# European Ecolabel ENV.G.1/SER2009/0100rl Industrial and Institutional Automatic Dishwasher Detergents Technical report

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## 1 Summary

This document supports the draft criteria for Industrial and Institutional Automatic Dishwasher Detergents, providing background information and explaining the choices made during the development of the criteria. The draft criteria and background document were discussed at two AHWG meetings in 2011 and at the EUEB meetings of November 2011 and March 2012.

## 2 Product group definition

## Proposed product group definition

Article 1 of the criteria defines the product group as follows:

The product group "Industrial and Institutional Automatic Dishwasher Detergents" shall comprise single and multi-component dishwasher detergents, rinse and pre-soaks, designed for use in professional dishwashers.

The following products are excluded from the scope of this product group: consumer automatic dishwasher detergents, detergents intended to be used in washers of medical devices or in special machines for cleaning industrial equipment, including in special machines for the food industry.

Sprays not dosed via automatic pumps are excluded from this product group.

#### **Motivation**

The proposed product group definition is inspired by the Nordic Swan and is in line with the definitions of the Regulation (EC) No 648/2004 on detergents. This definition makes it possible to label presoaks, dishwasher detergents and rinse aids either individually or as part of a system. During the criteria development the product group definition has been reworded according to the input received from the different stakeholders but the scope is still the original one of draft 1 and 2 of the criteria document.

At the second AHWG meeting in Brussels in September 2011 it was decided to add the term "automatic" in the name of the product group to clarify the scope.

Sprays not dosed via automatic pumps are not included because it is not possible to determine the dosage and hence is it not possible to make correct CDV-calculations. Automatically dosed spray products are on the contrary included.

# 3 Assessment and verification - in general

#### 3.1 Measurement thresholds

The following thresholds have been set:

Compliance with the ecological criteria is required for substances intentionally added, as well as for by-products and impurities from raw materials, the concentration of which equals or exceeds 0,010 % by weight of final formulation.

For biocides and colouring agents compliance with the criteria is required regardless of their concentration.

Substances meeting the threshold limit as listed above are hereby referred to as "Ingoing substances".

#### **Motivation**

The thresholds are set to ensure that the Ecolabel takes into account all intentionally added substances, as well as by-products and impurities from raw materials, when awarding a license. The threshold limits of 0,010 % by weight of final formulation are more comprehensive than threshold limits set for material safety data sheets due to the scope of EU Ecolabel – only products with the best environmental profile can be awarded an Ecolabel license. The threshold limit of 0,010 % have already been set for other similar EU Ecolabel product groups.

Biocides and colouring agents must comply with all the criteria regardless of their concentration. This is because biocides and colouring agents often provide a significant contribution to the overall environmental profile of the product (primarily the CDV), even in minute concentrations. This is a step further in respect to what requested in the criteria for household detergents for dishwashers, where the request for biocides and colouring agents to comply with the criteria regardless of their concentration was valid for all the criteria except the one on Hazardous substances and mixtures. The reasoning behind the sharpening of the criterion for this product group is that these ingoing substance often have a significant contribution to the overall environmental profile of the product (primarily the CDV), even at the low concentrations they are used. Biocides and colouring agents are moreover part of the CDV-calculation regardless of the concentration.

#### 3.2 Functional unit

The functional unit for this product group shall be expressed in g/l washing solution (grams per litre washing solution).

The functional unit relates to g/l washing solution and is an administrative unit used only for calculation of compliance with the ecological requirements. The functional unit enables the setting of common limits for various product types, independently of the total dosage per wash.

## 4 Proposed Ecolabel criteria

The proposed criteria set is based on the European stakeholders' answers to the questionnaire, common practices, best available techniques and the outcome of the two AHWG meetings in 2011 and at the EUEB meetings of November 2011 and March 2012.

## 4.1 Toxicity to aquatic organisms: Critical Dilution Volume (CDV)

## **Proposed criterion**

The critical dilution volume (CDVchronic) of a single or multi-component system must not exceed the following limits (at the highest recommended dose):

CDV at the highest recommended dose	Soft	Medium	Hard
Product type	0-6° dH	7-13 ° dH	> 14 ° dH
Pre-soaks	2 000	2 000	2 000
Dishwasher detergents	3 000	5 000	10 000
Multi-component-system	3 000	4 000	7 000
Rinse aids	3 000	3 000	3 000

The critical dilution volume toxicity ( $CDV_{chronic}$ ) is calculated for all ingredients (i) in the product using the following equation:

$$CDV_{chronic} = \sum CDV_{(i)} = \frac{weight_{(i)} \cdot DF_{(i)}}{TF_{chronic(i)}} \cdot 1 \ 000$$

where

*weight* = *the weight of the ingredient per recommended dose* 

DF = the degradation factor

TF = the chronic toxicity factor of the substance as stated in the DID list.

