Nordic Ecolabelling of

Cleaning Agents for Use in the Food Industry



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Draft for consultation

Nordic Ecolabelling

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This document is a translation of an original in Swedish. In case of dispute, the original document should be taken as authoritative.

Addresses

In 1989, the Nordic Council of Ministers decided to introduce a voluntary official ecolabel, the Nordic Ecolabel. These organisations/companies operate the Nordic ecolabelling system on behalf of their own country's government. For more information, see the websites:

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What are Nordic Ecolabelled Cleaning agents for use in the food industry?

Nordic Ecolabelled cleaning agents for use in the food industry are:

- Effective and with low environmental impact.
- The products contain substances which are not bioaccumulated, leading to a lower environmental impact on their discharge.
- Efficacy tested for use in specific application areas.

Why choose the Nordic Ecolabel?

- The producer of the cleaning agent for use in the food industry may use the Nordic Ecolabel trademark for marketing. The Nordic Ecolabel is a very well-known and well-reputed trademark in the Nordic region.
- The Nordic Ecolabel is a simple way of communicating environmental work and commitment to customers.
- The Nordic Ecolabel clarifies the most important environmental impacts and thus shows how a company can cut emissions, resource consumption and waste management.
- Environmentally suitable operations prepare for future environmental legislation.
- Nordic Ecolabelling can be seen as providing a business with guidance on the work of environmental improvements.
- The Nordic Ecolabel not only covers environmental issues but also quality requirements, since the environment and quality often go hand in hand. This means that a Nordic Ecolabel licence can also be seen as a mark of quality.

What can carry the Nordic Ecolabel?

The product group concerns cleaning agents intended for the cleaning of production premises (surfaces, walls and floors) and production equipment (pipe systems and other equipment) within the food industry, as well as cleaning agents for catering kitchens.

The food industry is defined as the following activities:

- Food production
- Production of beverages
- Processing and preserving of meat and meat products
- Processing and preserving of fish and crustacean and molluscan shellfish
- Processing and preserving of fruit, berries and vegetables
- Production of vegetable and animal oils and fats

- Production of dairy products and ice cream
- Production of grain mill products and starches
- Production of bakery and flour products
- Other food production
- Production of prepared animal feeds

The definition of the food industry is taken from the EU's statistical classification of economic activities, NACE, which is a statistical standard used to classify entities such as companies and workplaces according to their economic activities1.

Catering kitchens are kitchens intended for the preparation of a small number of dishes for many people at the same time, such as hospitals and schools. For products for restaurants, reference is made to the criteria for cleaning agents.

Products for both automatic and manual dosing can be Nordic Ecolabelled within the product group. Nordic Ecolabelled cleaning agents for use in the food industry can only be marketed to professional users.

The criteria do not include personal hygiene products, disinfectants, band lubricants, dishwasher detergents, products with microorganisms or two-component products. Disinfectants are not included in the product group since they are covered by the Biocides Directive.

With regard to products that cannot be Nordic Ecolabelled according to this criteria document, reference is made to Nordic Ecolabelling's other criteria documents, such as machine dishwasher detergents for professional use, cleaning agents or industrial cleaning and degreasing agents.

How to apply

Application and costs

For information about the application process and fees for this productgroup, please refer to the respective national web site. For addresses see page 2.

What is required?

The application must consist of an application form/web form and documentation showing that the requirements are fulfilled.

Each requirement is marked with the letter O (obligatory requirement) and a number. All requirements must be fulfilled to be awarded a licence.

The text describes how the applicant shall demonstrate fulfilment of each requirement. There are also icons in the text to make this clearer. These icons are:

✉ Enclose

🔑 The requirement checked on site

[1] SCB: http://www.scb.se/SNI2007/, (visited 2016-03-07)

All information submitted to Nordic Ecolabelling is treated confidentially. Suppliers can send documentation directly to Nordic Ecolabelling, and this will also be treated confidentially.

License validity

The ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be extended or adjusted, in which case the licence is automatically extended and the licensee informed.

Revised criteria shall be published at least one year prior to the expiry of the present criteria. The licensee is then offered the opportunity to renew their licence.

On-site inspection

In connection with handling of the application, Nordic Ecolabelling normally performs an on-site inspection to ensure adherence to the requirements. For such an inspection, data used for calculations, original copies of submitted certificates, test records, purchase statistics, and similar documents that support the application must be available for examination.

Queries

Please contact Nordic Ecolabelling if you have any queries or require further information. See page 2 for addresses. Further information and assistance (such as calculation sheets or electronic application help) may be available. Visit the relevant national website for further information.

1 Environmental requirements

The requirements in Chapter 1 of the criteria apply to all constituent substances in the product (cleaning agent), unless otherwise specified.

The calculations are based on the highest recommended dose stated as grammes of the product/litres of water.

Constituent substances and impurities

All substances in the product are counted as constituent substances, unless otherwise stated, including additives (e.g. preservatives and stabilisers) in the raw materials, but not impurities deriving from production, including raw materials production.

