-3
641	Benz(e)acephenanthrylene	205-99-2	205-911-9
642	Benzo(k)fluoranthene	207-08-9	205-916-6
643	Chrysene	218-01-9	205-923-4
644	2-Bromopropane	75-26-3	200-855-1
645	Trichloroethylene	79-01-6	201-167-4
646	1,2-Dibromo-3-chloropropane	96-12-8	202-479-3

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
647	2,3-Dibromopropan-1-ol	96-13-9	202-480-9
648	1,3-Dichloropropan-2-ol	96-23-1	202-491-9
649	$\alpha,\alpha,\alpha$ -Trichlorotoluene	98-07-7	202-634-5
650	$\alpha$ -Chlorotoluene (Benzyl chloride)	100-44-7	202-853-6
651	1,2-Dibromoethane	106-93-4	203-444-5
652	Hexachlorobenzene	118-74-1	204-273-9
653	Bromoethylene (Vinyl bromide)	593-60-2	209-800-6
654	1,4-Dichlorobut-2-ene	764-41-0	212-121-8
655	Methyloxirane (Propylene oxide)	75-56-9	200-879-2
656	(Epoxyethyl)benzene (Styrene oxide)	96-09-3	202-476-7
657	1-Chloro-2,3-epoxypropane (Epichlorohydrin)	106-89-8	203-439-8
658	R-1-Chloro-2,3-epoxypropane	51594-55-9	424-280-2
659	1,2-Epoxy-3-phenoxypropane (Phenyglycidyl ether)	122-60-1	204-557-2
660	2,3-Epoxypropan-1-ol (Glycidol)	556-52-5	209-128-3
661	R-2,3-Epoxy-1-propanol	57044-25-4	404-660-4
662	2,2'-Bioxirane (1,2:3,4-Diepoxybutane)	1464-53-5	215-979-1
663	(2RS,3RS)-3-(2-Chlorophenyl)-2-(4-fluorophenyl)-[1H-1,2,4-triazol-1-yl)methyl]oxirane; Epoxiconazole	133855-98-8	406-850-2
664	Chloromethyl methyl ether	107-30-2	203-480-1
665	2-Methoxyethanol and its acetate (2-Methoxyethyl acetate)	109-86-4/ 110-49-6	203-713-7/ 203-772-9
666	2-Ethoxyethanol and its acetate (2-Ethoxyethyl acetate)	110-80-5/ 111-15-9	203-804-1/ 203-839-2
667	Oxybis[chloromethane], bis (Chloromethyl) ether	542-88-1	208-832-8
668	2-Methoxypropanol	1589-47-5	216-455-5
669	Propiolactone	57-57-8	200-340-1
670	Dimethylcarbamoyl chloride	79-44-7	201-208-6
671	Urethane (Ethyl carbamate)	51-79-6	200-123-1
672	Moved or deleted		
673	Moved or deleted		
674	Methoxyacetic acid	625-45-6	210-894-6
675	Dibutyl phthalate	84-74-2	201-557-4
676	bis(2-Methoxyethyl) ether (Dimethoxydiglycol)	111-96-6	203-924-4
677	bis(2-Ethylhexyl) phthalate (Diethylhexyl phthalate)	117-81-7	204-211-0
678	bis(2-Methoxyethyl) phthalate	117-82-8	204-212-6
679	2-Methoxypropyl acetate	70657-70-4	274-724-2
680	2-Ethylhexyl[[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-methyl]thio]acetate	80387-97-9	279-452-8
681	Acrylamide, unless regulated elsewhere in this Regulation	79-06-1	201-173-7
682	Acrylonitrile	107-13-1	203-466-5
683	2-Nitropropane	79-46-9	201-209-1

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
684	Dinoseb, its salts and esters with the exception of those specified elsewhere in this list	88-85-7	201-861-7
685	2-Nitroanisole	91-23-6	202-052-1
686	4-Nitrobiphenyl	92-93-3	202-204-7
687	2,4-Dinitrotoluene; Dinitrotoluene, technical grade	121-14-2/ 25321-14-6	204-450-0/ 246-836-1
688	Binapacryl	485-31-4	207-612-9
689	2-Nitronaphthalene	581-89-5	209-474-5
690	2,3-Dinitrotoluene	602-01-7	210-013-5
691	5-Nitroacenaphthene	602-87-9	210-025-0
692	2,6-Dinitrotoluene	606-20-2	210-106-0
693	3,4-Dinitrotoluene	610-39-9	210-222-1
694	3,5-Dinitrotoluene	618-85-9	210-566-2
695	2,5-Dinitrotoluene	619-15-8	210-581-4
696	Dinoterb, its salts and esters	1420-07-1	215-813-8
697	Nitrofen	1836-75-5	217-406-0
698	Moved or deleted		
699	Diazomethane	334-88-3	206-382-7
700	1,4,5,8-Tetraaminoanthraquinone (Disperse Blue 1)	2475-45-8	219-603-7
701	Moved or deleted		
702	1-Methyl-3-nitro-1-nitrosoguanidine	70-25-7	200-730-1
703	Moved or deleted		
704	Moved or deleted		
705	4,4'-Methylenedianiline	101-77-9	202-974-4
706	4,4'-(4-Iminocyclohexa-2,5-dienylidenemethylene) dianiline hydrochloride	569-61-9	209-321-2
707	4,4'-Methylenedi-o-toluidine	838-88-0	212-658-8
708	o-Anisidine	90-04-0	201-963-1
709	3,3'-Dimethoxybenzidine (ortho-Dianisidine) and its salts	119-90-4	204-355-4
710	Moved or deleted		
711	o-Dianisidine based azo dyes		
712	3,3'-Dichlorobenzidine	91-94-1	202-109-0
713	Benzidine dihydrochloride	531-85-1	208-519-6
714	[[1,1'-Biphenyl]-4,4'-diyl]diammonium sulphate	531-86-2	208-520-1
715	3,3'-Dichlorobenzidine dihydrochloride	612-83-9	210-323-0
716	Benzidine sulphate	21136-70-9	244-236-4
717	Benzidine acetate	36341-27-2	252-984-8
718	3,3'-Dichlorobenzidine dihydrogen bis(sulphate)	64969-34-2	265-293-1
719	3,3'-Dichlorobenzidine sulphate	74332-73-3	277-822-3
720	Benzidine based azo dyes		
721	4,4'-Bi-o-toluidine (ortho-Tolidine)	119-93-7	204-358-0
722	4,4'-Bi-o-toluidine dihydrochloride	612-82-8	210-322-5
723	[3,3'-Dimethyl[1,1'-biphenyl]-4,4'-diyl]diammonium bis(hydrogen sulphate)	64969-36-4	265-294-7

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
724	4,4'-Bi-o-toluidine sulphate	74753-18-7	277-985-0
725	o-Tolidine based dyes		611-030-00-4
726	Biphenyl-4-ylamine (4-Aminobiphenyl) and its salts	92-67-1	202-177-1
727	Azobenzene	103-33-3	203-102-5
728	(Methyl-ONN-azoxy)methyl acetate	592-62-1	209-765-7
729	Cycloheximide	66-81-9	200-636-0
730	2-Methylaziridine	75-55-8	200-878-7
731	Imidazolidine-2-thione (Ethylene thiourea)	96-45-7	202-506-9
732	Furan	110-00-9	203-727-3
733	Aziridine	151-56-4	205-793-9
734	Captafol	2425-06-1	219-363-3
735	Carbadox	6804-07-5	229-879-0
736	Flumioxazin	103361-09-7	613-166-00-X
737	Tridemorph	24602-86-6	246-347-3
738	Vinclozolin	50471-44-8	256-599-6
739	Fluazifop-butyl	69806-50-4	274-125-6
740	Flusilazole	85509-19-9	014-017-00-6
741	1,3,5-Tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione (TGIC)	2451-62-9	219-514-3
742	Thioacetamide	62-55-5	200-541-4
743	Moved or deleted		
744	Formamide	75-12-7	200-842-0
745	N-Methylacetamide	79-16-3	201-182-6
746	N-Methylformamide	123-39-7	204-624-6
747	N,N-Dimethylacetamide	127-19-5	204-826-4
748	Hexamethylphosphoric-triamide	680-31-9	211-653-8
749	Diethyl sulphate	64-67-5	200-589-6
750	Dimethyl sulphate	77-78-1	201-058-1
751	1,3-Propanesultone	1120-71-4	214-317-9
752	Dimethylsulphamoyl-chloride	13360-57-1	236-412-4
753	Sulfallate	95-06-7	202-388-9
754	A mixture of: 4-[[bis-(4-Fluorophenyl)methylsilyl]methyl]-4H-1,2,4-triazole and 1-[[bis-(4-fluorophenyl)methylsilyl]methyl]-1H-1,2,4-triazole		403-250-2
755	(+/-)-Tetrahydrofurfuryl -(R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	119738-06-6	607-373-00-4
756	6-Hydroxy-1-(3-Isopropoxypropyl)-4-methyl-2-oxo-5-[4-(phenylazo)phenylazo]-1,2-dihydro-3-pyridinecarbonitrile	85136-74-9-	4 0-3400-3
757	(6-(4-Hydroxy-3-(2-methoxyphenylazo)-2-sulfonato-7-naphthylamino)-1,3,5-triazine-2,4-diyl)bis[(amino-1-methylethyl)ammonium] formate	108225-03-2	402-060-7
758	Trisodium [4'-(8-acetylamino-3,6-disulfonato-2-naphthylazo)-4''-(6-benzoylamino-3-Sulfonato-2-naphthylazo)-biphenyl-1,3',3'',1'''-tetraolato-O,O',O'',O'''] copper(II)		413-590-3

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
759	A mixture of: N-[3-Hydroxy-2-(2-methylacryloylaminomethoxy)propoxymethyl]-2-methylacrylamide and N-[2,3-bis-(2-Methylacryloylaminomethoxy)propoxymethyl]-2-methylacrylamide and methacrylamide and 2-methyl-N-(2-methylacryloylaminomethoxymethyl)-acrylamide and N-(2,3-dihydroxypropoxymethyl)-2-methylacrylamide		412-790-8
760	1,3,5-tris-[(2S and 2R)-2,3-Epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (Teroxirone)	59653-74-6	616-091-00-0
761	Erionite	12510-42-8	650-012-00-0
762	Asbestos	12001-28-4	650-013-00-6
763	Petroleum	8002-05-9	232-298-5
764	Distillates (petroleum), heavy hydrocracked, if they contain > 3 % w/w DMSO extract	64741-76-0	265-077-7
765	Distillates (petroleum), solvent-refined heavy paraffinic, if they contain > 3 % w/w DMSO extract	64741-88-4	265-090-8
766	Distillates (petroleum), solvent-refined light paraffinic, if they contain > 3 % w/w DMSO extract	64741-89-5	265-091-3
767	Residual oils (petroleum), solvent deasphalted, if they contain > 3 % w/w DMSO extract	64741-95-3	265-096-0
768	Distillates (petroleum), solvent-refined heavy naphthenic, if they contain > 3 % w/w DMSO extract	64741-96-4	265-097-6
769	Distillates (petroleum), solvent-refined light naphthenic, if they contain > 3 % w/w DMSO extract	64741-97-5	265-098-1
770	Residual oils (petroleum), solvent-refined, if they contain > 3 % w/w DMSO extract	64742-01-4	265-101-6
771	Distillates (petroleum), clay-treated heavy paraffinic, if they contain > 3 % w/w DMSO extract	64742-36-5	265-137-2
772	Distillates (petroleum), clay-treated light paraffinic, if they contain > 3 % w/w DMSO extract	64742-37-6	265-138-8
773	Residual oils (petroleum), clay-treated, if they contain > 3 % w/w DMSO extract	64742-41-2	265-143-5
774	Distillates (petroleum), clay-treated heavy naphthenic, if they contain > 3 % w/w DMSO extract	64742-44-5	265-146-1
775	Distillates (petroleum), clay-treated light naphthenic, if they contain > 3 % w/w DMSO extract	64742-45-6	265-147-7
776	Distillates (petroleum), hydrotreated heavy naphthenic, if they contain > 3 % w/w DMSO extract	64742-52-5	265-155-0
777	Distillates (petroleum), hydrotreated light naphthenic, if they contain > 3 % w/w DMSO extract	64742-53-6	265-156-6
778	Distillates (petroleum), hydrotreated heavy paraffinic, if they contain > 3 % w/w DMSO extract	64742-54-7	265-157-1
779	Distillates (petroleum), hydrotreated light paraffinic, if they contain > 3 % w/w DMSO extract	64742-55-8	265-158-7
780	Distillates (petroleum), solvent-dewaxed light paraffinic, if they contain > 3 % w/w DMSO extract	64742-56-9	265-159-2
781	Residual oils (petroleum), hydrotreated, if they contain > 3 % w/w DMSO extract	64742-57-0	265-160-8
782	Residual oils (petroleum), solvent-dewaxed, if they contain > 3 % w/w DMSO extract	64742-62-7	265-166-0



Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
783	Distillates (petroleum), solvent-dewaxed heavy naphthenic, if they contain > 3 % w/w DMSO extract	64742-63-8	265-167-6
784	Distillates (petroleum), solvent-dewaxed light naphthenic, if they contain > 3 % w/w DMSO extract	64742-64-9	265-168-1
785	Distillates (petroleum), solvent-dewaxed heavy paraffinic, if they contain > 3 % w/w DMSO extract	64742-65-0	265-169-7
786	Foots oil (petroleum), if it contains > 3 % w/w DMSO extract	64742-67-2	265-171-8
787	Naphthenic oils (petroleum), catalytic dewaxed heavy, if they contain > 3 % w/w DMSO extract	64742-68-3	265-172-3
788	Naphthenic oils (petroleum), catalytic dewaxed light, if they contain > 3 % w/w DMSO extract	64742-69-4	265-173-9
789	Paraffin oils (petroleum), catalytic dewaxed heavy, if they contain > 3 % w/w DMSO extract	64742-70-7	265-174-4
790	Paraffin oils (petroleum), catalytic dewaxed light, if they contain > 3 % w/w DMSO extract	64742-71-8	265-176-5
791	Naphthenic oils (petroleum), complex dewaxed heavy, if they contain > 3 % w/w DMSO extract	64742-75-2	265-179-1
792	Naphthenic oils (petroleum), complex dewaxed light, if they contain > 3 % w/w DMSO extract	64742-76-3	265-180-7
793	Extracts (petroleum), heavy naphthenic distillate solvent, arom. Conc., if they contain > 3 % w/w DMSO extract	68783-00-6	272-175-3
794	Extracts (petroleum), solvent-refined heavy paraffinic distillate solvent, if they contain > 3 % w/w DMSO extract	68783-04-0	272-180-0
795	Extracts (petroleum), heavy paraffinic distillates, solvent-deasphalted, if they contain > 3 % w/w DMSO extract	68814-89-1	272-342-0
796	Lubricating oils (petroleum), C <sub>20-50</sub> , hydrotreated neutral oil-based, high-viscosity, if they contain > 3 % w/w DMSO extract	72623-85-9	276-736-3
797	Lubricating oils (petroleum), C <sub>15-30</sub> , hydrotreated neutral oil-based, if they contain > 3 % w/w DMSO extract	72623- 86-0	276-737-9
798	Lubricating oils (petroleum), C <sub>20-50</sub> , hydrotreated neutral oil-based, if they contain > 3 % w/w DMSO extract	72623- 87-1	276-738-4
799	Lubricating oils, if they contain > 3 % w/w DMSO extract	74869-22-0	278-012-2
800	Distillates (petroleum), complex dewaxed heavy paraffinic, if they contain > 3 % w/w DMSO extract	90640-91-8	292-613-7
801	Distillates (petroleum), complex dewaxed light paraffinic, if they contain > 3 % w/w DMSO extract	90640-92-9	292-614-2
802	Distillates (petroleum), solvent dewaxed heavy paraffinic, clay-treated, if they contain > 3 % w/w DMSO extract	90640-94-1	292-616-3
803	Hydrocarbons, C <sub>20-50</sub> , solvent dewaxed heavy paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract	90640-95-2	292-617-9
804	Distillates (petroleum), solvent dewaxed light paraffinic, clay-treated, if they contain > 3 % w/w DMSO extract	90640-96-3	292-618-4
805	Distillates (petroleum), solvent dewaxed light paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract	90640-97-4	292-620-5
806	Extracts (petroleum), heavy naphthenic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract	90641-07-9	292-631-5

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
807	Extracts (petroleum), heavy paraffinic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract	90641-08-0	292-632-0
808	Extracts (petroleum), light paraffinic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract	90641-09-1	292-633-6
809	Residual oils (petroleum), hydrotreated solvent dewaxed, if they contain > 3 % w/w DMSO extract	90669-74-2	292-656-1
810	Residual oils (petroleum), catalytic dewaxed, if they contain > 3 % w/w DMSO extract	91770-57-9	294-843-3
811	Distillates (petroleum), dewaxed heavy paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract	91995-39-0	295-300-3
812	Distillates (petroleum), dewaxed light paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract	91995-40-3	295-301-9
813	Distillates (petroleum), hydrocracked solvent-refined, dewaxed, if they contain > 3 % w/w DMSO extract	91995-45-8	295-306-6
814	Distillates (petroleum), solvent-refined light naphthenic, hydrotreated, if they contain > 3 % w/w DMSO extract	91995-54-9	295-316-0
815	Extracts (petroleum), hydrotreated light paraffinic distillate solvent, if they contain > 3 % w/w DMSO extract	91995-73-2	295-335-4
816	Extracts (petroleum), light naphthenic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract	91995-75-4	295-338-0
817	Extracts (petroleum), light paraffinic distillate solvent, acid-treated, if they contain > 3 % w/w DMSO extract	91995-76-5	295-339-6
818	Extracts (petroleum), light paraffinic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract	91995-77-6	295-340-1
819	Extracts (petroleum), light vacuum gas oil solvent, hydrotreated, if they contain > 3 % w/w DMSO extract	91995-79-8	295-342-2
820	Foots oil (petroleum), hydrotreated, if it contains > 3 % w/w DMSO extract	92045-12-0	295-394-6
821	Lubricating oils (petroleum), C <sub>17-35</sub> , solvent-extd., dewaxed, hydrotreated, if they contain > 3 % w/w DMSO extract	92045-42-6	295-423-2
822	Lubricating oils (petroleum), hydrocracked nonarom solvent-deparaffined, if they contain > 3 % w/w DMSO extract	92045-43-7	295-424-8
823	Residual oils (petroleum), hydrocracked acid-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract	92061-86-4	295-499-7
824	Paraffin oils (petroleum), solvent-refined dewaxed heavy, if they contain > 3 % w/w DMSO extract	92129-09-4	295-810-6
825	Extracts (petroleum), heavy paraffinic distillate solvent, clay-treated, if they contain > 3 % w/w DMSO extract	92704-08-0	296-437-1
826	Lubricating oils (petroleum), base oils, paraffinic, if they contain > 3 % w/w DMSO extract	93572-43-1	297-474-6
827	Extracts (petroleum), heavy naphthenic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract	93763-10-1	297-827-4
828	Extracts (petroleum), solvent-dewaxed heavy paraffinic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract	93763-11-2	297-829-5

