

APPLICATION PACK FOR THE EU ECOLABEL



Guidance document and Application forms for Industrial and Institutional Automatic Dishwasher Detergents

Version 1 – December 2012

Commission Decision of 14 November 2012 on establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents

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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 Industrial and Institutional Automatic Dishwasher Detergents. 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.

Attention!

This manual only serves as a guiding document. The legal basis 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 14 November 2012 (2012/720/EU)** establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents”.

Which products are eligible for the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents?

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

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 dishwashing detergents, detergents intended to be used in washers for medical devices or in special machines for cleaning industrial equipment, including special machines for the food industry.

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

Who can apply for the EU Ecolabel?

Applications for the Ecolabel may be submitted by producers, manufacturers, importers, wholesalers, retailers or services providers. Retailers may submit applications for products placed on the market under their own brand names.

Where to apply?

- If a product originates in a single country of the European Economic Area market (European Union plus Iceland, Lichtenstein and Norway) the application shall be presented to a Competent Body of that country.
- If a product originates in the same form in several countries of the European Economic Area the application may be presented to a Competent Body in one of those countries.
- If a product originates outside the European Economic Area market (European Union plus Iceland, Lichtenstein and Norway) the application may be presented to a Competent Body in any of the countries of the European Economic Area in which the product is to be or has been placed on the market.

What does an application/contract cover?

As part of the application the applicant must report the trade names and identification or reference numbers of the products in question. All ingoing substances 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 **application form (part A of this application pack) and the product assessment and verification (part B of this application pack)** must be completed and submitted to the Competent Body. The applicant must compile documentation for all the relevant criteria for the product(s). For this purpose **part B** contains checklists and pre-made forms of declarations stating the information needed for the verification. Two different types of declarations are often used; declarations from the applicant/manufacture and declarations from the supplier. In case the suppliers wish to keep the information confidential i.e do not want to reveal it to the applicant, the declarations/information can be sent directly to the Competent Body. All information supplied to the Competent Body will be treated as strictly confidential.

An **Excel File** for calculating the various parameters in the ecological criteria is available at the official EU Ecolabel homepage at <http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html> under the related product group. All relevant documentation must be sent to the Competent Body along with the application. A copy of the application material must at all times be kept with the applicant (and/or supplier).

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):

- A) 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.

- B) 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.
- C) 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.
- D) 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.
- E) 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 period 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 undertaken 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 cases where continued tests or measurements are performed/required (e.g. changes in the product formulation or to support 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. In case data shows that the product no longer complies with the criteria, this

must be reported to the Competent Body immediately together with a statement explaining the non-compliance. The Competent Body will in each individual case decide the consequences of such non-compliance (e.g. demand for further testing, suspension of the label etc.).

Control with the compliance of the criteria

The Competent Body may undertake all or any necessary investigations to monitor the ongoing compliance by the contract holder – both with the specific Ecolabel criteria for the product group and the terms of use and provisions of the contract. For this purpose the Competent Body may request any relevant documentation to prove such compliance. The contract holder is obliged to provide this documentation. Furthermore the Competent Body may at any reasonable time and without notice request and be granted access to the premises.

Costs

The applicant must pay all expenses for tests and verifications related to the application, holding and use of the Ecolabel.

The Competent Body to which an application is made shall charge a fee according to Annex III of Regulation (EC) No 66/2010 of 25 November 2009.

Applicant may be charged for travel and accommodation costs where an on-site verification is needed outside the Member State in which the Competent Body is based.

The application process

Once you would like to start the application, we would advise you to contact your Competent Body immediately. See section above ***Where to apply?*** to know which Competent Body(ies) you can apply to. The contact details of Competent Bodies are available at:

<http://ec.europa.eu/environment/ecolabel/competent-bodies.html>

To get the EU Ecolabel licence, it is mandatory to apply using the online application tool, Ecat_admin. Please register at the following address: https://webgate.ec.europa.eu/ecat_admin.

Download the E-Catalogue User Manual at <http://ec.europa.eu/environment/ecolabel/how-to-apply-for-eu-ecolabel.html>. It will help you navigate the online system. If you have any problems using the system, contact your Competent Body.

Please note that the required paper file will also need to be submitted to the relevant Competent Body once the application in Ecat admin has been made.