Biocides and colouring agents present in the product must also be included in the CDV calculation even if the concentration is lower than 0,010 % (100 ppm).

#### **Motivation**

The CDV aims at setting a high standard for the Ecolabelled products based on all ingredients in the final product. The method of calculating the CDV has been set to fit the latest version of the DID list (2007 version).

For further explanation of the calculation method and DID list parameter, reference is made to Detergents Ingredients Database Part A and B available at the EU Ecolabel website.

The CDV levels for all products have largely been inspired from the Nordic Ecolabel Criteria for dishwasher detergents for professionals, version 2.0 (only soft water) and input from industry. The difference in the levels for a complete dishwasher detergent (1 single product) and a multi component system can be explained by the fact that the multi component system gives the possibility of a more optimal dosing of alkalinity. When dealing with higher water hardness, a higher builder concentration is needed to cope with the water hardness; this is needed to provide proper cleaning and to prevent scaling of machine and substrates. In case of a complete dishwasher detergent, both alkalinity and builder levels in the wash bath will be increased by a higher product dosage. In case of a multi component system, only more builder booster will be dosed in harder

water, while the level of alkalinity booster stays almost the same. In this way a more optimal wash process is developed.

Because alkalinity has a significant effect on CDV chronic, the CDV chronic values in harder water will be lower for the multi component system as compared to the single product detergent. Because alkalinity has no effect on aNBO and anNBO, these aNBO and anNBO values are the same for the single product detergent and the multi component system.

Generally, the use of chronic toxicity data is preferred to acute toxicity data as long term toxicity data are considered of higher quality and as giving a more precise/reliable estimate of environmental effects. The CDV values are thus based on chronic toxicity factors. Due to the lack of chronic data for certain substances (such as fragrances, silicates, and various surfactants) on the DID list, the "chronic" toxicity factors (TF) are, nevertheless, based on acute toxicity values and thereby result having a higher weight in the CDV<sub>chronic</sub> calculation than may be realistic. The proposed CDV values took this into account. However, it is important that new chronic data are presented and made available. For substances for which the chronic TF values on the DID list are based on acute toxicity data, chronic ecotoxicity values presented to the Competent Bodies should be considered, in order to correctly estimate the chronic TF for the substance.

Already approximately 30 products with the Nordic Ecolabel are on the market in Scandinavia (dishwasher detergents, pre-soaks and rinse aids) and comply with the proposed CDV levels. We are aware that these products on the Nordic market cannot be considered representative of all the products in the European market. Ecolabelling Denmark has received a limited amount of formulations from the rest of Europe that were taken into account in the formulation of the proposed CDV thresholds.

For some formulations with higher CDV values the substances that contributed most to CDV would have been restricted by the other EU Ecolabel criteria. Therefore it is difficult to estimate for how many products the proposed thresholds may preclude the award of the EU Ecolabel.

## 4.2 Biodegradability

## a)Biodegradability of surfactants

#### **Proposed criterion**

All surfactants must be biodegradable under aerobic and anaerobic conditions.

#### **Motivation**

Substances that do not degrade or degrade very slowly will accumulate in the environment and present a potential risk in the future even they are not acute toxic. The knowledge of these persistent substances is often not excising or incomplete. Quick and complete degradation has therefore a high environmental value. This is particularly relevant for surfactants as they constitute the main part of detergents.

A requirement for surfactants to be aerobic biodegradable is introduced because even if all the surfactants used in European market shall comply with the biodegradability criteria as laid down in Regulation (EC) N° 648/2004 on detergents, there is a possibility for industry to ask for derogation.

For professional automatic dishwashing applications only non-ionic surfactants are used. One of the key functions is to suppress foam, because foam is detrimental for professional automatic dishwashing processes with extremely high mechanical action. Foam has not only negative consequences for the washing process, but can even damage the washingpump. It is also for this reason that anionic surfactants are not used for professional automatic dishwashing processes [A.I.S.E].

A mandatory requirement of anaerobic biodegradability of surfactants will have consequences for professional automatic dishwashing processes because for several of non-ionic surfactants this aspect is not known (no information available on the DID-list or via the supplier), and products will have to be re-formulated. However, there are indications that it is possible to develop products which are based on non-ionic surfactants which are also anaerobically biodegradable [A.I.S.E].

The proof is that biodegradability under anaerobic conditions is already a mandatory requirement in the Nordic Ecolabel [Nordic Ecolabel, 2009]. Nordic Ecolabel has 3 licences with 24 products on the market.

34 non-ionic surfactants are listed on the DID list. 1 is not anaerobic biodegradable, 22 are anaerobic biodegradable and for 11 data are not available. BASF has also already provided information on suitable non-ionic surfactants.

