APPLICATION PACK FOR

THE ECOLABEL

Application form and guidance document for the application for all-purpose cleaners and sanitary cleaners

Commission Decision of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for all-purpose cleaners and sanitary cleaners

Version 1.1 – March 2012

Contents

1 Introduction

Purpose

The purpose of this User Manual is to describe how the Ecolabel application should be assembled, and the process of assessment to ensure that the product complies with the EU Ecolabel criteria for all-purpose cleaners and sanitary cleaners. Compliance is shown by a mixture of technical documents related to the product(s), tests and applicant's declarations. In addition the manual describes the requirements for demonstrating continued compliance once the Ecolabel has been granted.

Disclaimer

This manual only serves as a guiding document. The legal base for being awarded the Ecolabel is **Regulation (EC) No. 66/2010** of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel and **Commission Decision of 28 June 2011 (2011/383/EU)** establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners.

Which products are eligible for the EU Ecolabel for all-purpose cleaners and sanitary cleaners?

The following types of products can apply for the EU Ecolabel:

all-purpose cleaners comprising detergent products intended for the routine cleaning of floors, walls, ceilings, windows and other fixed surfaces, and which are either diluted in water prior to use or used without dilution. All-purpose cleaners shall mean products intended for indoor use in buildings which include domestic, commercial and industrial facilities.

window cleaners comprising specific cleaners intended for the routine cleaning of windows, and which are used without dilution.

sanitary cleaners comprising detergent products intended for the routine removal, including by scouring, of dirt and/or deposits in sanitary facilities, such as laundry rooms, toilets, bathrooms, showers and kitchens. This subgroup thus contains bathroom cleaners and kitchen cleaners.

The product group covers products for both private and professional use. The products shall be mixtures of chemical substances and must not contain microorganisms that have been deliberately added by the manufacturer.

Who can apply for EU Ecolabel?

Applications for the EU Ecolabel may be submitted by manufacturers, importers, services providers, traders and retailers. Traders and retailers may submit applications in respect of products placed on the traders market under their own brand names.

- If a product originates in a single Member State the application shall be presented in this Member State.
- If a product originates in the same form in several Member States the application may be presented in one of those Member States.
- If a product originates outside the Community the application may be presented in any one of the Member States in which the product is to be or has been placed on the market.

What does an application/contract cover?

At application the applicant must report the trade names and identification or reference numbers of the products in question. All chemicals used for the Ecolabelled product must be reported in the application. When the application has been processed and approved by the Competent Body a certificate is issued to the applicant, with reference to the company, the range of products incl. trade names of the products certified. The certificate is attended by a contract specifying the reference of the decision for the product group in question. The contract must be signed by the applicant and by the competent body. In case the applicant (contract holder) wishes to extend the range of products, the following conditions apply:

- Extension with new trade names (no formulation changes, no influence on Ecolabel criteria): An application form must be forwarded to the Competent Body specifying the new trade names and product labels must be forwarded for approval. The applicant must declare (e.g. in a letter or email) that the formulation is identical to that already approved under the EU Ecolabel scheme. Upon validation by the Competent Body an updated appendix to the contract is forwarded specifying the new trade names added.
- Extension with new technical characteristics (e.g. modified product formulation, new product formulations added or other changes with influence on the Ecolabel criteria): An application form must be forwarded to the Competent Body specifying the relevant changes and the extensions must be approved by the Competent Body prior to use/marketing. If new trade names apply, the Competent Body will forward an updated appendix to the contract specifying the new trade names added.
- Extension with new suppliers: Updated declarations from the new suppliers showing compliance with the criteria must be forwarded to the Competent Body. An application form is not required.

Compiling documentation

The applicant must compile documentation for all relevant criteria for the product. For this purpose the User manual contains pre-made forms of declarations and test reports stating the information needed for the application. Two different levels for declarations are often used: declarations from the applicant/producer and declarations from the supplier. In case where the supplier must provide information which he wants to be held confidential to the applicant it can be sent directly to the Competent Body, which is assigned to treat information confidential.

All relevant documentation has to be sent to the Competent Body together with the application. A copy of all material must be kept at the applicant.

Choice of analytical laboratory

The criteria document states that "where possible, the testing should be performed by laboratories that meet the general requirements of EN ISO 17025 or equivalent". There is a need for a common practice as on how this shall be interpreted. A decision hierarchy for acceptance of a laboratory is described in the following (in ranked priority):

1. Laboratory tests shall be performed by laboratories that are accredited for the specified test method according to ISO 17025 or GLP, where possible. The Competent Bodies accept accredited laboratories in all Member States in the EU/EEA and in countries that have signed the mutual recognition agreement according to ILAC, the International Accreditation Organisation. If one or more laboratories accredited according to ISO 170025 or complying with the OECD principles of Good Laboratory Practice (GLP) exist in the Member State of the applicant or in the Member State of the manufacturer or service provider; such a laboratory shall be used either in that Member State or another.