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

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

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 will judge the necessity of this on a case by case basis. When all requirements have been met, the Competent Body will sign a contract with the applicant specifying the terms of use of the EU Ecolabel, following the standard contract on Annex IV of the Regulation (EC) No. 66/2010 of 25 November 2009.

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.

For more information about the application process visit the EU Ecolabel website at:

<http://ec.europa.eu/environment/ecolabel/how-to-apply-for-eu-ecolabel.html>

Part A Application form



APPLICATION FORM

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

See the above section "***Where to apply***" to know where you have to send your EU Ecolabel application.

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 EU 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 European Economic Area market (European Union plus Iceland, Lichtenstein and Norway), 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):

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 or Blue Angel):

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. Please refer to the section for fees.

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 EU 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 complies with the EU 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;



Industrial and Institutional Automatic Dishwasher Detergents – Commission Decision 2012/720/EU

I take responsibility for the correct and proper use of the EU Ecolabel logo.

Signed:

Name in capitals:

Position in company:

Date:

Company stamp:

DECLARATION

to be used to set fees for the EU Ecolabel

cf.

- Regulation (EC) No 66/2010 of The European Parliament and of The Council of 25 November 2009 on the EU Ecolabel appendix III

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 and/or certified under ISO 14001 and has the company committed, in its environmental policy, to maintain compliance of its ecolabelled products with the EU Ecolabel criteria throughout the contract's period of validity? 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 EU Ecolabel can be awarded to "Industrial and Institutional Automatic Dishwasher Detergents" that comprise a single or 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 dishwashing detergents, detergents intended to be used in washers of medical devices or in special machines for cleaning industrial equipment, including special machines for the food industry.

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

The candidate product is designed for use in professional dishwashers:

Yes ☐ No ☐

The candidate product is not intended to be used in washers of medical devices or in special machines for cleaning industrial equipment, including special machines for the food industry:

Yes ☐ No ☐

The candidate product is a:

Single-functional dishwashing detergent ☐

Multi-functional dishwashing detergent² ☐

Rinse-aid ☐

Pre-soak ☐

The candidate product form is:

Powder ☐

Tablets ☐

Liquid (incl. gel) ☐

Other ☐ Specify: _____³

2 PRODUCT FORMULATION

The product formulation, including water, pre-products and in-going substances should be specified in the **Sheets "Formulation Pre-Products" and "Ingoing substances"** of the provided **Excel File**. According to the definition given in the criteria document, ingoing substances are preservatives and colouring agents, regardless of the concentration plus other substances

intentionally added, as well as by-products and impurities from raw materials, the concentration of which equals or exceeds 0.010 % by weight of final formulation

Compliance with the ecological criteria is required for all ingoing substances as defined above, unless otherwise specified.

Safety Data Sheets for each ingoing substance shall be submitted to the competent body in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

Dosage for soft, medium and hard water should be specified in the **Sheet "Results 1-2b-2g"** of the provided **Excel File**.

A sample of the artwork including dosage recommendations must be submitted to the Competent Body.

2.1 Modification of the product

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

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

MANUFACTURER'S DECLARATION

I/We as the 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 EU Ecolabel criteria, then the changed product will no longer be licensed to carry the EU Ecolabel.

Name (Block Capitals)

Date:

Signed

Position

Company Stamp or Seal

2.2 New chemicals/additional ingoing substances – applicants declaration

In the case of new chemicals or additional ingoing substances not listed in the Detergent Ingredients Database list Part A (available at <http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html>), the applicant must complete the following declaration and the summarised data may be

inserted in the associated table. Copies of the tests-reports shall be sent to the Competent Body.

APPLICANT'S DECLARATION

As I am responsible for assessing ingoing 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 associated table or otherwise enclosed with the application.

Signed

Name (Block Capitals)

Date

Position

Company Stamp or Seal

2.2 New chemicals/additional ingoing substances – summary of data

For ingoing substances not listed in the Detergent 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 ingredients 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

Ingoing substances	Toxicity		DF	Documentation, Appendix No.
	Lowest median NOEC (*)	TF _{chronic} (*)		

(*) Normally test results from long-term tests shall be used. If no such test results are available acute toxicity test results may be used. See description in the DID-list part B (Appendix 1).

