

DECISIONS ADOPTED JOINTLY BY THE EUROPEAN PARLIAMENT AND THE  
COUNCIL

DECISION No 1348/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 December 2008

**amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate**

(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) The risks posed to human health by 2-(2-methoxyethoxy)ethanol (DEGME), 2-(2-butoxyethoxy)ethanol (DEGBE), methylenediphenyl diisocyanate (MDI) and cyclohexane have been assessed in accordance with Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances <sup>(3)</sup>. The risk assessment for all these chemical substances identified the need to limit the risks posed to human health. Those conclusions were confirmed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment.

(2) Commission Recommendations 1999/721/EC of 12 October 1999 on the results of the risk evaluation and on the risk reduction strategies for the substances: 2-(2-butoxyethoxy)ethanol; 2-(2-methoxyethoxy)ethanol;

Alkanes, C10-13, chloro; Benzene, C10-13-alkyl derivs. <sup>(4)</sup> and 2008/98/EC of 6 December 2007 on risk reduction measures for the substances: Piperazine; Cyclohexane; Methylenediphenyl diisocyanate; But-2yne-1,4-diol; Methyloxirane; Aniline; 2-Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; 5-tert-butyl-2,4,6-trinitro-m-xylene <sup>(5)</sup>, adopted within the framework of Regulation (EEC) No 793/93, proposed a strategy for limiting the risks for DEGME, DEGBE, MDI and cyclohexane respectively, recommending that restriction measures under Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations <sup>(6)</sup> must be applied for preparations containing these substances placed on the market for supply to the general public.

(3) In order to protect consumers, it therefore appears necessary to restrict the placing on the market and the use of preparations containing DEGME, DEGBE, MDI or cyclohexane for specific applications.

(4) DEGME is very rarely used as a constituent of consumer paints, paint strippers, cleaning agents, self-shining emulsions and floor sealants. The aforementioned risk assessment has shown that there is a risk to the health of consumers through dermal exposure to paints and paint-strippers containing DEGME. DEGME used as a constituent of paints and paint strippers should therefore not be placed on the market for supply to the general public. Even though the use of DEGME as a constituent of cleaning agents, self-shining emulsions and floor sealants has not been assessed, it may pose a similar risk and therefore DEGME used as a constituent of those preparations should also not be placed on the market for supply to the general public. A limit value of 0,1 % by mass of DEGME in those preparations should be adopted for market surveillance purposes.

<sup>(1)</sup> OJ C 204, 9.8.2008, p. 13.

<sup>(2)</sup> Opinion of the European Parliament of 9 July 2008 (not yet published in the Official Journal) and Decision of the Council of 18 November 2008.

<sup>(3)</sup> OJ L 84, 5.4.1993, p. 1.

<sup>(4)</sup> OJ L 292, 13.11.1999, p. 42.

<sup>(5)</sup> OJ L 33, 7.2.2008, p. 8.

<sup>(6)</sup> OJ L 262, 27.9.1976, p. 201.