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
829	Hydrocarbons, hydrocracked paraffinic distn. residues, solvent-dewaxed, if they contain > 3 % w/w DMSO extract	93763-38-3	297-857-8
830	Foots oil (petroleum), acid-treated, if it contains > 3 % w/w DMSO extract	93924-31-3	300-225-7
831	Foots oil (petroleum), clay-treated, if it contains > 3 % w/w DMSO extract	93924-32-4	300-226-2
832	Hydrocarbons, C <sub>20-50</sub> , residual oil hydrogenation vacuum distillate, if they contain > 3 % w/w DMSO extract	93924-61-9	300-257-1
833	Distillates (petroleum), solvent-refined hydrotreated heavy, hydrogenated, if they contain > 3 % w/w DMSO extract	94733-08-1	305-588-5
834	Distillates (petroleum), solvent-refined hydrocracked light, if they contain > 3 % w/w DMSO extract	94733-09-2	305-589-0
835	Lubricating oils (petroleum), C <sub>18-40</sub> , solvent-dewaxed hydrocracked distillate-based, if they contain > 3 % w/w DMSO extract	94733-15-0	305-594-8
836	Lubricating oils (petroleum), C <sub>18-40</sub> , solvent-dewaxed hydrogenated raffinate-based, if they contain > 3 % w/w DMSO extract	94733-16-1	305-595-3
837	Hydrocarbons, C <sub>13-30</sub> , arom. -rich, solvent-extd. naphthenic distillate, if they contain > 3 % w/w DMSO extract	95371-04-3	305-971-7
838	Hydrocarbons, C <sub>16-32</sub> , arom. rich, solvent-extd. naphthenic distillate, if they contain > 3 % w/w DMSO extract	95371-05-4	305-972-2
839	Hydrocarbons, C <sub>37-68</sub> , dewaxed deasphalted hydrotreated vacuum distn. Residues, if they contain > 3 % w/w DMSO extract	95371-07-6	305-974-3
840	Hydrocarbons, C <sub>37-65</sub> , hydrotreated deasphalted vacuum distn. Residues, if they contain > 3 % w/w DMSO extract	95371-08-7	305-975-9
841	Distillates (petroleum), hydrocracked solvent-refined light, if they contain > 3 % w/w DMSO extract	97488-73-8	307-010-7
842	Distillates (petroleum), solvent-refined hydrogenated heavy, if they contain > 3 % w/w DMSO extract	97488-74-9	307-011-2
843	Lubricating oils (petroleum), C <sub>18-27</sub> , hydrocracked solvent-dewaxed, if they contain > 3 % w/w DMSO extract	97488-95-4	307-034-8
844	Hydrocarbons, C <sub>17-30</sub> , hydrotreated solvent-deasphalted atm. distn. residue, distn. lights, if they contain > 3 % w/w DMSO extract	97675-87-1	307-661-7
845	Hydrocarbons, C <sub>17-40</sub> , hydrotreated solvent-deasphalted distn. residue, vacuum distn. lights, if they contain > 3 % w/w DMSO extract	97722-06-0	307-755-8
846	Hydrocarbons, C <sub>13-27</sub> , solvent-extd. light naphthenic, if they contain > 3 % w/w DMSO extract	97722-09-3	307-758-4
847	Hydrocarbons, C <sub>14-29</sub> , solvent-extd. light naphthenic, if they contain > 3 % w/w DMSO extract	97722-10-6	307-760-5
848	Foots oil (petroleum), carbon-treated, if it contains > 3 % w/w DMSO extract	97862-76-5	308-126-0
849	Foots oil (petroleum), silicic acid-treated, if it contains > 3 % w/w DMSO extract	97862-77-6	308-127-6

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
850	Hydrocarbons, C <sub>27-42</sub> , dearomatised, if they contain > 3 % w/w DMSO extract	97862-81-2	308-131-8
851	Hydrocarbons, C <sub>17-30</sub> , hydrotreated distillates, distn. Lights, if they contain > 3 % w/w DMSO extract	97862-82-3	308-132-3
852	Hydrocarbons, C <sub>27-45</sub> , naphthenic vacuum distn., if they contain > 3 % w/w DMSO extract	97862-83-4	308-133-9
853	Hydrocarbons, C <sub>27-45</sub> , dearomatised, if they contain > 3 % w/w DMSO extract	97926-68-6	308-287-7
854	Hydrocarbons, C <sub>20-58</sub> , hydrotreated, if they contain > 3 % w/w DMSO extract	97926-70-0	308-289-8
855	Hydrocarbons, C <sub>27-42</sub> , naphthenic, if they contain > 3 % w/w DMSO extract	97926-71-1	308-290-3
856	Extracts (petroleum), light paraffinic distillate solvent, carbon-treated, if they contain > 3 % w/w DMSO extract	100684-02-4	309-672-2
857	Extracts (petroleum), light paraffinic distillate solvent, clay-treated, if they contain > 3 % w/w DMSO extract	100684-03-5	309-673-8
858	Extracts (petroleum), light vacuum, gas oil solvent, carbon-treated, if they contain > 3 % w/w DMSO extract	100684-04-6	309-674-3
859	Extracts (petroleum), light vacuum gas oil solvent, clay-treated, if they contain > 3 % w/w DMSO extract	100684-05-7	309-675-9
860	Residual oils (petroleum), carbon-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract	100684-37-5	309-710-8
861	Residual oils (petroleum), clay-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract	100684-38-6	309-711-3
862	Lubricating oils (petroleum), C <sub>&gt;25</sub> , solvent-extd., deasphalted, dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract	101316-69-2	309-874-0
863	Lubricating oils (petroleum), C <sub>17-32</sub> , solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract	101316-70-5	309-875-6
864	Lubricating oils (petroleum), C <sub>20-35</sub> , solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract	101316-71-6	309-876-1
865	Lubricating oils (petroleum), C <sub>24-50</sub> , solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract	101316-72-7	309-877-7
866	Distillates (petroleum), sweetened middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64741-86-2	265-088-7
867	Gas oils (petroleum), solvent-refined, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64741-90-8	265-092-9
868	Distillates (petroleum), solvent-refined middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64741-91-9	265-093-4
869	Gas oils (petroleum), acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-12-7	265-112-6
870	Distillates (petroleum), acid-treated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-13-8	265-113-1
871	Distillates (petroleum), acid-treated light, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-14-9	265-114-7

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
872	Gas oils (petroleum), chemically neutralised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-29-6	265-129-9
873	Distillates (petroleum), chemically neutralised middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-30-9	265-130-4
874	Distillates (petroleum), clay-treated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-38-7	265-139-3
875	Distillates (petroleum), hydrotreated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-46-7	265-148-2
876	Gas oils (petroleum), hydrodesulfurised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-79-6	265-182-8
877	Distillates (petroleum), hydrodesulfurised middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-80-9	265-183-3
878	Distillates (petroleum), catalytic reformer fractionator residue, high-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	68477-29-2	270-719-4
879	Distillates (petroleum), catalytic reformer fractionator residue, intermediate-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	68477-30-5	270-721-5
880	Distillates (petroleum), catalytic reformer fractionator residue, low-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	68477-31-6	270-722-0
881	Alkanes, C <sub>12-26</sub> , branched and linear, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	90622-53-0	292-454-3
882	Distillates (petroleum), highly refined middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	90640-93-0	292-615-8
883	Distillates (petroleum), catalytic reformer, heavy arom. conc., except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	91995-34-5	295-294-2
884	Gas oils, paraffinic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	93924-33-5	300-227-8
885	Naphtha (petroleum), solvent-refined hydrodesulfurised heavy, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97488-96-5	307-035-3
886	Hydrocarbons, C <sub>16-20</sub> , hydrotreated middle distillate, distn. Lights, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97675-85-9	307-659-6
887	Hydrocarbons, C <sub>12-20</sub> , hydrotreated paraffinic, distn. lights, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97675-86-0	307-660-1
888	Hydrocarbons, C <sub>11-17</sub> , solvent-extd. light naphthenic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97722-08-2	307-757-9

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
889	Gas oils, hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97862-78-7	308-128-1
890	Distillates (petroleum), carbon-treated light paraffinic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100683-97-4	309-667-5
891	Distillates (petroleum), intermediate paraffinic, carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100683-98-5	309-668-0
892	Distillates (petroleum), intermediate paraffinic, clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100683-99-6	309-669-6
893	Lubricating greases, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	74869-21-9	278-011-7
894	Slack wax (petroleum), except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-61-6	265-165-5
895	Slack wax (petroleum), acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	90669-77-5	292-659-8
896	Slack wax (petroleum), clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	90669-78-6	292-660-3
897	Slack wax (petroleum), hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	92062-09-4	295-523-6
898	Slack wax (petroleum), low-melting, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	92062-10-7	295-524-1
899	Slack wax (petroleum), low-melting, hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	92062-11-8	295-525-7
900	Slack wax (petroleum), low-melting, carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97863-04-2	308-155-9
901	Slack wax (petroleum), low-melting, clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97863-05-3	308-156-4
902	Slack wax (petroleum), low-melting, silicic acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97863-06-4	308-158-5
903	Slack wax (petroleum), carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100684-49-9	309-723-9
904	Petrolatum, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	8009-03-8	232-373-2
905	Petrolatum (petroleum), oxidised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64743-01-7	265-206-7
906	Petrolatum (petroleum), alumina-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	85029-74-9	285-098-5



Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
907	Petrolatum (petroleum), hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	92045-77-7	295-459-9
908	Petrolatum (petroleum), carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97862-97-0	308-149-6
909	Petrolatum (petroleum), silicic acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97862-98-1	308-150-1
910	Petrolatum (petroleum), clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100684-33-1	309-706-6
911	Distillates (petroleum), light catalytic cracked	64741-59-9	265-060-4
912	Distillates (petroleum), intermediate catalytic cracked	64741-60-2	265-062-5
913	Distillates (petroleum), light thermal cracked	64741-82-8	265-084-5
914	Distillates (petroleum), hydrodesulfurised light catalytic cracked	68333-25-5	269-781-5
915	Distillates (petroleum), light steam-cracked naphtha	68475-80-9	270-662-5
916	Distillates (petroleum), cracked steam-cracked petroleum distillates	68477-38-3	270-727-8
917	Gas oils (petroleum), steam-cracked	68527-18-4	271-260-2
918	Distillates (petroleum), hydrodesulfurised thermal cracked middle	85116-53-6	285-505-6
919	Gas oils (petroleum), thermal-cracked, hydrodesulfurised	92045-29-9	295-411-7
920	Residues (petroleum), hydrogenated steam-cracked naphtha	92062-00-5	295-514-7
921	Residues (petroleum), steam-cracked naphtha distn.	92062-04-9	295-517-3
922	Distillates (petroleum), light catalytic cracked, thermally degraded	92201-60-0	295-991-1
923	Residues (petroleum), steam-cracked heat-soaked naphtha	93763-85-0	297-905-8
924	Gas oils (petroleum), light vacuum, thermal-cracked hydrodesulfurised	97926-59-5	308-278-8
925	Distillates (petroleum), hydrodesulfurised middle coker	101316-59-0	309-865-1
926	Distillates (petroleum), heavy steam-cracked	101631-14-5	309-939-3
927	Residues (petroleum), atm. Tower	64741-45-3	265-045-2
928	Gas oils (petroleum), heavy vacuum	64741-57-7	265-058-3
929	Distillates (petroleum), heavy catalytic cracked	64741-61-3	265-063-0
930	Clarified oils (petroleum), catalytic cracked	64741-62-4	265-064-6
931	Residues (petroleum), catalytic reformer fractionator	64741-67-9	265-069-3
932	Residues (petroleum), hydrocracked	64741-75-9	265-076-1
933	Residues (petroleum), thermal cracked	64741-80-6	265-081-9
934	Distillates (petroleum), heavy thermal cracked	64741-81-7	265-082-4
935	Gas oils (petroleum), hydrotreated vacuum	64742-59-2	265-162-9
936	Residues (petroleum), hydrodesulfurised atmospheric tower	64742-78-5	265-181-2
937	Gas oils (petroleum), hydrodesulfurised heavy vacuum	64742-86-5	265-189-6
938	Residues (petroleum), steam-cracked	64742-90-1	265-193-8
939	Residues (petroleum), atmospheric	68333-22-2	269-777-3
940	Clarified oils (petroleum), hydrodesulfurised catalytic cracked	68333-26-6	269-782-0
941	Distillates (petroleum), hydrodesulfurised intermediate catalytic cracked	68333-27-7	269-783-6
942	Distillates (petroleum), hydrodesulfurised heavy catalytic cracked	68333-28-8	269-784-1



Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
943	Fuel oil, residues-straight-run gas oils, high-sulfur	68476-32-4	270-674-0
944	Fuel oil, residual	68476-33-5	270-675-6
945	Residues (petroleum), catalytic reformer fractionator residue distn.	68478-13-7	270-792-2
946	Residues (petroleum), heavy coker gas oil and vacuum gas oil	68478-17-1	270-796-4
947	Residues (petroleum), heavy coker and light vacuum	68512-61-8	270-983-0
948	Residues (petroleum), light vacuum	68512-62-9	270-984-6
949	Residues (petroleum), steam-cracked light	68513-69-9	271-013-9
950	Fuel oil, No 6	68553-00-4	271-384-7
951	Residues (petroleum), topping plant, low-sulfur	68607-30-7	271-763-7
952	Gas oils (petroleum), heavy atmospheric	68783-08-4	272-184-2
953	Residues (petroleum), coker scrubber, condensed-ring-arom. -contg	68783-13-1	272-187-9
954	Distillates (petroleum), petroleum residues vacuum	68955-27-1	273-263-4
955	Residues (petroleum), steam-cracked, resinous	68955-36-2	273-272-3
956	Distillates (petroleum), intermediate vacuum	70592-76-6	274-683-0
957	Distillates (petroleum), light vacuum	70592-77-7	274-684-6
958	Distillates (petroleum), vacuum	70592-78-8	274-685-1
959	Gas oils (petroleum), hydrodesulfurised coker heavy vacuum	85117-03-9	285-555-9
960	Residues (petroleum), steam-cracked, distillates	90669-75-3	292-657-7
961	Residues (petroleum), vacuum, light	90669-76-4	292-658-2
962	Fuel oil, heavy, high-sulfur	92045-14-2	295-396-7
963	Residues (petroleum), catalytic cracking	92061-97-7	295-511-0
964	Distillates (petroleum), intermediate catalytic cracked, thermally degraded	92201-59-7	295-990-6
965	Residual oils (petroleum)	93821-66-0	298-754-0
966	Residues, steam cracked, thermally treated	98219-64-8	308-733-0
967	Distillates (petroleum), hydrodesulfurised full-range middle	101316-57-8	309-863-0
968	Distillates (petroleum), light paraffinic	64741-50-0	265-051-5
969	Distillates (petroleum), heavy paraffinic	64741-51-1	265-052-0
970	Distillates (petroleum), light naphthenic	64741-52-2	265-053-6
971	Distillates (petroleum), heavy naphthenic	64741-53-3	265-054-1
972	Distillates (petroleum), acid-treated heavy naphthenic	64742-18-3	265-117-3
973	Distillates (petroleum), acid-treated light naphthenic	64742-19-4	265-118-9
974	Distillates (petroleum), acid-treated heavy paraffinic	64742-20-7	265-119-4
975	Distillates (petroleum), acid-treated light paraffinic	64742-21-8	265-121-5
976	Distillates (petroleum), chemically neutralised heavy paraffinic	64742-27-4	265-127-8
977	Distillates (petroleum), chemically neutralised light paraffinic	64742-28-5	265-128-3
978	Distillates (petroleum), chemically neutralised heavy naphthenic	64742-34-3	265-135-1
979	Distillates (petroleum), chemically neutralised light naphthenic	64742-35-4	265-136-7
980	Extracts (petroleum), light naphthenic distillate solvent	64742-03-6	265-102-1
981	Extracts (petroleum), heavy paraffinic distillate solvent	64742-04-7	265-103-7

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
982	Extracts (petroleum), light paraffinic distillate solvent	64742-05-8	265-104-2
983	Extracts (petroleum), heavy naphthenic distillate solvent	64742-11-6	265-111-0
984	Extracts (petroleum), light vacuum gas oil solvent	91995-78-7	295-341-7
985	Hydrocarbons, C <sub>26-55</sub> , arom. rich	97722-04-8	307-753-7
986	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate)	573-58-0	209-358-4
987	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate	1937-37-7	217-710-3
988	Tetrasodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonate]	2602-46-2	220-012-1
989	4-o-Tolylazo-o-toluidine	97-56-3	202-591-2
990	4-Aminoazobenzene	60-09-3	200-453-6
991	Disodium[5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulphophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]salicylate(4-)]cuprate(2-)	16071-86-6	240-221-1
992	Resorcinol diglycidyl ether	101-90-6	202-987-5
993	1,3-Diphenylguanidine	102-06-7	203-002-1
994	Heptachlor-epoxide	1024-57-3	213-831-0
995	4-Nitrosophenol	104-91-6	203-251-6
996	Carbendazim	10605-21-7	234-232-0
997	Allyl glycidyl ether	106-92-3	203-442-4
998	Chloroacetaldehyde	107-20-0	203-472-8
999	Hexane	110-54-3	203-777-6
1000	2-(2-Methoxyethoxy)ethanol (Diethylene glycol monomethyl ether; DEGME)	111-77-3	203-906-6
1001	(+/-)-2-(2,4-Dichlorophenyl)-3-(1 <i>H</i> -1,2,4-triazol-1-yl)propyl-1,1,2,2-tetrafluoroethylether (Tetraconazole - ISO)	112281-77-3	407-760-6
1002	4-[4-(1,3-Dihydroxyprop-2-yl)phenylamino]-1,8-dihydroxy-5-nitroanthraquinone	114565-66-1	406-057-1
1003	5,6,12,13-Tetrachloroanthra(2,1,9- <i>def</i> :6,5,10- <i>d'ef'</i> )diisoquinoline-1,3,8,10(2 <i>H</i> ,9 <i>H</i> )-tetrone	115662-06-1	405-100-1
1004	tris(2-Chloroethyl) phosphate	115-96-8	204-118-5
1005	4'-Ethoxy-2-benzimidazoleanilide	120187-29-3	407-600-5
1006	Nickel dihydroxide	12054-48-7	235-008-5
1007	N,N-Dimethylaniline	121-69-7	204-493-5
1008	Simazine	122-34-9	204-535-2
1009	bis(Cyclopentadienyl)-bis(2,6-difluoro-3-(pyrrol-1-yl)-phenyl)titanium	125051-32-3	412-000-1
1010	N,N,N',N'-Tetraglycidyl-4,4'-diamino-3,3'-diethyldiphenylmethane	130728-76-6	410-060-3
1011	Divanadium pentaoxide	1314-62-1	215-239-8
1012	Pentachlorophenol and its alkali salts	87-86-5/ 131-52-2/ 7778-73-6	201-778-6/ 205-025-2/ 231-911-3

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1013	Phosphamidon	13171-21-6	236-116-5
1014	N-(Trichloromethylthio)phthalimide (Folpet - ISO)	133-07-3	205-088-6
1015	N-2-Naphthylaniline	135-88-6	205-223-9
1016	Ziram	137-30-4	205-288-3
1017	1-Bromo-3,4,5-trifluorobenzene	138526-69-9	418-480-9
1018	Propazine	139-40-2	205-359-9
1019	3-(4-Chlorophenyl)-1,1-dimethyluronium trichloroacetate; monuron-TCA	140-41-0	006-043-00-1
1020	Isoxaflutole	141112-29-0	606-054-00-7
1021	Kresoxim-methyl	143390-89-0	607-310-00-0
1022	Chlordecone	143-50-0	205-601-3
1023	9-Vinylcarbazole	1484-13-5	216-055-0
1024	2-Ethylhexanoic acid	149-57-5	205-743-6
1025	Monuron	150-68-5	205-766-1
1026	Morpholine-4-carbonyl chloride	15159-40-7	239-213-0
1027	Daminozide	1596-84-5	216-485-9
1028	Alachlor (ISO)	15972-60-8	240-110-8
1029	UVCB condensation product of: tetrakis-hydroxymethylphosphonium chloride, urea and distilled hydrogenated C <sub>16-18</sub> tallow alkylamine	166242-53-1	422-720-8
1030	Ioxynil and Ioxynil octanoate (ISO)	1689-83-4/ 3861-47-0	216-881-1/ 223-375-4
1031	Bromoxynil (ISO) (3,5-Dibromo-4-hydroxybenzonitrile) and Bromoxynil heptanoate (ISO)	1689-84-5/ 56634-95-8	216-882-7/ 260-300-4
1032	2,6-Dibromo-4-cyanophenyl octanoate	1689-99-2	216-885-3
1033	Moved or deleted		
1034	5-Chloro-1,3-dihydro-2H-indol-2-one	17630-75-0	412-200-9
1035	Benomyl	17804-35-2	241-775-7
1036	Chlorothalonil	1897-45-6	217-588-1
1037	N'-(4-Chloro-o-tolyl)-N,N-dimethylformamidine monohydrochloride	19750-95-9	243-269-1
1038	4,4'-Methylenebis(2-ethylaniline)	19900-65-3	243-420-1
1039	Valinamide	20108-78-5	402-840-7
1040	[(p-Tolyloxy)methyl]oxirane	2186-24-5	218-574-8
1041	[(m-Tolyloxy)methyl]oxirane	2186-25-6	218-575-3
1042	2,3-Epoxypropyl o-tolyl ether	2210-79-9	218-645-3
1043	[(Tolyloxy)methyl]oxirane, cresyl glycidyl ether	26447-14-3	247-711-4
1044	Di-allate	2303-16-4	218-961-1
1045	Benzyl 2,4-dibromobutanoate	23085-60-1	420-710-8
1046	Trifluoriodomethane	2314-97-8	219-014-5
1047	Thiophanate-methyl	23564-05-8	245-740-7
1048	Dodecachloropentacyclo[5.2.1.0 <sup>2,6</sup> .0 <sup>3,9</sup> 0 <sup>5,8</sup> ]decane (Mirex)	2385-85-5	219-196-6
1049	Propyzamide	23950-58-5	245-951-4
1050	Butyl glycidyl ether	2426-08-6	219-376-4
1051	2,3,4-Trichlorobut-1-ene	2431-50-7	219-397-9