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

3 CRITERIA VERIFICATION										
3.1 MANUFACTURER'S CHECKLIST (Criteria No. 1-7)										
<p>This checklist summarises the EU Ecolabel requirements and the documentation to be provided. This declaration <u>must</u> be completed by the applicant or manufacturer for each product and at all recommended water hardness levels.</p> <p>The product is a:</p> <p>Pre- soak: <input type="checkbox"/></p> <p>Dishwasher detergent: <input type="checkbox"/></p> <p>Multi-component-system <input type="checkbox"/></p> <p>Rinse aid <input type="checkbox"/></p>										
CRITERION 1 – CRITICAL DILUTION VOLUME	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY									
<p>The CDVchronic in g/l washing solution is:</p> <p>(please fill in the figures from the Sheet "Results 1-2b-2g" of the provided Excel File; in the case of multi-component systems please fill the figures from the Sheet "Results 1-2b-2g (multi-comp.)" of the provided Excel File).</p> <table border="1"> <tr> <th colspan="3">Water hardness</th> </tr> <tr> <td>Soft</td> <td>Medium</td> <td>Hard</td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </table>	Water hardness			Soft	Medium	Hard				<p><input checked="" type="checkbox"/> Filled sheet(s) "Results 1-2b-2g" of the provided Excel File; in the case of multi-component systems the Sheet "Results 1-2b-2g (multi-comp.)" of the provided Excel File should be filled as well.</p>
Water hardness										
Soft	Medium	Hard								
CRITERION 2a – BIODEGRADABILITY OF SURFACTANTS	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY									
<p>All surfactants are biodegradable under aerobic and anaerobic conditions</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p><input checked="" type="checkbox"/> Sheet "Result 2a" of the provided Excel File.</p> <p><input checked="" type="checkbox"/> Documentation for the degradability of all surfactants</p>									

CRITERION 2b – BIODEGRADABILITY OF ORGANICS SUBSTANCES	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY																		
<p>The aNBO in g/kg washing solution is</p> <table border="1" data-bbox="180 454 743 562"> <thead> <tr> <th colspan="3">Water hardness</th> </tr> <tr> <th>Soft</th> <th>Medium</th> <th>Hard</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>The anNBO in g/kg washing solution is:</p> <table border="1" data-bbox="180 685 743 792"> <thead> <tr> <th colspan="3">Water hardness</th> </tr> <tr> <th>Soft</th> <th>Medium</th> <th>Hard</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>(please fill in the figures from the Sheets "Results 1-2b-2g" of the provided Excel File; in the case of multi-component systems please fill the figures from the Sheet "Results 1-2b-2g (multi-comp.)" of the provided Excel File).</p>	Water hardness			Soft	Medium	Hard				Water hardness			Soft	Medium	Hard				<p><input checked="" type="checkbox"/> Filled sheet(s) "Results 1-2b-2g" of the provided Excel File; in the case of multi-component systems the Sheet "Results 1-2b-2g (multi-comp.)" of the provided Excel File should be filled as well.</p>
Water hardness																			
Soft	Medium	Hard																	
Water hardness																			
Soft	Medium	Hard																	
CRITERION 3a – Specified excluded ingoing substances	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY																		
<p>The following ingoing substances are not included in the product, neither as part of the formulation nor as part of any mixture included in the formulation:</p> <ul style="list-style-type: none"> • EDTA (ethylenediamine tetraacetate) • Fragrances • Reactive chlorine compounds • APEO (Alkyl phenol ethoxylates) and APD (Alkylphenols and derivatives thereof) <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p><input checked="" type="checkbox"/> Declarations from manufacturers of substances, as appropriate</p>																		
CRITERION 3b – Hazardous substances and mixtures	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY																		
<p>The ingredients comply with the requirements described in the criterion 3b:</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Derogations</p> <p>The following substances are covered by derogations. Does your product contain one of the following ingoing substances?</p>	<p><input checked="" type="checkbox"/> Signed declaration 3.2</p> <p><input checked="" type="checkbox"/> Per each Ingoing Substance other than the substances listed in Annexes IV and V of REACH:</p> <p>- Safety Data Sheet referred to the form and the physical state(s) of the substance in the final product</p>																		

