Nordic Ecolabelling for

Cleaning Agents for Use in the Food Industry

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Nordic Ecolabelling

Content

070 Cleaning Agents for Use in the Food IndustryIndustry, version 2.3, 29 March 2022

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 Swan 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 Swan Ecolabelled Cleaning agents for use in the food industry?

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

- Effective and with low environmental impact:
  - Live up to strict requirements for ecotoxicity, biodegradability and bioaccumulation.
  - Efficacy tested for use in specific application areas.

Why choose the Nordic Swan Ecolabel?

- The producer of the cleaning agent for use in the food industry may use the Nordic Swan Ecolabel trademark for marketing. The Nordic Swan Ecolabel is a very well-known and well-reputed trademark in the Nordic region.
- The Nordic Swan Ecolabel is a simple way of communicating environmental work and commitment to customers.
- The Nordic Swan 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 Swan 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 Swan Ecolabel licence can also be seen as a mark of quality.

What can carry the Nordic Swan Ecolabel?

The product group concerns professional 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, including livestock slaughtering
- 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
- Pet care
- Fishing

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 activities[1].

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 Swan Ecolabelled within the product group. Nordic Swan Ecolabelled cleaning agents for use in the food industry can only be marketed to professional users.

The criteria do not include personal hygiene products, 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 Swan 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.

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

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

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

Ingoing substances and impurities

The requirements in the criteria document and accompanying appendices apply to all ingoing substances in the Nordic Swan Ecolabelled product. Impurities are not regarded as ingoing substances and are exempt from the requirements.

Ingoing substances and impurities are defined below, unless stated otherwise in the requirements

- Ingoing substances: all substances in the Nordic Swan Ecolabelled product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoing substances.

- Impurities: residuals, pollutants, contaminants etc. from production, incl. production of raw materials, that remain in the raw material/ingredient and/or in the Nordic Swan Ecolabelled product, in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the Nordic Swan Ecolabelled product.

- Impurities in the raw materials exceeding concentrations of 1.0% are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.

Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines.

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 Swan Ecolabelled".

Description of the product type (e.g. alkaline, acidic, CIP (cleaning in place)) 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 for calculating chemical requirements, see Appendix 1, section 8. 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 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**
Hazardous to the aquatic environment	Aquatic acute 1Aquatic 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*	RCarc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity *	Muta. 1A or 1B Muta. 2	H340 H341
Reproductive toxicity *	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Acute toxicity	Acute Tox. 1 or 2 Acute Tox. 1 or 2 Acute Tox. 1 or 2 Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Acute tox 4** Acute tox 4** Acute tox 4**	H300 H310 H330 H301 H311 H331 H302 H312 H332
Specific target organ toxicity, singel or repeated exposure	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Aspiration hazard	Asp. Tox. 1	H304
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B or products labelled EUH208: “Contains (name of sensitising substance). May cause an allergic reaction.”	H334 H317

Flammable aerosols and liquids	Flam. Aer. 1, 2 or 3 Flam. Liq. 1, 2 or 3	H222, H223, H229 H224, H225, H226

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

*** Exceptions: Products may be classified as Acute tox, Cat 4 with H332, H312 and/or H302 if the packaging is designed so that the user does not come into contact with the product. Examples on how packaging can be designed to minimize contact with the user are e.g. a dispenser or pump device or other solutions, that mean that users do not need to pour from one container to another when the product is diluted.*

**** Exception: Enzymes are exempted from the prohibition on EUH208 provided they are handled and used in closed systems (CIP) and are included maximum 1% in 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.

✉ Label or technical product data sheet and description of packaging design, which shows that a product with enzymes is only handled and used in closed systems (CIP) if the product is labelled with EUH208.

✉ Formulation with amount of enzymes of the product.

O3 Classification of a product's constituent substances

Ingoing substances may not be classified according to table O3 below.

Table O3 - Classification of a product's constituent substances

CLP Regulation 1272/2008		
Faroklass	Kod för faroklass och kategori	Hzard statement
Carcinogenic*	Carc 1A or 1B Carc 2	H350 H351
Mutagenic*	Muta 1A or 1B Muta 2	H340 H341
Reprotoxic*	Repr 1A or 1B Repr 2 Lact.	H360 H361 H362
Sensitising	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317

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

Exceptions:

- Enzymes (including stabilisers and preservatives in enzyme raw materials) are exempt from the requirement concerning sensitising substances, provided that
    - The enzymes are encapsulated (in solid form) or liquids/slurries.
    - Exemption does not apply to spray products.
    - The user should be made aware that the product contains enzymes and the handling and use of this product may require special safety measures.

