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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**Pursuant to Article 16 of Regulation (EC) No 648/2004 of the European Parliament and
of the Council of 31 March 2004 on detergents, concerning the biodegradation of main
non-surfactant organic detergent ingredients**

(Text with EEA relevance)

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1. INTRODUCTION TO NON-SURFACTANT ORGANIC INGREDIENTS

Article 16(2) of Regulation (EC) No 648/2004 on detergents¹ lays down that: “by 8 April 2009, the Commission shall carry out a review of the application of this Regulation, paying particular regard to the biodegradability of surfactants, and shall evaluate, submit a report on, and, where justified, present legislative proposals relating to:

- anaerobic biodegradation;
- **the biodegradation of main non-surfactant organic detergent ingredients”.**

This report will present the results of the Commission's review on the biodegradation of the main non-surfactant organic ingredients in detergents.

Apart from surfactants and builders (water-softening agents), detergent products contain a number of non-surfactant organic and inorganic ingredients. Table-1 lists the main groups of non-surfactant chemicals together with an outline of their role in detergents.

Table 1: Non-surfactant Detergent Ingredients (RPA, 2006)²

Chemical ingredient	Purpose
Acids-Bases	To ensure optimal pH of wash water
Bleaching agents, Activators and Stabilisers	Enhanced cleaning performance
Builders, complexing agents and Ion exchangers	Water-softening to maximise cleaning efficiency (i.e. removing dirt and keeping it in suspension)
Corrosion inhibitors	To prevent corrosion of washing machines
Dyes	To add colour to detergents
Dye transfer inhibitors	To prevent loss of garment dyes
Enzymes	‘Biological’ cleaning
Fluorescent whitening agents	Optical brightening
Foam regulators	To limit foam generation (machine washing)
Formulation aids	To improve detergent performance
Soil repellents/anti-redeposition	To prevent re-deposition of dirt during

¹ OJ L104, 8.4.2004, p. 1

² RPA report available at: http://ec.europa.eu/enterprise/chemicals/legislation/detergents/index_en.htm

agents	washing
Solvents	To keep ingredients in solution (particularly in liquid detergents)

Inorganic ingredients (e.g inorganic bases or bleaching agents) for which biodegradation is not applicable are not further considered in this report.

For the most important and commonly used non-surfactant organic ingredients a brief overview of their uses, the quantities used and their biodegradation characteristics is given below in Table 2.

Table 2: Overview of main non-surfactant organic detergent ingredients

Group of substances	Main ingredients	EU Consumption in detergents (tonnes/year)	Biodegradation
Acids	Acetic, Citric, Adipic	Citric acid: 100 000 t/year ³	Readily biodegradable
Builders, Complexing Agents and Ion Exchangers	(a) Phosphonates (b) Polycarboxylates (c) Ethylenediamine tetra acetate (EDTA) and salts Nitrilotriacetic-acid (NTA)	~ 30 000t/y ⁴ (AISE input for 2007) ~ 80.000 t/y (AISE input for 2007) ~ 11 600 and 1 800 t/y (in I&I and household detergent respectively) ⁵ > 20 000 t/y mainly in I&I detergents ⁶	Biodegradation aspects of these are analysed in sections 2 and 3
Dye transfer inhibitors	Polyvinylpyrrolidone-(PVP) is the most commonly used dye transfer inhibitor	~ 100 t/y	Not readily biodegradable
Enzymes	Proteases, α -amylases, (lipase, cellulases in small quantities)	Protease: ~ 1 000 t/y α -amylase: 150 t/y ⁷	Readily biodegradable
Fluorescent Whitening Agents (FWAs)	FWA-1 (CAS No: 273444-41-8) FWA-5 (CAS No: 16090-02-1)	2100 t/y 600 t/y ⁸	FWA-5 not readily biodegradable
Foam Regulators	n-paraffins	5 000 t/y	n-paraffins readily biodegradable

³ http://www.heraproject.com/files/37-F-05-HERA_citricacid_version1_April05.pdf

⁴ <http://www.heraproject.com/files/30-F-04-%20HERA%20Phosphonates%20Full%20web%20wd.pdf>

⁵ http://www.baua.de/nr_8874/de/Chemikaliengesetz-Biozidverfahren/Dokumente/RAR_062.pdf