<ul style="list-style-type: none"> • Surfactants meeting the criteria for classification with H400 <input type="checkbox"/> • Biocides (used for preservation) meeting the criteria for classification with H331, H334, H317 or H400 <input type="checkbox"/> • Enzymes meeting the criteria for classification with H334, H317 or H400 <input type="checkbox"/> • NTA as an impurity in MGDA/GLDA <input type="checkbox"/> 	- or Manufacturer's declaration 3.3 referred to the form and the physical state(s) of the substance in the final product.
CRITERION 3c – Substances listed in accordance with article 59(1) of Regulation (EC) No 1907/2006	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY
<p>At the time of application none of the ingoing substances, present in the product in concentrations > 0.010%, are substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006:</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p><input checked="" type="checkbox"/> Signed declaration 3.2</p> <p><input checked="" type="checkbox"/> Signed declarations 3.4 from the manufacturers of the ingoing substance</p>
CRITERION 3d – Biocides	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY
<p>(i) The product only includes 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):</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(ii) It is not claimed or suggested on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect:</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(iii) Biocides included in the products are not bioaccumulating (a biocide 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):</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Biocides' BFC or logKow information has to be provided in the Sheet "Ingoing substances" of the provided Excel File.</p>	<p><input checked="" type="checkbox"/> Material safety data sheets of the biocides used in the products</p> <p><input checked="" type="checkbox"/> Information by the manufacturer or supplier of the biocides on the dosage necessary to preserve the product.</p> <p><input checked="" type="checkbox"/> Texts and layouts of the packaging and/or an example of each different type of packaging</p> <p><input checked="" type="checkbox"/> Information on BCF or logKow for the biocides used</p>
CRITERION 3e – Colouring agents	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY
<p>Colouring agents included in the product are not bioaccumulating (a colouring agent is not considered</p>	<p><input checked="" type="checkbox"/> Information on BCF or log KOW of the colouring agents used</p>

<p>bioaccumulating if $BCF < 100$ or $\log K_{ow} < 3.0$. If both BCF and $\log K_{ow}$ values are available, the highest measured BCF value shall be used).</p> <p>The colouring agents are approved for use in foodstuff</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p>or</p> <p><input checked="" type="checkbox"/> Signed declaration that the colouring agents are approved for use in foodstuff</p>									
<p>CRITERION 3f – Enzymes</p>	<p>DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY</p>									
<p>Enzymes are in liquid form or dust-free granulate.</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Enzymes are free from micro-organism remnants from manufacture.</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p><input checked="" type="checkbox"/> SDS of any enzyme added</p> <p><input checked="" type="checkbox"/> Documentation ensuring that the enzymes used are free from microorganism remnants</p>									
<p>CRITERION 3g – Phosphorous</p>	<p>DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY</p>									
<p>The total quantity of phosphates and other phosphorous compounds does not exceed the limit values specified in the criteria document, calculated in grams of phosphorous per litre water.</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>The content of Phosphorus in the product is in g P /l water:</p> <table border="1" data-bbox="180 1232 742 1339"> <tr> <th colspan="3">Water hardness</th> </tr> <tr> <td>Soft</td> <td>Medium</td> <td>Hard</td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </table> <p>(please fill in the figures from the Sheets "Results 1-2b-2g" of the provided Excel File; in the case of multi-component systems please fill the figures from the Sheet "Results 1-2b-2g (multi-comp.)" of the provided Excel File).</p>	Water hardness			Soft	Medium	Hard				<p><input checked="" type="checkbox"/> Filled sheet(s) "Results 1-2b-2g" of the provided Excel File; in the case of multi-component systems the Sheet "Results 1-2b-2g (multi-comp.)" of the provided Excel File should be filled as well.</p>
Water hardness										
Soft	Medium	Hard								
<p>CRITERION 4 – PACKAGING REQUIREMENTS</p>	<p>DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY</p>									
<p>The following statements apply to the product's packaging or, in case of multi-component systems, to each component's packaging:</p> <p>WUR does not exceed the limits in the criteria document in grams per litre washing solution:</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p><input checked="" type="checkbox"/> Filled Sheet(s) "Packaging 4a" of the provided Excel file.</p> <p><input checked="" type="checkbox"/> Signed declaration 3.5 for the content of recycled or material from renewable origin in the packaging</p> <p><input checked="" type="checkbox"/> If refill packaging is used documentation that refills will be/are available for purchase on the market</p>									