- 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 encapsulated (in solid form) or liquids/slurries.

✉ For products with enzymes: Label, informational text, user instructions and/or safety data sheet, showing that the product is not a spray product, and showing the special safety measures needed.

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 H411 and 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, version 2016 or later. If the substance is not on the DID list, or data on the DID list is lacking, the substance is documented in accordance with ISO 11734, ECETOC no. 28 (June 1988) or OECD311, 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 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 for this calculation.

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.

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

☒ Calculation of the total amount of phosphorus (calculated as elemental phosphorus, P) in the in-use solution.

O7 Substances prohibited from products

The following compounds may not be included in the product:

- Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD)
- EDTA (Ethylene diamine tetraacetate and its salts) and DTPA (Diethylenetriamine pentaacetate)
- Organic chlorine compounds and hypochlorites
- > 1% 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) (The Candidate List can be found on the ECHA website at: http://echa.europa.eu/candidate-list-table)

- 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. See Appendix 1 section 7 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

  Nanomaterials/particles are defined in accordance with the European Commission's definition of nanomaterials dated 18 October 2011. "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 50%. Polymer emulsions are not considered to be nanomaterial.

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

O8 Surfactants, easily aerobically and anaerobically biodegradable

All surfactants must be easily biodegradable according to test method no. 301 A - F or no. 310 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, OECD 311 or equivalent testing methods.

✉ Reference to the DID list dated 2016 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.

O9 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 exempted 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, 2016 or later versions. For substances not included on the DID list, or if data on the DID list is lacking, the related documentation must be submitted.

O10 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, 2016 or later versions. For substances not on the DID list, or if data on the DID list is lacking, 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

O11 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 three test sites, which include the majority of the areas of use for which the product is intended. More than one test report from one company is accepted if they are from different applications or test locations. The dosage should not exceed that used in CDV calculations. The test period must represent the product's usage frequency and it must be justified in the test report. The product is to be used several times during the test period.

All 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 three 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.

O12 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 Ecolabelling requirements are fulfilled, the following procedures must be implemented.

O13 Responsible person and organisation

The company shall appoint individuals who are responsible for ensuring the fulfilment of Nordic Ecolabelling 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.

O14 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.

O15 Quality of cleaning agents for use in the food industry

The licensee must guarantee that the quality of the Nordic Swan 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 Swan Ecolabelled cleaning agent for use in the food industry.

🔑 The claims archive is checked on site.

O16 Planned changes

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

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

O17 Unplanned nonconformities

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

✉ Procedures detailing how unplanned nonconformities are handled.

O18 Traceability

The licensee must be able to trace the Nordic Swan Ecolabelled cleaning agent for use in the food industry in the production: A manufactured/sold product should be able to be traced back to the time (time and date) and the location (specific factory) and in relevant cases, the machine/production line where it was produced. In addition, it should be possible to connect it to the actually used raw materials (raw material batches, suppliers) in the product.

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

O19 Take-back system

Nordic Ecolabelling decided on the 9 October 2017 to remove this requirement.

O20 Legislation and regulations

The licensee shall ensure compliance with all applicable local laws and provisions at all production facilities for the Nordic Swan Ecolabelled product, e.g. with

regard to safety, working environment, environmental legislation and site-specific terms/permits.

✉ Duly signed application form.

Regulations for the Nordic Ecolabelling of products

When the Nordic Swan Ecolabel is used on products the licence number shall be included.

More information on graphical guidelines, regulations and fees can be found at www.svanen.se/regulations/ or at www.nordic-ecolabel.org/regulations/

Follow-up inspections

Nordic Ecolabelling may decide to check whether the cleaning agent for use in the food industry fulfils Nordic Ecolabelling 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.

Criteria version history

Nordic Ecolabelling adopted version 2.0 of the criteria for Cleaning Agents for Use in the Food Industry on 06 March 2017. The criteria are valid until 31 March 2022.

On the 9 October 2017 Nordic Ecolabelling decided to remove O19 Take-back system.

Nordic Ecolabelling decided on 31 March 2020 to prolong the criteria with 24 months to the 31 Marchr 2024. The new version is called 2.1.

Nordic Ecolabelling decided on 18 January 2022 to prolong the criteria with 9 months to the 31 December 2024. The new version is called 2.2.

