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COMMISSION DECISION

of 28 April 2011

on establishing the ecological criteria for the award of the EU Ecolabel to detergents for dishwashers

(notified under document C(2011) 2806)

(Text with EEA relevance)

(2011/263/EU)

(OJ L 111, 30.4.2011, p. 22)

Amended by:

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► <u>M1</u>	Commission Decision 2012/49/EU of 26 January 2012	L 26	36	28.1.2012
► <u>M2</u>	Commission Decision 2014/313/EU of 28 May 2014	L 164	74	3.6.2014

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► **C1** Corrigendum, OJ L 300, 18.10.2014, p. 69 (2014/313/EU)



COMMISSION DECISION

of 28 April 2011

on establishing the ecological criteria for the award of the EU Ecolabel to detergents for dishwashers

(notified under document C(2011) 2806)

(Text with EEA relevance)

(2011/263/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel ⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the European Union Ecolabelling Board,

Whereas:

- (1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to those products with a reduced environmental impact during their entire life cycle.
- (2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.
- (3) Commission Decision 1999/427/EC ⁽²⁾ has established the ecological criteria as well as the related assessment and verification requirements for detergents for dishwashers. Following the review of the criteria set out in that Decision, Commission Decision 2003/31/EC ⁽³⁾ has established revised criteria which are valid until 30 April 2011.
- (4) Those criteria have been further reviewed in the light of technological developments. It results from the review that it is necessary to modify the definition of the product group so as to include a new sub-product group and to establish new criteria. Those new criteria, as well as the related assessment and verification requirements, should be valid for 4 years from the date of adoption of this Decision.
- (5) Decision 2003/31/EC should therefore be INSERTED for reasons of clarity.
- (6) A transitional period should be allowed for producers whose products have been awarded the Ecolabel for detergents for dishwashers on the basis of the criteria set out in Decision 2003/31/EC, so that they have sufficient time to adapt their products to comply with the revised criteria and requirements. Producers should also be allowed to submit applications based on the criteria set out in Decision 2003/31/EC or on the criteria set out in this Decision until the lapse of validity of that Decision.

⁽¹⁾ OJ L 27, 30.1.2010, p. 1.

⁽²⁾ OJ L 167, 2.7.1999, p. 38.

⁽³⁾ OJ L 9, 15.1.2003, p. 11.

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- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

HAS ADOPTED THIS DECISION:

Article 1

The product group ‘Detergents for Dishwashers’ shall comprise detergents for dishwashers and products used as rinse aids, whether in powder, liquid or any other form, which are intended to be marketed and used exclusively in automatic domestic dishwashers and in automatic dishwashers for professional use, the size and usage of which is similar to that of domestic dishwashers.

Article 2

For the purpose of this Decision, the following definitions shall apply:

‘Substance’ means a chemical element and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Article 3

In order to be awarded the EU Ecolabel under Regulation (EC) No 66/2010, a detergent for dishwashers shall fall within the product group ‘Detergents for Dishwashers’ as defined in Article 1, and shall comply with the criteria set out in the Annex to this Decision.

Article 4

The criteria for the product group ‘Detergents for Dishwashers’, as well as the related assessment and verification requirements, shall be valid for 4 years from the date of adoption of this Decision.

Article 5

For administrative purposes the code number assigned to the product group ‘Detergents for dishwashers’ shall be ‘015’.

Article 6

Decision 2003/31/EC is repealed.

▼B*Article 7*

1. By derogation from Article 6, applications for the EU Ecolabel for products falling within the product group ‘Detergents for Dishwashers’ submitted before the date of adoption of this Decision shall be evaluated in accordance with the conditions laid down in Decision 2003/31/EC.

2. Applications for the EU Ecolabel for products falling within the product group ‘Detergents for Dishwashers’ submitted from the date of adoption of this Decision but by 30 April 2011 at the latest may be based either on the criteria set out in Decision 2003/31/EC or on the criteria set out in this Decision.

Those applications shall be evaluated in accordance with the criteria on which they are based.

3. Where the Ecolabel is awarded on the basis of an application evaluated according to the criteria set out in Decision 2003/31/EC, that Ecolabel may be used for 12 months from the date of adoption of this Decision.

Article 8

This Decision is addressed to the Member States.



ANNEX

FRAMEWORK

The aims of the criteria

The criteria aim, in particular, at promoting products that have a reduced impact on aquatic ecosystems, contain a limited amount of hazardous substances and whose performance has been tested.

CRITERIA

These criteria cover the following areas:

1. Total chemicals.
2. Excluded or limited substances or mixtures.
3. Toxicity to aquatic organisms: Critical Dilution Volume.
4. Biodegradability of organics.
5. Washing performance.
6. Packaging requirements.
7. Consumer information.
8. Information appearing on the EU Ecolabel.