<p>Cardboard/paper or plastic primary packaging consist of $\geq 80\%$ recycled material: Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Plastic primary packaging consist of $\geq 80\%$ material from renewable origin: Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Plastic parts in the primary packaging (excl. caps and pumps) is labelled acc. to DIN 6120, Part 2 or equiv.: Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Plastic packaging complies with the criterion on the use of phthalates: Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
CRITERION 5 – WASHING PERFORMANCE	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY
<p>The product(s) satisfy the requirements for the user test or internal testing in accordance with Appendix II in the criteria document. Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<input checked="" type="checkbox"/> A detailed test report including information/documentation as listed in Appendix II in the Criteria document.
CRITERION 6 – Automatic dosing system	DOCUMENTS TO BE SUBMITTED TO THE COMPETENT BODY
<p>The Multi-component system is offered together with an automatic and controlled dosing system: Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Customer visits is incorporated as a normal routine for manufacturers/suppliers and is performed at least once a year during the license period: Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<input checked="" type="checkbox"/> A written description of responsibility for, frequency and content of customer visits.
CRITERION 7a – Information on the packaging / product information sheet	
<p>The product complies with the requirement on Information on the packaging / product information sheet: Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<input checked="" type="checkbox"/> Product label or product sheet
CRITERION 7b – Information appearing on the EU Ecolabel	
<p>The EU Ecolabel logo is visible on the packaging and complies with the requirements in the criteria document and to the logo guidelines:</p>	

<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Does the label contain product claims? Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p><input checked="" type="checkbox"/> Appropriate test reports documenting eventual claims</p>
<p>Name Date: (Block Capitals)</p> <p>Signed</p> <p>Position</p>	
<p>Company Stamp or Seal</p>	

DECLARATIONS

3.2 HAZARDOUS SUBSTANCES AND MIXTURES (Criteria No. 3b and 3c)

MANUFACTURER'S DECLARATION

Certain specific ingredients shall not exceed a maximum content in the detergent formulation or are excluded. This declaration must be completed by the manufacturer.

I/We as the Person(s) responsible for manufacture of the detergent, declare that none of the ingoing substances listed in the product formulation table meet the criteria for classification with one or more of the following risk/hazard phrases in the form they are present in the product.

This criterion applies to 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, colouring agents and fragrance compliance with the criterion is required regardless of their concentration.

The risk phrases above generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall be applied.

Criterion 3b)

The candidate product does not contain ingoing substances which meet the criteria to be classified with 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	R23/26
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
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

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.

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

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

* Derogation is only for criterion 3b. Biocides shall comply with Criterion 3 d).

** 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%.

List all ingoing substances covered by the derogations:

Ingoing substance	Function	Concentrations (as in formulation)	H/R phrase

Criterion 3c)

I/We as the Person(s) responsible for manufacture of the detergent, declare that none of the ingoing substances present in the product in concentrations > 0.010%.are substances of very high concern included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006,

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 at:

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

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

3.3 HAZARDOUS SUBSTANCES AND MIXTURES (Criterion No. 3b)	
MANUFACTURER'S DECLARATION - INFORMATION ON RELEVANT CHARACTERISTICS OF SUBSTANCES* This form only has to be filled out if the form of the substance in the product is different than the form of the substance covered by the SDS or if no SDS is available for the substance in question.	
INGOING SUBSTANCE (or mixture):	
Form in the final product:	
Physical state(s) in the final product:	
PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE	
7.1. State of the substance at 20°C and 101,3 kPa	
7.2. Melting/freezing point	
7.3. Boiling point	
7.4. Relative density	
7.5. Vapour pressure	
7.6. Surface tension	
7.7. Water solubility	
7.8. Partition coefficient n-octanol/water	
7.9. Flash-point	
7.10. Flammability	
7.11. Explosive properties	
7.12. Self-ignition temperature	
7.13. Oxidising properties	
7.14. Granulometry	
TOXICOLOGICAL INFORMATION	
8.1. Skin irritation or skin corrosion The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reserve, (3) <i>in vitro</i> study for skin corrosion, (4) <i>in vitro</i> study for skin irritation.	

8.2. Eye irritation The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reserve, (3) <i>in vitro</i> study for eye irritation.	
8.3. Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human, animal and alternative data, (2) <i>In vivo</i> testing.	
8.4. Mutagenicity	
8.4.1. <i>In vitro</i> gene mutation study in bacteria	
8.5. Acute toxicity	
8.5.1. By oral route	
ECOTOXICOLOGICAL INFORMATION	
9.1. Aquatic toxicity	
9.1.1. Short-term toxicity testing on invertebrates (preferred species <i>Daphnia</i>) The registrant may consider long-term toxicity testing instead of short-term.	
9.1.2. Growth inhibition study aquatic plants (algae preferred)	
9.2. Degradation	
9.2.1. Biotic	
9.2.1.1. Ready biodegradability	
Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.	
On the basis of the information above, the substance meets the criteria for classification following risk/hazard phrase(s):	

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

*to see the specific rules according to which the required standard information may be omitted, replaced by other information, provided at different stage or adapted in another way, please refer to Annex VII of Regulation (EC) No 1907/2006.