On the 29 March 2022 Nordic Ecolabelling decided to adjust requirement O4 by also exempting H411 classified surfactants from the requirement. The new version is called 2.3.

New criteria

In future criteria (next revision), the following points should be reviewed:

- Possibility to set stricter packaging requirements.

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 according 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 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

Chronic aquatic toxicity is tested with the aid of test methods Nos. 210, 211, 215 and 229 in the OECD Guideline for the Testing of Chemicals (ISBN 92-64-1222144) or equivalent test methods. OECD 201 can be used as chronic test if chronic endpoints are chosen.

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.

OECD's 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), OECD 311 or some other scientifically approved method. In order for a substance to be regarded as anaerobically biodegradable in the ISO test, a minimum of 60% biodegradability 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 (Potential) endocrine disruptors

A (potential) endocrine disruptor is an exogenous substance or mixture of substances that changes the function(s) of the hormonal system and thus causes serious health effects in an unaffected organism, its offspring or populations.

Nordic Swan Ecolabelling counts all substances that in the EU are considered to be (potential) endocrine disruptors in categories 1 and 2 (“Category 1 - evidence of endocrine disrupting activity in at least one species using intact animals”; “Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption”). Where changes are made to the EU's list, it is the latest updated reports that apply. The most recent reports can be obtained from http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf and an Access database in which all evaluated substances listed can be downloaded at http://ec.europa.eu/environment/chemicals/endocrine/strategy/index_en.htm.

8 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 2016 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.

9 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 Swan 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)?_____

Ingoing substances and impurities are defined below, unless stated otherwise in the requirements

- *Ingoing substances: all substances in the Nordic Swan Ecolabelled product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoing substances.*

- *Impurities: residuals, pollutants, contaminants etc. from production, incl. production of raw materials, that remain in the raw material/ingredient and/or in the Nordic Swan Ecolabelled product, in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the Nordic Swan Ecolabelled product.*

- *Impurities in the raw materials exceeding concentrations of 1.0 % are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.*

Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines.

O3: Does the product contain substances classified with any of the hazard phrases below? Including all variants within the respective classification. For example, H350 also covers classification H350i.		
H350 – Carc 1A and 1B	Yes ☐	No ☐
H351 – Carc 2	Yes ☐	No ☐
H340 – Muta 1A and 1B	Yes ☐	No ☐
H341 – Muta 2	Yes ☐	No ☐
H360 – Repr 1A and 1B	Yes ☐	No ☐
H361 – Repr 2	Yes ☐	No ☐
H362 – Lact.	Yes ☐	No ☐
H334 – Resp Sens 1/1A/B	Yes ☐	No ☐
H317 – Skin sens 1/1A/B	Yes ☐	No ☐
O4: Does the product contain any substances classified as harmful to the environment with H410, H411 or H412? If yes, state state the amount (% by weight) per classification: _____ Note that an account of the hazard to environment (acute/chronic aquatic toxicity, biodegradability and/or bioaccumulation) is needed. Note that an exception is made for: Surfactants regardless of their function classified with H411 or H412 are exempted from the requirement, on condition that they are readily biodegradable and anaerobically biodegradable in line with the test methods specified in Appendix 1.	Yes ☐	No ☐
O5: Does the product contain any preservatives? If yes, state name of the preservative and log Kow or BCF: _____	Yes ☐	No ☐
If yes, is the preservative only added to preserve the product (or raw material)?	Yes ☐	No ☐
O6: Does the product contain phosphorous? If yes, attach a calculation of the total volume of phosphorus (calculated as elemental phosphorus, P) in the in-use solution.	Yes ☐	No ☐
O7: Does the product contain any of the following substances?		
Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD)	Yes ☐	No ☐
EDTA (Ethylene diamine tetraacetate and its salts) and DTPA (Diethylenetriamine pentaacetate)	Yes ☐	No ☐
Organic chlorine compounds and hypochlorites	Yes ☐	No ☐
> 1 % 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 vapor pressure > 0.01 kPa at 20°C.*	Yes ☐	No ☐
Fragrances	Yes ☐	No ☐
Benzalkonium chloride (CAS 8001-54-5)	Yes ☐	No ☐

	Fluorine surfactants and other per- and polyfluorinated compounds (PFC)	Yes ☐	No ☐
	Substances on the Candidate List (SVHC)* (The Candidate List can be found on the ECHA website at: http://echa.europa.eu/candidate-list-table)	Yes ☐	No ☐
	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. See Appendix 1 section 7 The full list can be seen at http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf (Annex L, page 238ff.)	Yes ☐	No ☐
	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.	Yes ☐	No ☐
	Nanomaterials/particles *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.*	Yes ☐	No ☐

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 Swan 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: _____

Can the appendix be added to the Nordic Swan Ecolabel internal chemical database?	Yes ☐ No ☐
Yes – Signed appendix needs to be sent once and can thereafter be used for all applications in all Nordic countires. No – A new signed appendix needs to be sent in by each applicant.	