⁶ http://ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/ntaENVsum307.pdf

⁷ http://www.heraproject.com/files/38-F-Hera_Bridging_document_28.10.05.pdf

⁸ <http://www.heraproject.com/files/11-F-04-HERA%20FWA5%20Full%20web%20wd.pdf>

	Polydimethyl siloxane (PDMS)	7 200 t/y ⁹	PDMS classified as very persistent
Formulation Aids	Toluene	17 000 t/year ¹⁰	Rapidly degrade under aerobic conditions
Anti-Redeposition Agents	Carboxymethyl cellulose (CMC)	20 000 t/year	Poorly biodegradable
Solvents	Various alcohols (ethanol, isopropanol, 2-butoxy ethanol, 1-decanol, glycerol) and triethanolamine (TEA)		Readily biodegradable with exceptions of TEA

The Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) gave an opinion¹¹ in March 2003 concluding, amongst others, that more information was needed on the health and environmental risks associated with the co-builders in detergents. The SCTEE considered that although considerable progress has been made in relation to surfactants, and in particular with regard to their biodegradability, through the implementation of the Detergents Regulation there remain some concern over other chemical ingredients in detergents, in particular with regard to certain organic compounds.

2. STUDY ON NON-SURFACTANT DETERGENT ORGANIC INGREDIENTS

2.1. Main findings concerning “Non-surfactant organic ingredients and zeolite-based detergents”

In 2005, the Commission services contracted a study to RPA (Risk & Policy Analysts Ltd) in order to fill the data gaps identified in the CSTEE opinion concerning the use, properties and environmental impacts for a representative range of non-surfactant organic detergent ingredients. The final report entitled “Non-surfactant organic ingredients and zeolite-based detergents”¹², was delivered in June 2006, and served as the basis for the Commission to review the biodegradation of the main non-surfactant organic ingredients in detergent formulations.

The RPA study examined the properties of about 50 representative detergent ingredients that belong to the groups of substances presented in Table 1. The substances which are readily biodegradable with no other properties of potential concern (such as high aquatic toxicity) were considered unlikely to present significant risks to human health or to the environment and were not analysed further. The substances or groups of substances retained for further analysis were those that are not readily biodegradable or that have properties of potential concern.

⁹ Environmental Risk Assessment of Polydimethylsiloxane used in Detergent Applications, report prepared for the Centre Européen des Silicones, dated 15 March 2006

¹⁰ <http://www.heraproject.com/files/24-F-HERA%20Hydrotropes%20Sept%202005.pdf>

¹¹ http://ec.europa.eu/health/ph_risk/committees/sct/sct_opinions_en.htm

¹² available at: http://ec.europa.eu/enterprise/chemicals/legislation/detergents/index_en.htm

The screening exercise of RPA resulted in a list of specific substances and substance groups being selected for further analysis, based on scientific evidence available from the various risk assessments. The findings were:

(1) Builders, Complexing Agents and Ion Exchangers

- (a) *Phosphonates*: There is a broad consensus that phosphonates degrade slowly and may present a risk to the environment with concern being focused on the potential aquatic chronic toxicity of HEDP (1- hydroxy ethane diphosphonic acid) and its salts to Daphnia.
- (b) *Polycarboxylates*: Polycarboxylates do not readily biodegrade, and while there are no available monitoring data, concentrations in sludge-treated soils may be significant.
- (c) *EDTA and its salts*: Available data indicate that EDTA and its salts may be of concern to the environment with regard to their use in industrial and institutional (I&I) cleaning - but not for household detergents where their use is limited. (ECB, 2004)¹³.
- (d) *Nitrilotriacetic acid (NTA)*: There is consensus that NTA is readily biodegradable using a range of standard tests – although, in some cases, the formation of metal-NTA complexes may slow the rate of degradation (ECB, 2005)¹⁴.

More information on the environmental effects of phosphonates, polycarboxylates, EDTA and NTA are given in section 3 below.

- (2) *Polyvinylpyrrolidone (PVP)*: PVP does not pose a risk for human health and there appears to be a general consensus that this is of limited environmental concern. Nevertheless, further data would be desirable to demonstrate that PVP presents no significant environmental risks.
- (3) *Fluorescent whitening agent FWA-5*: The reported concentrations of FWA-5 in the environment are more than an order of magnitude below the Predicted No Effect Concentration (PNEC). On this basis, FWA-5 is unlikely to present a significant risk to human health or to the environment. However, there remains the possibility that the degradation products are of potential concern.
- (4) *Foam regulators – in particular paraffins (assumed to be C10-C16 n-paraffins) and polydimethyl siloxane (PDMS)*: For n-paraffins, it is unlikely that significant amounts will reach the environment due to a combination of rapid biodegradation and waste water treatment. Nevertheless, available data on properties such as aquatic toxicity and bioaccumulation are highly uncertain which make it difficult to conclude with confidence that there are no risks to the environment. For PDMS, although considered

¹³ http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/edtasum061.pdf

¹⁴ http://ecb.jrc.ec.europa.eu/documents/ExistingChemicals/RISK_ASSESSMENT/SUMMARY/ntaENVsum307.

to be persistent, it degrades in the environment – particularly in dry, clay soils. Furthermore, there are few concerns over the risks associated with the higher molecular weight PDMS compounds used in detergents.

