Nordic Ecolabelling for Cleaning agents for use in the food industry



Version 3.0 • date - date

CONSULTATION



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Appendix 1 Declaration from the manufacturer of the cleaning agent for use in the food industry

Appendix 2 Declaration from the manufacturer/supplier of the raw material to the cleaning agent for use in the food industry

- Appendix 3 Analysis and test laboratories
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Contact information

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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Ecolabelling Norway info@svanemerket.no www.svanemerket.no This document may only be copied in its entirety and without any type of change. It may be quoted from provided that Nordic Ecolabelling is stated as the source.

1 Environmental communication guideline for Nordic Swan Ecolabel cleaning agents for use in the food industry

Nordic Swan Ecolabel cleaning agents for use in the food industry meet ambitious environmental requirements from a holistic life cycle perspective. This means that they are amongst the environmentally best in their category.

Nordic Swan Ecolabel cleaning agents for use in the food industry:

- Are efficacy tested for use in specific food industry areas.
- Meet strict environmental requirements for chemicals, focusing on ecotoxicity, bioaccumulation and degradability.
- Contain no substances classified as carcinogenic, mutagenic or harmful to reproduction.

2 What can carry the Nordic Swan Ecolabel?

Product group definition

Professional cleaning agents intended for cleaning production areas (such as surfaces, walls, and floors) and production equipment (including pipe systems and other machinery) in the food industry, as well as in fishing and aquaculture, can be Nordic Swan Ecolabelled.

The food industry includes the following activities:

- Food production
- Beverage production
- Processing and preserving of meat and meat products, including livestock slaughtering
- Processing and preserving of fish, crustaceans, and molluscan shellfish
- Processing and preserving of fruits, 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 activities
- Production of prepared animal feeds

Fishing and aquaculture include the following activities:

- Marine fishing
- Freshwater fishing
- Marine aquaculture
- Freshwater aquaculture

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The criteria do not cover band lubricants, products containing microorganisms, or twocomponent products.

Cleaning agents used in food service establishments, such as catering kitchens, restaurants, cafés, and canteens, can be Nordic Swan Ecolabelled under the product group 026 Cleaning Products.

Products within the scope of the Biocides Regulation 528/2012 cannot be Nordic Swan Ecolabelled.

2.1 Justification of the product group definition

For a description of the product group definition, see "What can carry the Nordic Swan Ecolabel".

Further background for the product group definition

The definitions of the food industry, fishing, and aquaculture are based on NACE, the EU's official statistical classification of economic activities. In this classification, the food industry includes activities under Section C, Divisions 10 and 11, covering the manufacture of food products and beverages. Fishing and aquaculture fall under Section A, Divisions 03.1 and 03.2.¹

Band lubricants, used for lubricating conveyor belts in industries such as dairies and breweries, are not classified as cleaning agents and, as such, are excluded from the criteria for cleaning agents in the food industry.

Some cleaning agents in the Nordic market contain microorganisms to enhance cleaning performance. These microorganisms break down organic materials such as proteins, fats, and starches in soil deposits. Nordic Ecolabelling permits their use in certain professional products, provided they meet specific requirements in addition to the other criteria outlined. For this product group, most producers reported that they do not manufacture products containing microorganisms for this sector. A few indicated that such products exist for specific applications within the food industry. However, due to limited industry interest in these products, Nordic Ecolabelling has decided not to include products with microorganisms in this product group.

Two-component products are excluded from the criteria for several reasons, primarily due to the potential formation of hazardous byproducts when certain chemicals are combined. Additionally, these systems typically require the use of stronger chemicals in larger quantities, resulting in increased chemical consumption and a greater environmental impact.

In generation 2 of the criteria, cleaning agents used in catering kitchens were included in the product group. However, in this criteria generation, all cleaning agents used in food service establishments - such as catering kitchens, restaurants, cafés, and canteens - are excluded

¹ Overview - NACE - Eurostat (Assessed 14 February 2025)

from the product group, as these are not classified as part of the food industry according to NACE. Additionally, Nordic Ecolabelling considers the product group 026 Cleaning Products to be better adapted to these types of products.

Products within the scope of the Biocides Regulation 528/2012 cannot be Nordic Swan Ecolabelled, as this does not comply with the regulation.

3 How to read this criteria document

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. This icon is:

T Upload

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

4 Summary

The product group comprises professional cleaning agents intended for cleaning production areas and equipment within the food industry, fishing, and aquaculture. The food industry covers various sectors, including food and beverage production, meat and seafood processing, and dairy and bakery manufacturing. Fishing and aquaculture include both marine and freshwater activities. The product group includes automatic and manual dosing products, which may only be marketed to professional users.