Impurities are residues from production, including raw materials production, which may be found in the product at concentrations below 100 ppm (0.0100% by weight, 100 mg/kg), but not substances that have been added to a raw material or product actively and for a particular purpose, irrespective of quantity. Impurities in concentrations exceeding 1.0% in of the raw material are considered to be constituent substances. Known degraded substances/products (such as formaldehyde or and arylamine) from constituent substances are also considered to be constituent substances.

O1 Information about the product

a) The applicant must give detailed information on the cleaning agent to which the application relates. The following information is required:

Description of the product's area of use, in accordance with "What can be Nordic Ecolabelled?"

Description of the product type (e.g. alkaline, acidic, CIP) and the product's use, in terms of whether it must be diluted or used without dilution.

b) The applicant must provide detailed information on the formulation of the product, and enclose a safety datasheet for each raw material. The information on the product's formulation must include:

- Trade name
- Chemical name
- Amount (both with and without solvents, e.g. water)
- CAS number of each constituent substance (if a raw material has several constituent substances, this must be stated)
- Function
- DID number for substances that can be placed in the DID list
- Classification

The DID number is an ingredient's number on the DID list, which is used on calculating chemical requirements. The DID list can be obtained from Nordic Ecolabelling's websites, see addresses on page 2.

✉ A complete declaration of the formulation of the product with information as set out in the requirement.

✉ Safety datasheet for each constituent raw material in accordance with the REACH Chemicals Regulation (1907/2006) Annex II.

✉ Signed and completed declaration of compliance with the product requirement, Appendix 2 or similar documentation.

O2 Classification of the product

The final product (cleaning agent) may not be classified according to table O2 below, according to the CLP Regulation 1272/2008 with subsequent amendments.

Table O2 - Classification of the product

CLP Regulation 1272/2008		
Hazard class	**Signal word, Category code**	**Hazard statement**
Toxic to aquatic organisms	Warning, Aquatic acute 1 Warning, Aquatic chronic 1 -, Aquatic chronic 2 -, Aquatic chronic 3 -, Aquatic chronic 4	H400 H410 H411 H412 H413
Hazardous to the ozone layer	Warning, Ozone	H420
Carcinogenicity*	Risk, Carc. 1A or 1B Warning, Carc. 2	H350 H351
May cause genetic defects*	Risk, Muta. 1A or 1B Warning, Muta. 2	H340 H341
Toxic for reproduction*	Risk, Repr. 1A or 1B Warning, Repr. 2 -, Lact.	H360 H361 H362
Acute toxicity	Risk, Acute Tox. 1 or 2 Risk, Acute Tox. 1 or 2 Risk, Acute Tox. 1 or 2 Risk, Acute Tox. 3 Risk, Acute Tox. 3 Risk, Acute Tox. 3 Warning, Acute tox 4** Warning, Acute tox 4** Warning, Acute tox 4**	H300 H310 H330 H301 H311 H331 H302 H312 H332
Specific target organ toxicity	Risk, STOT SE 1 Warning, STOT SE 2 Risk, STOT RE 1 Warning, STOT RE 2	H370 H371 H372 H373
Aspiration hazard	Risk, Asp. Tox. 1	H304
Airway or skin sensitising	Risk, Resp. Sens. 1, 1A or 1B Warning, Skin Sens. 1, 1A or 1B or products labelled EUH208: “Contains (name of sensitising substance). May cause an allergic reaction.”	H334 H317
Highly flammable	Flammable Aerosols 1, 2 or 3 Flammable Liquids 1, 2 or 3	H222, H223, H229 H224, H225, H226

* *The classifications in the Table concern all variants within the respective classification. For example, H350 also covers classification H350i.*

** *Exceptions: Products may be labelled as Acute tox, Cat 4 with H332, H312 and/or H302 if the packaging is designed so that the user is not in contact with the product.*

Please note that the producer/supplier is responsible for the classification.

✉ Safety datasheet for the end-product in accordance with the REACH Chemicals Regulation (1907/2006), Annex II.

✉ Description of the packaging design showing that the user is not in contact with the product for the products for which an exemption is made from the requirement of classification as H332, H312 and/or H302. Documentation in the form of a technical description and user instructions showing how the user avoids contact with the product.

O3 Classification of a product's constituent substances

The cleaning agent may not contain substances which are, or can give off substances that are carcinogenic (Carc), mutagenic (Muta) or reprotoxic (Repr) with the following hazard codes or risk phrases, or combinations thereof, see table O3 below. The cleaning agent may not contain substances which are classified as sensitising with H334 or H317, respectively, according to table O3 below.

Table O3 - Classification of a product's constituent substances

Classification under CLP Regulation 1272/2008	
Carcinogenic*	Carc 1A or 1B; H350 Carc 2; H351
Mutagenic*	Muta 1A or 1B; H340 Muta 2; H341
Reprotoxic *	Repr 1A or 1B; H360 Repr 2; H361 Lact. H362
Sensitising	Resp. Sens. 1, 1A or 1B H334 Skin Sens. 1, 1A or 1B H317

* *The classifications in the Table concern all classification variants. For example, H350 also covers classification H350i.*

Exemptions:

- Enzymes (including stabilisers and preservatives in enzyme raw materials) are exempt from the requirement concerning sensitising substances, provided that the enzymes are in liquid form or as non-dust-forming granulates.
- Complexing agents of the MGDA and GLDA type may contain NTA impurities in the raw material in concentrations of less than 0.2%, if the concentration of NTA in the cleaning agent is below 0.1%.