## b)Biodegradability of organic substances

#### **Proposed criterion**

The content of all organic substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the following limits:

#### **aNBO**

Product type	Soft	Medium	Hard
(g/1 washing solution)	0-6 ° dH	7-13 ° dH	>14 ° dH
Pre-soaks	0,4	0,4	0,4
Dishwasher detergents / Multi-component systems	0,4	0,4	0,4
Rinse aids	0,04	0,04	0,04

#### anNBO

Product type	Soft	Medium	Hard
(g/l washing solution)	0-6 ° dH	7-13 ° dH	>14 ° dH
Pre-soaks	0,4	0,4	0,4
Dishwasher detergents / Multi-component ststems	0,6	1,0	1,5
Rinse aids	0,04	0,04	0,04

#### **Motivation**

This general requirement reduces the content of not readily biodegradable and not anaerobically biodegradable organics to a minimum, providing the Ecolabelled products an optimal biodegradation profile and minimising the possible accumulation of non-biodegradable substances in waste water sludge and other relevant environmental compartments.

Substances commonly used in dishwasher detergents and rinse aids that are not aerobically biodegradable (aNBO) are the following: polycarboxylates, CMC, silicone, PVA/PVOHI, phosphonates, polymers and colouring agents.

Substances commonly used in dishwasher detergents that are not anaerobically biodegradable (anNBO) are surfactants (certain types), polycarboxylates, CMC, phosphonates, polymers, and colouring agents. Furthermore, data for anaerobic biodegradability are not available (according to the DID list) for a range of other substances commonly used, such as MGDA, various organic acids and glycol ethers etc.

In the second draft a criterion was introduced stating that each surfactant used must be readily and anaerobically biodegradable. However, after discussion at the second AHWG meeting this proposal was removed. The proposed criterion had not been included in the criteria for domestic dishwasher detergents due to an updated risk assessment. The Commission argued that as new knowledge has not been introduced since then, the proposed criterion was not appropriate.

The limits for soft water are mainly based on approximately 30 products with the Nordic Ecolabel such as dishwasher detergents, pre-soaks and rinse aids already on the market in Scandinavia. The levels are established so that the 30 products comply with the proposed levels of aNBO and anNBO. The products on the Nordic market are however not representative of all European products. The limits for medium and hard water are based on information from industry and supported by examples of formulations.

The following exemption has been introduced, in accordance with the Nordic Ecolabel criteria [Nordic Ecolabel 2009]:

In the absence of documentation in accordance with the above requirements a substance other than a surfactant may be exempted from the requirement for anaerobic degradability if one of the following three alternatives is fulfilled:

- 1. Readily degradable and has low adsorption (A < 25%) or
- 2. Readily degradable and has high desorption (D > 75%) or
- 3. Readily degradable and non-bioaccumulating.

Testing for adsorption/desorption may be conducted in accordance with OECD guidelines 106.

The exemption will allow producers to use ingredients were no data is available but it has been documented by one of the three mentioned alternatives that it is very unlikely that the ingredients will be found in the anaerobic compartment and therefore it is not considered as relevant whether or not the ingredients actually fulfil the anNBO criteria.

#### 4.3 Excluded or limited substances and mixtures

## a) Specified excluded ingoing substances

#### **Proposed criterion**

The following ingoing substances must not be included in the product, neither as part of the formulation nor as part of any preparation included in the formulation:

- EDTA (ethylenediamine tetraacetate)
- Fragrances
- Reactive chlorine compounds
- APEO (Alkyl phenol ethoxylates) and APD (Alkylphenol and derivatives thereof)

#### **Motivation**

#### **EDTA**

EDTA can re-mobilise metals from sediments and soils leading to contamination of surface and ground waters. The aerobic and anaerobic biodegradability of EDTA is furthermore limited. Risk assessment of EDTA has concluded a need for limitation of risk in a range of applications, although not for domestic detergents as the use of EDTA in these products is limited (EU RAR 2004). The exclusion of EDTA for this product group is mainly a preventive measure but it also allows communicating to the consumers that Ecolabelled products are EDTA free.

#### Fragrances

Since fragrances do not add a function to the product, they are considered unnecessary. Many fragrances are in addition classified as environmentally harmful and are as such unwanted in ecolabelled products.

#### Reactive chlorine compounds

Reactive chlorine compounds are still used in some dishwasher detergents for professionals, especially when the detergents need strong bleaching properties. Even if in 2007 a risk assessment of reactive chlorine compounds concluded that: "There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already" it is wished to address these compounds in ecolabelled products since they do have unwanted environmental properties. Reactive chlorine compounds in dishwasher detergents are used in many different forms. Sodium hypochlorite is still used in many European products despite being very toxic to aquatic organisms. According to the industry other kinds of chlorine products that are less toxic are sometimes used instead, and it might have been possible to suggest a criterion in which some chlorine compounds are allowed and some are not. However, as it would not be advisable to communicate to the public that chlorine compounds are allowed in EU Ecolabelled products, it has been decided to ban them.