- (5) *Anti-redeposition agents – in particular carboxymethyl-cellulose (CMC)*: It is unlikely that the use of CMC in detergents presents significant risks to human health or to the environment due to its low toxicity. However, further data on levels found in the environment would be needed to properly substantiate this view.
- (6) *Solvents - in particular 1-decanol and triethanolamine*: It is unlikely that the use of 1-decanol in detergents presents significant risks to human health or to the environment due to its rapid biodegradation. Further data are required to reach a firm conclusion on whether triethanolamine is likely to be of concern.

Overall, the analysis conducted by RPA on non-surfactant organic detergents ingredients concluded that even persistent ingredients may not pose risks for the environment (i.e. the PEC/PNEC ratio is less than one) due to environmental degradation and/or low environmental toxicity. Sufficient information on the biodegradability of particular ingredients is available and further testing is not deemed necessary.

2.2. Aspects on biodegradation and waste-water treatment of non-surfactant organic ingredients

The regulatory approach adopted in the EU for surfactants as organic ingredients of detergents is that they must be aerobically biodegradable. Organic substances that biodegrade under aerobic conditions are likely to be broken down in waste water treatment plants. The two key parameters in biodegradation are the degree to which the ingredients will ultimately biodegrade and the rate of biodegradation.

According to the findings of the study conducted by RPA, the primary and secondary phases of waste water treatment are likely to result in the substantial removal of many of the ingredients of potential concern which will limit discharges to the aquatic environment. However, EDTA is not removed by waste water treatment and TEA may be only partially removed. Furthermore, there is insufficient data to comment on whether detergent dyes will be removed by waste water treatment. Although there were insufficient monitoring data to provide confirmation, RPA considered that it is likely that PVP and CMC will be removed during waste water treatment due to adsorption to the sludge.

3. OPINIONS OF THE SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER)

3.1. 2007 SCHER opinion on RPA report concerning non-surfactant organic ingredients

In December 2006, the Commission requested the Scientific Committee on Health and Environmental Risks (SCHER) to assess the overall scientific quality of the RPA report and to comment on the methodology and the assumptions used. SCHER was asked to comment whether the RPA conclusions concerning the reviewed non-surfactant detergents ingredients are valid and in agreement with existing literature. Particular consideration should be given to the results concerning the health and environmental risks of the following co-builders in detergents formulations, for which the analysis by RPA indicated that either concern or some

uncertainties existed: (i) EDTA and EDTA tetrasodium salts (ii) Nitrilotriacetic acid (NTA), (iii) Phosphonates, and (iv) Polycarboxylates.

In June 2007, after considering all the available evidence on non-surfactant detergent organic ingredients, SCHER published a scientific opinion¹⁵ entitled “Non-surfactant Organic Ingredients and Zeolite-based Detergents”. The opinion considered that most of the assumptions used in the RPA study were acceptable and that the overall quality of the report was good. SCHER agreed that the RPA study constituted a reliable factual basis concerning non-surfactant organic ingredients in detergent formulations. Concerning the biodegradation properties and subsequent environmental risks of each of the four above-mentioned categories of detergent builders, the SCHER opinion concluded:

- (1) **EDTA and tetrasodium EDTA:** SCHER confirmed the earlier scientific opinion of SCTEE¹⁶, that there is no risk from the use of EDTA in household detergents, whilst for some other applications (industrial detergents, paper mills, circuit board producers etc) a more precise exposure assessment is needed to exclude potential risks.
- (2) **Nitrilotriacetic Acid (NTA and salts):** SCHER endorsed the conclusion of its earlier opinion¹⁷ that there are no environmental risks for all production and use patterns. Furthermore, SCHER underlined that in terms of health risks, although there is a clear evidence of carcinogenicity in rats and mice, no human carcinogenic data or evidence of teratogenicity and mutagenicity is available.
- (3) **Phosphonates:** Based on preliminary assessments and mainly considering the RPA and HERA reports, SCHER concluded that a potential risk for phosphonates used in zeolite-based (“phosphate-free”) compact powders has been identified for the aquatic and terrestrial (agricultural soil) compartments. SCHER underlined that the persistence of phosphonates and the inconsistencies regarding its bioaccumulation potential recommend a further assessment of long-term and secondary poisoning.
- (4) **Polycarboxylates:** SCHER concluded that a potential risk may exist due to polycarboxylates used in zeolite-based detergent formulations for aquatic organisms as the validity of data for chronic NOEC could not be confirmed, while uncertainties also exist for terrestrial organisms as there were not enough information for estimating a PNEC.