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1052	Chinomethionate	2439-01-2	219-455-3
1053	(R)- $\alpha$ -Phenylethylammonium (-)-(1R,2S)-(1,2-epoxypropyl)phosphonate monohydrate	25383-07-7	418-570-8
1054	5-Ethoxy-3-trichloromethyl-1,2,4-thiadiazole (Etridiazole - ISO)	2593-15-9	219-991-8
1055	Disperse Yellow 3	2832-40-8	220-600-8
1056	1,2,4-Triazole	288-88-0	206-022-9
1057	Aldrin (ISO)	309-00-2	206-215-8
1058	Diuron (ISO)	330-54-1	206-354-4
1059	Linuron (ISO)	330-55-2	206-356-5
1060	Nickel carbonate	3333-67-3	222-068-2
1061	3-(4-Isopropylphenyl)-1,1-dimethylurea (Isoproturon - ISO)	34123-59-6	251-835-4
1062	Iprodione	36734-19-7	253-178-9
1063	Moved or deleted		
1064	5-(2,4-Dioxo-1,2,3,4-tetrahydropyrimidine)-3-fluoro-2-hydroxymethyltetrahydrofuran	41107-56-6	415-360-8
1065	Crotonaldehyde	4170-30-3	224-030-0
1066	Hexahydrocyclopenta(c)pyrrole-1-(1H)-ammonium N-ethoxycarbonyl-N-(p-tolylsulfonyl)azanide		418-350-1
1067	4,4'-Carbonimidoylbis[N,N-dimethylaniline] and its salts	492-80-8	207-762-5
1068	DNOC (ISO)	534-52-1	208-601-1
1069	Toluidinium chloride	540-23-8	208-740-8
1070	Toluidine sulphate (1:1)	540-25-0	208-741-3
1071	2-(4-tert.-Butylphenyl)ethanol	5406-86-0	410-020-5
1072	Fenthion	55-38-9	200-231-9
1073	Chlordane, pur	57-74-9	200-349-0
1074	Hexan-2-one (Methyl butyl ketone)	591-78-6	209-731-1
1075	Fenarimol	60168-88-9	262-095-7
1076	Acetamide	60-35-5	200-473-5
1077	N-Cyclohexyl-N-methoxy-2,5-dimethyl-3-furamide (Furmecyclox - ISO)	60568-05-0	262-302-0
1078	Dieldrin	60-57-1	200-484-5
1079	4,4'-Isobutylethylidenediphenol	6807-17-6	401-720-1
1080	Chlordimeform	6164-98-3	228-200-5
1081	Amitrole	61-82-5	200-521-5
1082	Carbaryl	63-25-2	200-555-0
1083	Distillates (petroleum), light hydrocracked	64741-77-1	265-078-2
1084	1-Ethyl-1-methylmorpholinium bromide	65756-41-4	612-182-00-4
1085	(3-Chlorophenyl)-(4-methoxy-3-nitrophenyl)methanone	66938-41-8	423-290-4
1086	Fuels, diesel, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	68334-30-5	269-822-7
1087	Fuel oil, no. 2	68476-30-2	270-671-4
1088	Fuel oil, no. 4	68476-31-3	270-673-5
1089	Fuels, diesel, no. 2	68476-34-6	270-676-1

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1090	2,2-Dibromo-2-nitroethanol	69094-18-4	412-380-9
1091	1-Ethyl-1-methylpyrrolidinium bromide	69227-51-6	612-183-00-X
1092	Monocrotophos	6923-22-4	230-042-7
1093	Nickel	7440-02-0	231-111-4
1094	Bromomethane (Methyl bromide - ISO)	74-83-9	200-813-2
1095	Chloromethane (Methyl chloride)	74-87-3	200-817-4
1096	Iodomethane (Methyl iodide)	74-88-4	200-819-5
1097	Bromoethane (Ethyl bromide)	74-96-4	200-825-8
1098	Heptachlor	76-44-8	200-962-3
1099	Fentin hydroxide	76-87-9	200-990-6
1100	Nickel sulphate	7786-81-4	232-104-9
1101	3,5,5-Trimethylcyclohex-2-enone (Isophorone)	78-59-1	201-126-0
1102	2,3-Dichloropropene	78-88-6	201-153-8
1103	Fluazifop-P-butyl (ISO)	79241-46-6	607-305-00-3
1104	(S)-2,3-Dihydro-1H-indole-carboxylic acid	79815-20-6	410-860-2
1105	Toxaphene	8001-35-2	232-283-3
1106	(4-Hydrazinophenyl)-N-methylmethanesulfonamide hydrochloride	81880-96-8	406-090-1
1107	CI Solvent Yellow 14	842-07-9	212-668-2
1108	Chlozolate	84332-86-5	282-714-4
1109	Alkanes, C <sub>10-13</sub> , monochloro	85535-84-8	287-476-5
1110	Moved or deleted		
1111	2,4,6-Trichlorophenol	88-06-2	201-795-9
1112	Diethylcarbamoil-chloride	88-10-8	201-798-5
1113	1-Vinyl-2-pyrrolidone	88-12-0	201-800-4
1114	Myclobutanil (ISO) (2-(4-chlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile)	88671-89-0	410-400-0
1115	Fentin acetate	900-95-8	212-984-0
1116	Biphenyl-2-ylamine	90-41-5	201-990-9
1117	Trans-4-cyclohexyl-L-proline monohydro-chloride	90657-55-9	419-160-1
1118	2-Methyl-m-phenylene diisocyanate (Toluene 2,6-diisocyanate)	91-08-7	202-039-0
1119	4-Methyl-m-phenylene diisocyanate (Toluene 2,4-diisocyanate)	584-84-9	209-544-5
1120	m-Tolylidene diisocyanate (Toluene diisocyanate)	26471-62-5	247-722-4
1121	Fuels, jet aircraft, coal solvent extn., hydrocracked hydrogenated	94114-58-6	302-694-3
1122	Fuels, diesel, coal solvent extn., hydrocracked hydrogenated	94114-59-7	302-695-9
1123	Pitch, if it contains > 0,005 % w/w benzo[a]pyrene	61789-60-4	263-072-4
1124	2-Butanone oxime	96-29-7	202-496-6
1125	Hydrocarbons, C <sub>16-20</sub> , solvent-dewaxed hydrocracked paraffinic distn. Residue	97675-88-2	307-662-2
1126	α,α-Dichlorotoluene	98-87-3	202-709-2

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1127	Mineral wool, with the exception of those specified elsewhere in this Annex; [Man-made vitreous (silicate)fibres with random orientation with alkaline oxide and alkali earth oxide ( $\text{Na}_2\text{O} + \text{K}_2\text{O} + \text{CaO} + \text{MgO} + \text{BaO}$ ) content greater than 18 % by weight]		
1128	Reaction product of acetophenone, formaldehyde, cyclohexylamine, methanol and acetic acid		406-230-1
1129	Moved or deleted		
1130	Moved or deleted		
1131	Trisodium bis(7-acetamido-2-(4-nitro-2-oxidophenylazo)-3-sulfonato-1-naphtholato)chromate(1-)		400-810-8
1132	A mixture of: 4-allyl-2,6-bis(2,3-epoxypropyl)phenol, 4-allyl-6-(3-(6-(3-(4-allyl-2,6-bis(2,3-epoxypropyl)-phenoxy)-2-hydroxypropyl)-4-allyl-2-(2,3-epoxypropyl)phenoxy)-2-hydroxypropyl)-4-allyl-2-(2,3-epoxypropyl)-phenoxy-2-hydroxypropyl-2-(2,3-epoxypropyl)phenol, 4-allyl-6-(3-(4-allyl-2,6-bis(2,3-epoxypropyl)phenoxy)-2-hydroxypropyl)-2-(2,3-epoxypropyl)phenoxy)phenol and 4-allyl-6-(3-(6-(3-(4-allyl-2,6-bis(2,3-epoxypropyl)-phenoxy)-2-hydroxypropyl)-4-allyl-2-(2,3-epoxypropyl)phenoxy)-2-hydroxypropyl)-2-(2,3-epoxypropyl)phenol		417-470-1
1133	Costus root oil ( <i>Saussurea lappa</i> Clarke), when used as a fragrance ingredient	8023-88-9	
1134	7-Ethoxy-4-methylcoumarin, when used as a fragrance ingredient	87-05-8	201-721-5
1135	Hexahydrocoumarin, when used as a fragrance ingredient	700-82-3	211-851-4
1136	Peru balsam (INCI name: Myroxylon pereirae), when used as a fragrance ingredient	8007-00-9	232-352-8
1137	Isobutyl nitrite	542-56-2	208-819-7
1138	Isoprene (stabilized); (2-methyl-1,3-butadiene)	78-79-5	201-143-3
1139	1-Bromopropane; n-Propyl bromide	106-94-5	203-445-0
1140	Chloroprene (stabilized); (2-Chlorobuta-1,3-diene)	126-99-8	204-818-0
1141	1,2,3-Trichloropropane	96-18-4	202-486-1
1142	Ethylene glycol dimethyl ether (EGDME)	110-71-4	203-794-9
1143	Dinocap (ISO)	39300-45-3	254-408-0
1144	Diaminotoluene, technical product -mixture of [4-methyl- <i>m</i> -phenylenediamine] (*) and [2-methyl- <i>m</i> -phenylenediamine] (*) Methyl-phenylenediamine	25376-45-8	246-910-3
1145	<i>p</i> -Chlorobenzotrichloride	5216-25-1	226-009-1
1146	Diphenylether; octabromo derivate	32536-52-0	251-087-9
1147	1,2-bis(2-Methoxyethoxy)ethane; Triethylene glycol dimethyl ether (TEGDME)	112-49-2	203-977-3
1148	Tetrahydrothiopyran-3-carboxaldehyde	61571-06-0	407-330-8
1149	4,4'-bis(Dimethylamino)benzophenone (Michler's ketone)	90-94-8	202-027-5
1150	Oxiranemethanol, 4-methylbenzene-sulfonate, (S)-	70987-78-9	417-210-7
1151	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear [1]	84777-06-0 [1]	284-032-2
	n-Pentyl-isopentylphthalate [2]-	[2]	
	di-n-Pentyl phthalate [3]	131-18-0 [3]	205-017-9
	Diisopentylphthalate [4]	605-50-5 [4]	210-088-4

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1152	Benzyl butyl phthalate (BBP)	85-68-7	201-622-7
1153	1,2-Benzenedicarboxylic acid, di-C <sub>7-11</sub> , branched and linear alkyl esters	68515-42-4	271-084-6
1154	A mixture of: disodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-hydroxy-1-(4-sulfonatophenyl)pyrazol-4-yl)penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate and trisodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-oxido-1-(4-sulfonatophenyl)pyrazol-4-yl)penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate		402-660-9
1155	(Methylenebis(4,1-phenylenazo(1-(3-(dimethylamino)propyl)-1,2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5,3-diyl))) -1,1'-dipyridinium dichloride dihydrochloride		401-500-5
1156	2-[2-Hydroxy-3-(2-chlorophenyl)carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)carbamoyl-1-naphthylazo]fluoren-9-one		420-580-2
1157	Azafenidin	68049-83-2	
1158	2,4,5-Trimethylaniline [1] 2,4,5-Trimethylaniline hydrochloride [2]	137-17-7 [1] 21436-97-5 [2]	205-282-0
1159	4,4'-Thiodianiline and its salts	139-65-1	205-370-9
1160	4,4'-Oxydianiline (p-Aminophenyl ether) and its salts	101-80-4	202-977-0
1161	N,N,N',N'-Tetramethyl-4,4'-methylenedianiline	101-61-1	202-959-2
1162	6-Methoxy-m-toluidine; (p-Cresidine)	120-71-8	204-419-1
1163	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	421-150-7
1164	A mixture of: 1,3,5-tris(3-aminomethylphenyl)-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione and a mixture of oligomers of 3,5-bis(3-aminomethylphenyl)-1-poly [3,5-bis(3-aminomethylphenyl)-2,4,6-trioxo-1,3,5-(1H,3H,5H)-triazin-1-yl]-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione		421-550-1
1165	2-Nitrotoluene	88-72-2	201-853-3
1166	Tributyl phosphate	126-73-8	204-800-2
1167	Naphthalene	91-20-3	202-049-5
1168	Nonylphenol [1] 4-Nonylphenol, branched [2]	25154-52-3 [1] 84852-15-3 [2]	246-672-0 284-325-5
1169	1,1,2-Trichloroethane	79-00-5	201-166-9
1170	Moved or deleted		
1171	Moved or deleted		
1172	allyl chloride; (3-Chloropropene)	107-05-1	203-457-6
1173	1,4-Dichlorobenzene; (p-Dichlorobenzene)	106-46-7	203-400-5
1174	bis(2-Chloroethyl) ether	111-44-4	203-870-1
1175	Phenol	108-95-2	203-632-7
1176	Bisphenol A (4,4'-Isopropylidenediphenol)	80-05-7	201-245-8
1177	Trioxymethylene (1,3,5-Trioxan)	110-88-3	203-812-5
1178	Propargite (ISO)	2312-35-8	219-006-1
1179	1-Chloro-4-nitrobenzene	100-00-5	202-809-6
1180	Molinate (ISO)	2212-67-1	218-661-0
1181	Fenpropimorph (ISO)	67564-91-4	266-719-9
1182	Moved or deleted		
1183	Methyl isocyanate	624-83-9	210-866-3



Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1184	N,N-Dimethylanilinium tetrakis(pentafluorophenyl)borate	118612-00-3	422-050-6
1185	O,O'-(Ethenylmethylsilylene) di[(4-methylpentan-2-one) oxime]		421-870-1
1186	A 2:1 mixture of: 4-(7-hydroxy-2,4,4-trimethyl-2-chromanyl)resorcinol-4-yl-tris (6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate) and 4-(7-hydroxy-2,4,4-trimethyl-2-chromanyl)resorcinolbis (6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate)	140698-96-0	414-770-4
1187	A mixture of: reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxo-naphthalenesulfonate (1:2) and reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxonaphthalenesulfonate (1:3)		417-980-4
1188	Malachite green hydrochloride [1]	569-64-2 [1]	209-322-8
	Malachite green oxalate [2]	18015-76-4 [2]	241-922-5
1189	1-(4-Chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl) pentan-3-ol	107534-96-3	403-640-2
1190	5-(3-Butyryl-2,4,6-trimethylphenyl)-2-[1-(ethoxyimino)propyl]- 3-hydroxycyclohex-2-en-1-one	138164-12-2	414-790-3
1191	<i>trans</i> -4-Phenyl-L-proline	96314-26-0	416-020-1
1192	Moved or deleted		
1193	A mixture of: 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]- 2,5-diethoxyphenyl)azo]-2-[(3-phosphonophenyl)azo]benzoic acid and 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)azo]- 2,5-diethoxyphenyl)azo]-3-[(3-phosphonophenyl)azo]benzoic acid	163879-69-4	418-230-9
1194	2-[[4-(2-Ammoniopropylamino)-6-[]4-hydroxy-3-(5-methyl- 2-methoxy-4-sulfamoylphenylazo)-2-sulfonatophenyl]-7-ylamino[] -1,3,5-triazin-2-ylamino[]-2-aminopropyl formate		424-260-3
1195	5-Nitro- <i>o</i> -toluidine [1]	99-55-8 [1]	202-765-8
	5-Nitro- <i>o</i> -toluidine hydrochloride [2]	51085-52-0 [2]	256-960-8
1196	1-(1-Naphthylmethyl)quinolinium chloride	65322-65-8	406-220-7
1197	(R)-5-Bromo-3-(1-methyl-2-pyrrolidinylmethyl)-1H-indole	143322-57-0	422-390-5
1198	Pymetrozine (ISO)	123312-89-0	613-202-00-4
1199	Oxadiargyl (ISO)	39807-15-3	254-637-6
1200	Chlorotoluron (3-(3-chloro- <i>p</i> -tolyl)-1,1-dimethylurea)	15545-48-9	239-592-2
1201	N-[2-(3-Acetyl-5-nitrothiophen-2-ylazo)-5-diethylaminophenyl] acetamide		416-860-9
1202	1,3-bis(Vinylsulfonylacetamido)propane	93629-90-4	428-350-3
1203	<i>p</i> -Phenetidine (4-Ethoxyaniline)	156-43-4	205-855-5
1204	<i>m</i> -Phenylenediamine and its salts	108-45-2	203-584-7
1205	Residues (coal tar), creosote oil distn., if it contains > 0,005 % w/w benzo[a]pyrene	92061-93-3	295-506-3
1206	Creosote oil, acenaphthene fraction, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene	90640-84-9	292-605-3
1207	Creosote oil, if it contains > 0,005 % w/w benzo[a]pyrene	61789-28-4	263-047-8
1208	Creosote, if it contains > 0,005 % w/w benzo[a]pyrene	8001-58-9	232-287-5
1209	Creosote oil, high-boiling distillate, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene	70321-79-8	274-565-9
1210	Extract residues (coal), creosote oil acid, wash oil extract residue, if it contains > 0,005 % w/w benzo[a]pyrene	122384-77-4	310-189-4
1211	Creosote oil, low-boiling distillate, wash oil, if it contains > 0,005 % w/w benzo[a]pyrene	70321-80-1	274-566-4

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1212	6-Methoxy-2,3-Pyridinediamine and its HCl salt, when used as a substance in hair dye products	94166-62-8	303-358-9
1213	2,3-Naphthalenediol, when used as a substance in hair dye products	92-44-4	202-156-7
1214	2,4-Diaminodiphenylamine, when used as a substance in hair dye products	136-17-4	
1215	2,6-Bis(2-Hydroxyethoxy)-3,5-Pyridinediamine and its HCl salt, when used as a substance in hair dye products	117907-42-3	
1216	2-Methoxymethyl- <i>p</i> -Aminophenol and its HCl salt, when used as a substance in hair dye products	135043-65-1/ 29785-47-5	
1217	4,5-Diamino-1-Methylpyrazole and its HCl salt, when used as a substance in hair dye products	20055-01-0/ 21616-59-1	
1218	4,5-Diamino-1-((4-Chlorophenyl)Methyl)-1H-Pyrazole Sulfate, when used as a substance in hair dye products	163183-00-4	
1219	4-Chloro-2-Aminophenol, when used as a substance in hair dye products	95-85-2	202-458-9
1220	4-Hydroxyindole, when used as a substance in hair dye products	2380-94-1	219-177-2
1221	4-Methoxytoluene-2,5-Diamine and its HCl salt, when used as a substance in hair dye products	56496-88-9	
1222	5-Amino-4-Fluoro-2-Methylphenol Sulfate, when used as a substance in hair dye products	163183-01-5	
1223	N,N-Diethyl- <i>m</i> -Aminophenol, when used as a substance in hair dye products	91-68-9/ 68239-84-9	202-090-9/ 269-478-8
1224	N,N-Dimethyl-2,6-Pyridinediamine and its HCl salt, when used as a substance in hair dye products	—	
1225	N-Cyclopentyl- <i>m</i> -Aminophenol, when used as a substance in hair dye products	104903-49-3	
1226	N-(2-Methoxyethyl)- <i>p</i> -phenylenediamine and its HCl salt, when used as a substance in hair dye products	72584-59-9/ 66566-48-1	276-723-2
1227	2,4-Diamino-5-methylphenetol and its HCl salt, when used as a substance in hair dye products	113715-25-6	
1228	1,7-Naphthalenediol, when used as a substance in hair dye products	575-38-2	209-383-0
1229	3,4-Diaminobenzoic acid, when used as a substance in hair dye products	619-05-6	210-577-2
1230	2-Aminomethyl- <i>p</i> -aminophenol and its HCl salt, when used as a substance in hair dye products	79352-72-0	
1231	Solvent Red 1 (CI 12150), when used as a substance in hair dye products	1229-55-6	214-968-9
1232	Acid Orange 24 (CI 20170), when used as a substance in hair dye products	1320-07-6	215-296-9
1233	Acid Red 73 (CI 27290), when used as a substance in hair dye products	5413-75-2	226-502-1
1234	PEG-3,2',2'-di- <i>p</i> -Phenylenediamine	144644-13-3	
1235	6-Nitro- <i>o</i> -Toluidine	570-24-1	209-329-6
1236	HC Yellow No 11	73388-54-2	
1237	HC Orange No 3	81612-54-6	
1238	HC Green No 1	52136-25-1	257-687-7
1239	HC Red No 8 and its salts	13556-29-1/ 97404-14-3	- / 306-778-0
1240	Tetrahydro-6-nitroquinoxaline and its salts	158006-54-3/ 41959-35-7/ 73855-45-5	