2. Laboratories holding an accreditation for other tests than those required by the Ecolabel criteria can be accepted if they submit a declaration that the tests are done following the same quality management procedures as the tests for which they have obtained the accreditation. In case of doubt the Competent Body or national board shall inspect the laboratory that carries out the test or shall select an accredited auditor who will be charged to do so.

3. If neither option A) or B) can be satisfied, applicants should call on a non-accredited independent laboratory certified or approved by a Government Department or other public body in a Member State. In case of doubt, the Competent Body or national board shall inspect the laboratory that carries out the test or shall select an accredited auditor who will be charged to do so.

4. If none of options A-C) are possible, applicants may have the tests performed by an independent laboratory that is neither accredited nor approved by authorities according to option C). Laboratories with a quality management system shall be preferred. A laboratory situated in an organisation holding and ISO 9001 certificate may be accepted if the scope of the certification includes the laboratory. The competent body or other national board shall verify the competence of the laboratory that carries out the tests or shall select an accredited auditor who will be charged to do so.

5. If none of the above mentioned options can be fulfilled, the applicant may have the tests carried out in a company laboratory (that is not accredited according to ISO 17025 or does not comply with the OECD GLP principles, as such a laboratory is covered by option A). The Competent Body or national board shall ensure that the tests are properly carried out or shall select and accredited auditor who will be charged to do so. In this case, the laboratory shall have a quality management system. A laboratory within an organisation holding an ISO 9001 certificate is accepted as being under appropriate quality management if the scope of the certification includes the laboratory. This option may e.g. be used for testing fitness for use where no standardised test method (e.g. ISO, OECD etc) exists.

Test periods and test frequency

Test results/test reports will be required by the Competent Body upon application. It is the responsibility of the contract holder that the products are in continuous compliance with the Ecolabel criteria.

Once the products covered by the Ecolabel application have been awarded the Ecolabel, random tests (e.g. fitness for use) can be realized during the validity period of the Ecolabel by the Competent Body in order to check whether the products still comply with the Ecolabel criteria.

Continuous control – the responsibility of the applicant

After an Ecolabel has been granted the applicant must keep the dossier up to date. In case where continued tests or measurements are performed/required (e.g. in case of changes of the product formulation or for support of new product claims), the contract holder or the supplier is responsible for keeping a journal of the test results and the associated documentation. This documentation must be available at all times to the Competent Body if considered to be of influence on the continued compliance with the Ecolabel criteria. In case data shows that the product during the validity period no longer complies with the criteria this must be reported to the Competent Body immediately together with a statement for the non-compliance. The Competent Body will in each individual case decide the consequences of the non-compliance (e.g. demand for further testing, suspension of the label etc.).

Control of compliance with the criteria

The Competent Body may undertake all or any necessary investigations to monitor holder's compliance with both the product group criteria and the terms of use and provisions of the contract. To this end, the Competent Body may request, and the holder shall provide, any relevant documentation to prove such compliance.

Further, the Competent Body may, at any reasonable time and without notice, request, and the holder shall grant, access to the premises.

Costs

Application fee	**Amount (2011 figures)**
Application fee, first application	1200 €
Application fee, first application, for SME's and applicants from developing countries [1)]	600 €
Application fee, first application, for micro-enterprises [2)]	350 €
Application fee, renewal [3)]	600 €
Application fee, renewal, for SME's and applicants from developing countries [1,3)]	300 €
Application fee, renewal, for micro-enterprises [2,3)]	200 €
Fee for extension of a license	Spent working hours (fixed unit price per hour), max 1200/600/350 € (not exceeding the application fee).

[1)] SME's (Small and Medium-sized Enterprises): More than 10 but less than 250 employees and a yearly turnover equal to or less than 50 mio. € (according to Commission recommendation 2003/361/EC of May 6, 2003)
[2)] Micro-enterprise: Less than 10 employees and a yearly turnover equal to or less than 2 mio. € (according to Commission recommendation 2003/361/EC of May 6, 2003)
[3)] If application for renewal of a license is sent in after the license has expired a normal application fee corresponding to 1200/600/,50 € will apply

In addition, if the enterprise is either EMAS or ISO 14001 certified, an additional 20% discount on the application fee is given provided that the requirements to the Ecolabel are incorporated in the certification.

Annual Fee	**Amount**
Annual fee	1500 €
Annual fee for SME	750 €
Annual fee for micro-enterpises	350 €

Transition period for existing Ecolabelled products:

A transition period of 12 months applies in order to allow adjustment of products licensed according to the former version of the Ecolabel (criteria adopted in 2005).

Article 7, paragraph 3 of the revised criteria **(Commission Decision of 28 June 2011 (2011/383/EU)** states that "*Where the Ecolabel is awarded on the basis of an application evaluated according to the criteria set out in Decision 2005/344/EC, that Ecolabel may be used for 12 months from the date of adoption of this decision*".