- (5) DEGBE is used as a constituent of paints and cleaners. The aforementioned risk assessment for DEGBE has shown that there is a risk to the health of consumers through inhalation exposure during spray painting application. A derived safe concentration limit of 3 % for DEGBE in spray paints should be introduced to prevent the risk of inhalation exposure for consumers. Even though the use of DEGBE as a constituent of spray cleaners in aerosol dispensers has not been assessed, it may pose a similar risk and therefore DEGBE used as a constituent of those cleaners should also not be placed on the market for supply to the general public in concentrations equal to or greater than 3 % by mass. Aerosol dispensers should comply with the requirements of Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers <sup>(1)</sup>.
- (6) For paints other than spray paints, a warning against using such paints in spraying equipment should be required where those paints contain DEGBE in a concentration which is equal to or greater than 3 % by mass.
- (7) In order to ensure an appropriate phase-out of spray paints and spray cleaners in aerosol dispensers not meeting the concentration limits for DEGBE, different dates should be fixed for the applicability of the restriction in respect of the first placing on the market and the final sale for DEGBE in spray paints and spray cleaners in aerosol dispensers.
- (8) The risk assessment for MDI has shown that there is a need to limit the risks during consumer applications of preparations containing MDI due to concerns relating to inhalation and dermal exposure. To prevent and limit these risks, the placing on the market for supply to the general public of preparations containing MDI should be permitted only under certain conditions such as the mandatory supply of appropriate protective gloves and of additional instructions with the packaging. These gloves should comply with the requirements of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment <sup>(2)</sup>. As the provision of the protective equipment and the printing of relevant instructions will require specific efforts by producers, a longer period of transition should be provided.
- (9) The risk assessment for cyclohexane focused on the exposure of consumers during the use of preparations containing cyclohexane for carpet laying and concluded that restriction measures were necessary to limit the risk for consumers during such applications. Neoprene-based contact adhesives containing cyclohexane should therefore only be placed on the market for supply to the general public with a reduced package size. Harmonised instructions provided with the product should warn consumers against use under conditions of poor ventilation or for carpet laying.
- (10) Ammonium nitrate, which is widely used throughout the Community as a fertiliser, can act as an oxidising agent. In particular, it has the ability to explode when mixed with certain other substances. Ammonium nitrate fertilisers should therefore meet certain requirements when placed on the market to ensure that they are safe against accidental detonation.
- (11) Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers <sup>(3)</sup> provides for harmonised requirements, including safety requirements, for ammonium nitrate fertilisers. Fertilisers complying with those requirements may be labelled 'EC fertiliser' and may circulate freely within the internal market.
- (12) For fertilisers intended for sale only within a single Member State, manufacturers may choose to conform only to requirements existing at national level. Therefore those fertilisers may not comply with the safety requirements set at Community level. To ensure a uniform level of safety within the Community, all ammonium nitrate fertilisers should therefore conform to the same safety requirements.
- (13) Annex III to Regulation (EC) No 2003/2003 specifies a test of resistance to detonation for ammonium nitrate fertilisers containing more than 28 % by mass of nitrogen in relation to ammonium nitrate. It also specifies a number of physical characteristics and limits on the chemical impurity content for such fertilisers in order to minimise the risk of detonation. Ammonium nitrate fertilisers that comply with those requirements, or that contain less than 28 % by mass of nitrogen, are accepted by all Member States as being safe for use in agriculture.
- (14) All ammonium nitrate fertilisers placed on the market within the Community should therefore conform to the safety requirements set out in Regulation (EC) No 2003/2003.

<sup>(1)</sup> OJ L 147, 9.6.1975, p. 40.

<sup>(2)</sup> OJ L 399, 30.12.1989, p. 18.

<sup>(3)</sup> OJ L 304, 21.11.2003, p. 1.

- (15) Ammonium nitrate fertilisers have been misused for the illicit manufacture of explosives. Fertiliser types that can be used for this purpose have a nitrogen content as low as 16 %. Access to fertiliser types and types of preparations that contain more than 16 % by mass of nitrogen in relation to ammonium nitrate should therefore be limited to farmers and professional users. For this purpose, the concepts of 'farmer' and 'agricultural activity' need to be defined so that farming and other similar professional activities such as the maintenance of parks, gardens or sport pitches can still benefit from the use of fertilisers with a higher content of nitrogen. Member States may, however, for socio-economic reasons, apply a limit of up to 20 % by mass of nitrogen in relation to ammonium nitrate for their territories.
- (16) The provisions of this Decision are adopted with a view to being incorporated into Annex XVII to 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, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC<sup>(1)</sup> as set out in Article 137(3) of that Regulation.
- (17) Directive 76/769/EEC should be amended accordingly.
- (18) This Decision is without prejudice to the Community legislation laying down minimum requirements for the protection of workers, such as Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and

health of workers at work<sup>(2)</sup> and individual Directives based thereon, in particular Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC (codified version)<sup>(3)</sup> and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>(4)</sup>,

HAVE ADOPTED THIS DECISION:

*Article 1*

Annex I to Directive 76/769/EEC is hereby amended in accordance with the Annex to this Decision.

*Article 2*

This Decision shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

*Article 3*

This Decision is addressed to the Member States.

Done at Strasbourg, 16 December 2008.

*For the European Parliament*  
The President  
H.-G. PÖTTERING

*For the Council*  
The President  
B. LE MAIRE

<sup>(1)</sup> OJ L 396, 30.12.2006, p. 1. Corrected by OJ L 136, 29.5.2007, p. 3.

<sup>(2)</sup> OJ L 183, 29.6.1989, p. 1.

<sup>(3)</sup> OJ L 158, 30.4.2004, p. 50. Corrected by OJ L 229, 29.6.2004, p. 23.

<sup>(4)</sup> OJ L 131, 5.5.1998, p. 11.