1. Assessment and verification

(a) Requirements

The specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, it is understood that these may originate from the applicant, and/or his supplier(s), and/or their supplier(s), etc., as appropriate.

Where possible, the testing should be performed by laboratories that meet the general requirements of EN ISO 17025 or equivalent.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Appendix I makes reference to the detergent ingredient database (DID list) which contains the most widely used ingredients used in detergent formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) and for the assessment of the biodegradability of the ingredients. For substances not present on the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website or via the websites of the individual competent bodies.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

(b) Measurement thresholds

Constituent substances the concentration of which exceeds 0,010 % by weight of the preparation shall comply with the ecological criteria.

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For preservatives, colouring agents and fragrance compliance with the criteria is required regardless of their concentration except for criterion 2(b) on the content of hazardous substances and mixtures.

Ingoing substances are defined as all substances in the product including additives (e.g. preservatives or stabilizers) in the ingredients. Impurities resulting from the raw material production, which are present in concentrations > 0,010 % by weight of the final formulation shall also comply with the criteria.

If the product has a water-soluble foil intended not to be removed before washing, the foil must be considered to be part of the product formulation in all requirements.

2. Functional unit

The functional unit shall be the quantity of product required to wash 12 place settings with a standard soil (as defined by DIN or ISO standards).

3. Reference dosage

The dosage recommended by the manufacturer to consumers for normally soiled dishes and 12 place settings is taken as a reference dosage under standard conditions, as laid down in the IKW washing performance test referred to in criterion 5.

Requirements relating to assessment and verification of (2) Functional unit and (3) Reference dosage: The full formulation comprising trade name, chemical name, CAS No, DID No (*), ingoing quantity including and excluding water, and function of all the ingoing ingredients (regardless of concentration) in the product must be submitted to the competent body. A sample of the artwork including dosage recommendations must be submitted to the competent body.

Safety data sheets for each ingredient shall be submitted to the competent body in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽¹⁾.

The DID list can be found on the EU Ecolabel website: http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/did_list_en.htm

EU ECOLABEL CRITERIA

Criterion 1 – Total chemicals

Total chemicals (TC) are the recommended dosage in g/wash minus the water content.

The amount of total chemicals shall not exceed the following amounts:

(a) Single-functional dishwasher detergents: $TC_{max} = 20,0 \text{ g/wash}$

(b) Multi-functional dishwasher detergents: $TC_{max} = 22,0 \text{ g/wash}$

When calculating the CDV, aNBO and anNBO a dosage of rinse aid of 3 ml shall be used.

Assessment and verification: Calculation of the TC of the product. The density (g/ml) shall be stated for liquid products.

(*) DID No is the number of the ingredient on the DID list ('Detergent Ingredient Database' list), and is used in determining compliance with criteria 3 and 4. See Appendix I.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

▼B**Criterion 2 – Excluded or limited substances or mixtures***(a) Specified excluded ingredients*

The following ingredients must not be included in the product, neither as part of the formulation nor as part of any mixture included in the formulation:

- Phosphates
- DTPA (Diethylene triamine pentaacetic acid)
- Perborates
- Reactive chlorine compounds
- EDTA (ethylenediamine tetraacetate)
- Nitromusks and polycyclic musks

Assessment and verification: the applicant shall provide a completed and signed declaration of compliance.

(b) Hazardous substances and mixtures

According to Article 6(6) of the Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any part of it thereof shall not contain substances or mixtures meeting the criteria for classification with the hazard classes or categories in accordance with Regulation (EC) No 1272/2008 specified below nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006.

List of hazard statements:

GHS Hazard Statement ⁽¹⁾	EU Risk Phrase ⁽²⁾
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



GHS Hazard Statement ⁽¹⁾	EU Risk Phrase ⁽²⁾
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
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 through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	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 harmful 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 difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43

⁽¹⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽²⁾ Council Directive 67/548/EEC with adjustment to Regulation (EC) No 1907/2006 according to Directive 2006/121/EC of the European Parliament and of the Council and Directive 1999/45/EC of the European Parliament and of the Council as amended.

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This criterion applies to all ingredients present in concentrations $\geq 0,010$ %, including preservatives, colouring agents and fragrances.

The use of substances or mixtures which upon processing change their properties (e.g. become no longer bioavailable, undergo chemical modification) in a way that the identified hazard no longer applies are exempted from the above requirement.

Derogations: the following substances or mixtures are specifically exempted from this requirement:

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Subtilisin	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product	H400: Very toxic to aquatic life	R50
Surfactants in total concentrations < 25 % in the final product (*)	H412: Harmful to aquatic life with long-lasting effects	R52-53
Biocides used for preservation purposes (**)	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
Fragrances	H412: Harmful to aquatic life with long-lasting effects	R52-53
Enzymes (***)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA (****)	H351: Suspected of causing cancer	R40

(*) This derogation is applicable provided that they are ready degradable and anaerobically degradable.