The Ecolabel criteria for all-purpose cleaners and sanitary cleaners in 2005 expire 30 June 2011 and manufacturers or operators holding a license according to these criteria will thus need to apply for re-assessment according to the revised Ecolabel criteria set in **Commission Decision of 28 June 2011 (2011/383/EU)**. In order to maintain the license the products shall be evaluated and approved by a Competent Body no later than 28 June 2012.

The application process:

When ready to apply the applicant will have to fill in an application form which is found in this User's Manual part A. The application form must be send together with the relevant documentation to the Competent Body.

After receiving an application the Competent Body examines the documentation material including the possible material sent directly from the suppliers. The Competent Body can ask for further information, if necessary. The case officer at the Competent Body makes a status of any additional documentation required in order to comply with the Ecolabel criteria, if any. This status is forwarded to the applicant who will have to ensure that the relevant documentation is forwarded.

After all documentation has been approved the Competent Body may carry out an on-site visit to the applicant and/or his suppliers. The Competent Body judges from case to case whom to visit. When all requirements have been met, the Competent Body notifies the application in the European Commission who registers the contract.

When criteria documents are revised, the license holders will have to apply for re-assessment of their license according to the revised criteria. A transition period for adjusting the products and apply for re-assessment will apply. This will be announced by the European Commission.

Part A Application form

APPLICATION FORM

Application for the EU Ecolabel under Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel

The application form and application must be sent to:

[Insert name of Competent Body and contact details including address, telephone and fax numbers, email address]

Applicant's full name and address:

Contact Person:	Position:
Phone:	Fax:
Email:	Website:
VAT number:	If relevant, existing license No: XX/YYY

Information on the applicant:

In what capacity are you applying for the Ecolabel:

- ☐ Manufacturer
- ☐ Importer
- ☐ Service provider
- ☐ Wholesaler
- ☐ Retailer

Information on the product:

1. Product group:

2. Designation and specification of the product(s), including registered name(s):

3. Name and address of manufacturing site(s) (if different from above):

4. In case the product is made outside the EU, please confirm that it has been or will be placed on the market in *[insert name of country where application is received]*.

5. Other EU countries in which this product is sold (if sold under different names, please state names to be registered):

6. Rough estimate of annual number/volume of ecolabelled articles produced (please specify items, kilograms and/or litres):

7. Rough estimated value of annual sales, excluding VAT, in the European Economic Area (ie the European Community plus Norway, Iceland and Liechtenstein) of the product at ex-factory prices in € or *[insert local currency if applicable]*:

Information on the application:

Is this the first application for the EU Ecolabel for the product(s) specified above:

Yes: ☐ No: ☐

If no, please state when and where the first application was made, and with what outcome:

Please indicate if an application for the same product has been successful under other environment label schemes (e.g. the Nordic Ecolabel):

Application fee

An invoice will be sent when the application scheme and the attached declarations are received. Before the application can be processed, the applicant must pay the application fee relevant for the company.

Applicant's undertaking:

As the applicant for an EU Ecolabel, I hereby declare that:

I understand and accept the provisions of Regulation EC No. 66 / 2010 on the EU Ecolabel scheme, and in particular Article 6, paragraph 6, which states that the Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with 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 [11], nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. (*Note that article 7 enables the Commission to adopt measures to grant derogations from paragraph 6 under certain conditions*);

I undertake to ensure that the product compiles with the Ecolabel criteria at all times and to notify the *[Insert name of Competent Body]* immediately of any significant modification to it or to the production processes;

I take responsibility for the correct and proper use of the EU Ecolabel and the logo. For further information see *[Insert web address of Competent Body]*.

Signed:

Name in capitals:

Position in company:

Date: Company stamp:

DECLARATION

to be used to set fees for the European Ecolabelling

cf.

- Regulation (EC) No 66/2010 of The European Parliament and of The Council of 25 November 2009 on the EU Ecolabel appendix III and
- Statutory order from the Ministry of Environment and Energy No 274 of 26 April 2008 on the Community and the Nordic eco-labels *[Applicable for Member States joining the Nordic Ecolabel]*.

All questions below have to be answered before handling of the application can begin.

Is the company a micro sized company as defined in the Commission's Recommendation 2003/361/EC - i.e. under 10 employees and an annual turnover or total annual balance not exceeding 2 mill. Euro? ☐ Yes ☐ No

Is the company a small or medium sized company as defined in the Commission's Recommendation 2003/361/EC – i.e. under 250 employees and an annual turnover not exceeding 50 mill. Euro or total annual balance not exceeding 43 mill. Euro ? ☐ Yes ☐ No

Is the company situated in a developing country (as defined in the OECD's Development Assistance Committee's list of countries receiving development aid)? ☐ Yes ☐ No

Is the company registered under EMAS or certified under ISO 14001 and has the company in its environmental policy promised to keep the product group criterion in the standard-contracts period of validity, and is this promise established in the company's environmental objective? [1] ☐ Yes ☐ No

Date: _____ Company name: _____

Company stamp:

_____
Responsible person's signature

_____
Repeat with block letters

[1] If confirmed the company must send a copy of the annual affirmative environmental statement (EMAS) or valid ISO 14001 certificate and copy of the companies environmental policy and objectives (ISO 14001) in connection with the application and information on the annual turnover.