Ingoing substances and impurities are defined below, unless stated otherwise in the requirements

- *Ingoing substances: all substances in the Nordic Swan Ecolabelled product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoing substances.*

- *Impurities: residuals, pollutants, contaminants etc. from production, incl. production of raw materials, that remain in the raw material/ingredient and/or in the in the Nordic Swan Ecolabelled product, in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the Nordic Swan Ecolabelled product.*

- *Impurities in the raw materials exceeding concentrations of 1.0 % are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.*

Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products, scavengers, and detergents for production equipment and carry-over from other or previous production lines.

Note: If the raw material contains impurities listed in this Appendix, enter the amount at the end of the Appendix. The producer of the Nordic Swan Ecolabelled product is responsible for calculating if the requirements in the criteria are met.

O3: Does the ingredient contain substances classified with any of the hazard phrases below? Incl. all variants within the respective classification. For example, H350 also covers classification H350i		
H350 – Carc 1A and 1B	Yes ☐	No ☐
H351 – Carc 2	Yes ☐	No ☐
H340 – Muta 1A and 1B	Yes ☐	No ☐
H341 – Muta 2	Yes ☐	No ☐
H360 – Repr 1A and 1B	Yes ☐	No ☐
H361 – Repr 2	Yes ☐	No ☐
H362 – Lact.	Yes ☐	No ☐
H334 – Resp Sens 1/1A/B	Yes ☐	No ☐
H317 – Skin sens 1/1A/B	Yes ☐	No ☐
O4: Does the ingredient contain any substances classified as harmful to the environment with H410, H411 or H412? If yes, state state the amount (% by weight) per classification: _____ Note that an account of the hazard to environment (acute/chronic aquatic toxicity, biodegradability and/or bioaccumulation) is needed. If data is not available (e.g. SDS Section 12), the substance is assessed according to a worst case scenario (H410).	Yes ☐	No ☐
O5: Does the ingedient contain any preservatives? If yes, state log Kow or BCF: _____	Yes ☐	No ☐
If yes, is the preservative only added to preserve the raw material?	Yes ☐	No ☐
O6: Does the raw material contain phosphorous? If yes, state the amount (%)calculated as elemental phosphorus, P: _____	Yes ☐	No ☐
O7: Does the ingredient contain any of the following substances?		
Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD)	Yes ☐	No ☐
EDTA (Ethylene diamine tetraacetate and its salts) and DTPA (Diethylenetriamine pentaacetate)	Yes ☐	No ☐
Organic chlorine compounds and hypochlorites	Yes ☐	No ☐
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* vapor *pressure > 0.01 kPa at 20°C.*	Yes ☐	No ☐
Fragrances	Yes ☐	No ☐
Benzalkonium chloride (CAS 8001-54-5)	Yes ☐	No ☐
Fluorine surfactants and other per- and polyfluorinated compounds (PFC)	Yes ☐	No ☐

Substances on the Candidate List (SVHC)(The Candidate List can be found on the ECHA website at: http://echa.europa.eu/candidate-list-table)	Yes ☐	No ☐
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. See Appendix 1 section 7 The full list can be seen at: http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf (Annex L, page 238ff.)	Yes ☐	No ☐
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.	Yes ☐	No ☐
Nanomaterials/particles *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.*	Yes ☐	No ☐

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 three test sites. The dosage should not exceed that used in the CDV calculations. The test period must represent the product's usage frequency and it must be justified in the test report.

All 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 in-use solution)	(g/l in-use solution)
Is the dosing in accordance with the producer's recommendation?	Yes ☐ No ☐
Test period	Start date:
	End date:
Justifications of the length of the test period	
How many times was the product used during the stated test period?	
In which types of enterprises 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 that you usually use is considered to be:

Unsatisfactory	☐
Satisfactory	☐
Very satisfactory	☐
Other comments on the assessment of the product:	

Details of the test site

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