3.4 HAZARDOUS SUBSTANCES AND MIXTURES (Criteria No. 3a, 3b, 3c)

Declaration of the manufacturer of raw materials

Manufacturer:

Product (raw material):

Criterion 3 — Excluded or limited substances and mixtures (Criterion 3a) Specified excluded ingoing substances

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

- EDTA (ethylene-diamine-tetra-acetic-acid) and its salts
- Fragrances
- Reactive chlorine compounds
- APEOs (Alkyl phenol ethoxylates) and APD (Alkyphenols and derivatives thereof)

It is hereby declared that these substances neither as part of the formulation nor as part of any mixture are included in the formulation (Limit 0,010%)

Exceptions:

Substance	CAS-No	Risk Phrase or Hazard Statement	Concentration in the product

(Criterion 3b) Hazardous substances and mixtures

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:

GHS Hazard statement⁴

Risk phrase⁵

CMR substances

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	R23/26
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
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

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.

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

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

* Derogation is only for criterion 3b. Biocides shall comply with Criterion 3 d).

** 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%.

It is hereby declared that these substances neither as part of the formulation nor as part of any mixture are included in the formulation (Limit 0,010%).

Exceptions (Example: all surfactants with risk phrase R50 must be listed):

Substance	CAS-No	Risk Phrase or Hazard Statement	Concentration in the product

(Criterion 3.c) Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006

No derogation from the exclusion in Article 6(6) of Regulation (EC) No 66/2010 may 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 %.

The list 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

It is hereby declared that actual listed substances neither as part of the formulation nor as part of any mixture are included in the formulation (Limit 0,010%)

Exceptions:

Substance	CAS-No	Risk Phrase or Hazard Statement	Concentration in the product

Date: _____

Place: _____

Name: _____ (Block Capitals)

Position: _____

Legally binding signature: _____

Company Stamp or Seal:

3.5 PACKAGING (Criteria No. 4a and 4b)		
DECLARATION FROM MANUFACTURER OF PACKAGING MATERIAL		
The packaging must fulfil certain requirements. This declaration <u>must</u> be completed by the manufacturer of the packaging material.		
<p>4 a) The primary packaging is:</p> <div style="text-align: right; margin-top: 10px;"> ____% recycled material (if any): ____% plastic material from renewable origin (if any): </div>		
Plastic	<input type="checkbox"/>	____%
Cardboard/paper	<input type="checkbox"/>	____%
Other	<input type="checkbox"/> Specify: _____	____%
<p>I/We as the Person(s) responsible for manufacture of packaging material, declare that the candidate product meets the following criteria:</p> <p style="margin-left: 40px;">4 b) Plastic packaging does not contain phthalates that at the time of application have been risk assessed and have not been classified according to requirement 4b (and combinations hereof).</p>		
Name (Block Capitals) Signed Position		Date:
Company Stamp or Seal		

4	EXCLUSION OF INAPPROPRIATE INFORMATION OR ADVERTISING CLAIMS	
This declaration <u>must</u> be completed by the applicant.		
APPLICANT'S DECLARATION		
<p>I/We as the person(s) responsible for marketing of the candidate product, declare that product and advertising claims are in conformity with Directive 84/450/EEC concerning misleading advertising.</p> <p>Neither we nor our agents shall use any form of advertising or product claim that would mislead a potential buyer of the product.</p> <p>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 or will be made available to the Competent Body on request.</p>		
Name (Block Capitals) Signed Position		Date:
Company Stamp or Seal		

5 CERTIFICATION OF COMPLIANCE WITH EU 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 carrying out the assessment required for this application for the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents, declare that the data and calculation of ingoing substances and packaging criteria are true record of the results and that the product

.....(name of the product)

meets the criteria laid down by the Commission Decision of 14 November 2012 (2012/720/EU) establishing the ecological criteria for the award of the EU Ecolabel to Industrial and Institutional Automatic Dishwasher Detergents.

Product assessed by:.....(Block capitals)

Signed.....

Position.....

Date.....

Report checked by.....(Block Capitals)

Signed.....

Position.....

Date.....

Company Stamp or Seal