✉ A signed and completed declaration of compliance with the requirement for the product (Appendix 2 or equivalent documentation) and the raw materials (Appendix 3 or equivalent documentation).

✉ Safety datasheet for each constituent raw material in accordance with the REACH Chemicals Regulation (1907/2006) Annex II (see O1).

✉ Documentation on the safety datasheet or similar that the enzymes are in liquid form or in the form of non-dust-forming granulate.

O4 Long-term environmental effects

The use of substances which are classified with any of the hazard statements H410, H411 or H412 is limited as follows:

$100*C_{H410} + 10*C_{H411} + C_{H412} \leq 0.0010$ grammes/litre in-use solution

where

C_{H410} = concentration of substances with H410 in grammes/litre in-use solution

C_{H411} = concentration of substances with H411 in grammes/litre in-use solution

C_{H412} = concentration of substances with H412 in grammes/litre in-use solution

Exemptions

- Protease/Subtilisin classified as Aquatic Chronic 2 (H411) is exempt from the requirement, see also the requirement concerning enzymes in O3.
- Surfactants classified as H412 are exempted from the requirement, on condition that they are readily biodegradable* and anaerobically biodegradable**.

[*] *In accordance with the DID list. If the substance is not on the DID list, or data on the DID list is lacking, the substance is documented in accordance with test method no. 301 A-F or no. 310 in the OECD guidelines for testing of chemicals, or other equivalent test methods.*

[**] *In accordance with the DID list. If the substance is not on the DID list, the substance is documented in accordance with ISO 11734, ECETOC no. 28 (June 1988) or other equivalent test methods, where biodegradability of at least 60% is achieved in anaerobic conditions.*

If information about the substance being hazardous to the environment (in the form of data concerning toxicity and biodegradability, or toxicity and bioaccumulability) is not available, the substance is treated as a worst case, i.e. as environmentally hazardous, H410.

✉ Report on surfactants that are to be exempted from the requirement (quantity, classification, biodegradability).

✉ Summary of the product's content in % by weight of substances classified as H410, H411 and H412.

✉ Appendices 2 (product) and 3 (raw material) signed and completed, or alternatively equivalent signed information.

✉ Calculation according to the above formula showing that the requirement is fulfilled.

O5 Preservatives

a) Preservatives that are included in the end product or in one of the constituent substances may not be bioaccumulative. Preservatives are assessed to be non-bioaccumulative if BCF < 500 or logKow < 4. If both values are available, the value for the highest measured BCF is to be used.

b) The concentration of the preservative must be optimised and a Challenge test or equivalent must be performed to show this.

c) Preservatives are only permitted to conserve products or raw materials and not to give the product an antibacterial or disinfecting effect.

✉ Documentation of BCF or logKow (e.g. safety datasheet, see requirement O1).

✉ Appendices 2 (product) and 3 (raw material) signed and completed, or alternatively equivalent signed information.

✉ Test report for the completed Challenge test or equivalent showing that an optimum concentration of the preservative is used in the product. See Appendix 1 concerning test laboratory requirements and for information on Challenge tests.

✉ Signed and completed declaration that preservatives have only been added to conserve the product or raw material (Appendices 2 and 3, or equivalent documentation).

O6 Colourants

Colourants included in the product or constituent substances may not be bioaccumulative. Colourants are assessed to be non-bioaccumulative if BCF < 500 or logKow < 4.0. If there is information on both BCF and logKow, the value for the highest measured BCF must be used. Colourants approved for food products are also accepted (with E number).

✉ Documentation of the colourant's BCF or logKow (e.g. safety datasheet, see O1) or state E number.

✉ Appendices 2 (product) and 3 (raw material) signed and completed, or alternatively equivalent signed information.

O7 Phosphorus

The total amount of phosphorus from phosphates, phosphonates and other phosphorus compounds may not exceed 0.50 g P/litre of in-use solution, calculated as grammes of phosphorus per litre of in-use solution. The highest recommended dose must be used to calculate phosphorus.

Observe the national legislation concerning phosphorus where the product is to be sold/marketed. In Norway, phosphorus is subject to the "Regulation on restrictions to the use of health- and environmentally-hazardous chemicals and other products (Product Regulations)", Sections 2-12.

✉ Calculation of the total volume of phosphorus (calculated as elementary phosphorus, P) in the in-use solution.