The relevant environmental impacts found in the life cycle of industrial cleaning and degreasing agents are the following: Degradability and toxicity to aquatic organisms, exposure of chemicals harmful to health, eutrophication from phosphorous compounds, user information, dosing and performance and packaging. The criteria contain requirements in those areas.

The most important changes from the previous generation of the criteria are:

- The product group definition has been clarified regarding the activities and NACE codes included.
- Cleaning agents used in catering kitchens have been excluded from the product group and moved to product group 026, Cleaning Products.
- The new EUH hazard classifications for endocrine disruptors, PBT/vPvB, and PMT/vPvM have been added to both the list of prohibited product classifications and the list of prohibited classifications for ingoing substances.
- Hazard classifications for specific target organ toxicity due to repeated exposure (STOT RE 1) and substances hazardous to the ozone layer have been added to the prohibited classifications for ingoing substances.
- The list of substances that are excluded from use in products has been extended, including microplastics.

- The requirements for potential or identified endocrine disruptors, nanomaterials/-particles, and PBT and vPvB substances have been updated.
- Surfactants classified as H411 and H412 are no longer exempt from the requirement on long-term environmental effects. Additionally, the multiplying factor M for H410, as described in the CLP Regulation (EC) No 1272/2008, has been included in the calculation.
- The limit values for organic substances that are aerobically non-biodegradable (aNBO) and anaerobically non-biodegradable (anNBO) have been tightened, and the separate limit value for ready-to-use products has been removed.
- The limit value for Critical Dilution Volume (CDV) has been tightened, and the separate limit value for ready-to-use products has been removed.
- A new requirement has been introduced for primary packaging up to 20 litres, ensuring recyclability.

4.1 Changes compared to previous generation

Here, the most important changes compared to the previous generation are briefly listed.

Table 1	Overview of changes to criteria for Cleaning agents for use in the food industry
	generation 3 compared with previous generation 2

Proposed requirement generation 3	Requirement generation 2	Same requirement	Change	New requirement	Comments
O1 Description of the product	O1 Information about the product	X			
O2 Classification of the product	O2 Classification of the product		X		The new EUH hazard classifications for endocrine disruptors, PBT/vPvB, and PMT/vPvM have been added to the prohibited classifications.
O3 Classification of ingoing substances	O3 Classification of a product's constituent substances		x		The new EUH hazard classifications for endocrine disruptors, PBT/vPvB, and PMT/vPvM have been added to the prohibited classifications. Additionally, hazard classifications for specific target organ toxicity due to repeated exposure (STOT RE 1) and substances hazardous to the ozone layer have been added to the prohibited classifications for ingoing substances.
O4 Surfactants	O8 Surfactants, easily aerobically	×			

			T		
	and anaerobically biodegradable				
O5 Preservatives	O5 Preservatives		x		Updated according to Nordic Ecolabelling's policy on preservatives. A Challenge test is no longer required.
O6 Phosphorus	O6 Phosphorus	х			
O7 Excluded substances	O7 Substances prohibited from products		X		 The list of substances that are excluded from use in products has been extended with: Aminopolyphosphonates Bisphenols and bisphenol derivatives Boric acid, borates, and perborates LAS (linear alkylbenzene sulphonates) NTA (nitrilotriacetic acid, CAS-no. 139-13-9) and its salts Per- and polyfluoroalkyl substances (PFAS) Siloxanes D4, D5, D6 and HMDS The requirements for potential or identified endocrine disruptors and PBT and vPvB substances have been updated.
O8 Microplastics				х	
O9 Nanomaterials				Х	
O10 Long-term environmental effects	O4 Long-term environmental effects		X		Surfactants classified as H411 and H412 are no longer exempt from the requirement. The exemption for protease/subtilisin regarding the H411 classification has been removed. The multiplying factor M for H410, as described in the CLP Regulation (EC) No 1272/2008, has been included in the calculation.
O11 Biodegradability	O9 Content of substances which are not aerobically and/or anaerobically biodegradable		×		The limit values have been tightened. The separate limit value for ready-to-use products has been removed. The exemption for iminodisuccinat regarding anNBO has been removed.
O12 Critical dilution volume (CDV)	O10 CDV (Critical		X		The limit value has been tightened.

	dilution volume)				The separate limit value for ready-to-use products has been removed.
O13 Performance	O11 Performance and user test	x			
O14 User information	O12 Information text and user and dosing information	Х			
O15 Packaging				X	A new requirement has been introduced for primary packaging up to 20 litres, ensuring recyclability.
O16 Customer complaints	O15 Quality of cleaning agents for use in the food industry		×		
O17 Traceability	O18 Traceability		x		

5 Requirements and justification of these

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 product including additives (e.g. preservatives and stabilisers) from the raw materials. Substances released from ingoing substances (e.g. biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances.