3.2. 2008 SCHER opinion on anaerobic biodegradation and polycarboxylates

New scientific information on polycarboxylates (including its homo- & copolymers) became available in 2007 in the form of a targeted risk assessment report prepared by HERA. In March 2008, the Commission mandated SCHER to produce an updated scientific opinion and to comment whether it agreed with the main conclusion of the HERA report on polycarboxylates in detergents¹⁸, i.e. that the use of polycarboxylates in detergents does not pose risks for environmental compartments with the exception of the soil local compartment for P-AA/MA (a copolymer of acrylic and maleic acids or its sodium salt). In November 2008,

¹⁵ available at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_057.pdf

¹⁶ available at: http://ec.europa.eu/health/ph_risk/committees/sct/documents/out194_en.pdf

¹⁷ available at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_001.pdf

¹⁸ available at: http://www.heraproject.com/files/32-F-HERA_polycarboxylates_final_Sept07.pdf

SCHER adopted a scientific opinion¹⁹ indicating that the changes in the PNEC for aquatic organisms that were proposed by HERA for P-AA/MA have consequences for the outcome of the risk assessment. However, SCHER could not provide a final answer on the potential environmental risk (a) due to the lack of information on the reliability of fish chronic studies and (b) considering that information on soil microbial functions is essential for the risk assessment of these chemicals.

Overall, SCHER concluded that additional information is required before it can be concluded that these chemicals are of low environmental concern. SCHER did not find any additional information on phosphonates, therefore the conclusion of its 2007 opinion on potential environmental risks remained unchanged.

4. CONSULTATION WITH STAKEHOLDERS

The findings of the RPA and HERA studies as well as their evaluation by the Scientific Committees have been discussed at several meetings of the Working Group of the Competent Authorities responsible for the implementation of the Detergents Regulation in June 2007, July 2008, and February 2009. Those meetings were attended by representatives of the Member States, and various industry associations such as: Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (AISE), and European Chemical Industry Council (CEFIC).

Overall, Member States agreed that the RPA report served as a useful basis in particular for reviewing the environmental risks of non-surfactant detergent organic ingredients and that it should be the responsibility of industry to collect further available information on certain detergent ingredients of potential concern. The HERA project has been a good example of such a voluntary action from industry. Furthermore, Member States noted that in the near future, industry will be subjected to such responsibility under the registration procedure of the REACH Regulation (EC) 1907/2006²⁰, where detailed information on the chemicals ingredients used in detergents formulations will have to be provided.

AISE contested some conclusions made by RPA concerning triethanolamine and the complexing agents EDTA and NTA for which there are EU Risk Assessment Reports (RARs) with more recent information. AISE stressed that information and conclusions of these RARs have not been consistently recognised in the RPA report, which thereby raises unnecessary concerns. Finally, AISE stressed that the Industrial & Institutional (I&I) sector is using these materials as they provide specific technical functionalities required for difficult professional cleaning conditions. EDTA has also been included in Annex III of Directive 2008/105/EC²¹ and is subject to review for possible identification as priority substance or priority hazardous substance in the Water Framework Directive. The Commission will report the outcome of its review to the European Parliament and to the Council by 13 January 2011.

In January 2009, AISE provided some updated information concerning the consumption of polycarboxylates in the EU, which was estimated at 80.000 for 2007, out of which 10 % were used in the I&I sector. The observed increase in the consumption of polycarboxylates

¹⁹ available at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_109.pdf

²⁰ OJ L 396, 30.12.2006, p.1

²¹ Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, OJ L 348, 24.12.2008, p. 84

(compared to the RPA 2006 report value of ~ 50 000 t/y) is linked to the increasing move towards the use of phosphate-free laundry detergents and the associated product re-formulation.

Furthermore, the Commission received from BASF Company (January, 2009) data from recently performed studies regarding the terrestrial toxicity of polycarboxylates. According to BASF, these data demonstrate that for P-AA/MA the PEC/PNEC for all environmental compartments is below 1, showing that there is no risk from P-AA/MA for terrestrial organisms. It was agreed that the 2007 HERA report on polycarboxylates will be updated by inserting this new data and that the revised HERA report will be forwarded to SCHER in April 2009 for further evaluation and an opinion as to whether the identified uncertainties have been cleared.