O8 Substances prohibited from products

The following compounds may not be included in the product or exist as actively added substances in the raw materials:

- Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD)
- EDTA (Ethylene diamine tetraacetate and its salts) and DTPA (Diethylenetriamine pentaacetate)
- Organic chlorine compounds and hypochlorites
- Volatile organic compounds (VOC)
- Volatile organic compounds are defined in accordance with the European Commission's directive 1999/13/EC on the limitation of emissions of volatile organic compounds with steam pressure > 0.01 kPa at 20°C.
- Fragrances
- Benzalkonium chloride (CAS 8001-54-5)
- Fluorine surfactants and other per- and polyfluorinated compounds (PFC)
- Substances on the Candidate List (SVHC)*.
- Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects. The full list can be seen at
- http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf (Annex L, page 238ff.)
- Substances evaluated by the EU to be PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated, but which meet these criteria.
- Nanomaterials/particles **

* *The Candidate List can be found on the ECHA website at: http://echa.europa.eu/candidate-list-table*

** *Nanomaterials/particles are defined in accordance with the European Commission's definition of nanomaterials dated 18 October 2011, with the exception that the limit for the particle size distribution is reduced to 1%. "Nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm." Examples are ZnO, TiO_2, SiO_2, Ag and laponite with particles of nanosize in concentrations exceeding 1%. Polymer emulsions are not considered to be nanomaterial.*

✉ Signed and completed declaration that the aforementioned substances are not included in the end-product (Appendix 2 or equivalent), nor actively added to the raw material (Appendix 3 or equivalent).

O9 Surfactants, easily aerobically and anaerobically biodegradable

All surfactants must be easily biodegradable according to test method no. 301 A - F in the OECD guidelines for testing of chemicals or other equivalent testing methods.

All surfactants must be anaerobically biodegradable in accordance with ISO 11734, ECETOC no. 28, DIN 38414 part 8 or equivalent testing methods.

✉ Reference to the DID list dated 2014 or later versions. If the DID list lacks the relevant data for surfactants, data may be taken from the safety datasheet on condition that the data is reliable and that the test methods are in agreement with Appendix 1. Section B of the DID list shows how to make the calculations of the various factors. It is also permitted to refer to analogous observations, as long as they are carried out by a competent third party, and refer to relevant data from literature that has been subject to scientific scrutiny.

O10 Content of substances which are not aerobically and/or anaerobically biodegradable

The product's total content of substances that are not aerobically (aNBO) biodegradable may not exceed the following limits per litre of in-use solution. The product's total content of substances that are not anaerobically (anNBO) biodegradable may not exceed the following limits per litre of in-use solution.

Note that all surfactants must be aerobically and anaerobically biodegradable in accordance with O9. See also the exemption from the requirement of anaerobic biodegradability for substances which are not surfactants (Appendix 1, item 6, Anaerobic biodegradability).

Table O10: Threshold values for aNBO and anNBO

Category	aNBO (g/litre of in-use solution)	anNBO (g/litre of in-use solution)
Concentrated products	0.40	0.50
Ready-to-use products	0.40	0.50

Note that the following exemptions apply:

- Iminodisuccinate (DID 2555) can be excluded from the calculation of anNBO.

✉ Calculation of the concentration of aNBO and anNBO for the cleaning agent in grammes/litre of in-use solution.

Reference to the DID list, 2014 or later versions. For substances not included on the DID list, the related documentation must be submitted.

O11 CDV (critical dilution volume)

The critical dilution volume (CDV) is calculated for all constituent substances included in the cleaning agent. CDV is a theoretical value that takes account of each substance's toxicity and biodegradability in the environment.

The product's critical dilution volume (CDV) is calculated on the basis of the highest recommended dosage stated on the packaging.

The product's critical dilution volume (CDV) may not exceed the following threshold value for $CDV_{chronic}$.

Table O11. CDV threshold value

Category	$CDV_{chronic}$
Concentrated products	30000
Ready-to-use products	300000

CDV is calculated using the following formula for all substances in the product:

$CDV_{chronic} = \sum CDVi = \sum (dose_i \times DF_i \times 1000 / TF_{i\ chronic})$

$dose_i$ = the constituent volume of each individual substance "i", in g/l in-use solution

DF_i = biodegradation factor for substance "i", in accordance with the DID list

$TF_{i\ chronic}$ = chronic toxicity factor for substance "i", in accordance with the DID list. If $TF_{i\ chronic}$ is lacking, $TF_{i\ acute}$ can be used.

There are calculation sheets for the calculation of CDV on the respective secretariats' websites.

✉ Calculation of CDVchronic for the cleaning agent.

Reference to the DID list, 2014 or later versions. For substances not on the DID list, the parameters must be calculated based on the guidance in part B of the DID list, and the related documentation must be submitted.

2 Performance, packaging and information text

O12 Performance and user test

Products must show satisfactory performance/quality within the application areas for which they are intended. The product's performance/quality must be documented by user tests, see Appendix 4.

The user test must be performed by at least five test sites, which include the majority of the areas of use for which the product is intended. Dosing must be in accordance with the producer's recommendations for normal soiling. The test period must be at least four weeks.

At least 80% of the test sites must assess the product's performance/quality as "satisfactory" or "very satisfactory", compared to the product which they normally use (see Appendix 4), for the requirement to be fulfilled.