*N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance (Unknown or Variable composition, Complex reaction products or of Biological materials) are also regarded separately, and all known constituents shall be regarded.

Impurities: Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials that remain in the product in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%). Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.

Examples of impurities are: Background environmental pollutants from feedstock, as well as contaminants and residues from production such as reactants (incl. monomers), reagents, catalysts, by-products, scavengers, detergents for production equipment, carry-over from other or previous production lines.

5.1 General requirement area

O1 Description of the product

The applicant must provide the following information about the product.

- Description of the product and its area of use.
- A complete recipe for the product. The recipe must, if possible, include for each ingoing substance:
 - Trade name
 - o Chemical name
 - Amount (both with and without solvents, e.g., water)
 - o CAS No. and/or EC number
 - DID number for substances that can be placed in the DID-list 2023 or later versions*
 - Function

If a raw material consists of several substances, data for all ingoing substances is to be stated in the recipe.

* DID-list: "Detergents Ingredients Database" list, see Appendix 3 for a detailed description.

- $\overline{\mathbf{1}}$ Label and description of the product and its area of use.
- Appendix 1 or equivalent declaration completed and signed.
- Complete recipe in line with the requirement. Nordic Ecolabelling's calculation sheet for Cleaning agents for use in the food industry can be used. It is available from Nordic Ecolabelling's websites.
- T Safety data sheet for each raw material in line with prevailing legislation in the country of application, e.g., Annex II to REACH (Regulation 1907/2006/E2EC).

Background to requirement O1 Description of the product

A description of the product and its area of use is required to assess whether the product falls within the product group definition. Nordic Ecolabelling needs to know the complete formulation, with all ingoing raw materials. This is necessary to control the individual requirements below and make the calculations necessary in respect of each requirement.

The requirement is unchanged compared to generation 2 of the criteria.

O2 Classification of the product

The product must not be classified with the hazard codes listed in the table below, in accordance with CLP Regulation 1272/2008.

 Table 2
 Classification of the product

Hazard class	Hazard class and category	Hazard code
Carcinogenicity*	Carc. 1A or 1B	H350
	Carc. 2	H351
Germ cell mutagenicity*	Muta. 1A or 1B	H340
	Muta. 2	H341
Reproductive toxicity*	Repr. 1A or 1B	H360
	Repr. 2	H361
	Lact.	H362
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B	H334
	Skin Sens. 1, 1A or 1B	H317
		EUH208: "Contains
		(name of sensitising
		substance). May cause an allergic
		reaction." **
Acute toxicity	Acute Tox. 1 or 2	H300
	Acute Tox. 1 or 2	H310
	Acute Tox. 1 or 2	H330
	Acute Tox. 3	H301
	Acute Tox. 3	H311
	Acute Tox. 3	H331
	Acute Tox. 4	H302***
	Acute Tox. 4	H312***
	Acute Tox. 4	H332***
Hazardous to aquatic environment	Aquatic Acute 1	H400
	Aquatic Chronic 1	H410
	Aquatic Chronic 2	H411
	Aquatic Chronic 3	H412
	Aquatic Chronic 4	H413
Hazardous to the ozone layer	Ozone	H420
Specific target organ toxicity, single or	STOT SE 1	H370
repeated exposure	STOT SE 2	H371
	STOT RE 1	H372
	STOT RE 2	H373
Aspiration hazard	Asp. Tox. 1	H304
Flammable aerosols	Flam. Aer. 1, 2 or 3	H222
		H223
		H229
Flammable liquids	Flam. Liq. 1, 2 or 3	H224
		H225
		H226
Endocrine disruption for human health	ED HH 1	EUH380
	ED HH 2	EUH381
Endocrine disruption for the environment	ED ENV 1	EUH430
	ED ENV 2	EUH431

Persistent, Bioaccumulative and Toxic properties Very Persistent, Very Bioaccumulative properties	PBT vPvB	EUH440 EUH441
Persistent, Mobile, and Toxic properties	PMT	EUH450
Very Persistent, Very Mobile properties	vPvM	EUH451

* Including all combinations of stated exposure routes and stated specific effect. For example, H350 also covers classification H350i.