20 detergents for dishwashers without chlorine compounds have been awarded the Nordic Ecolabel. This indicates that chlorine might only be necessary in a limited amount of products and that indeed it is possible to produce detergents for dishwashers without chlorine.

#### APEO and APD

APEO and APD are a group of persistent surfactants that have displayed endocrine disruptive characteristics. The substances are being phased out from the majority of products through legislation. However, Nordic Ecolabelling has found them present in some ingredients and this is why it has decided to explicitly ban them.

In the first draft of the criteria, Nitromusks and polycyclic musks, Potential endocrine disrupters and PBT (Persistent, bioaccumulable and toxic) and vPvB (very persistent and very bioaccumulable) substances were mentioned here as specified excluded ingredients. However, they have been deleted since they are already prohibited according to criterion 4b.

#### b) Hazardous substances and mixtures

## **Proposed criterion**

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any component of it shall not contain substances meeting criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EC nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006. The risk phrases below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

List of hazard statements:

Hazard Statement <sup>1</sup>	Risk Phrase <sup>2</sup>
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63

H2C2 Management have to be need for distribution	DC4
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22
H372 Causes damage to organs	R48/25/24/23
H373 May cause damage to organs	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41
Sensitising substances	
H334: May cause allergy or asthma symptoms or breathing	R42
difficulties if inhaled	
H317: May cause allergic skin reaction	R43

<sup>&</sup>lt;sup>1</sup> Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Note that this criterion also applies to known degradation products such as formaldehyde from formaldehyde releasers.

Substances or mixtures which change their properties through processing (e.g., become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard) are exempted from the above requirement.

The final product must not be labelled according to the hazard statements above.

#### **Motivation**

This requirement regarding CMR substances and environmentally hazardous substances is a standard requirement for Ecolabelled products. By this requirement, the most critical substances potentially affecting human health and the environment are excluded from the products. Substances fulfilling the PBT criteria as defined under REACH will be restricted through this criterion (i.e. by exclusion of substances classified as environmentally hazardous with R50/53 or R51/53).

The requirement from Article 6(6) of Regulation (EC) No 66/2010 has been expanded to include sensitizing substances. The purpose of the requirement is to limit the risk of allergic reactions from chemicals still presents in the laundry after washing. Allergy is an increasing problem. Some ingredients used in laundry detergents and auxiliary products are designed to stay in /leave traces in

<sup>&</sup>lt;sup>2</sup> Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC and Directive 1999/45/EC as amended

the textile (e.g. fragrances, cationic surfactants in fabric softeners) while other substances may be left in the textile due to incrustation of poorly soluble substances or poor / insufficient rinsing in the washing process. Thus, a limitation in content of sensitizing substances will minimise the risk of allergic reactions.

The requirement on the final product not to be labelled according to the hazard statements listed is added as a precautionary measure, to limit the hazardous subtances eventually derogated to an amount that would not lead to the labelling of the product.

## **Derogations**

The following substances are specifically exempted from this requirement:

		1
Surfactants	H400 Very toxic to aquatic life	R 50
<15%		
Biocides used for preservation	H331: Toxic if inhaled	R23
purpose in rinse aids*	H334: May cause allergy or asthma symptoms or	R42
(only for liquids with pH	breathing difficulties if inhaled	
between 2 and 12 and maximum	H317: May cause allergic skin reaction	R43
0,10 % w/w of active material)	H400: Very toxic to aquatic life	R50
	-	KJU
Enzymes**	H334: May cause allergy or asthma symptoms or	R42
	breathing difficulties if inhaled	
	H317: May cause allergic skin reaction	R43
	H400 Very toxic to aquatic life	_
		R50
NTA as in impurity in MGDA	H351: Suspected of causing cancer	R40
and GLDA**	The first suspense of suspense outlier	11.0

<sup>\*</sup> Referred to in Criterion 3 d). This exemption is applicable provided that biocides' bioaccumulation potentials are characterised by log  $P_{ow}$  (log octanol/water partition coefficient) < 3.0 or an experimentally determined bioconcentration factor (BCF)  $\leq$  100.

#### **Motivation for the derogations**

According to the EU Ecolabel Regulation, derogation is allowed if it is not technically possible to substitute a substance or if the overall environmental benefit from using it can be demonstrated. The motivation for the derogations introduced is provided below.

#### Surfactants

Surfactants meeting the requirements for classification as *R50/H400: Toxic to aquatic life* are derogated because the most effective surfactants have this classification and otherwise a larger amount of less effective surfactants will be used.