✉ At least five user tests designed in accordance with Appendix 4.

✉ A report that describes which and how many test sites were asked and a summary of the results.

O13 Labelling of packaging

Plastic packaging must be labelled in accordance with DIN 6120 part 2, ISO 11469 1469:2000 or the equivalent. Plugs, caps and pumps are exempt from this requirement.

✉ Documentation of primary packaging showing that the labelling is in accordance with DIN 6120 or equivalent labelling, images of the product's labelling, or datasheets showing the labelling. Labelling can also be shown on an attached label, if this is supplemented with documentation of the type of plastic from the packaging producer.

O14 Information text and user and dosing information

A technical description of the product or information included with the product, stating the following information:

- Recommended dose for normal use and on normal soiling (applies to products for dilution before use).
- Recommended dose can be stated as e.g. number of ml or dl, pump strokes or caps.

- Description of how the user avoids contact with the product using e.g. protective equipment.
- The information text on the packaging must adhere to the detergent regulations, 648/2004/EC and 907/2006/EC.

✉ Label, draft label or copy of the information (information text and user instructions) on the primary packaging and technical product datasheet (if found), showing the dose and user instructions in accordance with the requirement. The information on labels and/or product datasheets must be in the languages in which the product is marketed.

3 Quality and regulatory requirements

To ensure that Nordic Ecolabel requirements are fulfilled, the following procedures must be implemented.

O15 Responsible person and organisation

The company shall appoint individuals who are responsible for ensuring the fulfilment of Nordic Ecolabel requirements, for marketing and for finance, as well as a contact person for communications with Nordic Ecolabelling.

✉ Organisational chart showing who is responsible for the above.

O16 Documentation

The licensee must archive the documentation that is sent in with the application, or in a similar way maintain information in the Nordic Ecolabelling data system.

🔎 Checked on site as necessary.

O17 Quality of cleaning agents for the use in food industry

The licensee must guarantee that the quality of the Nordic Ecolabelled product does not deteriorate during the validity period of the licence.

✉ Procedures for archiving claims and, where necessary, dealing with claims and complaints regarding the quality of the Nordic Ecolabelled cleaning agent for the use in food industry.

🔎 The claims archive is checked on site.

O18 Planned changes

Written notice must be given to Nordic Ecolabelling of planned changes in products and markets that have a bearing on Nordic Ecolabel requirements.

✉ Procedures detailing how planned changes in products and markets are handled.

O19 Unplanned nonconformities

Unplanned nonconformities that have a bearing on Nordic Ecolabel requirements must be reported to Nordic Ecolabelling in writing and journalled.

✉ Procedures detailing how unplanned nonconformities are handled.

O20 Traceability

The licensee must be able to trace the Nordic Ecolabelled cleaning agent for the use in food industry in the production.

✉ Description of/procedures for the fulfilment of the requirement.

O21 Take-back system

Relevant national regulations, legislation and/or agreements within the sector regarding the recycling systems for products and packaging shall be met in the Nordic countries in which the Nordic Ecolabelled XX are marketed.

✉ Declaration from the applicant regarding adherence to existing recycling/take-back agreements.

O22 Legislation and regulations

The licensee shall ensure compliance with all applicable local laws and provisions at all production facilities for the Nordic Ecolabelled product, e.g. with regard to safety, working environment, environmental legislation and site-specific terms/permits.

✉ Duly signed application form.

Marketing

The Nordic Ecolabel is a very well-known and well-reputed trademark in the Nordic region. Nordic Ecolabelled products and services may be marketed using the Nordic Ecolabel so long as the associated licence is valid.

The label must be positioned so that there is no doubt as to what the label refers and so that it is clear that the cleaning agent for the use in food industry is ecolabelled.

More information on marketing can be found in "Regulations for the Nordic Ecolabelling of products" 22 June 2011 or later versions.

Design of the Nordic Ecolabel

Design of the Nordic Ecolabel:



Each licence has a unique eight-figured licence number that must be displayed along with the label.

More information on the design of the label can be found in "Regulations for the Nordic Ecolabelling of products" 22 June 2011 or later versions.

Follow-up inspections

Nordic Ecolabelling may decide to check whether the cleaning agent for the use in food industry fulfils Nordic Ecolabel requirements during the licence period. This may involve a site visit, random sampling or similar test.

The licence may be revoked if it is evident that the cleaning agent for use in the food industry does not meet the requirements.

Random samples may also be taken in-store and analysed by an independent laboratory. If the requirements are not met, Nordic Ecolabelling may charge the analysis costs to the licensee.

History of the criteria

Nordic Ecolabelling adopted version X.X of the criteria for XX on DAY MONTH YEAR. The criteria are valid until DAY MONTH YEAR.

New criteria

- This section will be filled out after the consultation

Appendix 1 Analyses, test methods and calculations

1 Requirements on the analysis laboratory

The following stipulations apply regarding ecotoxic effects, microorganisms and Challenge tests. The analysis laboratory must be competent and impartial as specified below.