Part B Product assessment and verification

1 FIELD OF APPLICATION

APPLICANT'S DECLARATION

The Ecolabel can be awarded to *all-purpose cleaners and sanitary cleaners*.

The product group 'all-purpose cleaners and sanitary cleaners' is subdivided into three subgroups, which are defined as follows:

All-purpose cleaners comprising detergent products intended for the routine cleaning of floors, walls, ceilings, windows and other fixed surfaces, and which are either diluted in water prior to use or used without dilution. All-purpose cleaners shall mean products intended for indoor use in buildings which include domestic, commercial and industrial facilities.

Window cleaners comprising specific cleaners intended for the routine cleaning of windows, and which are used without dilution.

Sanitary cleaners comprising detergent products intended for the routine removal, including by scouring, of dirt and/or deposits in sanitary facilities, such as laundry rooms, toilets, bathrooms, showers and kitchens. This subgroup thus contains bathroom cleaners and kitchen cleaners.

The criteria for all-purpose cleaners and for sanitary cleaners are not applicable to cleaners that serve a particular purpose, such as to clean equipment or devices (for example, oven cleaners)

The product group shall cover products for both private and professional use.

The candidate product is a:

Consumer product ☐

I&I product ☐ Please specify: .....

All-purpose cleaner ☐

Window cleaner ☐

Sanitary cleaner ☐

2 PRODUCT FORMULATION

All substances in the product, including additives (e.g. preservatives or stabilizers) in the ingredients, of which the concentration exceeds 0.010% by weight of the final formulation shall comply with the EU Ecolabel criteria.

For Criterion 1, where each intentionally added substance should be included, irrespective of its weight. Impurities resulting from the production of the ingredients which are present in concentrations >0.010% by weight of the final formulation shall also comply with the criteria.

The water content and the substances of the candidate product must be listed below. If an ingredient (except perfume) consists of more than one chemical substance all individual substances must be listed and the concentration specified (in % (weight/weight) of the product). A Safety Data Sheet (SDS) shall be enclosed for all substances in the product. The concentration of substances in the product, which implies a requirement for documentation of compliance with the EU Ecolabel criteria, is generally defined at ≥0.010% by weight of the mixture.

MANUFACTURER'S DECLARATION

Water content of the candidate product: …..... % (w/w)

Substance		Function in product (e.g. surfactant, builder, preservative)	CAS No. (or CI No. or other precise description)	DID Number (if applicable)	Concentration (%, w/w)	SDS, Appendix No.
Trade name	Chemical name					

2.1 Modification of the product

Once the candidate product has been awarded an Ecolabel, the manufacturer is free to modify the product formulation or packaging so long as compliance with the criteria is maintained.

To cover its contingency, the following declaration must be completed by the manufacturer.

MANUFACTURER'S DECLARATION

I/We as person(s) responsible for manufacturing the candidate product agree to inform the CBs of any changes made to the product, during the entire period of the license, before the changed product is marketed, declaring whether or not the changes to formulation necessitate a new performance test.

I/We understand that if changes to the product formulation or packaging result in a break of compliance with the Ecolabel criteria, then the changed product will no longer be licensed to carry an Ecolabel.

Name ..... (Block Capitals) Signed ..... Position	Date:

Company Stamp or Seal

3 CRITERIA ON SUBSTANCES			
MANUFACTURER'S DECLARATION			
Criterion	Result	Unit	Pass criterion
1. Toxicity to aquatic organisms; Critical Dilution Volume toxicity (CDV_{tox})			
All-purpose cleaners, diluted in water prior to use, per litre of washing water		L	≤18000
All-purpose cleaners, used without dilution, per 100 g of product		L	≤52000
Window cleaners, per 100 g product		L	≤4800
Sanitary cleaners, per 100 g product		L	≤80000
2 a. Each surfactant used in the product shall be readily biodegradable	Yes ☐ No ☐	No unit	Yes
2 b. The total weight of anaerobically non-biodegradable surfactants must not exceed the limits listed in application form 3.4.	Yes ☐ No ☐	No unit	Yes
3 a-e. The substances comply with the requirements described in the criterion on excluded or limited substances and mixtures	Yes ☐ No ☐	No unit	Yes
4. The substances comply with the requirements described in the criterion on fragrances	Yes ☐ No ☐	No unit	Yes
Product does not contain fragrances	Yes ☐	Not relevant	
5. Total volatile organic compounds in the product.			
All-purpose cleaners and sanitary cleaners (as sold)		% (by weight)	≤6
All purpose cleaners and sanitary cleaners (in the washing water)		% (by weight)	≤0.2
Window cleaners		% (by weight)	≤10
9. Total phosphorus content			
All-purpose cleaners, diluted in water prior to use, per litre of washing water		g	0.02
All purpose cleaners, used without dilution, per 100 g product		g	0.2
Window cleaners		g	0
Sanitary cleaners, per 100 g product		g	1.0

3.1 Substances not included in the Detergents Ingredients Database list

In the case of substances not included in the Detergents Ingredients Database list Part A, the applicant must complete the following declaration and enter the summary data in the table in application form 3.2.