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1241	Disperse Red 15, except as impurity in Disperse Violet 1	116-85-8	204-163-0
1242	4-Amino-3-fluorophenol	399-95-1	402-230-0
1243	N,N'-dihexadecyl-N,N'-bis(2-hydroxyethyl)propanediamide Bishydroxyethyl Biscetyl Malonamide	149591-38-8	422-560-9
1244	1-Methyl-2,4,5-trihydroxybenzene and its salts, when used as a substance in hair dye products	1124-09-0	214-390-7
1245	2,6-Dihydroxy-4-methylpyridine and its salts, when used as a substance in hair dye products	4664-16-8	225-108-7
1246	5-Hydroxy-1,4-benzodioxane and its salts, when used as a substance in hair dye products	10288-36-5	233-639-0
1247	3,4-Methylenedioxyphenol and its salts, when used as a substance in hair dye products	533-31-3	208-561-5
1248	3,4-Methylenedioxyaniline and its salts, when used as a substance in hair dye products	14268-66-7	238-161-6
1249	Hydroxypyridinone and its salts, when used as a substance in hair dye products	822-89-9	212-506-0
1250	3-Nitro-4-aminophenoxyethanol and its salts, when used as a substance in hair dye products	50982-74-6	
1251	2-methoxy-4-nitrophenol (4-Nitroguaiacol) and its salts, when used as a substance in hair dye products	3251-56-7	221-839-0
1252	CI Acid Black 131 and its salts, when used as a substance in hair dye products	12219-01-1	
1253	1,3,5-Trihydroxybenzene (Phloroglucinol) and its salts, when used as a substance in hair dye products	108-73-6	203-611-2
1254	1,2,4-Benzenetriacetate and its salts, when used as a substance in hair dye products	613-03-6	210-327-2
1255	Ethanol, 2,2'-iminobis-, reaction products with epichlorohydrin and 2-nitro-1,4-benzenediamine (HC Blue No. 5) and its salts, when used as a substance in hair dye products	68478-64-8/ 158571-58-5	
1256	N-Methyl-1,4-diaminoanthraquinone, reaction products with epichlorohydrin and monoethanolamine (HC Blue No. 4) and its salts, when used as a substance in hair dye products	158571-57-4	
1257	4-Aminobenzenesulfonic acid (Sulfanilic acid) and its salts, when used as a substance in hair dye products	121-57-3/ 515-74-2	204-482-5/ 208-208-5
1258	3,3'-(Sulfonylbis(2-nitro-4,1-phenylene)imino)bis(6-(phenylamino))benzenesulfonic acid and its salts, when used as a substance in hair dye products	6373-79-1	228-922-0
1259	3(or5)-((4-(Benzylmethylamino)phenyl)azo)-1,2-(or1,4)-dimethyl-1H-1,2,4-triazolium and its salts, when used as a substance in hair dye products	89959-98-8/ 12221-69-1	289-660-0
1260	2,2'-((3-Chloro-4-((2,6-dichloro-4-nitrophenyl)azo)phenyl)imino)bisethanol (Disperse Brown 1) and its salts, when used as a substance in hair dye products	23355-64-8	245-604-7
1261	Benzothiazolium, 2-[[4-[ethyl(2-hydroxyethyl)amino]phenyl]azo]-6-methoxy-3-methyl-, and its salts, when used as a substance in hair dye products	12270-13-2	235-546-0
1262	2-[(4-Chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutanamide (Pigment Yellow 73) and its salts, when used as a substance in hair dye products	13515-40-7	236-852-7

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1263	2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutanamide] (Pigment Yellow 12) and its salts, when used as a substance in hair dye products	6358-85-6	228-787-8
1264	2,2'-(1,2-Ethenediyl)bis[5-((4-ethoxyphenyl)azo)benzenesulfonic acid] and its salts, when used as a substance in hair dye products	2870-32-8	220-698-2
1265	2,3-Dihydro-2,2-dimethyl-6-[(4-(phenylazo)-1-naphthalenyl)azo]-1H-pyrimidine (Solvent Black 3) and its salts, when used as a substance in hair dye products	4197-25-5	224-087-1
1266	3(or5)-[[4-[(7-amino-1-hydroxy-3-sulphonato-2-naphthyl)azo]-1-naphthyl]azo]salicylic acid and its salts, when used as a substance in hair dye products	3442-21-5/ 34977-63-4	222-351-0/ 252-305-5
1267	2-Naphthalenesulfonic acid, 7-(benzoylamino)-4-hydroxy-3-[[4-[(4-sulfophenyl)azo]phenyl]azo]-, and its salts, when used as a substance in hair dye products	2610-11-9	220-028-9
1268	(μ-((7,7'-Iminobis(4-hydroxy-3-((2-hydroxy-5-(N-methylsulphamoyl)phenyl)azo)naphthalene-2-sulphonato))((6-)))dicuprate(2-) and its salts, when used as a substance in hair dye products	37279-54-2	253-441-8
1269	3-[(4-(Acetylamino)phenyl)azo]-4-hydroxy-7-[[[5-hydroxy-6-(phenylazo)-7-sulfo-2-naphthalenyl]amino]carbonyl]amino]-2-naphthalenesulfonic acid and its salts, when used as a substance in hair dye products	3441-14-3	222-348-4
1270	2-Naphthalenesulfonic acid, 7,7'-(carbonyldiimino)bis(4-hydroxy-3-[[2-sulfo-4-[(4-sulfophenyl)azo]phenyl]azo]-, and its salts, when used as a substance in hair dye products	2610-10-8/ 25188-41-4	220-027-3
1271	Ethanaminium, N-(4-[bis[4-(diethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene)-N-ethyl-, and its salts, when used as a substance in hair dye products	2390-59-2	219-231-5
1272	3H-Indolium, 2-[[[(4-methoxyphenyl)methylhydrazono]methyl]-1,3,3-trimethyl-, and its salts, when used as a substance in hair dye products	54060-92-3	258-946-7
1273	3H-Indolium, 2-(2-((2,4-dimethoxyphenyl)amino)ethenyl)-1,3,3-trimethyl-, and its salts, when used as a substance in hair dye products	4208-80-4	224-132-5
1274	Nigrosine spirit soluble (Solvent Black 5), when used as a substance in hair dye products	11099-03-9	
1275	Phenoxazin-5-ium, 3,7-bis(diethylamino)-, and its salts, when used as a substance in hair dye products	47367-75-9/ 33203-82-6	251-403-5
1276	Benzo[a]phenoxazin-7-ium, 9-(dimethylamino)-, and its salts, when used as a substance in hair dye products	7057-57-0/ 966-62-1	230-338-6/ 213-524-1
1277	6-Amino-2-(2,4-dimethylphenyl)-1H-benz[de]isoquinoline-1,3(2H)-dione (Solvent Yellow 44) and its salts, when used as a substance in hair dye products	2478-20-8	219-607-9
1278	1-Amino-4-[[4-[(dimethylamino)methyl]phenyl]amino]anthraquinone and its salts, when used as a substance in hair dye products	67905-56-0/ 12217-43-5	267-677-4/ 235-398-7
1279	Laccaic Acid (CI Natural Red 25) and its salts, when used as a substance in hair dye products	60687-93-6	
1280	Benzenesulfonic acid, 5-[(2,4-dinitrophenyl)amino]-2-(phenylamino)-, and its salts, when used as a substance in hair dye products	6373-74-6/ 15347-52-1	228-921-5/ 239-377-3
1281	4-[(4-Nitrophenyl)azo]aniline (Disperse Orange 3) and its salts, when used as a substance in hair dye products	730-40-5/ 70170-61-5	211-984-8
1282	4-Nitro-m-phenylenediamine and its salts, when used as a substance in hair dye products	5131-58-8	225-876-3

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1283	1-Amino-4-(methylamino)-9,10-anthracenedione (Disperse Violet 4) and its salts, when used as a substance in hair dye products	1220-94-6	214-944-8
1284	N-Methyl-3-nitro-p-phenylenediamine and its salts, when used as a substance in hair dye products	2973-21-9	221-014-5
1285	N1-(2-Hydroxyethyl)-4-nitro-o-phenylenediamine (HC Yellow No. 5) and its salts, when used as a substance in hair dye products	56932-44-6	260-450-0
1286	N1-(Tris(hydroxymethyl)methyl-4-nitro-1,2-phenylenediamine (HC Yellow No. 3) and its salts, when used as a substance in hair dye products	56932-45-7	260-451-6
1287	2-Nitro-N-hydroxyethyl-p-anisidine and its salts, when used as a substance in hair dye products	57524-53-5	
1288	N,N'-Dimethyl-N-Hydroxyethyl-3-nitro-p-phenylenediamine and its salts, when used as a substance in hair dye products	10228-03-2	233-549-1
1289	3-(N-Methyl-N-(4-methylamino-3-nitrophenyl)amino)propane-1,2-diol and its salts, when used as a substance in hair dye products	93633-79-5	403-440-5
1290	4-Ethylamino-3-nitrobenzoic acid (N-Ethyl-3-Nitro PABA) and its salts, when used as a substance in hair dye products	2788-74-1	412-090-2
1291	(8-[(4-Amino-2-nitrophenyl)azo]-7-hydroxy-2-naphthyl) trimethylammonium and its salts, except Basic Red 118 (CAS 71134-97-9) as impurity in Basic Brown 17, when used as a substance in hair dye products	71134-97-9	275-216-3
1292	5-((4-(Dimethylamino)phenyl)azo)-1,4-dimethyl-1H-1,2,4-triazolium and its salts, when used as a substance in hair dye products	12221-52-2	
1293	m-Phenylenediamine, 4-(phenylazo)-, and its salts, when used as a substance in hair dye products	495-54-5	207-803-7
1294	1,3-Benzenediamine, 4-methyl-6-(phenylazo)- and its salts, when used as a substance in hair dye products	4438-16-8	224-654-3
1295	2,7-Naphthalenedisulfonic acid, 5-(acetylamino)-4-hydroxy-3-((2-methylphenyl)azo)-, and its salts, when used as a substance in hair dye products	6441-93-6	229-231-7
1296	4,4'-[(4-Methyl-1,3-phenylene)bis(azo)]bis[6-methyl-1,3-benzenediamine] (Basic Brown 4) and its salts, when used as a substance in hair dye products	4482-25-1	224-764-1
1297	Benzenaminium, 3-[[4-[[[diamino(phenylazo)phenyl]azo]-2-methylphenyl]azo]-N,N,N-trimethyl-, and its salts, when used as a substance in hair dye products	83803-99-0	280-920-9
1298	Benzenaminium, 3-[[4-[[[diamino(phenylazo)phenyl]azo]-1-naphthalenyl]azo]-N,N,N-trimethyl-, and its salts, when used as a substance in hair dye products	83803-98-9	280-919-3
1299	Ethanaminium, N-[4-[(4-(diethylamino)phenyl)phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl- and its salts, when used as a substance in hair dye products	633-03-4	211-190-1
1300	9,10-Anthracenedione, 1-[(2-hydroxyethyl)amino]-4-(methylamino)-, and its derivatives and salts, when used as a substance in hair dye products	2475-46-9/ 86722-66-9	219-604-2/ 289-276-3
1301	1,4-Diamino-2-methoxy-9,10-anthracenedione (Disperse Red 11) and its salts, when used as a substance in hair dye products	2872-48-2	220-703-8
1302	1,4-Dihydroxy-5,8-bis[(2-hydroxyethyl)amino]anthraquinone (Disperse Blue 7) and its salts, when used as a substance in hair dye products	3179-90-6	221-666-0

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1303	1-[(3-Aminopropyl)amino]-4-(methylamino)anthraquinone and its salts, when used as a substance in hair dye products	22366-99-0	244-938-0
1304	N-[6-[(2-Chloro-4-hydroxyphenyl)imino]-4-methoxy-3-oxo-1,4-cyclohexadien-1-yl]acetamide (HC Yellow No. 8) and its salts, when used as a substance in hair dye products	66612-11-1	266-424-5
1305	[6-[[3-Chloro-4-(methylamino)phenyl]imino]-4-methyl-3-oxocyclohexa-1,4-dien-1-yl]urea (HC Red No. 9) and its salts, when used as a substance in hair dye products	56330-88-2	260-116-4
1306	Phenothiazin-5-ium, 3,7-bis(dimethylamino)-, and its salts, when used as a substance in hair dye products	61-73-4	200-515-2
1307	4,6-Bis(2-Hydroxyethoxy)-m-Phenylenediamine and its salts, when used as a substance in hair dye products	94082-85-6	
1308	5-Amino-2,6-Dimethoxy-3-Hydroxypyridine and its salts, when used as a substance in hair dye products	104333-03-1	
1309	4,4'-Diaminodiphenylamine and its salts, when used as a substance in hair dye products	537-65-5	208-673-4
1310	4-Diethylamino-o-toluidine and its salts, when used as a substance in hair dye products	148-71-0/ 24828-38-4/ 2051-79-8	205-722-1/ 246-484-9/ 218-130-3
1311	N,N-Diethyl-p-phenylenediamine and its salts, when used as a substance in hair dye products	93-05-0/ 6065-27-6/ 6283-63-2	202-214-1/ 227-995-6/ 228-500-6
1312	N,N-Dimethyl-p-phenylenediamine and its salts, when used as a substance in hair dye products	99-98-9/ 6219-73-4	202-807-5/ 228-292-7
1313	Toluene-3,4-Diamine and its salts, when used as a substance in hair dye products	496-72-0	207-826-2
1314	2,4-Diamino-5-methylphenoxyethanol and its salts, when used as a substance in hair dye products	141614-05-3/ 113715-27-8	
1315	6-Amino-o-cresol and its salts, when used as a substance in hair dye products	17672-22-9	
1316	Hydroxyethylaminomethyl-p-aminophenol and its salts, when used as a substance in hair dye products	110952-46-0/ 135043-63-9	
1317	2-Amino-3-nitrophenol and its salts, when used as a substance in hair dye products	603-85-0	210-060-1
1318	2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine and its salts, when used as a substance in hair dye products	50610-28-1	256-652-3
1319	2-Nitro-p-phenylenediamine and its salts, when used as a substance in hair dye products	5307-14-2/ 18266-52-9	226-164-5/ 242-144-9
1320	Hydroxyethyl-2,6-dinitro-p-anisidine and its salts, when used as a substance in hair dye products	122252-11-3	
1321	6-Nitro-2,5-pyridinediamine and its salts, when used as a substance in hair dye products	69825-83-8	
1322	Phenazinium, 3,7-diamino-2,8-dimethyl-5-phenyl-, and its salts, when used as a substance in hair dye products	477-73-6	207-518-8
1323	3-Hydroxy-4-[(2-hydroxynaphthyl)azo]-7-nitronaphthalene-1-sulphonic acid and its salts, when used as a substance in hair dye products	16279-54-2/ 5610-64-0	240-379-1/ 227-029-3

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1324	3-[(2-nitro-4-(trifluoromethyl)phenyl)amino]propane-1,2-diol (HC Yellow No. 6) and its salts, when used as a substance in hair dye products	104333-00-8	
1325	2-[(4-chloro-2-nitrophenyl)amino]ethanol (HC Yellow No. 12) and its salts, when used as a substance in hair dye products	59320-13-7	
1326	3-[[4-[(2-Hydroxyethyl)Methylamino]-2-Nitrophenyl]Amino]-1, 2-Propanediol and its salts, when used as a substance in hair dye products	173994-75-7/ 102767-27-1	
1327	3-[[4-[Ethyl(2-Hydroxyethyl)Amino]-2-Nitrophenyl]Amino]-1, 2-Propanediol and its salts, when used as a substance in hair dye products	114087-41-1/ 114087-42-2	
1328	Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, and its salts, when used as a substance in hair dye products	2390-60-5	219-232-0

(<sup>1</sup>) OJ L 159, 29.6.1996, p. 1

(<sup>2</sup>) Modified INN-name.

(<sup>3</sup>) OJ L 273, 10.10.2002, p. 1.

(<sup>4</sup>) for the individual ingredient see reference number 364 in Annex II.

(<sup>5</sup>) for the individual ingredient see reference number 413 in Annex II.



## ANNEX III

## LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
1a	Boric acid, borates and tetraborates with the exception of substance No 1184 in Annex II	Boric acid	10043-35-3/ 11113-50-1	233-139-2/ 234-343-4	(a) Talc	(a) 5 % (as boric acid)	(a) Not to be used in products for children under 3 years of age  Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1,5 % (as boric acid)	(a) Not to be used for children under 3 years of age  Not to be used on peeling or irritated skin
					(b) Oral products	(b) 0,1 % (as boric acid)	(b) Not to be used in products for children under 3 years of age	(b) Not to be swallowed  Not to be used for children under 3 years of age
					(c) Other products (excluding bath products and hair waving products)	(c) 3 % (as boric acid)	(c) Not to be used in products for children under 3 years of age  Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1,5 % (as boric acid)	(c) Not to be used for children under 3 years of age  Not to be used on peeling or irritated skin
1b	Tetraborates, see also 1a)				(a) Bath products	(a) 18 % (as boric acid)	(a) Not to be used in products for children under 3 years of age	(a) Not to be used for children under 3 years of age
					(b) Hair products	(b) 8 % (as boric acid)		(b) Rinse well

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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
2a	Thioglycolic acid and its salts	Thioglycolic acid	68-11-1	200-677-4	(a) Hair products	8 %	General use  ready for use pH 7 to 9,5	Conditions of use:  (a) (b) (c)  Avoid contact with eyes  In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice  (a) (c)  Wear suitable gloves  Warnings: (a) (b) (c)  Contains thioglycolate  Follow the instructions  Keep out of reach of children
						11 %	Professional use  ready for use pH 7 to 9,5	
					(b) Depilatories	5 %	ready for use pH 7 to 12,7	(a) For professional use only
					(c) Hair rinse-off products	2 %  The abovementioned percentages are calculated as thioglycolic acid	ready for use pH 7 to 9,5	



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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
5	Tosylchloramide sodium (INN)	Chloramine-T	127-65-1	204-854-7		0,2 %		
6	Chlorates of alkali metals	Sodium chlorate	7775-09-9	231-887-4	(a) Toothpaste (b) Other products	(a) 5 % (b) 3 %		
		Potassium chlorate	3811-04-9	223-289-7				
7	Dichloromethane	Dichloromethane	75-09-2	200-838-9		35 % (when mixed with 1,1,1-trichloro-ethane, total concentration must not exceed 35 %)	0,2 % as maximum impurity content	
8	p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylene-diamine <sup>(1)</sup> , with the exception of those derivatives listed elsewhere in this Annex and under reference numbers 1309, 1311, and 1312 in Annex II	p-Phenylenediamine	106-50-3	203-404-7	Oxidising colouring agents for hair dyeing	6 % (as free base)	(a) General use Not to be used on eyebrows	(a) Can cause an allergic reaction Contains phenylene-diamines Do not use to dye eyelashes or eyebrows
							(b) Professional use	(b) For professional use only Contains phenylene-diamines Can cause an allergic reaction Wear suitable gloves

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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
9	Methylphenylene-diamines, their N-substituted derivatives <sup>(1)</sup> and their salts with the exception of substances under reference numbers 364, 413, 1144, 1310 and 1313 in Annex II	Toluene-2,5-diamine	95-70-5	202-442-1	Oxidising colouring agents for hair dyeing	10 % (as free base)	(a) General use Not to be used on eyebrows  (b) Professional use	(a) Can cause an allergic reaction Contains phenylene-diamines Do not use to dye eyelashes or eye-brows  (b) For professional use only Contains phenylene-diamines Can cause an allergic reaction Wear suitable gloves
10	Diaminophenols <sup>(1)</sup>				Oxidising colouring agents for hair dyeing	10 % (as free base)	(a) General use Not to be used on eyebrows  (b) Professional use	(a) Can cause an allergic reaction Do not use to dye eyelashes or eye-brows  (b) For professional use only Can cause an allergic reaction Wear suitable gloves
11	Dichlorophen	Dichlorophen	97-23-4	202-567-1		0,5 %		Contains Dichlorophen



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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
					(b) Artificial nail systems	0,02 % (after mixing for use)	Professional use	(b) For professional use only Avoid skin contact Read directions for use carefully
15a	Potassium or sodium hydroxide	Potassium hydroxide/sodium hydroxide	1310-58-3/ 1310-73-2	215-181-3/ 215-185-5	(a) Nail cuticle solvent	(a) 5 % <sup>(5)</sup>		(a) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children
					(b) Hair straightener	2 % <sup>(5)</sup>	General use	Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children
						4,5 % <sup>(5)</sup>	Professional use	For professional use only Avoid contact with eyes Can cause blindness
					(c) pH adjuster for depilatories		(c) pH < 12,7	(c) Keep out of reach of children Avoid contact with eyes
					(d) Other uses as pH adjuster		(d) pH < 11	



Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
15b	Lithium hydroxide	Lithium hydroxide	1310-65-2	215-183-4	(a) Hair straighteners	2 % (6)	General use	(a) Contains alkali  Avoid contact with eyes  Can cause blindness  Keep out of reach of children
						4,5 % (6)	Professional use	Avoid contact with eyes  Can cause blindness
					(b) pH adjuster for depilatories		pH < 12,7	(b) Contains alkali  Keep out of reach of children  Avoid contact with eyes
					(c) Other uses as pH adjuster (for rinse-off products only)		pH < 11	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
15c	Calcium hydroxide	Calcium hydroxide	1305-62-0	215-137-3	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt  (b) pH adjuster for depilatories  (c) Other uses (e.g. pH adjuster, processing aid)	(a) 7 % (as calcium hydroxide)	(b) pH < 12,7  (c) pH < 11	(a) Contains alkali  Avoid contact with eyes  Keep out of reach of children  Can cause blindness  (b) Contains alkali  Keep out of reach of children  Avoid contact with eyes
16	1-Naphthol and its salts	1-Naphtol	90-15-3	201-969-4	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %	Can cause an allergic reaction
17	Sodium nitrite	Sodium nitrite	7632-00-0	231-555-9	Rust inhibitor	0,2 %	Not to be used with secondary and/or tertiary amines or other substances forming nitrosamines	
18	Nitromethane	Nitromethane	75-52-5	200-876-6	Rust inhibitor	0,3 %		
19	Moved or deleted							
20	Moved or deleted							



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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
25	Zinc 4-hydroxybenzene sulphonate	Zinc phenolsulfonate	127-82-2	204-867-8	Deodorants, antiperspirants and astringent lotions	6 % (as % anhydrous substance)		Avoid contact with eyes
26	Ammonium monofluorophosphate	Ammonium monofluorophosphate	20859-38-5/ 66115-19-3		Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains ammonium monofluorophosphate</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
27	Disodium fluorophosphate	Sodium monofluorophosphate	10163-15-2/ 7631-97-2	233-433-0/ 231-552-2	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains sodium monofluorophosphate</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p>

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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
								'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'
28	Dipotassium fluorophosphate	Potassium monofluorophosphate	14104-28-0	237-957-0	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains potassium monofluorophosphate</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
29	Calcium fluorophosphate	Calcium monofluorophosphate	7789-74-4	232-187-1	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains calcium monofluorophosphate

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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
								<p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
30	Calcium fluoride	Calcium fluoride	7789-75-5	232-188-7	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains calcium fluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>

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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
31	Sodium fluoride	Sodium fluoride	7681-49-4	231-667-8	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains sodium fluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
32	Potassium fluoride	Potassium fluoride	7789-23-3	232-151-5	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains potassium fluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>



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a	b	c	d	e	f	g	h	i
33	Ammonium fluoride	Ammonium fluoride	12125-01-8	235-185-9	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains ammonium fluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
34	Aluminium fluoride	Aluminium fluoride	7784-18-1	232-051-1	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains aluminium-fluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
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a	b	c	d	e	f	g	h	i
35	Tin difluoride	Stannous fluoride	7783-47-3	231-999-3	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains stannous fluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
36	Hexadecyl ammonium fluoride	Cetylamine hydrofluoride	3151-59-5	221-588-7	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains Cetylamine hydrofluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>

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a	b	c	d	e	f	g	h	i
37	3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride		—	—	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
38	N,N',N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride		—	—	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains N,N',N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p>

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
								'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'
39	9-Octadecenamine, hydrofluoride	Octadecenyl-ammonium fluoride	2782-81-2	—	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains octadecenyl-ammonium fluoride</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
40	Disodium hexafluoro-silicate	Sodium fluorosilicate	16893-85-9	240-934-8	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains sodium fluoro-silicate

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	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
								<p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
41	Dipotassium hexafluorosilicate	Potassium fluorosilicate	16871-90-2	240-896-2	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains potassium fluorosilicate</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
42	Ammonium hexafluorosilicate	Ammonium fluorosilicate	16919-19-0	240-968-3	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains ammonium fluorosilicate</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>
43	Magnesium hexafluorosilicate	Magnesium fluorosilicate	16949-65-8	241-022-2	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		<p>Contains magnesium fluorosilicate</p> <p>For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:</p> <p>'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'</p>

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
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a	b	c	d	e	f	g	h	i
44	1,3-Bis (hydroxymethyl) imidazolidine-2-thione	Dimethylol ethylene thiourea	15534-95-9	239-579-1	(a) Hair- products  (b) Nail- products	(a) 2 %  (b) 2 %	(a) Not to be used in aerosol dispensers (sprays)  (b) pH < 4	Contains Dimethylol ethylene thiourea
45	Benzyl alcohol (7)	Benzyl alcohol	100-51-6	202-859-9	Solvents, perfumes and flavourings		For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product	
46	6-Methylcoumarin	6-Methylcoumarin	92-48-8	202-158-8	Oral products	0,003 %		
47	3-Pyridinemethanol, hydrofluoride	Nicomethanol hydrofluoride	62756-44-9	—	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains nicomethanol hydrofluoride  For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:  'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'
48	Silver nitrate	Silver nitrate	7761-88-8	231-853-9	Only for colouring eye-lashes and eyebrows	4 %		Contains silver nitrate  Rinse eyes immediately if product comes into contact with them



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a	b	c	d	e	f	g	h	i
49	Selenium sulfide	Selenium disulphide	7488-56-4	231-303-8	Antidandruff shampoos	1 %		Contains selenium disulphide Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxide complexes $Al_xZr(OH)_yCl_z$ and the aluminium zirconium chloride hydroxide glycine complexes				Anti-perspirants	20 % (as anhydrous aluminium zirconium chloride hydroxide) 5,4 % (as zirconium)	1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10  2. The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0,9 and 2,1  3. Not to be used in aerosol dispensers (sprays)	Do not apply to irritated or damaged skin
51	Quinolin-8-ol and bis (8-hydroxy-quinolium) sulphate	Oxyquinoline and oxyquinoline sulfate	148-24-3/134-31-6	205-711-1/ 205-137-1	Stabilizer for hydrogen peroxide in rinse-off hair- products  Stabilizer for hydrogen peroxide in leave-on hair products	0,3 % (as base)  0,03 % (as base)		
52	Methanol	Methyl alcohol	67-56-1	200-659-6	Denaturant for ethanol and isopropyl alcohol	5 % (as a % ethanol and isopropyl alcohol)		

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a	b	c	d	e	f	g	h	i
53	(1-Hydroxyethylidene-diphosphonic acid) and its salts	Etidronic acid	2809-21-4	220-552-8	(a) Hair- product  (b) Soap	1,5 % (as etidronic acid)  0,2 % (as etidronic acid)		
54	1-Phenoxypropan-2-ol <sup>(8)</sup>	Phenoxyisopropanol	770-35-4	212-222-7	Use only in rinse-off products  Not to be used in oral products	2 %	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product	
55	Moved or deleted							
56	Magnesium fluoride	Magnesium fluoride	7783-40-6	231-995-1	Oral products	0,15 % (as F). When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0,15 %		Contains magnesium fluoride  For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory:  'Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor'



Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
60	Fatty acid dialkylamides and dialkanolamides					Maximum secondary amine content: 0,5 %	<ul style="list-style-type: none"> <li>— Not to be used with nitrosating systems</li> <li>— Maximum secondary amine content: 5 % (applies to raw materials)</li> <li>— Maximum nitrosamine content: 50 µg/kg</li> <li>— Keep in nitrite-free containers</li> </ul>	
61	Monoalkylamines, monoalkanolamines and their salts					Maximum secondary amine content: 0,5 %	<ul style="list-style-type: none"> <li>— Not to be used with nitrosating systems- Minimum purity: 99 %</li> <li>— Maximum secondary amine content: 0,5 % (applies to raw materials)</li> <li>— Maximum nitrosamine content: 50 µg/kg</li> <li>— Keep in nitrite-free containers</li> </ul>	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
62	Trialkylamines, trialkanolamines and their salts				(a) Leave-on products (b) Rinse-off products	(a) 2,5 %	(a) (b) — Not to be used with nitrosating systems — Minimum purity: 99 % — Maximum secondary amine content: 0,5 % (applies to raw materials) — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	
63	Strontium hydroxide	Strontium hydroxide	18480-07-4	242-367-1	pH adjuster for depilatories	3,5 % (as strontium)	pH ≤ 12,7	Keep out of reach of children Avoid contact with eyes
64	Strontium peroxide	Strontium peroxide	1314-18-7	215-224-6	Rinse-off hair products	4,5 % (as strontium)	All products must meet the hydrogen peroxide release requirements Professional use	Avoid contact with eyes Rinse eyes immediately if product comes into contact with them For professional use only Wear suitable gloves

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
65	Benzalkonium chloride, bromide and saccharinate (*)	<p>Benzalkonium bromide</p> <p>Benzalkonium chloride</p> <p>Benzalkonium saccharinate</p>	<p>91080-29-4</p> <p>63449-41-2/ 68391-01-5/ 68424-85-1/ 85409-22-9</p> <p>68989-01-5</p>	<p>293-522-5</p> <p>264-151-6/ 269-919-4/ 270-325-2/ 287-089-1</p> <p>273-545-7</p>	Rinse-off hair (head) products	3 % (as benzalkonium chloride)	<p>In the final products the concentrations of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C<sub>14</sub>, or less must not exceed 0,1 % (as benzalkonium chloride)</p> <p>For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product</p>	Avoid contact with eyes
66	Polyacrylamides				<p>(a) Body- leave-on products</p> <p>(b) Other products</p>		<p>(a) Maximum residual acrylamide content 0,1 mg/kg</p> <p>(b) Maximum residual acrylamide content 0,5 mg/kg</p>	
67	2-Benzylideneheptanal	Amyl cinnamal	122-40-7	204-541-5			<p>The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds:</p> <p>— 0,001 % in leave-on products</p> <p>— 0,01 % in rinse-off products</p>	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
68	Benzyl alcohol	Benzyl alcohol	100-51-6	202-859-9			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
69	Cinnamyl alcohol	Cinnamyl alcohol	104-54-1	203-212-3			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
70	3,7-Dimethyl-2,6-octadienal	Citral	5392-40-5	226-394-6			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	



Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
71	Phenol, 2-methoxy-4-(2-propenyl)	Eugenol	97-53-0	202-589-1			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
72	7-Hydroxycitronellal	Hydroxycitronellal	107-75-5	203-518-7			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
73	Phenol, 2-methoxy-4-(1-propenyl)-	Isoeugenol	97-54-1	202-590-7			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
74	2-Pentyl-3-phenylprop-2-en-1-ol	Amylcinnamyl alcohol	101-85-9	202-982-8			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
75	Benzyl salicylate	Benzyl salicylate	118-58-1	204-262-9			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
76	2-Propenal, 3-phenyl-	Cinnamal	104-55-2	203-213-9			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
77	2H-1-Benzopyran-2-one	Coumarin	91-64-5	202-086-7			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
78	2,6-Octadien-1-ol, 3,7-dimethyl-, (2E)-	Geraniol	106-24-1	203-377-1			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
79	3 and 4-(4-Hydroxy-4-methylpentyl)cyclohex-3-ene-1-carbaldehyde	Hydroxyisohexyl 3-cyclohexene carboxaldehyde	51414-25-6/ 31906-04-4	257-187-9/ 250-863-4			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
80	4-Methoxybenzyl alcohol	Anise alcohol	105-13-5	203-273-6			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
81	2-Propenoic acid, 3-phenyl-, phenylmethyl ester	Benzyl cinnamate	103-41-3	203-109-3			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
82	2,6,10-Dodecatrien-1-ol, 3,7,11-trimethyl-	Farnesol	4602-84-0	225-004-1			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
83	2-(4-tert-Butylbenzyl) propionaldehyde	Butylphenyl methylpropional	80-54-6	201-289-8			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
84	1,6-Octadien-3-ol, 3,7-dimethyl-	Linalool	78-70-6	201-134-4			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
85	Benzyl benzoate	Benzyl benzoate	120-51-4	204-402-9			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
86	Citronellol/(±)-3,7-dimethyloct-6-en-1-ol	Citronellol	106-22-9/ 26489-01-0	203-375-0/ 247-737-6			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
87	2-Benzylideneoctanal	Hexyl cinnamal	101-86-0	202-983-3			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
88	(4R)-1-Methyl-4-(1-methylethenyl)cyclohexene	Limonene	5989-27-5	227-813-5			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
89	Methyl heptin carbonate	Methyl 2-octynoate	111-12-6	203-836-6			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
90	3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	alpha-Isomethyl ionone	127-51-5	204-846-3			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	
91	Oak moss extract	Evernia prunastri extract	90028-68-5	289-861-3			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: <ul style="list-style-type: none"> <li>— 0,001 % in leave-on products</li> <li>— 0,01 % in rinse-off products</li> </ul>	



Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
92	Treemoss extract	Evernia furfuracea extract	90028-67-4	289-860-8			The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds:  — 0,001 % in leave-on products — 0,01 % in rinse-off products	
93	2,4-Pyrimidinediamine, 3-oxide	Diaminopyrimidine oxide	74638-76-9	—	Hair products	1,5 %		
94	Dibenzoyl peroxide	Benzoyl peroxide	94-36-0	202-327-6	Artificial nail systems	0,7 % (after mixing for use)	Professional use	For professional use only Avoid skin contact Read directions for use carefully
95	Hydroquinone methylether/Mequinol	p-Hydroxyanisol	150-76-5	205-769-8	Artificial nail systems	0,02 % (after mixing for use)	Professional use	For professional use only Avoid skin contact Read directions for use carefully
96	5-tert-Butyl-2,4,6-trinitro-m-xylene	Musk xylene	81-15-2	201-329-4	All cosmetic products, with the exception of oral products	(a) 1,0 % in fine fragrance (b) 0,4 % in eau de toilette (c) 0,03 % in other products		

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
97	4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone	Musk ketone	81-14-1	201-328-9	All cosmetic products, with the exception of oral products	(a) 1,4 % in fine fragrance (b) 0,56 % in eau de toilette (c) 0,042 % in other products		
98	Benzoic acid, 2-hydroxy- <sup>(10)</sup>	Salicylic acid	69-72-7	200-712-3	(a) Rinse-off hair products (b) Other products	(a) 3,0 % (b) 2,0 %	Not to be used in preparations for children under 3 years of age, except for shampoos  For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product	Not to be used for children under 3 years of age <sup>(11)</sup>
99	Inorganic sulfites and bisulfites <sup>(12)</sup>				(a) Oxidative hair dye products  (b) Hair straightening products  (c) Self-tanning products for the face  (d) Other self-tanning products	(a) 0,67 % (as free SO <sub>2</sub> )  (b) 6,7 % (as free SO <sub>2</sub> )  (c) 0,45 % (as free SO <sub>2</sub> )  (d) 0,40 % (as free SO <sub>2</sub> )	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
100	1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea <sup>(13)</sup>	Triclocarban	101-20-2	202-924-1	Rinse-off products	1,5 %	Purity criteria:  3,3',4,4'-Tetrachloroazobenzene ≤ 1 ppm  3,3',4,4'-Tetrachloroazoxybenzene ≤ 1 ppm  For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product	
101	Pyrithione zinc <sup>(14)</sup>	Zinc pyrithione	13463-41-7	236-671-3	Leave-on hair products	0,1 %	For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product	
102	1,2-Dimethoxy-4-(2-propenyl)-benzene	Methyl eugenol	93-15-2	202-223-0	Fine fragrance  Eau de toilette  Fragrance cream  Other leave-on products and oral products  Rinse-off products	0,01 %  0,004 %  0,002 %  0,0002 %  0,001 %		

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
215	4-Amino-3-nitrophenol and its salts	4-Amino-3-nitrophenol	610-81-1	210-236-8	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 %  (b) 3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	(a) (b) Can cause allergic reaction
216	2,7-Naphthalenediol and its salts	Naphthalene-2,7-diol	582-17-2	209-478-7	Oxidising colouring agents for hair dyeing	1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,5 %  Not to be used after 31.12.2009	
217	m-Aminophenol and its salts	3-Aminophenol	591-27-5	209-711-2	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	Can cause allergic reaction
218	2,6-Dihydroxy-3,4-dimethylpyridine and its salts	2,6-Dihydroxy-3,4-dimethylpyridine	84540-47-6	283-141-2	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
219	1-Hydroxy-3-nitro-4-(3-hydroxypropylamino)benzene and its salts	4-Hydroxy-propylamino-3-nitrophenol	92952-81-3	406-305-9	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 5,2 %  (b) 2,6 %	In combination with hydrogen peroxide the maximum use concentration upon application is 2,6 %  Not to be used after 31.12.2009	(a) (b) Can cause allergic reaction
220	1-[(2'-Methoxyethyl)amino]-2-nitro-4-[di-(2'-hydroxyethyl)amino]benzene and its salts	HC Blue No 11	23920-15-2	459-980-7	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 %  (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	(a) (b) Can cause allergic reaction
221	1-Methyl-3-nitro-4-(.beta.-hydroxyethyl)aminobenzene and its salts	Hydroxyethyl-2-nitro-p-toluidine	100418-33-5	408-090-7	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 %  (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	(a) (b) Can cause allergic reaction
222	1-Hydroxy-2-.beta.-hydroxyethylamino-4,6-dinitrobenzene and its salts	2-Hydroxyethyl-picramic acid	99610-72-7	412-520-9	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 %  (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	(a) (b) Can cause allergic reaction

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
223	4-Methylaminophenol and its salts	p-Methylaminophenol	150-75-4	205-768-2	Oxidising colouring agent for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	Can cause allergic reaction
224	1-(3-Hydroxypropylamino)-2-nitro-4-bis(2-hydroxyethylamino) benzene and its salts	HC Violet No 2	104226-19-9	410-910-3	Non-oxidising colouring agent for hair dyeing	2,0 %	Not to be used after 31.12.2009	
225	1-(beta.-Hydroxyethyl) amino-2-nitro-4-N-ethyl-N-(beta.-hydroxyethyl) aminobenzene and its salts	HC Blue No 12	104516-93-0	407-020-2	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 1,5 %  (b) 1,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,75 %  Not to be used after 31.12.2009	(a) (b) Can cause allergic reaction
226	4,4'-[1,3-Propanediylbis(oxy)]bis-, benzene-1,3-diamine and its salts	1,3-Bis-(2,4-diaminophenoxy)propane	81892-72-0	279-845-4	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	Can cause allergic reaction
227	3-Amino-2,4-dichlorophenol and its salts	3-Amino-2,4-dichlorophenol	61693-43-4	262-909-0	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	Can cause allergic reaction

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
228	3-Methyl-1-phenyl-5-pyrazolone and its salts	Phenyl methyl pyrazolone	89-25-8	201-891-0	Oxidising colouring agents for hair dyeing	0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %  Not to be used after 31.12.2009	
229	5-[(2-Hydroxyethyl) amino]-o-cresol and its salts	2-Methyl-5-hydroxyethylaminophenol	55302-96-0	259-583-7	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	Can cause allergic reaction
230	3,4-Dihydro-2H-1,4-benzoxazin-6-ol and its salts	Hydroxybenzomorpholine	26021-57-8	247-415-5	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	Can cause allergic reaction
231	1,5-bis(.beta.-Hydroxyethyl) amino-2-nitro-4-chlorobenzene and its salts	HC Yellow No 10	109023-83-8	416-940-3	Non-oxidising colouring agents for hair dyeing	0,2 %	Not to be used after 31.12.2009	
232	3,5-Diamino-2,6-dimethoxypyridine and its salts	2,6-Dimethoxy-3,5-pyridinediamine HCl	85679-78-3/ 56216-28-5	- / 260-062-1	Oxidising colouring agents for hair dyeing	0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %  Not to be used after 31.12.2009	Can cause allergic reaction

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
233	1-(2-Aminoethyl) amino-4-(2-hydroxyethyl)oxy-2-nitrobenzene and its salts	HC Orange No 2	85765-48-6	416-410-1	Non-oxidising colouring agents for hair dyeing	1,0 %	Not to be used after 31.12.2009	
234	Ethanol, 2-[(4-amino-2-methyl-5-nitrophenyl) amino]-and its salts	HC Violet No 1	82576-75-8	417-600-7	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 %  (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %  Not to be used after 31.12.2009	
235	2-[3-(Methylamino)-4-nitrophenoxy] ethanol and its salts	3-Methylamino-4-nitro-phenoxyethanol	59820-63-2	261-940-7	Non-oxidising colouring agents for hair dyeing	1,0 %	Not to be used after 31.12.2009	
236	2-[(2-Methoxy-4-nitrophenyl)amino]et- hanol and its salts	2-Hydroxy-ethylamino-5-nitro-anisole	66095-81-6	266-138-0	Non-oxidising colouring agents for hair dyeing	1,0 %	Not to be used after 31.12.2009	
237	2,2'-[(4-Amino-3-nitrophenyl)imino-]bisethanol hydrochloride and other salts	HC Red No 13	94158-13-1	303-083-4	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 2,5 %  (b) 2,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,25 %  Not to be used after 31.12.2009	
238	Naphthalene-1,5-diol and its salts	1,5-Naphthalenediol	83-56-7	201-487-4	Oxidising colouring agents for hair dyeing	1,0 %	Not to be used after 31.12.2009	



Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
239	Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) and its salts	Hydroxypropyl bis(N-hydroxyethyl-p-phenyldiamine) HCl	128729-30-6	416-320-2	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	Can cause allergic reaction
240	o-Aminophenol and its salts	o-Aminophenol	95-55-6	202-431-1	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	
241	5-Amino-o-cresol and its salts	4-Amino-2-hydroxytoluene	2835-95-2	220-618-6	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	
242	2,4-Diaminophenoxyethanol and its salts	2,4-Diaminophenoxyethanol HCl	66422-95-5	266-357-1	Oxidising colouring agents for hair dyeing	4,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 2,0 %  Not to be used after 31.12.2009	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
243	1,3-Benzenediol, 2-methyl-, and its salts -	2-Methylresorcinol	608-25-3	210-155-8	Oxidising colouring agents for hair dyeing	2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	
244	4-Amino-m-cresol and its salts	4-Amino-m-cresol	2835-99-6	220-621-2	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	
245	2-[(3-amino-4-methoxyphenyl)amino]ethanol and its salts	2-Amino-4-hydroxyethylaminoanisole	83763-47-7	280-733-2	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	
246	Hydroxyethyl-3,4-methylenedioxyaniline 2-(1,3-benzodioxol-5-ylamino)ethanol hydrochloride and other salts	Hydroxyethyl-3,4-methylenedioxyaniline HCl	81329-90-0	303-085-5	Oxidising colouring agents for hair dyeing	3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	
247	2,2'-[[4-[(2-Hydroxyethyl)amino]-3-nitrophenyl]imino]bisethanol. and its salts	HC Blue No 2	33229-34-4	251-410-3	Non-oxidising colouring agents for hair dyeing	2,8 %	Not to be used after 31.12.2009	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
248	4-[(2-Hydroxyethyl)amino]-3-nitrophenol and its salts	3-Nitro-p-hydroxyethylaminophenol	65235-31-6	265-648-0	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 6,0 %  (b) 6,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 3,0 %  Not to be used after 31.12.2009	
249	1-(.beta.-Ureidoethyl)amino-4-nitrobenzene and its salts	4-Nitrophenyl aminothylurea	27080-42-8	410-700-1	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 %  (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %  Not to be used after 31.12.2009	
250	1-amino-2-nitro-4-(2',3'-dihydroxypropyl)amino-5-chlorobenzene and 1,4-bis-(2',3'-dihydroxypropyl)amino-2-nitro-5-chlorobenzene and its salts	HC Red No 10 and HC Red No 11	95576-89-9 and 95576-92-4	—	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 %  (b) 1,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	
251	Phenol, 2-chloro-6-(ethylamino)-4-nitro- and its salts	2-Chloro-6-ethylamino-4-nitrophenol	131657-78-8	411-440-1	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 3,0 %  (b) 3,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,5 %  Not to be used after 31.12.2009	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
252	2-Amino-6-chloro-4-nitrophenol and its salts	2-Amino-6-chloro-4-nitrophenol	6358-09-4	228-762-1	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 2,0 %  (b) 2,0 %	In combination with hydrogen peroxide the maximum use concentration upon application is 1,0 %  Not to be used after 31.12.2009	
253	[4-[[4-Anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (CI 44045) and other salts	Basic Blue 26 (CI 44045)	2580-56-5	219-943-6	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 0,5 %  (b) 0,5 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,25 %  Not to be used after 31.12.2009	
254	Disodium 5-amino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate (CI 17200) and other salts	Acid Red 33 (CI 17200)	3567-66-6	222-656-9	Non-oxidising colouring agents for hair dyeing	2,0 %	Not to be used after 31.12.2009	
255	Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate (CI 14700) and other salts	Ponceau SX (CI 14700)	4548-53-2	224-909-9	Non-oxidising colouring agents for hair dyeing	2,0 %	Not to be used after 31.12.2009	

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
256	(4-(4-Aminophenyl) (4-iminocyclohexa-2,5-dienylidene) methyl)-2-methylaniline hydrochloride (CI 42510) and other salts	Basic Violet 14 (CI 42510)	632-99-5	211-189-6	(a) Oxidising colouring agents for hair dyeing  (b) Non-oxidising colouring agents for hair dyeing	(a) 0,3 %  (b) 0,3 %	In combination with hydrogen peroxide the maximum use concentration upon application is 0,15 %  Not to be used after 31.12.2009	

<sup>(1)</sup> These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1.

<sup>(2)</sup> For use as a preservative, see Annex V, No. 5.

<sup>(3)</sup> Only if the concentration exceeds 0,05 %.

<sup>(4)</sup> These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 2.

<sup>(5)</sup> The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column g.

<sup>(6)</sup> The concentration of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In case of mixtures, the sum should not exceed the limits given in column g.

<sup>(7)</sup> For use as a preservative, see Annex V, No. 34.

<sup>(8)</sup> For use as a preservative, see Annex V, No 43.

<sup>(9)</sup> For use as a preservative, see Annex V, No. 54.

<sup>(10)</sup> For use as a preservative, see Annex V, No 3.

<sup>(11)</sup> Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.

<sup>(12)</sup> For use as a preservative, see Annex V, No 9.

<sup>(13)</sup> For use as a preservative, see AnnexV, No 23.

<sup>(14)</sup> For use as a preservative, see Annex V, No 8.

## ANNEX IV

## LIST OF COLORANTS ALLOWED IN COSMETIC PRODUCTS

## Preamble

Without prejudice to other provisions in this Regulation, a colorant shall include its salts and lakes and when a colorant is expressed as a specific salt, its other salts and lakes shall also be included.

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
1	Sodium tris(1,2-naphthoquinone 1-oximato-O,O')ferrate(1-)	10006			Green	Rinse-off products			
2	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-)	10020			Green	Not to be used in products applied on mucous membranes			
3	Disodium 5,7-dinitro-8-oxidonaphthalene-2-sulphonate and its insoluble barium, strontium and zirconium lakes, salts and pigments	10316			Yellow	Not to be used in eye products			
4	2-[(4-Methyl-2-nitrophenyl)azo]-3-oxo-N-phenylbutyramide	11680			Yellow	Not to be used in products applied on mucous membranes			
5	2-[(4-Chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide	11710			Yellow	Not to be used in products applied on mucous membranes			
6	2-[(4-Methoxy-2-nitrophenyl)azo]-3-oxo-N-(o-tolyl)butyramide	11725			Orange	Rinse-off products			
7	4-(Phenylazo)resorcinol	11920			Orange				
8	4-[(4-Ethoxyphenyl)azo]naphthol	12010			Red	Not to be used in products applied on mucous membranes			

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
9	1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol and its insoluble barium, strontium and zirconium lakes, salts and pigments	12085			Red		3 %		
10	1-[(4-Methyl-2-nitrophenyl)azo]-2-naphthol	12120			Red	Rinse-off products			
11	3-Hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	12370			Red	Rinse-off products			
12	N-(4-Chloro-2-methylphenyl)-4-[(4-chloro-2-methylphenyl)azo]-3-hydroxynaphthalene-2-carboxamide	12420			Red	Rinse-off products			
13	4-[(2,5-Dichlorophenyl)azo]-N-(2,5-dimethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide	12480			Brown	Rinse-off products			
14	N-(5-Chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide	12490			Red				
15	2,4-Dihydro-5-methyl-2-phenyl-4-(phenylazo)-3H-pyrazol-3-one	12700			Yellow	Rinse-off products			
16	Disodium 2-amino-5-[(4-sulphonatophenyl)azo]benzenesulphonate	13015			Yellow				
17	Sodium 4-(2,4-dihydroxyphenylazo)benzenesulphonate	14270			Orange				
18	Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate	14700			Red				
19	Disodium 4-hydroxy-3-[(4-sulphonatonaphthyl)azo]naphthalenesulphonate	14720		222-657-4	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 122)	

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
20	Disodium 6-[(2,4-dimethyl-6-sulphonatophenyl)azo]-5-hydroxynaphthalene-1-sulphonate	14815			Red				
21	Sodium 4-[(2-hydroxy-1-naphthyl)azo]benzenesulphonate and its insoluble barium, strontium and zirconium lakes, salts and pigments	15510			Orange	Not to be used in eye products			
22	Calcium disodium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]-4-sulphonatobenzoate]	15525			Red				
23	Barium bis[4-[(2-hydroxy-1-naphthyl)azo]-2-methylbenzenesulphonate]	15580			Red				
24	Sodium 4-[(2-Hydroxy-1-naphthyl)azo]naphthalenesulphonate	15620			Red	Rinse-off products			
25	Sodium 2-[(2-hydroxynaphthyl)azo]naphthalenesulphonate and its insoluble barium, strontium and zirconium lakes, salts and pigments	15630			Red		3 %		
26	Calcium bis[3-hydroxy-4-(phenylazo)-2-naphthoate]	15800			Red	Not to be used in products applied on mucous membranes			
27	Disodium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate and its insoluble barium, strontium and zirconium lakes, salts and pigments	15850		226-109-5	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 180)	
28	Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate and its insoluble barium, strontium and zirconium lakes, salts and pigments	15865			Red				



Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
29	Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate	15880			Red				
30	Disodium 6-hydroxy-5-[(3-sulphonatophenyl)azo]naphthalene-2-sulphonate	15980			Orange				
31	Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene-2-sulphonate and its insoluble barium, strontium and zirconium lakes, salts and pigments	15985		220-491-7	Yellow			Purity criteria as set out in Commission Directive 95/45/EC (E 110)	
32	Disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo]naphthalene-2-sulphonate	16035		247-368-0	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 129)	
33	Trisodium 3-hydroxy-4-[(4'-sulphonatonaphthyl)azo]naphthalene-2,7-disulphonate	16185		213-022-2	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 123)	
34	Disodium 7-hydroxy-8-(phenylazo)naphthalene-1,3-disulphonate	16230			Orange	Not to be used in products applied on mucous membranes			
35	Trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate and its insoluble barium, strontium and zirconium lakes, salts and pigments	16255		220-036-2	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 124)	
36	Tetrasodium 7-hydroxy-8-[(4-sulphonato-1-naphthyl)azo]naphthalene-1,3,6-trisulphonate	16290			Red				
37	Disodium 5-amino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate and its insoluble barium, strontium and zirconium lakes, salts and pigments	17200			Red				

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
38	Disodium 5-acetylamino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate	18050		223-098-9	Red	Not to be used in products applied on mucous membranes		Purity criteria as set out in Commission Directive 95/45/EC (E 128)	
39	2,7-Naphthalenedisulfonic acid, 3-((4-cyclohexyl-2-methylphenyl)azo)-4-hydroxy-5-(((4-methylphenyl)sulfonyl)amino)-, disodium salt	18130			Red	Rinse-off products			
40	Hydrogen bis[2-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]benzoato(2-)]chromate(1-)	18690			Yellow	Rinse-off products			
41	Disodium hydrogen bis[5-chloro-3-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-2-hydroxybenzenesulphonato(3-)]chromate(3-)	18736			Red	Rinse-off products			
42	Sodium 4-(3-hydroxy-5-methyl-4-(phenylazo)pyrazol-2-yl)benzenesulphonate	18820			Yellow	Rinse-off products			
43	Disodium 2,5-dichloro-4-(5-hydroxy-3-methyl-4-((sulphophenyl)azo)pyrazol-1-yl)benzenesulphonate	18965			Yellow				
44	Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-((4-sulphophenyl)azo)pyrazole-3-carboxylate and its insoluble barium, strontium and zirconium lakes, salts and pigments	19140		217-699-5	Yellow			Purity criteria as set out in Commission Directive 95/45/EC (E 102)	
45	N,N'-(3,3'-Dimethyl[1,1'-biphenyl]-4,4'-diyl)bis[2-[(2,4-dichlorophenyl)azo]-3-oxobutyramide]	20040			Yellow	Rinse-off products		Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm	
46	Sodium 4-amino-5-hydroxy-3-((4-nitrophenyl)azo)-6-(phenylazo)naphthalene-2,7-disulphonate	20470			Black	Rinse-off products			

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
47	2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]	21100			Yellow	Rinse-off products		Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm	
48	2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]	21108			Yellow	Rinse-off products		Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm	
49	2,2'-[Cyclohexylidenebis[(2-methyl-4,1-phenylene)azo]]bis[4-cyclohexylphenol]	21230			Yellow	Not to be used in products applied on mucous membranes			
50	Disodium 4,6-dihydroxy-3-[[4-[1-[4-[[1-hydroxy-7-[(phenylsulphonyl)oxy]-3-sulphonato-2-naphthyl]azo]phenyl]cyclohexyl]phenyl]azo]naphthalene-2-sulphonate	24790			Red	Rinse-off products			
51	1-(4-(Phenylazo)phenylazo)-2-naphthol	26100			Red	Not to be used in products applied on mucous membranes		Purity criteria: aniline ≤ 0,2 % 2-naphthol ≤ 0,2 % 4-aminoazobenzene ≤ 0,1 % 1-(phenylazo)-2-naphthol ≤ 3 % 1-[2-(phenylazo)phenylazo]-2-naphthalenol ≤ 2 %	
52	Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate	27755			Black				
53	Tetrasodium 1-acetamido-2-hydroxy-3-(4-((4-sulphonatophenylazo)-7-sulphonato-1-naphthylazo))naphthalene-4,6-disulphonate	28440		219-746-5	Black			Purity criteria as set out in Commission Directive 95/45/EC (E 151)	

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
54	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-, disodium salt, reaction products with 4-[(4-aminophenyl)azo] benzenesulfonic acid, sodium salts	40215			Orange	Rinse-off products			
55	beta Carotene	40800		230-636-6	Orange			Purity criteria as set out in Commission Directive 95/45/EC (E160a)	
56	8'-apo-.beta.-Caroten-8'-al	40820			Orange			Purity criteria as set out in Commission Directive 95/45/EC (E 160e)	
57	Ethyl 8'-apo-.beta.-caroten-8'-oate	40825		214-173-7	Orange			Purity criteria as set out in Commission Directive 95/45/EC (E 160f)	
58	Canthaxanthin	40850		208-187-2	Orange			Purity criteria as set out in Commission Directive 95/45/EC (E 161g)	
59	Ammonium, (4-(alpha-(p-(diethylamino)phenyl)-2,4-disulfo-benzylidene)-2,5-cyclohexadien-1-ylidene)diethyl-, hydroxide, monosodium salt	42045			Blue	Not to be used in products applied on mucous membranes			
60	Ethanaminium, N-(4-((4-(diethylamino)phenyl)(5-hydroxy-2,4-disulfo-phenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, calcium salt (2:1) and its insoluble barium, strontium and zirconium lakes, salts and pigments	42051		222-573-8	Blue			Purity criteria as set out in Commission Directive 95/45/EC (E 131)	
61	Benzene-methanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulfo-phenyl)methyl)amino)phenyl)(4-hydroxy-2-sulfo-phenyl)methylene)-2,5-cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt	42053			Green				

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
62	Hydrogen (benzyl)[4-[[4-[benzylethylamino]phenyl](2,4-disulphonatophenyl)methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)ammonium, sodium salt	42080			Blue	Rinse-off products			
63	Benzene-methanaminium, N-ethyl-N-(4-(((4-(ethyl((3-sulfofenyl)methyl)amino)phenyl)(2-sulfofenyl)methylene)-2,5-cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt	42090		223-339-8	Blue			Purity criteria as set out in Commission Directive 95/45/EC (E 133)	
64	Hydrogen [4-[(2-chlorophenyl)[4-ethyl(3-sulphonatobenzyl)amino]phenyl]methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt	42100			Green	Rinse-off products			
65	Hydrogen [4-[(2-chlorophenyl)[4-ethyl(3-sulphonatobenzyl)amino]-o-tolyl]methylene]-3-methylcyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt	42170			Green	Rinse-off products			
66	(4-(4-Aminophenyl)(4-iminocyclohexa-2,5-dienylidene)methyl)-2-methylaniline hydrochloride	42510			Violet	Not to be used in products applied on mucous membranes			
67	4-[(4-Amino-m-tolyl)(4-imino-3-methylcyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine monohydrochloride	42520			Violet	Rinse-off products	5ppm		
68	Hydrogen [4-[[4-(diethylamino)phenyl][4-ethyl[(3-sulphonatobenzyl)amino]-o-tolyl]methylene]-3-methylcyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt	42735			Blue	Not to be used in products applied on mucous membranes			

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
69	[4-[[4-Anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride	44045			Blue	Not to be used in products applied on mucous membranes			
70	Hydrogen [4-[4-(dimethylamino)-.alpha.-(2-hydroxy-3,6-disulphonato-1-naphthyl)benzylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium, monosodium salt	44090		221-409-2	Green			Purity criteria as set out in Commission Directive 95/45/EC (E 142)	
71	Hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphonatophenyl)xanthylium, sodium salt	45100			Red	Rinse-off products			
72	Hydrogen 9-(2-carboxylatophenyl)-3-(2-methylanilino)-6-(2-methyl-4-sulphoanilino)xanthylium, monosodium salt	45190			Violet	Rinse-off products			
73	Hydrogen 9-(2,4-disulphonatophenyl)-3,6-bis(ethylamino)-2,7-dimethylxanthylium, monosodium salt	45220			Red	Rinse-off products			
74	Disodium 2-(3-oxo-6-oxidoxanthen-9-yl)benzoate	45350			Yellow		6 %		
75	4',5'-Dibromo-3',6'-dihydroxy Spiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one and its insoluble barium, strontium and zirconium lakes, salts and pigments	45370			Orange			Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid	
76	Disodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigments	45380			Red			Not more than 1 % 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid	
77	3',6'-Dihydroxy-4',5'-dinitrospiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one	45396			Orange		1 %, when used in lip products	Only in free acid form, when used in lip products	

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
78	Dipotassium 3,6-dichloro-2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthene-9-yl)benzoate	45405			Red	Not to be used in eye products		Not more than 1 % 2-(6-hydroxy-3-oxo-3H xanthene-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthene-9-yl) benzoic acid	
79	3,4,5,6-Tetrachloro-2-(1,4,5,8-tetrabromo-6-hydroxy-3-oxoxanthene-9-yl)benzoic acid and its insoluble barium, strontium and zirconium lakes, salts and pigments	45410			Red			Not more than 1 % 2-(6-hydroxy-3-oxo-3H xanthene-9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo-3H-xanthene-9-yl) benzoic acid	
80	Disodium 2-(2,4,5,7-tetraiodo-6-oxido-3-oxoxanthene-9-yl)benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigments	45430		240-474-8	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 127)	
81	1,3-Isobenzofurandione, reaction products with methylquinoline and quinoline	47000			Yellow	Not to be used in products applied on mucous membranes			
82	1H-Indene-1,3(2H)-dione, 2-(2-quinolinyl)-, sulfonated, sodium salts	47005		305-897-5	Yellow			Purity criteria as set out in Commission Directive 95/45/EC (E 104)	
83	Hydrogen 9-[(3-methoxyphenyl)amino]-7-phenyl-5-(phenylamino)-4,10-disulphonatobenzo[a]phenazinium, sodium salt	50325			Violet	Rinse-off products			
84	Sulfonated nigrosine color	50420			Black	Not to be used in products applied on mucous membranes			
85	8,18-Dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine	51319			Violet	Rinse-off products			
86	1,2-Dihydroxyanthraquinone	58000			Red				
87	Trisodium 8-hydroxypyrene-1,3,6-trisulphonate	59040			Green	Not to be used in products applied on mucous membranes			

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
88	1-Anilino-4-hydroxyanthraquinone	60724			Violet	Rinse-off products			
89	1-Hydroxy-4-(p-toluidino)anthraquinone	60725			Violet				
90	Sodium 4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]toluene-3-sulphonate	60730			Violet	Not to be used in products applied on mucous membranes			
91	1,4-bis(p-Tolylamino)anthraquinone	61565			Green				
92	Disodium 2,2'-(9,10-dioxoanthracene-1,4-diyl-diimino)bis(5-methylsulphonate)	61570			Green				
93	Sodium 3,3'-(9,10-dioxoanthracene-1,4-diyl-diimino)bis(2,4,6-trimethylbenzenesulphonate)	61585			Blue	Rinse-off products			
94	Sodium 1-amino-4-(cyclohexylamino)-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate	62045			Blue	Rinse-off products			
95	6,15-Dihydroanthrazine-5,9,14,18-tetrone	69800			Blue				
96	7,16-dichloro-6,15-dihydroanthrazine-5,9,14,18-tetrone	69825			Blue				
97	Bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione	71105			Orange	Not to be used in products applied on mucous membranes			
98	2-(1,3-Dihydro-3-oxo-2H-indazol-2-ylidene)-1,2-dihydro-3H-indol-3-one	73000			Blue				
99	Disodium 5,5'-(2-(1,3-dihydro-3-oxo-2H-indazol-2-ylidene)-1,2-dihydro-3H-indol-3-one)disulphonate	73015		212-728-8	Blue			Purity criteria as set out in Commission Directive 95/45/EC (E 132)	
100	6-Chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one	73360			Red				



Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
101	5-Chloro-2-(5-chloro-7-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-7-methylbenzo[b]thiophene-3(2H)-one	73385			Violet				
102	5,12-Dihydroquino[2,3-b]acridine-7,14-dione	73900			Violet	Rinse-off products			
103	5,12-Dihydro-2,9-dimethylquino[2,3-b]acridine-7,14-dione	73915			Red	Rinse-off products			
104	29H,31H-Phthalocyanine	74100			Blue	Rinse-off products			
105	29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32 copper	74160			Blue				
106	Disodium [29H,31H-phthalocyaninedisulphonato (4-)-N29,N30,N31,N32] cuprate (2-)	74180			Blue	Rinse-off products			
107	Polychloro copper phthalocyanine	74260			Green	Not to be used in eye products			
108	8,8'-diapo-,psi.,,psi.-Carotenedioic acid	75100			Yellow				
109	Annatto	75120		215-735-4/ 289-561-2/ 230-248-7	Orange			Purity criteria as set out in Commission Directive 95/45/EC (E 160b)	
110	Lycopene	75125		—	Yellow			Purity criteria as set out in Commission Directive 95/45/EC (E 160d)	
111	CI Food Orange 5	75130		214-171-6	Orange			Purity criteria as set out in Commission Directive 95/45/EC (E 160a)	
112	(3R)-beta-4-Caroten-3-ol	75135			Yellow				
113	2-Amino-1,7-dihydro-6H-purin-6-one	75170			White				

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
114	Curcumins	75300		207-280-5	Yellow			Purity criteria as set out in Commission Directive 95/45/EC (E 100)	
115	Carmines	75470		215-680-6/ 215-023-3/ 215-724-4	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 120)	
116	Trisodium (2S-trans)-[18-carboxy-20-(carboxymethyl)-13-ethyl-2,3-dihydro-3,7,12,17-tetramethyl-8-vinyl-21H,23H-porphine-2-propionato(5-)-N21,N22,N23,N24]cuprate(3-)(Chlorophylls)	75810		215-800-7/ 207-536-6/ 208-272-4/ 287-483-3/ 239-830-5/ 246-020-5	Green			Purity criteria as set out in Commission Directive 95/45/EC (E 140, E 141)	
117	Aluminium	77000		231-072-3	White			Purity criteria as set out in Commission Directive 95/45/EC (E 173)	
118	Aluminium hydroxide sulphate	77002			White				
119	Natural hydrated aluminium silicate, Al <sub>2</sub> O <sub>3</sub> .2SiO <sub>2</sub> .2H <sub>2</sub> O, containing calcium, magnesium or iron carbonates, ferric hydroxide, quartz-sand, mica, etc. as impurities	77004			White				
120	Lazurite	77007			Blue				
121	Aluminum silicate coloured with ferric oxide	77015			Red				
122	Barium sulfate	77120			White				
123	Bismuth chloride oxide	77163			White				

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
124	Calcium carbonate	77220		207-439-9/ 215-279-6	White			Purity criteria as set out in Commission Directive 95/45/EC (E 170)	
125	Calcium sulfate	77231			White				
126	Carbon black	77266		215-609-9	Black			Purity criteria as set out in Commission Directive 95/45/EC (E 153)	
127	Charcoal, bone. A fine black powder obtained by burning animal bones in a closed container. It consists primarily of calcium phosphate and carbon	77267			Black				
128	Coke black	77268:1			Black				
129	Chromium (III) oxide	77288			Green			free from chromate ion	
130	Chromium (III) hydroxide	77289			Green			free from chromate ion	
131	Cobalt Aluminum Oxide	77346			Green				
132	Copper	77400			Brown				
133	Gold	77480		231-165-9	Brown			Purity criteria as set out in Commission Directive 95/45/EC (E 175)	
134	Iron oxide	77489			Orange				
135	Iron Oxide Red	77491		215-168-2	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 172)	

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
136	Iron Oxide Yellow	77492	51274-00-1	257-098-5	Yellow			Purity criteria as set out in Commission Directive 95/45/EC (E 172)	
137	Iron Oxide Black	77499		235-442-5	Black			Purity criteria as set out in Commission Directive 95/45/EC (E 172)	
138	Ferric Ammonium Ferrocyanide	77510			Blue			free from cyanide ions	
139	Magnesium carbonate	77713			White				
140	Ammonium manganese(3+) diphosphate	77742			Violet				
141	Trimanganese bis (orthophosphate)	77745			Red				
142	Silver	77820		231-131-3	White			Purity criteria as set out in Commission Directive 95/45/EC (E 174)	
143	Titanium dioxide ( <sup>1</sup> )	77891		236-675-5	White			Purity criteria as set out in Commission Directive 95/45/EC (E 171)	
144	Zinc oxide	77947			White				
145	Riboflavin	Lactoflavin		201-507-1/ 204-988-6	Yellow			Purity criteria as set out in Commission Directive 95/45/EC (E 101)	
146	Caramel	Caramel		232-435-9	Brown			Purity criteria as set out in Commission Directive 95/45/EC (E 150a-d)	

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
147	Paprika extract, Capsanthin, capsorubin	Capsanthin, capsorubin		207-364-1/ 207-425-2	Orange			Purity criteria as set out in Commission Directive 95/45/EC (E 160c)	
148	Beetroot red	Beetroot Red	7659-95-2	231-628-5	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 162)	
149	Anthocyanins (Cyanidin, Peonidin Malvidin Delphinidin Petunidin Pelargonidin)	Anthocyanins	528-58-5 134-01-0 528-53-0 643-84-5 134-04-3	208-438-6 205-125-6 211-403-8 208-437-0 — 205-127-7	Red			Purity criteria as set out in Commission Directive 95/45/EC (E 163)	
150	Aluminium, zinc, magnesium and calcium stearates	Aluminum stearate Zinc stearate Magnesium stearate Calcium stearate	7047-84-9 557-05-1 557-04-0 216-472-8	230-325-5 209-151-9 209-150-3 216-472-8	White				
151	Phenol, 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bis[2-bromo-3-methyl-6-(1-methylethyl)-, S,S-dioxide	Bromothymol blue	76-59-5	200-971-2	Blue	Rinse-off products			
152	Phenol, 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bis[2,6-dibromo-3-methyl-,S,S-dioxide	Bromocresol green	76-60-8	200-972-8	Green	Rinse-off products			
153	Sodium 4-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-3-hydroxynaphthalene-1-sulphonate	Acid red 195	12220-24-5	—	Red	Not to be used in products applied on mucous membranes			

(<sup>1</sup>) For use as a UV-Filter, see Annex VI, No. 27.

## ANNEX V

## LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS

## Preamble

1. For the purposes of this list:

— 'Salts' is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.

— 'Esters' is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.

2. All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0,05 %.

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
1	Benzoic acid and its sodium salt	Benzoic acid	65-85-0	200-618-2	Rinse-off products, except oral products	2,5 % (acid)		
		Sodium Benzoate	532-32-1	208-534-8	Oral products	1,7 % (acid)		
					Leave-on products	0,5 % (acid)		
1a	Salts of benzoic acid other than that listed under reference number 1 and esters of benzoic acid	Ammonium benzoate, calcium benzoate, potassium benzoate, magnesium benzoate, MEA-benzoate, methyl benzoate, ethyl benzoate, propyl benzoate, butyl benzoate, isobutyl benzoate, isopropyl benzoate, phenyl benzoate	1863-63-4, 2090-05-3, 582-25-2, 553-70-8, 4337-66-0, 93-58-3, 93-89-0, 2315-68-6, 136-60-7, 120-50-3, 939-48-0, 93-99-2	217-468-9, 218-235-4, 209-481-3, 209-045-2, 224-387-2, 202-259-7, 202-284-3, 219-020-8, 205-252-7, 204-401-3, 213-361-6, 202-293-2		0,5 % (acid)		

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
2	Propionic acid and its salts	Propionic acid, ammonium propionate, calcium propionate, magnesium propionate, potassium propionate, sodium propionate	79-09-4, 17496-08-1, 4075-81-4, 557-27-7, 327-62-8, 137-40-6	201-176-3, 241-503-7, 223-795-8, 209-166-0, 206-323-5, 205-290-4		2 % (acid)		
3	Salicylic acid <sup>(1)</sup> and its salts	Salicylic acid, calcium salicylate, magnesium salicylate, MEA-salicylate, sodium salicylate, potassium salicylate, TEA-salicylate	69-72-7, 824-35-1, 18917-89-0, 59866-70-5, 54-21-7, 578-36-9, 2174-16-5	200-712-3, 212-525-4, 242-669-3, 261-963-2, 200-198-0, 209-421-6, 218-531-3		0,5 % (acid)	Not to be used in products for children under 3 years of age, except for shampoos	Not to be used for children under 3 years of age <sup>(2)</sup>
4	Hexa-2,4-dienoic acid and its salts	Sorbic acid, calcium sorbate, sodium sorbate, potassium sorbate	110-44-1, 7492-55-9, 7757-81-5, 24634-61-5	203-768-7, 231-321-6, 231-819-3, 246-376-1		0,6 % (acid)		
5	Formal-dehyde, paraformaldehyde <sup>(3)</sup>	Formaldehyde  Paraformaldehyde	50-00-0, 30525-89-4	200-001-8	Oral products  Other products	0,1 % (free formaldehyde)  0,2 % (free formaldehyde)	Not to be used in aerosol dispensers (sprays)	
6	Moved or deleted							
7	Biphenyl-2-ol, and its salts	o-Phenylphenol, sodium o-phenylphenate, potassium o-phenylphenate, MEA o-phenylphenate	90-43-7, 132-27-4, 13707-65-8, 84145-04-0	201-993-5, 205-055-6, 237-243-9, 282-227-7		0,2 % (as phenol)		
8	Pyrithione zinc <sup>(4)</sup>	Zinc pyrithione	13463-41-7	236-671-3	Hair products  Other products	1,0 %  0,5 %	Only in rinse-off products  Not to be used in oral products	

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
9	Inorganic sulphites and hydrogen- sulphites (5)	Sodium sulfite, ammonium bisulfite, ammonium sulfite, potassium sulfite, potassium hydrogen sulfite, sodium bisulfite, sodium metabisulfite, potassium metabisulfite	7757-83-7, 10192-30-0, 10196-04-0, 10117-38-1, 7773-03-7, 7631-90-5, 7681-57-4, 16731-55-8	231-821-4, 233-469-7, 233-484-9, 233-321-1, 231-870-1, 231-548-0, 231-673-0, 240-795-3		0,2 % (as free SO <sub>2</sub> )		
10	Moved or deleted							
11	Chlorobutanol	Chlorobutanol	57-15-8	200-317-6		0,5 %	Not to be used in aerosol dispensers (sprays)	Contains Chlorobutanol
12	4-Hydroxybenzoic acid and its salts and esters	4-Hydroxybenzoic acid, methylparaben, butylparaben, potassium ethylparaben, potassium paraben, propylparaben, isobutylparaben, sodium methylparaben, sodium ethylparaben, sodium propylparaben, sodium butylparaben, sodium isobutylparaben, ethylparaben, sodium paraben, isopropylparaben, potassium methylparaben, potassium butylparaben, potassium propylparaben, sodium propylparaben, calcium paraben, phenylparaben	99-96-7, 99-76-3, 94-26-8, 36457-19-9, 16782-08-4, 94-13-3, 4247-02-3, 5026-62-0, 35285-68-8, 35285-69-9, 36457-20-2, 84930-15-4, 120-47-8, 114-63-6, 4191-73-5, 2611-07-2, 38566-94-8, 84930-17-4, 35285-69-9, 69959-44-0, 17696-62-7	202-804-9, 202-785-7, 202-318-7, 253-048-1, 240-830-2, 202-307-7, 224-208-8, 225-714-1, 252-487-6, 252-488-1, 253-049-7, 284-595-4, 204-399-4, 204-051-1, 224-069-3, 247-464-2, 254-009-1, 284-597-5, 252-488-1, 274-235-4, 241-698-9		0,4 % (as acid) for single ester,  0,8 % (as acid) for mixtures of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione and its salts	Dehydroacetic acid, sodium dehydroacetate	520-45-6, 4418-26-2, 16807-48-0	208-293-9, 224-580-1		0,6 % (as acid)	Not to be used in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt	Formic acid, sodium formate	64-18-6, 141-53-7	200-579-1, 205-488-0		0,5 % (as acid)		



Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
15	3,3'-Dibromo-4,4'-hexamethylenedioxydibenzamidine and its salts (including isethionate)	Dibromohexamidine Isethionate	93856-83-8	299-116-4		0,1 %		
16	Thiomersal	Thimerosal	54-64-8	200-210-4	Eye products	0,007 % (of Hg)  If mixed with other mercurial compounds authorised by this Regulation, the maximum concentration of Hg remains fixed at 0,007 %		Contains Thiomersal
17	Phenylmercuric salts (including borate)	Phenyl Mercuric Acetate, Phenyl Mercuric Benzoate	62-38-4, 94-43-9	200-532-5, 202-331-8	Eye products	0,007 % (of Hg)  If mixed with other mercurial compounds authorised by this Regulation, the maximum concentration of Hg remains fixed at 0,007 %		Contains Phenylmercuric compounds
18	Undec-10-enoic acid and its salts	Undecylenic acid, potassium undecylenate, sodium undecylenate, calcium undecylenate, TEA-undecylenate, MEA-undecylenate	112-38-9, 6159-41-7, 3398-33-2, 1322-14-1, 84471-25-0, 56532-40-2	203-965-8, 222-264-8, 215-331-8, 282-908-9, 260-247-7		0,2 % (as acid)		
19	5- Pyrimidinamine, 1,3-bis (2-ethylhexyl) hexahydro-5-methyl-	Hexetidine	141-94-6	205-513-5		0,1 %		

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
20	5-Bromo-5-nitro-1,3-dioxane	5-Bromo-5-nitro-1,3-dioxane	30007-47-7	250-001-7	Rinse-off products	0,1 %	Avoid formation of nitro-samines	
21	Bronopol	2-Bromo-2-nitropropane-1,3-diol	52-51-7	200-143-0		0,1 %	Avoid formation of nitro-samines	
22	2,4-Dichlorobenzyl alcohol	Dichlorobenzyl Alcohol	1777-82-8	217-210-5		0,15 %		
23	1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl) urea (°)	Triclocarban	101-20-2	202-924-1		0,2 %	Purity criteria:  3,3',4,4'-Tetrachloroazobenzene < 1 ppm  3,3',4,4'-Tetrachloroazoxybenzene < 1 ppm	
24	Chlorocresol	p-Chloro-m-Cresol	59-50-7	200-431-6	Not to be used in products applied on mucuous membranes	0,2 %		
25	5-Chloro-2- (2,4- dichlorophenoxy) phenol	Triclosan	3380-34-5	222-182-2		0,3 %		
26	Chloro-xilenol	Chloroxylenol	88-04-0	201-793-8		0,5 %		
27	N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioximidazolidin-4-yl)]urea]	Imidazolidinyl urea	39236-46-9	254-372-6		0,6 %		
28	Poly(methylene),.alpha.,.omega.-bis[(((aminoiminomethyl)amino)iminomethyl) amino]-, dihydrochloride	Polyaminopropyl biguanide	70170-61-5, 28757-47-3, 133029-32-0			0,3 %		
29	2-Phenoxyethanol	Phenoxyethanol	122-99-6	204-589-7		1,0 %		
30	Methenamine	Methenamine	100-97-0	202-905-8		0,15 %		

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
31	Methenamine 3-chloroallylochloride	Quaternium-15	4080-31-3	223-805-0		0,2 %		
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one	Climbazole	38083-17-9	253-775-4		0,5 %		
33	1,3-Bis (hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	DMDM Hydantoin	6440-58-0	229-222-8		0,6 %		
34	Benzyl alcohol (?)	Benzyl alcohol	100-51-6	202-859-9		1,0 %		
35	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl) 2-pyridon, Piroctone Olamine	50650-76-5, 68890-66-4	272-574-2	Rinse-off products	1,0 %		
					Other products	0,5 %		
36	Moved or deleted							
37	2,2'-methylenebis(6-bromo-4-chlorophenol)	Bromochlorophene	15435-29-7	239-446-8		0,1 %		
38	4-Isopropyl-m-cresol	o-Cymen-5-ol	3228-02-2	221-761-7		0,1 %		
39	Mixture of 5-Chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	Methylchloroisothiazolinone and Methylisothiazolinone	26172-55-4, 2682-20-4, 55965-84-9	247-500-7, 220-239-6		0,0015 % (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol 3(2H)-one and 2-methylisothiazol-3 (2H)-one		
40	2-Benzyl-4-chlorophenol	Chlorophene	120-32-1	204-385-8		0,2 %		
41	2-Chloroacetamide	Chloroacetamide	79-07-2	201-174-2		0,3 %		Contains chloroacetamide

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
42	N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine and its digluconate, diacetate and dihydrochloride	Chlorhexidine, Chlorhexidine Diacetate, Chlorhexidine Digluconate, Chlorhexidine Dihydrochloride	55-56-1, 56-95-1, 18472-51-0, 3697-42-5	200-238-7, 200-302-4, 242-354-0, 223-026-6		0,3 % (as chlorhexidine)		
43	1-Phenoxypropan-2-ol <sup>(8)</sup>	Phenoxyisopropanol	770-35-4	212-222-7	Only for rinse-off products	1,0 %		
44	Alkyl (C <sub>12-22</sub> ) trimethyl ammonium bromide and chloride	Behentrimonium chloride, cetrimonium bromide, cetrimonium chloride, laurrimonium bromide, laurrimonium chloride, steartrimonium bromide, steartrimonium chloride	17301-53-0, 57-09-0, 112-02-7, 1119-94-4, 112-00-5, 1120-02-1, 112-03-8	241-327-0, 200-311-3, 203-928-6, 214-290-3, 203-927-0, 214-294-5, 203-929-1		0,1 %		
45	4,4-Dimethyl-1,3-oxazolidine	Dimethyl Oxazolidine	51200-87-4	257-048-2		0,1 %	pH > 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl) urea	Diazolidinyl Urea	78491-02-8	278-928-2		0,5 %		
47	Benzenecarboximidamide, 4,4'-(1,6-hexanediylbis(oxy))bis- and its salts (including isethionate and p-hydroxybenzoate)	Hexamidine, Hexamidine diisethionate, Hexamidine paraben	3811-75-4, 659-40-5, 93841-83-9	211-533-5, 299-055-3		0,1 %		
48	Glutaraldehyde (Pentane-1,5-dial)	Glutaral	111-30-8	203-856-5		0,1 %	Not to be used in aerosols (sprays)	Contains glutaral <sup>(9)</sup>
49	5-Ethyl-3,7-dioxo-1-azabicyclo [3.3.0] octane	7-Ethylbicyclooxazolidine	7747-35-5	231-810-4		0,3 %	Not to be used in oral products and in products applied on mucous membranes	

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
50	3-(p-Chlorophenoxy)-propane-1,2 diol	Chlorphenesin	104-29-0	203-192-6		0,3 %		
51	Sodium hydroxymethylamino acetate	Sodium Hydroxymethylglycinate	70161-44-3	274-357-8		0,5 %		
52	Silver chloride deposited on titanium dioxide	Silver chloride	7783-90-6	232-033-3		0,004 % (as AgCl)	20 % AgCl (w/w) on TiO <sub>2</sub> . Not to be used in products for children under 3 years of age, in oral products and in eye and lip products	
53	Benzenemethanaminium, N,N-dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]-, chloride	Benzethonium Chloride	121-54-0	204-479-9	(a) Rinse-off products  (b) Leave-on products other than oral products	0,1 %		
54	Benzalkonium chloride, bromide and saccharinate <sup>(10)</sup>	Benzalkonium chloride, benzalkonium bromide, benzalkonium saccharinate	8001-54-5, 63449-41-2, 91080-29-4, 68989-01-5, 68424-85-1, 68391-01-5, 61789-71-7, 85409-22-9	264-151-6, 293-522-5, 273-545-7, 270-325-2, 269-919-4, 263-080-8, 287-089-1		0,1 % (as benzalkonium chloride)		Avoid contact with eyes
55	Methanol, (phenylmethoxy-)	Benzylhemiformal	14548-60-8	238-588-8	Rinse-off products	0,15 %		

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
56	3-Iodo-2-propynylbutylcarbamate	Iodopropynyl butylcarbamate	55406-53-6	259-627-5	(a) Rinse-off products  (b) Leave-on products  (c) Deodorants/anti-perspirants	(a) 0,02 %  (b) 0,01 %, (c) 0,0075 %	Not to be used in oral and lip products  (a) Not to be used in products for children under 3 years of age, except in bath products/shower gels and shampoo  (b) Not to be used in body lotion and body cream <sup>(13)</sup>  (b) and (c) Not to be used in products for children under 3 years of age	(a) Not to be used for children under 3 years of age <sup>(11)</sup>  (b) and (c) Not to be used for children under 3 years of age <sup>(12)</sup>
57	2-Methyl-2H-isothiazol-3-one	Methylisothiazolinone	2682-20-4	220-239-6		0,01 %		

<sup>(1)</sup> For use other than as a preservative, see Annex III, No. 98.