The analysis laboratory used shall fulfil the general requirements of standard EN ISO 17025 or have official GLP status.

For Challenge tests, the applicant's own analysis laboratory/test procedure may be approved for analysis and testing if:

- The manufacturer has a quality management system encompassing sampling and analysis and has been certified to ISO 9000.
- The test method for performance test is part of the quality system.
- Nordic Ecolabelling shall have access to all raw data from performance testing.

2 Ecotoxicological test methods

International test methods (OECD Guidelines for the Testing of Chemicals, ISBN 92-64-1222144) or similar methods must be used. If equivalent methods are used, these must be evaluated by an independent body to ensure that the test results are equivalent. The test methods to be used are specified below.

3 Acute aquatic toxicity

Acute aquatic toxicity is tested with the aid of test methods Nos. 201, 202 and 203 in OECD guidelines for testing of chemicals (ISBN 92-64-1222144) or equivalent test methods

4 Bioaccumulation

A substance is considered bioaccumulating if tested for bioaccumulation on fish according to method OECD 305 A-E and its bioconcentration factor (BCF) is >500. If no BCF value has been determined, a substance is considered bioaccumulating if its logKow value ≥ 4.0 according to method 107, 117 or 123 in the OECD Guidelines for the Testing of Chemicals (ISBN 92-64-1222144) or equivalent method, unless proven otherwise. If the maximum measured BCF ≤ 500, the substance is not considered bioaccumulating even if logKow ≥ 4.0.

OECDs test method 107 cannot be used for surface-active substances, which are both fat and water soluble. Based on current knowledge, for such substances it must be shown to a high degree of certainty that the substance itself and its decomposition products do not pose a long-term hazard to aquatic organisms

Data models (such as BIOWIN) are permitted but if the results of an approximation are close to the set limit values or if Nordic Ecolabelling holds contradictory information, more reliable information is required.

5 Aerobic biodegradability

Test methods 301 (A to F) or 310 in the OECD Guidelines for the Testing of Chemicals (ISBN 92-64-1222144) should be used to test aerobic biodegradability. Other scientifically accepted test methods may also be used. The test results of such equivalent methods must be evaluated by an independent body.

6 Anaerobic biodegradability,

Anaerobic degradability can be tested in accordance with ISO 11734, ECETOC No 28 (June 1988), DIN 38414 part 8 or some other scientifically approved method. In order for a substance to be regarded as anaerobically degradable in the ISO test, a minimum of 60% degradability under anaerobic conditions is required.

Substances that are not surfactants and are not found on the DID-list, may be exempted from the anaerobic degradability requirements if they are aerobically degradable and not toxic to aquatic organisms (LC50/EC50/IC50>10 mg/l), and if any of the following criteria are fulfilled:

- readily degradable aerobically and have low adsorption (A<25 %) or
- readily degradable aerobically and have high desorption (D>25 %) or
- readily degradable aerobically and are not potentially bioaccumulable

Adsorption/desorption is determined using method 106 in OECD Guidelines or ISO CD 18749 "Water quality – Adsorption of substances on activated sludge".

7 DID list

The DID list is common to the European ecolabel and Nordic Ecolabelling. The list has been established in collaboration with stakeholders from industry and consumer and environmental organisations. The list contains information on the toxicity and biodegradability of substances that may be used in chemical/technical products. The DID list does not show which substances can be used in ecolabelled products.

The DID list cannot be used to document the toxicity of individual substances for classification purposes. For this purpose, MSDS, pertinent literature and information from the primary producer shall be used.

The DID list is available from the ecolabelling body or via the relevant national Nordic Ecolabelling website (see page 2 for addresses).

For this criteria document the requirements refer to the DID-list from 2014 or later version.

For calcualtions of the CDV (Critical Dilution Volume) in requirement O11 there are spread sheets available from the Nordic Ecolabelling organizations.

If no data for chronic toxicity are available, acute data and the associated safety factor can be used to estimate the chronic toxicity factor.

8 Challenge test

To avoid the unnecessary use of preservatives and to ensure that the quantity of preservatives is sufficient, a requirement is set regarding the quantity of preservatives in relation to the volume of the product. This is documented using a challenge test or equivalent and shall be performed during the development of the product.

Challenge test designates a group of tests used to determine the correct/ necessary concentration of preservatives in products. Test samples are prepared with different concentrations of preservatives as well as a control without preservatives. A mixture of bacteria, yeasts and moulds are added to the samples which are tested for growth after seven days. This continues for a minimum of 28 days (some tests require a minimum of six weeks). The sample with the lowest concentration of preservatives that does not exhibit microbial growth has the correct/optimum concentration of preservatives. The optimal amounts of preservatives can be affected by process technical aspects. Different manufacturers and suppliers of preservatives use different challenge tests/methods to determine the correct concentration of preservative. Examples include: Koko Test (Test Method SM 021), USP Challenge Test (US Pharmacopoeia) and CTFA Challenge Test (Cosmetics Toiletries and Fragrance Association).