APPLICANT'S DECLARATION

As responsible for assessing substances used that are not listed on the DID list Part A, I declare that the experimental data for the candidate product provided by the manufacturer support the values for Toxicity Factor (TF chronic) and Degradation Factor (DF) that are summarised in the table in application form 3.2.

Signed .....

Name ..... (Block Capitals)

Date .....

Position .....

Company Stamp or Seal

3.2 Substances not included in the Detergents Ingredients Database list

For substances not included in the Detergents Ingredients Database list Part A, the applicant shall estimate the values of the Toxicity Factor (TF chronic) and Degradation Factor (DF) by use of the 'Procedure for establishing parameter values for substances not on the DID-list' (DID list, Part B). Relevant documentation in the form of test reports or copy of published data shall be enclosed.

APPLICANT'S DECLARATION

Substance	Toxicity		DF	Documentation, Appendix No.
	EC50, LC50 or NOEC	TF		

3.3 Biodegradability of surfactants (Criterion 2a)

All surfactants used in the product must be easily biodegradable, both under aerobic and anaerobic conditions.

This declaration must be completed by the surfactant manufacturer.

DECLARATION FROM THE SURFACTANT MANUFACTURER

Name of substances: …….

I/We as Person(s) responsible for manufacture of the surfactant, declare that the surfactant meets the following criteria:

a) The surfactant is readily biodegradable.

Compliance can be demonstrated by referring to the relevant DID-list number. If the compound is not on the list or it is not indicated as readily biodegradable, biodegradation tests must be performed. Documentation can be test report or copy of published data.

b) The total weight of anaerobically non-biodegradable surfactants must not exceed the limits listed in application form 3.4. Compliance can be demonstrated by referring to the relevant DID-list number. If the compound is not on the list or it is not indicated as anaerobically biodegradable, the approach described in the criteria (Appendix I) shall be used to provide documentation of anaerobic biodegradability. It follows from this approach that new biodegradation tests may be necessary to provide documentation. Documentation may be a test report or copy of published data.

Name ..... (Block Capitals) Signed ..... Position	Date:

Company Stamp or Seal

3.4 Anaerobic biodegradability of surfactants (Criterion 2b)

The total weight of anaerobically non-biodegradable surfactants does not exceed the following values:

All-purpose cleaners
(diluted in water prior to use) 0.40 g of the recommended dose for 1 litre of washing solution

All-purpose cleaners (used without dilution)
4.0 g per 100 g product

Sanitary cleaners
2.0 g per 100 g product

Window cleaners 2.0 g per 100 g product

APPLICANT'S DECLARATION

Substance	Weight (g) Per litre of washing solution or per 100 g product	Documentation, Appendix No.
Total		

3.5 Excluded or limited substances and mixtures (Criterion 3)

Certain specific substances shall not be included in the product, either as a part of the formulation or as part of any mixture included in the formulation. This declaration must be completed by the manufacturer.

MANUFACTURER'S DECLARATION

I/We as Person(s) responsible for manufacture, declare that the candidate product meets the following criteria:

The requirements stated in (a), (b) and (c) shall apply to each substance, including biocides, colouring agents and fragrances that exceeds 0.010% by weight of the final product. This includes also each substance of any mixture used in the formulation that exceeds 0.010% by weight of the final product. Nanoforms intentionally added to the product shall prove compliance with the criterion 3c) for any concentration.

a) The following substances shall not be included in the product, either as part of the formulation or as part of any mixture included in the formulation:

- Alkyl phenol ethoxylates (APEOs) and derivatives thereof
- EDTA (ethylene-diamine-tetra-acetate) and its salts
- 5-Bromo-5-nitro-1,3-dioxane
- 2-Bromo-2-nitropropane-1,3-diol
- Diazolinidylurea
- Formaldehyde
- Sodium hydroxy methyl glycinate
- Nitromusks and polycyclic musks, including for example:
  - Musk xylene: 5-Tert-butyl-2,4,6-trinitro-m-xylene
  - Musk ambrette: 4-Tert-butyl-3-methoxy-2,6-dinitrotoluene
  - Moskene: 1,1,3,3,5-Pentamethyl-4,6-dinitroindan
  - Musk tibetine: 1-Tert-butyl-3,4,5-trimethyl-2,6-dinitrobenzene
  - Musk ketone: 4'-Tert-butyl-2',6'-dimethyl-3',5'-dinitroacetaphenone
  - HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta(g)-2-benzopyran)
  - AHTN (6-Acetyl-1,1,2,4,4,7-hexamethyltetralin)

b) Quaternary ammonium salts that are not readily biodegradable shall not be used.