Arguments for having this derogation have been made by A.I.S.E.: a key point is that professional automatic dishwashing machines apply much higher mechanical action than domestic machines. This allows them to reduce the washing time by a factor of more than 50 and consequently to

<sup>\*\*</sup> Including stabilisers and other auxiliary substances in the preparations

<sup>\*\*\*</sup> In concentrations lower than 1.0% in the raw material as long as the total concentration in the final product is lower than 0.10%

reduce also water, energy and detergent consumption by 75%. These are therefore significant environmental savings in the overall LCA analysis which have to be taken into account. With the weaker non classified defoaming type of non-ionic surfactant, more surfactants would need to be added into the product. Foam formation, caused by these less effective defoamers, will also lead to reduced cleaning and so more rewash. Overall, this will have a negative effect on the eco-profile of the wash process.

Arguments for not having a derogation has been made by EEB/BEUC and some Member States stating that by this derogation, the Ecolabel will not promote the development of efficient and less toxic surfactants. A lot of surfactants on the DID (Detergent Ingredient Database) list that are not very toxic can still be used in detergents. From 71 different surfactants listed on DID only 11 have toxicity values indicating that they would be classified as R50.

#### Biocides

Biocides meeting the requirements for classification as *R50/H400*: Very toxic to aquatic life, *R23/H331*: Toxic if inhaled, *R42/H334*: May cause allergy or asthma symptoms or breathing difficulties if inhaled, *R43/H317*: May cause allergic skin reaction are exempted from exclusion. The reasoning is that no alternative biocides with the same efficiency but without these R-phrases seem to be available. Effective biocides are necessary to ensure that the products keep their performance and thereby ensure that they are not degraded and discarded.

This derogation has been kept in order to allow some preservatives like Glutaraldehyde and CMIT:MIT (5-Chlor-2-methyl-2H-isothiazol-3-on, 2-Methyl-2H-isothiazol-3-on (1:3) CAS 55965-84-9) that, according to A.I.S.E, are used in a very significant part of the products on the market. If these biocides are banned, testing would be needed to find other suitable substances. These tests require very long periods (with many samples at different storage temperatures), significant resources and costs. Substitute will therefore not be available in the short term.

These biocides are only needed in liquid products, with a pH-value between 2 and 12. In case of automatic dishwashing that actually applies only to rinse aids. Furthermore as the need for preservation is very much dependent on the level of free water (more concentrated products generally require less or no preservation), it has been decided to limit the concentration of active material allowed in the final product to 0.1%. This will also guarantee that the final product does not have to be labelled "contains (name of substance) may cause an allergic reaction" according to the Classification Labelling and Packaging Regulation (CLP).

In the criteria for the Nordic Ecolabel for the same types of products [Nordic Ecolabel 2010] biocides meeting the requirement for classification as R42 or R43 are allowed as well.

#### Enzymes

Due to high pH values, enzymes are normally not used in dishwasher detergents where the washing performance is obtained by alkalines, high temperature and water injection on the dishes.

However in pre-soaks enzymes can be used in order to remove soils and food leftover before washing. Enzymes (including additives in the enzyme formulations such as stabilisers) meeting the requirements for classification as *R42/H334*: *May cause allergy or asthma symptoms or breathing difficulties if inhaled*, *R43/H317*: *May cause allergic skin reaction* and *R50/H400*: *Very toxic to aquatic life* are derogated from criterion 3 b.

From a cleaning performance as well as a sustainability point of view, enzymes are highly desirable ingredients of detergents. They cannot be substituted - but may substitute other, less desirable substances. Enzymes enable improved cleaning. They are renewable and readily biodegradable substances. They are specific and very active catalysts, enabling compaction of detergents. Enzymes (enzyme products) are without any exception mixtures containing active enzyme protein and formulation ingredients including stabilizers. All active enzyme proteins are classified as respiratory sensitizers (R42/H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled). Commercial enzyme products used for professional dishwasher detergents are formulated as low-dusting granulates, or liquids ensuring exposure of active enzyme protein to users that are well below the safety concern level.

Enzyme products may contain necessary stabilizers and other formulation components, some of which may also be classified as skin sensitizers (*R43/H317: May cause allergic skin reaction*). Therefore some enzyme products may also be classified as skin sensitizer. When enzyme products are used in the professional dishwasher products, such stabilizers are diluted so that concentration is well below safety concern level.

One of the most used protease in the detergent industry is a subtilisin (EINECS 232-752-2, CAS 9014-01-1). A REACH dossier was submitted in 2010 by Novozymes A/S as Lead Registrant. Subtilisin has a proteolytic activity leading to acute effect on aquatic organisms e.g. daphnia. We have concluded based on data that protease (subtilisin) should be classified as *R50/H400: Very Toxic to aquatic life* due to acute toxicity to aquatic organisms.