## ANNEX

In Annex I to Directive 76/769/EEC, the following points are added:

<p>53. 2-(2-methoxyethoxy) ethanol (DEGME) CAS No: 111-77-3 Einecs No: 203-906-6</p>	<p>Shall not be placed on the market after 27 June 2010, for supply to the general public, as a constituent of paints, paint strippers, cleaning agents, self-shining emulsions or floor sealants in concentrations equal to or greater than 0,1 % by mass.</p>
<p>54. 2-(2-butoxyethoxy) ethanol (DEGBE) CAS No: 112-34-5 Einecs No: 203-961-6</p>	<p>(1) Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of spray paints or spray cleaners in aerosol dispensers in concentrations equal to or greater than 3 % by mass.</p> <p>(2) Spray paints and spray cleaners in aerosol dispensers containing DEGBE and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.</p> <p>(3) Without prejudice to other Community legislation concerning the classification, packaging and labelling of dangerous substances and preparations, paints, other than spray paints, containing DEGBE in concentrations equal to or greater than 3 % by mass that are placed on the market for supply to the general public shall be visibly, legibly and indelibly marked by 27 December 2010 as follows:</p> <p>“Do not use in paint spraying equipment”.</p>
<p>55. Methylenediphenyl diisocyanate (MDI) CAS No: 26447-40-5 Einecs No: 247-714-0</p>	<p>(1) Shall not be placed on the market after 27 December 2010, as a constituent of preparations in concentrations equal to or greater than 0,1 % by mass for supply to the general public, unless the packaging:</p> <p>(a) contains protective gloves which comply with the requirements of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (*).</p> <p>(b) is marked visibly, legibly and indelibly as follows, and without prejudice to other Community legislation concerning the classification, packaging and labelling of dangerous substances and preparations:</p> <p>— Persons already sensitised to diisocyanates may develop allergic reactions when using this product.</p> <p>— Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product.</p> <p>— This product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used.”</p> <p>(2) By way of derogation, paragraph 1(a) shall not apply to hot melt adhesives.</p>
<p>56. Cyclohexane CAS No: 110-82-7 Einecs No: 203-806-2</p>	<p>(1) Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of neoprene-based contact adhesives in concentrations equal to or greater than 0,1 % by mass in package sizes greater than 350 g.</p> <p>(2) Neoprene-based contact adhesives containing cyclohexane and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.</p> <p>(3) Without prejudice to other Community legislation concerning the classification, packaging and labelling of dangerous substances and preparations, neoprene-based contact adhesives containing cyclohexane in concentrations equal to or greater than 0,1 % by mass that are placed on the market for supply to the general public after 27 December 2010 shall be visibly, legibly and indelibly marked as follows:</p> <p>— This product is not to be used under conditions of poor ventilation.</p> <p>— This product is not to be used for carpet laying.”</p>

57. Ammonium nitrate (AN) CAS No 6484-52-2 Einecs No 229-347-8	<p>(1) Shall not be placed on the market for the first time after 27 June 2010 as a substance, or in preparations that contain more than 28 % by mass of nitrogen in relation to ammonium nitrate, for use as a solid fertiliser, straight or compound, unless the fertiliser complies with the technical provisions for ammonium nitrate fertilisers of high nitrogen content set out in Annex III to Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (**).</p> <p>(2) Shall not be placed on the market after 27 June 2010 as a substance, or in preparations that contain 16 % or more by mass of nitrogen in relation to ammonium nitrate except for supply to:</p> <p>(a) downstream users and distributors, including natural or legal persons licensed or authorised in accordance with Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil use (**);</p> <p>(b) farmers for use in agricultural activities, either full time or part time and not necessarily related to the size of the land area.</p> <p>For the purposes of this subparagraph:</p> <p>(i) "farmer" shall mean a natural or legal person, or a group of natural or legal persons, whatever legal status is granted to the group and its members by national law, whose holding is situated within Community territory, as referred to in Article 299 of the Treaty, and who exercises an agricultural activity,</p> <p>(ii) "agricultural activity" shall mean the production, rearing or growing of agricultural products including harvesting, milking, breeding animals and keeping animals for farming purposes, or maintaining the land in good agricultural and environmental condition as established under Article 5 of Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers (****);</p> <p>(c) natural or legal persons engaged in professional activities such as horticulture, plant growing in greenhouses, maintenance of parks, gardens or sport pitches, forestry or other similar activities.</p> <p>(3) However, for the restrictions in paragraph 2, Member States may until 1 July 2014, for socioeconomic reasons, apply a limit of up to 20 % by mass of nitrogen in relation to ammonium nitrate for substances and preparations placed on the market within their territories. They shall inform the Commission and other Member States thereof.</p>
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(\*) OJ L 399, 30.12.1989, p. 18.

(\*\*) OJ L 304, 21.11.2003, p. 1.

(\*\*\*) OJ L 121, 15.5.1993, p. 20.

(\*\*\*\*) OJ L 270, 21.10.2003, p. 1.