Quaternary ammonium salts are not used in the product ☐

Quaternary ammonium salts that are readily biodegradable are used and documentation for the biodegradability of these substances is attached ☐

c) The candidate product does not contain substances (in any forms, including nanoforms) meeting the criteria for classification with any of the following hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EEC.

For evaluation of compliance with this criterion, the hazard statements and risk phrases below refer to substances. Mixtures of enzymes and fragrances, where information on substances may be difficult to obtain, may be classified by using the rules for mixtures:

The candidate product does not contain ingredients which are classified as having one of the following risk/hazard phrases:

CMR substances

GHS Hazard statement	**EU Risk phrase**
H340: May cause genetic defects	R46
H341: Suspected of causing genetic defects	R68
H350: May cause cancer	R45
H350i: May cause cancer if inhaled	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: May damage fertility. May damage the unborn child	R62-63
H362: May cause harm to breast-fed children	R64

Acutely toxic substances / Specific target organ toxicity

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	R26
H331: Toxic if inhaled	R23
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	R48/23/24/25
H373: May cause damage to organs	R48/20/21/22

Sensitizing substances

H317: May cause allergic skin reaction	R43
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42

Environmentally hazardous substances

H400: Very toxic to aquatic life	R50/50-53
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

Physical/chemical or other properties

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

This criterion applies to all ingredients present in the formulation in concentrations ≥ 0.010%, including preservatives, colouring agents and fragrances. The risk phrases above generally refer to substances. However, for mixtures of enzymes and fragrances, where information on substances cannot be obtained, the classification rules for mixtures shall be applied.

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:

Surfactants In concentrations < 25% in the product*	H400 Very toxic to aquatic life	R 50
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
Enzymes**	H317: May cause allergic skin reaction	R43
NTA as an impurity in MGDA and GLDA***	H351 Suspected of causing cancer	R40

** The percentage must be divided by the M-factor established in accordance with the Regulation (EC) No 1272/2008*

***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%*

d) The candidate product, on the date of application, does not contain substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) 1907/2006 present in mixtures in concentrations higher than 0.010%

The list can be found here:
http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Concentration limits shall be specified in the safety data sheets in accordance with Article 31 of

Regulation (EC) No 1907/2006	
Name ..... (Block Capitals) Signed ..... Position	Date:
Company Stamp or Seal	

3.6 Excluded or limited substances and mixtures - verification (Criterion 3)

Certain specific substances shall not be included in the product, either as a part of the formulation or as part of any mixture included in the formulation. This declaration must be completed by the manufacturer.

In the absence of general definition, the term "**nanomaterial**" is used in this paper as a general term to cover manufactured (or engineered) nano-sized and nanostructured materials, without further specifying whether these materials are substances, forms of substances etc.

The term "**substance at nanoscale**" describes substances with properties specific for nanomaterials. The term does not distinguish between substances which only exist at the nanoscale and nanoforms of substances which also exist in bulk form. The term "**nanoscale**" mainly refers to the size of the particles, where one or more external dimensions is in the size range 1 nm - 100 nm. .

The term "**nanoform**" will be useful in cases where reference is made to particular forms of a substance with nanomaterial properties, as opposed to the "bulk form" of the same substance, i.e. (the) form(s) of the substance without nanomaterial properties.

Many substances have internal structures at the nanoscale, for example atoms, molecules, crystal layers etc., that individually could be considered as being at the nanoscale. As long as these are embedded in the matrix of larger sized structures they will not exert the specific characteristics of the nanoscale units. As defined by ISO (TS 27687), aggregates and agglomerates are "nanostructured materials". "Nanostructured materials" are a subcategory of the term "nanomaterial". Aggregates and agglomerates, often existing at a micro size, may have some of the behaviour and effects of their smaller sub units, e.g. due to an increased surface area. Thus, the terms nanomaterials, substances at nanoscale and nanoforms cover both 'nano-objects' and 'nano-structured materials' as defined by ISO (TS 27687).

DECLARATION FROM SUPPLIER OF THE SUBSTANCE

I/We as Person(s) responsible for manufacture, declare that the candidate product meets the following requirement:

Annex VII of the Regulation 1907/2006 as a minimum data set provided.

Name ..... (Block Capitals) Signed ..... Position	Date:
Company Stamp or Seal	

3.7 Biocides (Criterion 3e)

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.

Biocides, either as part of the formulation or as part of any mixture included in the formulation, that are used to preserve the product and that are classified as H410/R50-53 or H411/R51-53 in accordance with Directive 67/548/EEC, Directive 1999/45/EC or Regulation (EC) No 1272/2008 are permitted but only if their bioaccumulation potential is characterized by a log P_{ow} (log octanol/water partition coefficient) < 3.0 or an experimentally determined bioconcentration factor (BCF) ≤ 100).