<sup>(2)</sup> Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.

<sup>(3)</sup> For use other than as a preservative, see Annex III, No. 13.

<sup>(4)</sup> For use other than as a preservative, see Annex III, No. 101.

<sup>(5)</sup> For use other than as a preservative, see Annex III, No. 99.

<sup>(6)</sup> For use other than as a preservative, see Annex III, No. 100.

<sup>(7)</sup> For use other than as a preservative, see Annex III, No. 45, 68.

<sup>(8)</sup> For use other than as a preservative, see Annex III, No. 54.

<sup>(9)</sup> Only if the concentration exceeds 0,05 %.

<sup>(10)</sup> For use other than as a preservative, see Annex III, No. 65.

<sup>(11)</sup> Solely for products, other than bath products/shower gels and shampoo, which might be used for children under 3 years of age.

<sup>(12)</sup> Solely for products which might be used for children under 3 years of age.

<sup>(13)</sup> Concerns any products aimed to be applied on a large part of the body.

## ANNEX VI

## LIST OF UV FILTERS ALLOWED IN COSMETIC PRODUCTS

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN/XAN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
1	4-Aminobenzoic acid	PABA	150-13-0	205-753-0		5 %		
2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl)anilinium methyl sulfate 1	Camphor Benzalkonium Methosulfate	52793-97-2	258-19 -8		6 %		
3	Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester/Homosalate	Homosalate	118-56-9	204-260-8		10 %		
4	2-Hydroxy-4-methoxybenzophenone/Oxybenzone	Benzophenone-3	131-57-7	205-031-5		10 %		Contains Benzophenone-3 <sup>(1)</sup>
5	Moved or deleted							
6	2-Phenylbenzimidazole-5-sulfonic acid and its potassium, sodium and triethanolamine salts/Ensulizole	Phenylbenzimidazole Sulfonic Acid	27503-81-7	248-502-0		8 %(as acid)		
7	3,3'-(1,4-Phenylenedimethylene) bis(7, 7-dimethyl-2-oxobicyclo-[2.2.1]hept-1-yl-methanesulfonic acid) and its salts/Ecamsule	Terephthalylidene Dicamphor Sulfonic Acid	92761-26-7, 90457-82-2	410-960-6		10 %(as acid)		
8	1-(4-tert-Butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione/Avobenzone	Butyl Methoxydibenzoylmethane	70356-09-1	274-581-6		5 %		
9	alpha-(2-Oxoborn-3-ylidene)-toluene-4-sulphonic acid and its salts	Benzylidene Camphor Sulfonic Acid	56039-58-8			6 % (as acid)		
10	2-Cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester/Octocrilene	Octocrylene	6197-30-4	228-250-8		10 % (as acid)		
11	Polymer of N-[(2 and 4)-[(2-oxoborn-3-ylidene)methyl]benzyl] acrylamide	Polyacrylamidomethyl Benzylidene Camphor	113783-61-2			6 %		
12	2-Ethylhexyl 4-methoxycinnamate/Octinoxate	Ethylhexyl Methoxycinnamate	5466-77-3	226-775-7		10 %		
13	Ethoxylated ethyl-4-aminobenzoate	PEG-25 PABA	116242-27-4			10 %		
14	Isopentyl-4-methoxycinnamate/Amiloxate	Isoamyl p-Methoxycinnamate	71617-10-2	275-702-5		10 %		

Reference number	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN/XAN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
15	2,4,6-Trianilino-(p-carbo-2'-ethylhexyl-1'-oxy)-1,3,5-triazine	Ethylhexyl Triazone	88122-99-0	402-070-1		5 %		
16	Phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6-(2-methyl-3-(1,3,3,3-tetramethyl-1-(trimethylsilyloxy)-disiloxanyl)propyl)	Drometrizole Trisiloxane	155633-54-8			15 %		
17	Benzoic acid, 4,4-((6-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino)-1,3,5-triazine-2,4-diyl)diimino)bis-, bis (2-ethylhexyl) ester/Isotrizinol (USAN)	Diethylhexyl Butamido Triazone	154702-15-5			10 %		
18	3-(4-Methylbenzylidene)-d1 camphor/Enzacamene	4-Methylbenzylidene Camphor	38102-62-4/ 36861-47-9	- / 253-242-6		4 %		
19	3-Benzylidene camphor	3-Benzylidene Camphor	15087-24-8	239-139-9		2 %		
20	2-Ethylhexyl salicylate/Octisalate	Ethylhexyl Salicylate	118-60-5	204-263-4		5 %		
21	2-Ethylhexyl 4-(dimethylamino)benzoate/Padimate O (USAN:BAN)	Ethylhexyl Dimethyl PABA	21245-02-3	244-289-3		8 %		
22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid and its sodium salt/Sulisobenzone	Benzophenone-4, Benzophenone-5	4065-45-6/ 6628-37-1	223-772-2 / -		5 % (as acid)		
23	2,2'-Methylene-bis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethyl-butyl)phenol) / Bisotrizole	Methylene Bis-Benzotriazolyl Tetramethylbutylphenol	103597-45-1	403-800-1		10 %		
24	Sodium salt of 2,2'-bis(1,4-phenylene)-1H-benzimidazole-4,6-disulfonic acid) / Bisdisulizole disodium (USAN)	Disodium Phenyl Dibenzimidazole Tetrasulfonate	180898-37-7	429-750-0		10 % (as acid)		
25	2,2'-(6-(4-Methoxyphenyl)-1,3,5-triazine-2,4-diyl)bis(5-((2-ethylhexyl)oxy)phenol) / Bemotrizinol	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	187393-00-6			10 %		
26	Dimethicodiethylbenzalmalonate	Polysilicone-15	207574-74-1	426-000-4		10 %		
27	Titanium dioxide <sup>(2)</sup>	Titanium Dioxide	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 205-280-1/ 215-282-2		25 %		
28	Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester	Diethylamino Hydroxybenzoyl Hexyl Benzoate	302776-68-7	443-860-6		10 % in sun-screen products		

<sup>(1)</sup> Not required if concentration is 0,5 % or less and when it is used only for product protection purposes.

<sup>(2)</sup> For use other than as a colorant, see Annex IV, No. 143.



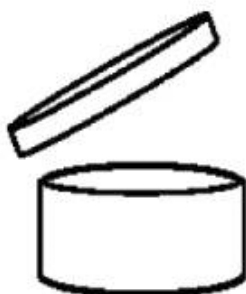
## ANNEX VII

## SYMBOLS USED ON PACKAGING/CONTAINER

## 1. Reference to enclosed or attached information



## 2. Period-after-opening



## 3. Date of minimum durability



## ANNEX VIII

**LIST OF VALIDATED ALTERNATIVE METHODS TO ANIMAL TESTING**

This Annex lists the alternative methods validated by the European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre available to meet the requirements of this Regulation and which are not listed in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). As animal testing may not be replaced completely by an alternative method, it should be mentioned in Annex VIII whether the alternative method fully or partially replaces animal testing.

Reference number	Validated alternative methods	Nature of replacement full or partial
A	B	C

## ANNEX IX

## PART A

**Repealed Directive with its successive amendments****(referred to in Article 33)**

Council Directive 76/768/EEC of 27 July 1976	(OJ L 262, 27.9.1976, p. 169)
Council Directive 79/661/EEC of 24 July 1979	(OJ L 192, 31.7.1979, p. 35)
Commission Directive 82/147/EEC of 11 February 1982	(OJ L 63, 6.3.1982, p. 26)
Council Directive 82/368/EEC of 17 May 1982	(OJ L 167, 15.6.1982, p. 1)
Commission Directive 83/191/EEC of 30 March 1983	(OJ L 109, 26.4.1983, p. 25)
Commission Directive 83/341/EEC of 29 June 1983	(OJ L 188, 13.7.1983, p. 15)
Commission Directive 83/496/EEC of 22 September 1983	(OJ L 275, 8.10.1983, p. 20)
Council Directive 83/574/EEC of 26 October 1983	(OJ L 332, 28.11.1983, p. 38)
Commission Directive 84/415/EEC of 18 July 1984	(OJ L 228, 25.8.1984, p. 31)
Commission Directive 85/391/EEC of 16 July 1985	(OJ L 224, 22.8.1985, p. 40)
Commission Directive 86/179/EEC of 28 February 1986	(OJ L 138, 24.5.1986, p. 40)
Commission Directive 86/199/EEC of 26 March 1986	(OJ L 149, 3.6.1986, p. 38)
Commission Directive 87/137/EEC of 2 February 1987	(OJ L 56, 26.2.1987, p. 20)
Commission Directive 88/233/EEC of 2 March 1988	(OJ L 105, 26.4.1988, p. 11)
Council Directive 88/667/EEC of 21 December 1988	(OJ L 382, 31.12.1988, p. 46)
Commission Directive 89/174/EEC of 21 February 1989	(OJ L 64, 8.3.1989, p. 10)
Council Directive 89/679/EEC of 21 December 1989	(OJ L 398, 30.12.1989, p. 25)
Commission Directive 90/121/EEC of 20 February 1990	(OJ L 71, 17.3.1990, p. 40)
Commission Directive 91/184/EEC of 12 March 1991	(OJ L 91, 12.4.1991, p. 59)
Commission Directive 92/8/EEC of 18 February 1992	(OJ L 70, 17.3.1992, p. 23)
Commission Directive 92/86/EEC of 21 October 1992	(OJ L 325, 11.11.1992, p. 18)
Council Directive 93/35/EEC of 14 June 1993	(OJ L 151, 23.6.1993, p. 32)
Commission Directive 93/47/EEC of 22 June 1993	(OJ L 203, 13.8.1993, p. 24)
Commission Directive 94/32/EC of 29 June 1994	(OJ L 181, 15.7.1994, p. 31)
Commission Directive 95/17/EC of 19 June 1995	(OJ L 140, 23.6.1995, p. 26)
Commission Directive 95/34/EC of 10 July 1995	(OJ L 167, 18.7.1995, p. 19)
Commission Directive 96/41/EC of 25 June 1996	(OJ L 198, 8.8.1996, p. 36)
Commission Directive 97/1/EC of 10 January 1997	(OJ L 16, 18.1.1997, p. 85)
Commission Directive 97/18/EC of 17 April 1997	(OJ L 114, 1.5.1997, p. 43)
Commission Directive 97/45/EC of 14 July 1997	(OJ L 196, 24.7.1997, p. 77)
Commission Directive 98/16/EC of 5 March 1998	(OJ L 77, 14.3.1998, p. 44)
Commission Directive 98/62/EC of 3 September 1998	(OJ L 253, 15.9.1998, p. 20)
Commission Directive 2000/6/EC of 29 February 2000	(OJ L 56, 1.3.2000, p. 42)
Commission Directive 2000/11/EC of 10 March 2000	(OJ L 65, 14.3.2000, p. 22)
Commission Directive 2000/41/EC of 19 June 2000	(OJ L 145, 20.6.2000, p. 25)
Commission Directive 2002/34/EC of 15 April 2002	(OJ L 102, 18.4.2002, p. 19)
Commission Directive 2003/1/EC of 6 January 2003	(OJ L 5, 10.1.2003, p. 14)

Commission Directive 2003/16/EC of 19 February 2003	(OJ L 46, 20.2.2003, p. 24)
Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003	(OJ L 66, 11.3.2003, p. 26)
Commission Directive 2003/80/EC of 5 September 2003	(OJ L 224, 6.9.2003, p. 27)
Commission Directive 2003/83/EC of 24 September 2003	(OJ L 238, 25.9.2003, p. 23)
Commission Directive 2004/87/EC of 7 September 2004	(OJ L 287, 8.9.2004, p. 4)
Commission Directive 2004/88/EC of 7 September 2004	(OJ L 287, 8.9.2004, p. 5)
Commission Directive 2004/94/EC of 15 September 2004	(OJ L 294, 17.9.2004, p. 28)
Commission Directive 2004/93/EC of 21 September 2004	(OJ L 300, 25.9.2004, p. 13)
Commission Directive 2005/9/EC of 28 January 2005	(OJ L 27, 29.1.2005, p. 46)
Commission Directive 2005/42/EC of 20 June 2005	(OJ L 158, 21.6.2005, p. 17)
Commission Directive 2005/52/EC of 9 September 2005	(OJ L 234, 10.9.2005, p. 9)
Commission Directive 2005/80/EC of 21 November 2005	(OJ L 303, 22.11.2005, p. 32)
Commission Directive 2006/65/EC of 19 July 2006	(OJ L 198, 20.7.2006, p. 11)
Commission Directive 2006/78/EC of 29 September 2006	(OJ L 271, 30.9.2006, p. 56)
Commission Directive 2007/1/EC of 29 January 2007	(OJ L 25, 1.2.2007, p. 9)
Commission Directive 2007/17/EC of 22 March 2007	(OJ L 82, 23.3.2007, p. 27)
Commission Directive 2007/22/EC of 17 April 2007	(OJ L 101, 18.4.2007, p. 11)
Commission Directive 2007/53/EC of 29 August 2007	(OJ L 226, 30.8.2007, p. 19)
Commission Directive 2007/54/EC of 29 August 2007	(OJ L 226, 30.8.2007, p. 21)
Commission Directive 2007/67/EC of 22 November 2007	(OJ L 305, 23.11.2007, p. 22)
Commission Directive 2008/14/EC of 15 February 2008	OJ L 42, 16.2.2008, p. 43
Commission Directive 2008/42/EC of 3 April 2008	OJ L 93, 4.4.2008, p. 13
Commission Directive 2008/88/EC of 23 September 2008	OJ L 256, 24.9.2008, p. 12
Commission Directive 2008/123/EC of 18 December 2008	OJ L 340, 19.12.2008, p. 71
Commission Directive 2009/6/EC of 4 February 2009	OJ L 36, 5.2.2009, p. 15
Commission Directive 2009/36/EC of 16 April 2009	OJ L 98, 17.4.2009, p. 31

## PART B

**List of time-limits for transposition into national law and application  
(referred to in Article 33)**

Directive	Time-limit for transposition
Council Directive 76/768/EEC of 27 July 1976	30.1.1978
Council Directive 79/661/EEC of 24 July 1979	30.7.1979
Commission Directive 82/147/EEC of 11 February 1982	31.12.1982
Council Directive 82/368/EEC of 17 May 1982	31.12.1983
Commission Directive 83/191/EEC of 30 March 1983	31.12.1984
Commission Directive 83/341/EEC of 29 June 1983	31.12.1984
Commission Directive 83/496/EEC of 22 September 1983	31.12.1984
Council Directive 83/574/EEC of 26 October 1983	31.12.1984
Commission Directive 84/415/EEC of 18 July 1984	31.12.1985
Commission Directive 85/391/EEC of 16 July 1985	31.12.1986

Directive	Time-limit for transposition
Commission Directive 86/179/EEC of 28 February 1986	31.12.1986
Commission Directive 86/199/EEC of 26 March 1986	31.12.1986
Commission Directive 87/137/EEC of 2 February 1987	31.12.1987
Commission Directive 88/233/EEC of 2 March 1988	30.9.1988
Council Directive 88/667/EEC of 21 December 1988	31.12.1993
Commission Directive 89/174/EEC of 21 February 1989	31.12.1989
Council Directive 89/679/EEC of 21 December 1989	3.1.1990
Commission Directive 90/121/EEC of 20 February 1990	31.12.1990
Commission Directive 91/184/EEC of 12 March 1991	31.12.1991
Commission Directive 92/8/EEC of 18 February 1992	31.12.1992
Commission Directive 92/86/EEC of 21 October 1992	30.6.1993
Council Directive 93/35/EEC of 14 June 1993	14.6.1995
Commission Directive 93/47/EEC of 22 June 1993	30.6.1994
Commission Directive 94/32/EC of 29 June 1994	30.6.1995
Commission Directive 95/17/EC of 19 June 1995	30.11.1995
Commission Directive 95/34/EC of 10 July 1995	30.6.1996
Commission Directive 96/41/EC of 25 June 1996	30.6.1997
Commission Directive 97/1/EC of 10 January 1997	30.6.1997
Commission Directive 97/18/EC of 17 April 1997	31.12.1997
Commission Directive 97/45/EC of 14 July 1997	30.6.1998
Commission Directive 98/16/EC of 5 March 1998	1.4.1998
Commission Directive 98/62/EC of 3 September 1998	30.6.1999
Commission Directive 2000/6/EC of 29 February 2000	1.7.2000
Commission Directive 2000/11/EC of 10 March 2000	1.6.2000
Commission Directive 2000/41/EC of 19 June 2000	29.6.2000
Commission Directive 2002/34/EC of 15 April 2002	15.4.2003
Commission Directive 2003/1/EC of 6 January 2003	15.4.2003
Commission Directive 2003/16/EC of 19 February 2003	28.2.2003
Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003	10.9.2004
Commission Directive 2003/80/EC of 5 September 2003	11.9.2004
Commission Directive 2003/83/EC of 24 September 2003	23.9.2004
Commission Directive 2004/87/EC of 7 September 2004	1.10.2004
Commission Directive 2004/88/EC of 7 September 2004	1.10.2004
Commission Directive 2004/94/EC of 15 September 2004	21.9.2004
Commission Directive 2004/93/EC of 21 September 2004	30.9.2004
Commission Directive 2005/9/EC of 28 January 2005	16.2.2006
Commission Directive 2005/42/EC of 20 June 2005	31.12.2005
Commission Directive 2005/52/EC of 9 September 2005	1.1.2006
Commission Directive 2005/80/EC of 21 November 2005	22.5.2006
Commission Directive 2006/65/EC of 19 July 2006	1.9.2006
Commission Directive 2006/78/EC of 29 September 2006	30.3.2007

Directive	Time-limit for transposition
Commission Directive 2007/1/EC of 29 January 2007	21.8.2007
Commission Directive 2007/17/EC of 22 March 2007	23.9.2007
Commission Directive 2007/22/EC of 17 April 2007	18.1.2008
Commission Directive 2007/53/EC of 29 August 2007	19.4.2008
Commission Directive 2007/54/EC of 29 August 2007	18.3.2008
Commission Directive 2007/67/EC of 22 November 2007	31.12.2007
Commission Directive 2008/14/EC of 15 February 2008	16.8.2008
Commission Directive 2008/42/EC of 3 April 2008	4.10.2008
Commission Directive 2008/88/EC of 23 September 2008	14.2.2009
Commission Directive 2008/123/EC of 18 December 2008	8.7.2009
Commission Directive 2009/6/EC of 4 February 2009	5.8.2009
Commission Directive 2009/36/EC of 16 April 2009	15.11.2009

## ANNEX X

## CORRELATION TABLE

Directive 76/768/EEC	This Regulation
Article 1	Article 2(1)(a)
Article 2	Article 3
Article 3	—
Article 4(1)	Article 14(1)
Article 4(2)	Article 17
Article 4a	Article 18
Article 4b	Article 15(1)
Article 5	—
Article 5a	Article 33
Article 6(1),(2)	Article 19(1),(2),(3),(4)
Article 6(3)	Article 20
Article 7(1)	Article 9
Article 7(2)	Article 19(5), (6)
Article 7(3)	Article 13
Article 7a (1) (h)	Article 21
Article 7a(1),(2),(3)	Article 10, 11, Annex I
Article 7a(4)	Article 13
Article 7a(5)	Article 29, 34
Article 8(1)	Article 12
Article 8(2)	Article 31
Article 8a	—
Article 9	Article 35
Article 10	Article 32
Article 11	—
Article 12	Article 27
Article 13	Article 28
Article 14	—
Article 15	—
Annex I	Preamble, No. 7
Annex II	Annex II
Annex III	Annex III
Annex IV	Annex IV
Annex V	—
Annex VI	Annex V
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Annex VIII	Annex VII
Annex VIIIa	Annex VII
Annex IX	Annex VIII
—	Annex IX
—	Annex X





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