(**) Referred to in Criterion 2(e). This derogation is applicable provided that biocides' bioaccumulation potentials are characterised by log Pow (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) ≤ 100 .

(***) Including stabilisers and other auxiliary substances in the preparations.

(****) 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 %.

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Assessment and verification: The applicant shall provide the exact formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures.

▼M2

For derogated surfactants meeting the criteria for classification with the hazard classes H412, the applicant shall provide documentation for their degradability making reference to the DID list. For surfactants not included in the DID list, reference shall be done to the relevant information from literature or other sources, or appropriate test results, as described in Appendix I.

▼B*(c) Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006*

No derogation from the exclusion in Article 6(6) 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 concentrations higher than 0,010 %.

Assessment and verification: The list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Reference to the list shall be made on the date of application. The applicant shall provide the exact formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures.

(d) Specified limited ingredients – fragrances

Any ingredients added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on IFRA website: <http://www.ifraorg.org>.

The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer.

Fragrance substances subject to the declaration requirement provided for in Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents (Annex VII) and which are not already excluded by criterion 2b and (other) fragrance substances classified H317/R43 (May cause allergic skin reaction) and/or H334/R42 (May cause allergy or asthma symptoms or breathing difficulties if inhaled) shall not be present in quantities $\geq 0,010$ % (≥ 100 ppm) per substance.

Assessment and verification: The applicant shall provide a signed declaration of compliance indicating the amount of fragrances in the product. The applicant shall also provide a declaration from the fragrance manufacturer specifying the content of each of the substances in the fragrances which are listed in Annex III, Part I to Council Directive 76/768/EEC as well as the content of (other) substances which have been assigned the risk phrases H317/R43 and/or H334/R42.

(e) Biocides

- (i) The product may only include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

Assessment and verification: the applicant shall provide copies of the material safety data sheets of any preservatives added, together with information on their exact concentration in the product. The manufacturer or supplier of the preservatives shall provide information on the dosage necessary to preserve the product (e.g. results of a challenge test or equivalent).

- (ii) It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial action.

Assessment and verification: the applicant shall provide texts and layouts used on each type of packaging and/or an example of each different type of packaging to the competent body.

▼B**Criterion 3 – Toxicity to aquatic organisms: Critical Dilution Volume (CDV)**

The critical dilution volume (CDV_{chronic}) of the product must not exceed the following limits for CDV_{chronic} :

Product type	Limit CDV_{chronic}
Single-functional dishwasher detergents	25 000 l/wash
Multi-functional dishwasher detergents	30 000 l/wash
Rinse aid	10 000 l/wash

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

$$CDV_{\text{chronic}} = \sum CDV_{(i)} = \sum \frac{\text{weight}_{(i)} \times DF_{(i)}}{TF_{\text{chronic}(i)}} \times 1,000$$

where

weight (i) = 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.

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

Assessment and verification: Calculation of the CDV_{chronic} of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website.

The values of the DF and TF parameters shall be as given in the Detergent Ingredient Database list (DID list). If the substance is not found on the DID list, the parameters shall be calculated using the guidelines in Part B of the DID list and attaching the associated documentation.

Criterion 4 – Biodegradability of organics

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

Product type	aNBO	anNBO
Dishwasher detergents	1,0 g/wash	5,50 g/wash
Rinse aid	0,15 g/wash	0,50 g/wash

Assessment and verification: Calculation of aNBO and anNBO for the product. A spreadsheet for use in calculating aNBO and anNBO values is available at the EU Ecolabel website.

Refer to the DID list. For ingredients which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically and anaerobically biodegradable shall be provided. See Appendix I.

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Note that TAED should be considered anaerobically biodegradable.

Criterion 5 – Washing performance (fitness for use)

The product shall have a satisfactory washing performance at the recommended dosage according to the standard test developed by IKW or the standard EN 50242 as modified as follows.

The tests shall be carried out at 55 °C or at a lower temperature if the product claims to be efficient at this temperature.

When applying for rinse aids in combination with dishwasher detergents, the rinse aid shall be used in the test instead of the reference rinse aid.

For multifunctional products the applicant must submit documentation proving the effect of the claimed functions.

Assessment and verification: The test report shall be submitted to the Competent Body. A test other than the IKW test or the modified version of EN 50242 may be used if the Competent Body assessing the application accepts its equivalence.