DECLARATION FROM SUPPLIER OF THE BIOCIDE

I/We as Person(s) responsible for supplying the biocide ……..……..., declare:

The concentration of the biocide appropriate solely for the purpose of preserving the candidate product (and not for other purposes like, e.g., disinfection) is the following:

_____

The biocide:

Fulfils the criteria for classification as H410/ R50-53 ☐

Fulfils the criteria for classification as H411/R51-53 ☐

Does not fulfil the criteria for classification as H410/R50-53 or H411/R51-53 ☐

The biocide is not potentially bioaccumulative ☐

Log P_{ow} of the biocide: …….

Experimentally determined BCF (if available): ……..

Name ..... (Block Capitals) Signed ..... Position	Date:

4 FRAGRANCES	
DECLARATION FROM APPLICANT	
I declare that the product contains the following fragrances: Name of the fragrance:_____Amount in the product (%):_____ Name of the fragrance:_____Amount in the product (%):_____ Name of the fragrance:_____Amount in the product (%):_____ …	
Name ..... (Block Capitals) Signed ..... Position	Date:
Company Stamp or Seal	

4 FRAGRANCES

DECLARATION FROM PERFUME MANUFACTURER

Name of the fragrance: …….

I/We as Person(s) responsible for perfume manufacture, declare that the fragrance meets the following criteria:

a) The fragrance does not contain Nitromusks or polycyclic musks

b) The fragrance has been manufactured and/or handled following the code of practice of the International Fragrance Association (IFRA). The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials have been followed.

c) The fragrance contains the following amount of substances listed in Annex III, Part I to Council directive 76/768/EEC and substances which have been assigned the risk phrases R43/H317 and/or R42/H334:

Name of the substance:_____ Amount in the fragrance:_____

Name of the substance:_____ Amount in the fragrance:_____

Name of the substance:_____ Amount in the fragrance:_____

…

Name ..... (Block Capitals) Signed ..... Position	Date:

Company Stamp or Seal

5 VOLATILE ORGANIC COMPOUNDS (Criterion 5)	
All-purpose and sanitary cleaner (as sold): does not contain more than 6 % (by weight) of volatile organic compounds with a boiling point lower than 150 °C.	☐
Concentrated products to be diluted in water: the total concentration of volatile organic compounds with a boiling point lower than 150 °C does not exceed 0,2 % (by weight) in the washing water.	☐
Window cleaners (as sold) Does not contain more than 10 % (by weight) of volatile organic compounds with a boiling point lower than 150 °C.	☐

Name ..... (Block Capitals) Signed ..... Position	Date:
Company Stamp or Seal	
Copies of the material safety data sheets of each organic solvent together with details of the calculations of the total concentration of volatile organic compounds with a boiling point lower than 150 °C are to be provided.	

6 PHOSPHORUS (Criterion 6)

The total quantity of elemental phosphorous in the product should be calculated on the basis of the dosage of the product recommended by the manufacturer for preparing 1 litre of washing water for cleaning of normally soiled surfaces (for products diluted in water prior to use) or per 100 g of product (for products used without dilution) taking into account all substances containing phosphorus (e.g. phosphates and phosphonates).

For all-purpose cleaners, which are diluted in water prior to use:

the total phosphorus content (P) shall not exceed 0,02 g of the dosage of the product recommended by the manufacturer for 1 litre of washing water.

For all-purpose cleaners, which are used without dilution:

the total phosphorus content (P) shall not exceed 0,2 g per 100 g of product.

For sanitary cleaners:
the total phosphorus content (P) shall not exceed 1,0 g per 100 g of product.

Substances used in **window cleaners** must not contain phosphorus.

MANUFACTURER'S DECLARATION

I/We as Person(s) ……..…….., declare that the product meets the requirement as listed above.

Name ..... (Block Capitals) Signed ..... Position	Date:

Company Stamp or Seal

Exact formulation of the product is to be provided to the competent body, together with the details of the calculations showing compliance with this Criterion.

7 PACKAGING REQUIREMENTS

MANUFACTURER'S DECLARATION

The primary packaging (main container) is composed of:

Plastic ☐	Marked according to Dir. 94/62/EC or DIN 6120 Parts 1 and 2 in connection with DIN 7728 Part 1: Yes ☐ No ☐
Recycled material ☐	Any indication of the use of recycled material is in conformity with ISO 14021 standard: Yes ☐ No ☐

Spray contains propellants Yes ☐ No ☐

Product also sold as trigger spray Yes ☐ No ☐

Product will be sold as a part of refillable system Yes ☐ No ☐

The weight utility ratio (WUR) of the primary packaging does not exceed the following value:

☐ Products, including liquid concentrates and solids, i.e. products that are diluted in water prior to use.

WUR ≤ 1.20 g packaging per litre use solution

Yes ☐

No ☐

☐ Ready to use products, used by the consumer without further dilution.