However, the acute effect disappears as soon as proteases are deactivated. In both industrial sewage treatment plan (STP), where sewage from the production facility is treated, and municipal STP, where sewage from primarily private households is treated, it was found through measurement that more than 99.99% of subtilisin is deactivated/degraded in waste water treatment plants. In addition, use and transport in the sewer system can be assumed to be 80% based on monitoring data from STP's.

Based on the available information it is concluded that the use of protease (subtilisin) for professional dishwasher detergents is safe for the environment. This was already recognized through the Commission Decision of 26 January 2012 amending both Laundry detergents and Detergents for Dishwashers criteria to allow the use of subtilisin.

#### **NTA**

NTA has been classified as *R40/H351*: Suspected of causing cancer. Carcinogenic substances are generally unwanted in Ecolabelled products, but NTA is unavoidable as an impurity in MGDA and GLDA and is therefore accepted regardless of its classification.

## c) Substances listed in accordance with article 59(1) of Regulation (EC) No 1907/2006

#### **Proposed criterion**

No derogation from the exclusion in Article 6(6) of the Regulation (EC) No66/2010 shall be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in mixtures, in an article or in any homogenous part of a complex article in concentrations higher than 0,010%.

#### **Motivation**

This requirement ensures that no derogation from the exclusion of Hazardous Substances and Mixtures is given to substances of very high concern. It is in line with the requirements of Regulation EC/66/2010. The limit is set at 0,010% similarly to the one for dishwasher detergents for consumers.

#### d) Specified limited ingoing substances - Biocides

#### **Proposed criterion**

The product may contain biocides provided that the they are not bioaccumulating. A biocide is not considered bioaccumulating if BCF < 100 or logKow < 3,0. If both BCF and logKow values are available, the highest measured BCF value shall be used.

#### **Motivation**

Biocides can be added to liquid products to prevent bacterial growth. In general, biocides are highly toxic to aquatic organisms and can produce hypersensitivity and allergies. Bioaccumulating substances collect in the fatty tissues of living organisms and can cause long-term damage to the environment. That is why it is requested to biocides in the product not to be bioaccumulating

## e) Colouring agents

#### **Proposed criterion**

Colouring agents allowed in the product must not be bioaccumulating. In the case of colouring agents approved for use in foodstuffs it is not necessary to submit documentation of bioaccumulation potential. A colouring agent is considered not bioaccumulating if BCF < 100 or logKow < 3,0. If both BCF and logKow values are available, the highest measured BCF value shall be used. Colouring agents approved for use in foodstuffs can be approved.

#### **Motivation**

Colouring agents do not clean but may be considered necessary for the product group for safety reasons to enable the differentiation of various products. Colouring agents may be added to products if they are not bioaccumulating. Colouring agents approved as food additives can be used, since they are supposed to be evaluated as safe.

#### f) Enzymes

## **Proposed criterion**

Enzymes must be in liquid form or dust-free granulate. Enzymes must be free from micro-organism remnants from manufacture.

#### **Motivation**

Enzymes are rarely used in industrial and institutional automatic dishwasher detergents today, but are used in drying and pre-soaks. As the current public attention focus on climate change and energy consumption, it is not unreasonable to predict that dishwasher detergents that are more effective at lower temperatures will be developed, and that these might contain enzymes. It has been

therefore decided for the EU Ecolabel to be one step ahead and set criteria on enzymes already at this point in time.

Moreover enzymes might be used in pre-soaks in spray products in order to dose directly on stains.

## g) Phosphorous

## **Proposed criterion**

The total quantity of phosphates and other phosphorous compounds must not exceed the limit values specified in table below, calculated in grams of phosphorous per litre water.

The highest recommended dosage must be used for the phosphorous calculations.

Product type Phosphorous (g P/l water)	Soft	Medium	Hard
<b>F</b> ( <b>G</b>	0-6 ° dH	7-13 ° dH	>14 ° dH
Pre-soaks	0,08	0,08	0,08
Detergents	0,15	0,30	0,50
Rinse aids	0,02	0,02	0,02

#### **Motivation**

The current debate on the possible regulation of *phosphorous* in detergents confirms that eutrophication caused by the use of phosphates is still a subject of high relevance.

Phosphate emission from agriculture is one of the major contributors of P to the aquatic environment (EEA 2005). Phosphates from detergents may only play a minor role in the overall phosphate emissions to the aquatic environment, especially in areas where phosphate is effectively removed in waste water. Generally the emissions of P via point sources (including waste water) have decreased during the last 30 years. This is mainly due to improved waste water treatment, especially in Northern and Western Europe, following the implementation of the EU Waste Water Treatment Directive (1991/271/EC) (EEA 2005). Eastern European countries also seem to follow this development, although Directive 1991/271/EC is not fully implemented in many Member States (EEA 2005, CEEP 2007). That is why a limitation of Phosphorus it is proposed for this product group.