5. SUMMARY AND CONCLUSIONS

The Commission has taken a number of steps to establish the knowledge base needed to conduct a review of the *“biodegradability of the main non-surfactant organic detergent ingredients”* as required by Article 16 (2) of Regulation 648/2004.

When the Detergents Regulation was adopted in 2004, the criterion of ultimate biodegradability was considered to be an effective and proportionate way of ensuring that detergent surfactants do not pose a risk to the environment. Biodegradability was used as a proxy for environmental toxicity because insufficient direct data on the environmental toxicity of surfactants was available at that time. However, in the meantime, and in preparation for REACH, much effort has gone into carrying out targeted risk assessments on detergent ingredients. The Commission has therefore been able to go further than required by Article 16(2) and has been able to evaluate not only the biodegradability, but also the risk posed by those substances.

A study conducted for the Commission in 2006 reviewed the biodegradability and ecotoxicity of the main non-surfactant organic detergent ingredients. The findings of the study together with the related opinions of the Commission’s Scientific Committee in June 2007 and November 2008 were discussed with delegates from Member States and industry associations in a number of meetings of the Commission Detergents Working Group.

No risk to the environment has been identified for any of the non-surfactant organic detergent ingredients. Although, risk cannot be definitely excluded for a few of those substances, as information on them is incomplete, the amount of additional data needed for a complete risk assessment is now relatively small. It is, therefore, not considered appropriate to propose legislation to impose a requirement of ultimate biodegradability on the non-surfactant organic ingredients. In fact, many of the non-surfactant organic ingredients for which data is complete are not ultimately biodegradable, but are neither toxic to human health nor to the environment. Applying a surrogate risk indicator such as ultimate biodegradability to the non-surfactant organic ingredients would therefore ban a number of them where it is known that they do not pose risks. It would therefore be more proportionate, as well as more scientifically robust, to complete instead the risk assessments on the few outstanding substances.

Uncertainties remain concerning the environmental fate of: (a) polycarboxylates and phosphonates, both of which are used in considerable tonnages in household detergent formulations and (b) EDTA and its salts (mainly used in I&I detergents), triethanolamine,

FWA-5 and paraffins for which existing data are not yet sufficient to exclude the possibility of environmental risk.

The information requirements of the REACH registration dossiers will ensure that for most of these substances, comprehensive data on hazard properties and possible risks to human health or the environment will be submitted by industry to the European Chemical Agency (ECHA). In fact, for substances manufactured or imported in quantities of 1 000 tonnes or more per year registrations are due by December 2010 and chemical safety reports as part of the registration dossiers will need to demonstrate the safe use throughout their life cycle.

Therefore, the REACH registration information should be sufficient to decide whether restrictions on the above-mentioned detergent organic ingredients are needed on grounds of environmental risk, and if so, the restriction procedure of REACH would be the most appropriate instrument to impose such restrictions. Concerning polycarboxylates, for which according to REACH only the monomers need to be registered, a revised HERA risk assessment is foreseen in the near future which should clarify the remaining uncertainties with regard to potential environmental risks. The revised report will be submitted to SCHER in April 2009. Furthermore EDTA will be also reviewed by the Commission by 2011 in view of a possible identification as a priority substance under the Water Framework Directive.

Consequently, the Commission does not intend to propose legislation concerning the biodegradability of non-surfactant organic ingredients. The concept of using biodegradability as an acceptance criterion for detergent ingredients has become redundant in light of comprehensive risk assessment data on the environmental toxicity of the substances.

6. LIST OF ABBREVIATIONS

AISE: Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien

CEFIC: European Chemical Industry Council

CMC: Carboxymethyl cellulose

ECB: European Chemical Bureau

EDTA: Ethylenediamine tetra acetate

FWAs: Fluorescent whitening agents

HEDP 1: Hydroxy ethane diphosphonic acid

HERA: Human and Environmental Risk Assessment (AISE-CEFIC cooperative project)

I&I: Industrial and institutional

NOEC: No Observed Effect Concentration

NTA: Nitrilotriacetic acid

P(AA-MA): Copolymer of acrylic acid and maleic acid

PDMS: Polydimethyl siloxane

PEC: Predicted Environmental Concentration

PNEC: Predicted No-Effect Concentration

PVP: Polyvinylpyrrolidone

RAR: Risk Assessment Report

REACH: Registration Evaluation Authorisation of Chemicals

RCR: Risk characterization ratios

RPA: Risk & Policy Analysts

SCHER: Scientific Committee on Health and Environmental Risks

SCTEE: Scientific Committee on Toxicity, Ecotoxicity and the Environment

TAED: Tetra acetyl ethylene diamine

TEA: Triethanolamine

WFD: Water Framework Directive