Appendix 2 Declaration from the manufacturer of the cleaning agent for use in food industry

To be used in conjunction with an application for a licence for the Nordic Ecolabelling of Cleaning agents for use in the food industry. To complete the following declaration, you will need declarations for all raw materials (Appendix 3 or equivalent declaration).

This declaration is based on the knowledge we have at the time of the application, based on tests and/or declarations from raw material manufacturers, with reservations for new advances and new knowledge. Should such new knowledge arise, the undersigned is obliged to submit an updated declaration to Nordic Ecolabelling.

Product name: _____

Product type (e.g alkaline, acidic, CIP, foam): _____

Area of usage (for example cleaning of floors and walls, pipe systems, membrane cleaning): _____

In what types of sites is the product used (food processing, bakery, dairy, catering kitchens etc)?_____

All substances in the product are counted as constituent substances, unless otherwise stated, including additives (e.g. preservatives and stabilisers) in the raw materials, but not impurities deriving from production, including raw materials production.

Impurities are residues from production, including raw materials production, which may be found in the product at concentrations below 100 ppm (0.0100% by weight, 100 mg/kg), but not substances that have been added to a raw material or product actively and for a particular purpose, irrespective of quantity. Impurities in concentrations exceeding 1.0% in of the raw material are considered to be constituent substances. Known degraded substances/products (such as formaldehyde or and arylamine) from constituent substances are also considered to be constituent substances.

	Yes	No
O3: Does the product contain substances classified with any of the hazard phrases below?		
H350 – Carc 1A and 1B	☐	☐
H351 – Carc 2	☐	☐
H340 – Muta 1A and 1B	☐	☐
H341 – Muta 2	☐	☐
H360 – Repr 1A and 1B	☐	☐
H361 – Repr 2	☐	☐
H362 –Lact.	☐	☐
H334 - Resp Sens 1/1A/B	☐	☐
H317 - Skin sens 1/1A/B	☐	☐

	Yes	No
O4: Does the product contain any substances classified as harmful to the environment with the following risk phrases or combinations of them?		
H410 (R50/53) - Aquatic Chronic 1	☐	☐
H411 (R51/53) - Aquatic Chronic 2	☐	☐
H412 (R52/53) - Aquatic Chronic 3	☐	☐
O5: Does the product contain any preservatives?	☐	☐
If yes, state log Kow or BCF: _____		
Is the preservative only added to preserve the product?	☐	☐
O6: Does the product contain colourants?	☐	☐
If yes, state log Kow or BCF: _____		
O8: Does the product contain any of the following substances?		
Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD)	☐	☐
EDTA (Ethylene diamine tetraacetate and its salts) and DTPA (Diethylenetriamine pentaacetate)	☐	☐
Organic chlorine compounds and hypochlorites	☐	☐
Volatile organic compounds (VOC) Volatile organic compounds are defined in accordance with the European Commission's directive 1999/13/EC on the limitation of emissions of volatile organic compounds with steam pressure > 0.01 kPa at 20°C.	☐	☐
Fragrances	☐	☐
Benzalkonium chloride (CAS 8001-54-5)	☐	☐
Fluorine surfactants and other per- and polyfluorinated compounds (PFC)	☐	☐
Substances on the Candidate List (SVHC)*.	☐	☐
Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects. The full list can be seen at http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf (Annex L, page 238ff.)	☐	☐
Substances evaluated by the EU to be PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated, but which meet these criteria.	☐	☐
Nanomaterials/particles **	☐	☐

* *The Candidate List can be found on the ECHA website at: http://echa.europa.eu/candidate-list-table*

** *Nanomaterials/particles are defined in accordance with the European Commission's definition of nanomaterials dated 18 October 2011, with the exception that the limit for the particle size distribution is reduced to 1%. "Nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm." Examples are ZnO, TiO_2, SiO_2, Ag and laponite with particles of nanosize in concentrations exceeding 1%. Polymer emulsions are not considered to be nanomaterial.*

If the answer to any of the above questions is Yes, state the CAS no. (where possible), chemical name and level (in ppm, % by weight or mg/kg). For nano-particles, also state what type of particles. Also state if the substance is present as an impurity or as an added substance.

_____

_____

_____

_____

In the event of any change to the composition of the product, a new declaration of fulfilment of the requirements is to be submitted to Nordic Ecolabelling.

Place and date:	Company name/stamp:
Responsible person:	Signature of responsible person:
Phone number:	E-mail:

Appendix 3 Declaration from the manufacturer of the raw material/ingredient

To be used in conjunction with an application for a licence for the Nordic Ecolabelling of cleaning agent for use in the food industry.

This declaration is based on the knowledge we have at the time of the application, based on tests and/or declarations from raw material manufacturers, with reservations for new advances and new knowledge. Should such new knowledge arise, the undersigned is obliged to submit an updated declaration to Nordic Ecolabelling.

Raw material/Ingredient name: _____

Raw material's/ingredient's function: _____

All substances in the product are counted as constituent substances, unless otherwise stated, including additives (e.g. preservatives and stabilisers) in the raw materials, but not impurities deriving from production, including raw materials production.