Even if the the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorous compounds in consumer detergents does not affect industrial and institutional detergents since technically and economically feasible alternatives seem to be not yet available throughout the EU, it has been decided to go a step further with the limitation on total amount of P in this criteria document as Ecolabel is a voluntary tool for environmental excellence.

The values proposed are based on input from the industry and reflect that more phosphorus is needed in areas with hard water.

It has been decided to go for a restriction instead of a total ban of P because more than one chemical (such as chelating agents, polycarboxylates, ethylenediaminetetraacetic acid, phosphonates) are necessary to replace its functions and current trends point to more compact and concentrated products with lower dosage and use of chemicals that, according to several manufactures, are difficult to produce without phosphates.

## 4.4 Packaging requirements

## a) Weight/utility ratio (WUR)

## **Proposed criterion**

The weight/utility ratio (WUR) of the product shall not exceed the following values:

Product type	WUR			
	0-6 ° dH	7-13 ° dH	>14 ° dH	
Powders [g/l washing solution]	0,8	1,4	2,0	
Liquids [g/l washing solution ]	1,0	1,8	2,5	

WUR shall only be calculated for primary packaging (including caps, stoppers and hand pumps/spraying devices) using the formula below:

$$WUR = \sum [(W_i + U_i)/(D_i * r_i)]$$

#### Where:

Wi = the weight (g) of the packaging component (i) including the label if applicable.

Ui = the weight (g) of non-recycled (virgin) material in the packaging component (i). If the proportion of recycled material in the packaging component is 0% then <math>Ui = Wi.

Di = the number of functional units contained in the packaging component (i). The functional unit = dosage in g/l washing solution

ri = recycling figure, i.e. the number of times the packaging component (i) is used for the same purpose through a return or refill system (r=1, if the packaging is not re-used for the same purpose. If the packaging is reused r is set to 1 unless the applicant can document a higher number. (See background report for further details)

#### **Exceptions**:

Plastic/paper/cardboard packaging containing more than 80% recycled material or more than 80% plastic from renewable origin is exempted from this requirement.

Packaging is regarded as recycled if the raw material used to make the packaging has been collected from packaging manufacturers at the distribution stage or at the customer stage. If the raw material

is industrial waste from the material manufacturer's own production process, then the material will not be regarded as recycled.

#### **Motivation**

In a life-cycle perspective, the packaging has a relatively low impact on the environment. However, it is still relevant to reduce the consumption of packaging material to a minimum in accordance with the aim of the packaging and packaging waste directive (Directive 94/62/EC). From a communication point of view, it is also an important signal to the customers that packaging is reduced to a minimum for Ecolabelled products.

The requirement limiting the amount of packaging per wash has been adopted from the Ecolabel Criteria for dishwashing detergents for domestic use with minor modifications based on suggestions from industry.

Exemptions are made to encourage the use of recycled material and plastic from renewable origins.

## b) Plastic packaging

## **Proposed criterion**

Only phthalates that were risk assessed at the time of the application and have not been classified according to criterion 3(b) (and combinations hereof) may be used in the plastic packaging. In order to allow for identification of different parts of the packaging for recycling, plastic parts in the primary packaging must be marked in accordance with DIN 6120, Part 2 or the equivalent. Caps and pumps are exempted from this requirement.

#### **Motivation**

This requirement will prohibit the use of phthalates as plasticisers in plastic packaging. Some of the phthalates most frequently used in plastics are classified as being toxic to reproduction (DEHP, DBP, BBP). Several other phthalates are suspected of causing endocrine disrupting effects [DHI, 2007]. Due to these concerns, the phthalates DEHP, DBP, BBP, DINP, DIDP and DNOP have been prohibited / limited for use in toys and childcare articles (Directive 2005/84/EC). The possible risk associated with the use of phthalates in plastic packaging for dishwasher detergents is unknown, but the use of potentially endocrine disrupters in Ecolabelled dishwasher detergents and their packaging is generally unwanted. Since alternative plastics are available the, abovementioned exclusion has been suggested.

Labelling of plastic packaging will ease the sorting of packaging waste in countries / regions where plastic packaging is recycled after use.

## 4.5 Washing performance (fitness for use)

#### **Proposed criterion**

The performance and efficiency of the product must be satisfactory. The product must fulfil the requirements for the user test or internal testing in accordance with Appendix II.

#### **Motivation**

The performance of the single or multi-component system must be satisfactory at the recommended dosage. The performance must be tested at the same dosage as used for other calculations.

Most manufacturers perform a number of internal tests before releasing a new product. Since no standardized test method exist for this product group it was agreed at the AHWG meetings that the performance is documented through these internal tests. The frames for the internal tests are described in Appendix II.

## 4.6 Automatic dosing systems

#### **Proposed criterion**

Multi-component systems must be offered together with an automatic and controlled dosing system.