WUR ≤ 150 g packaging per litre use solution

Yes ☐

No ☐

Name ..... (Block Capitals) Signed ..... Position	Date:

Company Stamp or Seal

7.1 Packaging material	
Requirements to packaging material.	
DECLARATION FROM MANUFACTURER OF PACKAGING MATERIAL	
I/We as Person(s) responsible for manufacture of packaging material, declare that the candidate product meets the following criteria: Plastic materials *that are used for the main container* shall be marked according to Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste, or DIN 6120 Parts 1 and 2 in connection with DIN 7728 Part 1. If the primary packaging is made of recycled material, any indication of this on the packaging shall be in conformity with the ISO 14021 standard 'Environmental labels and declarations – Self declared claims (type II environmental labelling)'. Only phthalates that at the time of application have been risk assessed and have not been classified according to criterion 3c may are used in plastic packaging.	
Name ..... (Block Capitals) Signed ..... Position	Date:
Company Stamp or Seal	

8 FITNESS FOR USE

The performance of the product must either be tested by an adequate and justifiable laboratory test, or an adequate and justifiable consumer test.

Both tests must be carried out and reported within specified parameters as stated in the framework described in 'Framework for testing the performance of all-purpose cleaners, window cleaners and sanitary cleaners' that can be found here: http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/pdf/purpose_cleaners/performance_test.pdf

A copy of the test report(s) shall be enclosed.

MANUFACTURER'S DECLARATION

I/We as Person(s) responsible for manufacture, declare that the candidate product meets the following criteria:

The product shall be fit for use, meeting the needs of the consumers.

For all purpose cleaners and window cleaners the cleaning ability must be equivalent to or better than that of a market-leading or generic reference product, approved by a Competent Body.

For sanitary cleaners the cleaning ability must be equivalent to or better than that of the generic reference detergent specified below.

The generic reference substance shall be the one prescribed in IKW performance test 'Recommendation for the quality assessment of acidic toilet cleaners' (SÖFW-Journal, 126, 11, pp. 50-56, 2000). The reference detergent is applicable for toilet cleaners and bathroom cleaners; however the pH must be reduced to 3.5 for the testing of the bathroom cleaners.

The IKW performance test 'Recommendation for the quality assessment of acidic toilet cleaners' can be downloaded from: http://www.ikw.org./pdf/broschuren/EQ_WC_Reiniger_English.pdf

Name ..... (Block Capitals) Signed ..... Position	Date:
Company Stamp or Seal	

9 CONSUMER INFORMATION

A sample of the product packaging, including the label, shall be provided to the Competent Body. This declaration must be completed by the manufacturer.

MANUFACTURER'S DECLARATION

I/We as persons(s) responsible for manufacture, declare that the packaging complies with the following criteria:

It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial action (see criterion 3e on 'Biocides').

Regulation (EC) No. 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents shall be applied.

Information on the recommended dosage of all-purpose cleaners and sanitary cleaners shall appear on the packaging in a reasonably sufficient size and against a visible background. In the case of a concentrated product, it shall be clearly indicated on the packaging that only a small quantity of the product is needed compared to normal (i.e. diluted) products.

The following text (or equivalent text) shall appear on the packaging:
'Proper dosage saves costs and minimises environmental impacts'.

The following safety advice (or equivalent text) shall appear on the product in text form or pictogram:

'Keep away from children'
'Do not mix different cleaners'
'Avoid inhaling sprayed product' (only for products that are packaged as sprays).

Optional label with text box shall contain the following text:

- reduced impact of aquatic life
- reduced use of hazardous substances
- reduced packaging waste
- clear user instructions

Name ..... (Block Capitals) Signed ..... Position	Date:
Company Stamp or Seal	

10 EXCLUSION OF INAPPROPRIATE INFORMATION OR ADVERTISING CLAIMS

This declaration must be completed by the manufacturer.

MANUFACTURER'S DECLARATION

I/We as person(s) responsible for manufacture of the candidate product, declare that product and advertising claims are in conformity with Directive 84/450/EEC concerning misleading advertising.

Neither we nor our agents shall use any form of advertising or product claim which would mislead a potential buyer of the product.

Documents justifying the validity and accuracy of any claims made in advertisements relating to the product or on the product packaging about environmental aspects of the candidate product are included in the documentation submitted to demonstrate compliance with the ecolabelling criteria.

Name ..... (Block Capitals) Signed ..... Position	Date:
Company Stamp or Seal	

11 CERTIFICATION OF COMPLIANCE WITH ECOLABEL CRITERIA

This declaration should be completed by the person responsible for assessing that the candidate product complies with the criteria.

APPLICANT'S DECLARATION

I/We as responsible for carrying out the assessment required for this application for the Ecolabel for all-purpose cleaners and cleaners for sanitary facilities, declare that the data and calculation of ingredient and packaging criteria are a true record of the results and that the product

..... (Name of Product/Type)

meets the criteria laid down in the Commission Decision **2011/383/EU** establishing the ecological criteria for the award of the Community eco-label to all-purpose cleaners and cleaners for sanitary facilities.

Product Assessed by ..... (Block Capitals)

Signed .....

Position .....

Date .....

Report Checked by ..... (Block Capitals)

Signed .....

Position .....

Date .....

Company Stamp or Seal