Impurities are residues from production, including raw materials production, which may be found in the product at concentrations below 100 ppm (0.0100% by weight, 100 mg/kg), but not substances that have been added to a raw material or product actively and for a particular purpose, irrespective of quantity. Impurities in concentrations exceeding 1.0% in of the raw material are considered to be constituent substances. Known degraded substances/products (such as formaldehyde or and arylamine) from constituent substances are also considered to be constituent substances.

	Yes	No
O3: Does the ingredient contain substances classified with any of the hazard phrases below?		
H350 – Carc 1A and 1B	☐	☐
H351 – Carc 2	☐	☐
H340 – Muta 1A and 1B	☐	☐
H341 – Muta 2	☐	☐
H360 – Repr 1A and 1B	☐	☐
H361 – Repr 2	☐	☐
H362 –Lact.	☐	☐
H334 - Resp Sens 1/1A/B	☐	☐
H317 - Skin sens 1/1A/B	☐	☐
O4: Does the ingredient contain any substances classified as harmful to the environment with the following risk phrases or combinations of them?		
H410 (R50/53) - Aquatic Chronic 1	☐	☐
H411 (R51/53) - Aquatic Chronic 2	☐	☐
H412 (R52/53) - Aquatic Chronic 3	☐	☐

	Yes	No
O5: Does the ingedient contain any preservatives?	☐	☐
If yes, state log Kow or BCF: _____		
O6: Does the ingredient contain colourants?	☐	☐
If yes, state log Kow or BCF: _____		
O8: Does the ingredient contain any of the following substances?		
Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD)	☐	☐
EDTA (Ethylene diamine tetraacetate and its salts) and DTPA (Diethylenetriamine pentaacetate)	☐	☐
Organic chlorine compounds and hypochlorites	☐	☐
Volatile organic compounds (VOC) *Volatile organic compounds are defined in accordance with the European Commission's directive 1999/13/EC on the limitation of emissions of volatile organic compounds with steam pressure > 0.01 kPa at 20°C.*	☐	☐
Fragrances	☐	☐
Benzalkonium chloride (CAS 8001-54-5)	☐	☐
Fluorine surfactants and other per- and polyfluorinated compounds (PFC)	☐	☐
Substances on the Candidate List (SVHC)*.	☐	☐
Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects. The full list can be seen at: http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf (Annex L, page 238ff.)	☐	☐
Substances evaluated by the EU to be PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated, but which meet these criteria.	☐	☐
Nanomaterials/particles **	☐	☐
* *The Candidate List can be found on the ECHA website at: http://echa.europa.eu/candidate-list-table*		
** *Nanomaterials/particles are defined in accordance with the European Commission's definition of nanomaterials dated 18 October 2011, with the exception that the limit for the particle size distribution is reduced to 1%. "Nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm." Examples are ZnO, TiO_2, SiO_2, Ag and laponite with particles of nanosize in concentrations exceeding 1%. Polymer emulsions are not considered to be nanomaterial.*		

If the answer to any of the above questions is Yes, state the CAS no. (where possible), chemical name and level (in ppm, % by weight or mg/kg). For nano-particles, also state what type of particles. Also state if the substance is present as an impurity or as an added substance.

_____

_____

_____

_____

In the event of any change to the composition of the product, a new declaration of fulfilment of the requirements is to be submitted to Nordic Ecolabelling.

Place and date:	Company name/stamp:
Responsible person:	Signature of responsible person:
Phone number:	E-mail:

Appendix 4 Performance test/User test of cleaning agents for use in the food industry

Products must show satisfactory performance/quality within the application areas for which they are intended. The product's performance/quality must be documented by user tests, as stated below.

User tests must be performed by at least five test sites. Dosing must be in accordance with the producer's recommendations for normal soiling. The test period must be at least four weeks.

At least 80% of the test sites must assess the product's performance/quality as "satisfactory" or "very satisfactory", for the requirement to be fulfilled.

Information about the product

Full product name:	
Producer:	
Area of use (e.g. floors, walls, pipe systems):	
Type of product:	
Membrane cleaning	☐
CIP	☐
Acidic cleaning agent	☐
Alkaline cleaning agent	☐
Foam cleaning agent	☐
Other (specify)	☐

User test of the product

Dosing on testing (unit g/l working solution)	(g/l working solution)
Is the dosing in accordance with the producer's recommendation?	Yes ☐ No ☐
Test period	Start date: End date:
How many times was the product used during the stated test period?	
In which types of enterprise was the product tested (e.g. bakery, food industry, catering kitchen)?	

Assessment of the product's performance/quality

Cleanness after use of the product is assessed visually after the end of the test period (stated above). The product's performance/quality compared to the product which you usually use is considered to be:

Unsatisfactory	☐
Satisfactory	☐
Very satisfactory	☐
Other comments on the assessment of the product:	
State which product is normally used and at which dose:	

Details of the test site

Company	
Address	
Contact person	Title
Tel. no.	E-mail
Place and date	Signature