If EN 50242:2008 is used, the following modifications shall apply:

- the tests shall be carried out at 55 °C ± 2 °C (or at a lower temperature if the detergent claims to be efficient at a temperature below 55 °C) with cold pre-wash without detergent,
- the machine used in the test shall be connected to cold water and must hold 12 place settings with a washing index of between 3,35 and 3,75,
- the machine's drying programme shall be used, but only the cleanliness of the dishes shall be assessed,
- a weak acidic rinsing agent in accordance with the standard (formula III) shall be used,
- the rinsing agent setting shall be between 2 and 3,
- the dosage of dishwasher detergent shall be as recommended by the manufacturer,
- three attempts shall be carried out at a water hardness in accordance with the standard,
- an attempt consists of five washes where the result is read after the fifth wash without the dishes being cleaned between the washes,
- the result shall be better than or identical to the reference detergent after the fifth wash,
- recipe for the reference detergent (Detergent B IEC 436) and rinsing agent (formula III), see Appendix B in the standard EN 50242:2008 (the surfactants are to be stored in a cool place in watertight containers not exceeding 1 kg and are to be used within 3 months).

If rinse aid and salt functions are a part of a multifunctional product the effect must be documented by test.

The applicant must be able to document the effect of other functions in multifunctional detergents.

▼B**Criterion 6 – Packaging requirements***(a) Primary packaging per functional unit*

Primary packaging shall not exceed 2,0 grams per wash.

(b) Cardboard packaging

Cardboard primary packaging shall consist of ≥ 80 % recycled material.

(c) Labelling of plastic packaging

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.

(d) Plastic packaging

Only phthalates that at the time of application have been risk assessed and have not been classified according to criterion 2(b) may be used in the plastic packaging.

Assessment and verification: The applicant shall provide the calculation of the quantity of primary packaging and a declaration regarding the percentage of recycled material in cardboard packaging to the competent body. The applicant shall provide completed and signed declaration of compliance with 6d.

Criterion 7 – Consumer information*(a) Information on the packaging*

The following text (or equivalent) shall appear on or in the product:

‘This Ecolabelled detergent works well at low temperatures (*). Select low temperature washing cycles on the dishwasher, wash full loads and do not exceed the recommended dosage. This will minimise both energy and water consumption and reduce water pollution.

(*) The applicant shall insert here the recommended temperature or range of temperatures that shall not exceed 55 °C.’

(b) Dosage instructions

Dosage instructions shall appear on the product packages. The recommended dosages shall be specified for the ranges of water hardness appropriate to where the product is marketed. The instructions shall specify how to make best use of the product according to the soil.

The applicant shall take suitable steps to help the consumer respect the recommended dosage, for example by making available a dosage device (for powdered or liquid products), and/or by indicating the recommended dosage at least in ml (for powdered or liquid products).

(c) Information and labelling of ingredients

The type of enzymes shall be indicated on the packaging.

Assessment and verification: The applicant shall provide a sample of the product label together with a declaration of compliance with each Part (a), (b) and (c) of this criterion.

▼B**Criterion 8 – Information appearing on the EU Ecolabel**

Optional label with text box shall contain the following text:

- ‘— Reduced impact on aquatic ecosystems
- Restricted 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/promo/logos_en.htm

Assessment and verification: The applicant shall provide a sample of the label.

▼B*Appendix I***Detergents Ingredients Database (DID) list**

The DID list (Part A) is a list containing information of the aquatic toxicity and biodegradability of ingredients typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in Part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for calculation of the critical dilution volume). The list is a generic source of information and substances present on the DID list are not automatically approved for use in EU Ecolabelled products. The DID list (Parts A and B) can be found on the EU Ecolabel website.

For substances with no data regarding aquatic toxicity and degradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst-case approach shall be applied, using the parameters below:

Worst-case approach:

Ingredient	Acute toxicity			Chronic toxicity			Degradation		
	LC50/EC50	SF _(acute)	TF _(acute)	NOEC (*)	SF _(chronic) (*)	TF _(chronic)	DF	Aerobic	Anaerobic
'Name'	1 mg/l	10 000	0,0001			0,0001	1	P	N

(*) If no acceptable chronic toxicity data are found, these columns are empty. In that case TF(chronic) is defined as equal to TF(acute).

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

- (1) Until 1 December 2010 and during transition period from 1 December 2010 to 1 December 2015:

The test methods for ready biodegradability provided for in Directive 67/548/EEC, in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10 days window principle shall not apply for surfactants. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

- (2) After 1 December 2015 and during transition period from 1 December 2010 to 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008.

Documentation of anaerobic biodegradability

The reference test for anaerobic degradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate degradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate degradability has been attained under anaerobic conditions.

▼B*Extrapolation for substances not listed in the DID-list*

Where the ingredients that are not listed in the DID-list the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

- (1) Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic degradability of structurally related surfactants. Where anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID-list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g. C12-15 A 1-3 EO sulphate [DID No 8] is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g. literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)).
- (2) Perform screening test for anaerobic degradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent method.
- (3) Perform low-dosage degradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by ¹⁴C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.