In order to ensure correct dosage in the automatic dosing systems, customer visits must be incorporated as a normal routine for manufacturers/suppliers. These customer visits are performed at all premises at least once a year during the license period; they must include calibration of the dosage equipment. Also, a third party can perform customer visits.

In exceptional cases, customer visits may be dispensed with if the distance and method of delivery makes the visit impracticable.

#### **Motivation**

The environmental impact imposed by the automatic dishwasher detergent is strongly related to the dosage. Since the multi-component systems do not have dosage possibility, a criterion has been set to ensure correct dosing for automatic dosage. Furthermore, the criterion includes follow-up and calibration of the dosage equipment to ensure the correct dosage at any time.

#### 4.7 User information

#### **Proposed criteria**

#### a) Information on the packaging / product information sheet

The following recommendations must appear on the packaging, and / or on product information sheet or equivalent.

- Dose according to the degree of soil and water hardness. Follow the dosing instructions
- Using this EU Ecolabelled product according to the dosage instructions will contribute to the reduction of water pollution and waste production.

## b) Information appearing on the EU Ecolabel

The logo should be visible and legible. The use of the EU Ecolabel logo is protected in primary EU law. The EU Ecolabel registration/licence number must appear on the product, and again it must be legible and clearly visible.

The optional label with text box must contain the following text:

- Reduced impact on aquatic ecosystems
- Limited hazardous substances
- Performance tested.

The guidelines for the use of the optional label with text box can be found in the "Guidelines for use of the Ecolabel logo" on the website:

http://ec.europa.eu/environment/ecolabel/documents/logo\_guidelines.pdf

#### **Motivation**

The environmental impact of a dishwasher detergent is strongly related to the dosage and temperature. In order to ensure the best environmental performance in the use phase, user information on how to act to reduce its environmental impact is needed.

## 5 Ecolabel criteria and other legislation

#### **REACH**

In the future regulatory situation dominated by REACH, the EU Ecolabel may in particular bring added value within the following areas:

#### Critical Dilution Volume

The Ecolabel aims at setting a high standard based on all ingredients in the final product, through requirements regarding substances not easily degradable in the product formulation, as well as the use of the Critical Dilution Volume (toxicity). These aspects are not covered by REACH and only partly covered by the Detergents Regulation. The Detergents Regulation requires all surfactants to be easily aerobic biodegradable, but derogation can be made for surfactants used in products for professional users. The Ecolabel limits substances that are not degradable aerobic and anaerobic and hence covers substances other than surfactants. The use of the CDV for limiting the amount of toxic substances in the product is also in addition to the current legislation (both REACH and the Detergent Regulation).

#### Intrinsic properties

By defining criteria which imply that substances characterised by certain intrinsic properties shall not be used in products awarding the Ecolabel, the Ecolabel may respond to concerns in relation to the safe use of specific chemicals, and thereby address environmental or consumer concerns (e.g. substances that are classified with the risk phrase R50-53: "very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment"). Substances anticipated to enter the candidate list for authorisation under REACH are not allowed in Ecolabelled products through the criterion 4b referring to risk phrases.

#### **Globally Harmonized System - GHS**

The use of the GHS will impact the Ecolabel as the GHS is implemented in European legislation through the CLP Regulation. These criteria are valid during the transition period; from the classification directives for substances and mixtures to the classification regulation (CLP). The criteria refer to the classifications made according to both the directives and the CLP Regulation.

# 6 Abbreviations and definitions

A.I.S.E.	The International Association for Soaps, Detergents and	
A.1.5.E.	Maintenance products	
aNBO	Anaerobically not biodegradable substances	
anNBO	Anaerobically not biodegradable substances  Anaerobically not biodegradable substances	
BCF	Bioconcentration Factor	
CDV	Critical Dilution Volume	
°dH	German degree of hardness	
DID-list	Detergents Ingredients Database list	
EDTA	Ethylenediamine tetraacetate	
Functional unit	The quantity of detergent (in grams) used per kg textile	
	during washing/treatment.	
GHS	Globally Harmonised System of Classification and	
	Labelling of Chemicals	
GLDA	Glutamic acid diacetic acid	
GMM	Genetically modified micro-organisms	
IFRA	International Fragrance Organisation	
<b>LogKow</b> Log Octanol-Water partition coefficient		
Low-temperature product	A low-temperature product is in the Ecolabel criteria	
	defined as products that have a documented washing	
	performance at> 20°C to ≤ 30°C	
MGDA	Methylglycinediacetic Acid	
NTA	Nitrilotriacetic acid	
PPM	Parts per million. Measuring unit (100 ppm = 0.010%)	
TC	Total Chemicals	
WUR	Weight Utility Ratio	
WWTP	Waste water treatment plant	
PBT	Persistent Bio accumulative Toxic	
vPvB	Very persistent and very bioaccumulative	

#### 7 References

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