** Products labelled with EUH208 ("Contains <name of sensitising substance>. May produce an allergic reaction.") can only be Nordic Swan Ecolabelled if the sensitising substance is an enzyme, the enzyme content does not exceed 1% of the product, and the product is handled and used in closed systems (CIP).

*** Products may be classified as H302, H312, and/or H332 if the packaging is designed to prevent direct contact with the product.

- Safety data sheet for the product in line with prevailing European legislation (Annex II to REACH Regulation, 1907/2006/EC).
- **†** Appendix 1 or equivalent declaration completed and signed.
- T If the product is labelled with EUH208: Formulation specifying the enzyme content of the product.
- If the product is labelled with EUH208: Copy of label or accompanying product sheet demonstrating that the product is handled and used exclusively in closed systems (CIP).
- T If the product is classified as H302, H312 and/or H332: A description of the packaging design demonstrating that the user does not come into contact with the product.

Background to requirement O2 Classification of the product

Nordic Ecolabelling sets requirements regarding environmental and health classifications of the product to ensure that products that are toxic or harmful to the environment and/or human health cannot be awarded the Nordic Swan Ecolabel. The list includes classifications that are standard to include in all product groups if we do not get information that they are irrelevant, as we apply the precautionary principle.

An analysis of the classification of cleaning agents used in the food industry that are not Nordic Swan Ecolabelled reveals the presence of products on the market that are classified as hazardous to the aquatic environment. This underscores the importance and potential of the classification requirement.

The prohibition on EUH208 does not apply to enzymes, provided the enzyme content does not exceed 1% of the product and the product is handled and used in closed systems (CIP). In these systems, the risk of enzyme exposure is lower and easier to control compared to partially closed or open systems. Additionally, the enzyme concentration plays a key role in mitigating the risk of exposure.

Products may be classified as H302, H312, and/or H332 if the packaging is designed to prevent direct user contact with the product. Examples of packaging designs that minimise user contact include dosing systems, pump devices, or other solutions that, for instance, eliminate the need for the user to pour from one container to another during dilution.

The requirement has changed compared to generation 2 of the criteria regarding the following: The Nordic Swan Ecolabel has included the new EUH CLP classifications to align with the European Green Deal's goal of a toxic-free environment. This inclusion reflects the need to establish hazard identification for endocrine disruptors and addresses criteria for environmental toxicity, persistency, mobility and bioaccumulation. By incorporating these classifications, Nordic Swan Ecolabel ensures that the criteria relate to up-to-date scientific understanding and regulatory compliance. Additionally, the inclusion of PMT and vPvM substances is crucial due to their persistence, mobility and potential impact on water quality. The Nordic Swan Ecolabel aims for comprehensive hazard identification and protection of the environment and human health.

O3 Classification of ingoing substances

Ingoing substances must not be classified with the hazard codes listed in the table below, in accordance with CLP Regulation 1272/2008.

Hazard class	Hazard class and category	Hazard code
Carcinogenicity*	Carc. 1A or 1B	H350
	Carc. 2	H351**
Germ cell mutagenicity*	Muta. 1A or 1B	H340
	Muta. 2	H341
Reproductive toxicity*	Repr. 1A or 1B	H360
	Repr. 2	H361
	Lact.	H362
Respiratory or skin sensitisation***	Resp. Sens. 1, 1A or 1B	H334
	Skin Sens. 1, 1A or 1B	H317
Specific target organ toxicity, repeated exposure	STOT RE 1	H372
Hazardous to the ozone layer	Ozone	H420
Endocrine disruption for human	ED HH 1	EUH380
health****	ED HH 2	EUH381
Endocrine disruption for the	ED ENV 1	EUH430
environment****	ED ENV 2	EUH431
Persistent, Bioaccumulative and Toxic	РВТ	EUH440
properties****	vPvB	EUH441
Very Persistent, Very Bioaccumulative properties****		
Persistent, Mobile, and Toxic properties	PMT	EUH450
Very Persistent, Very Mobile properties	vPvM	EUH451

Table 3 Classification of ingoing substances

* Including all combinations of stated exposure routes and stated specific effect. For example, H350 also covers classification H350i.

** 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 product is below 0.1%.

*** Enzymes in liquid form or as solid granulates (including stabilisers and preservatives in enzyme raw materials) may be classified as H334 or H317. However, the exemption does

not apply to spray products, and users should be informed that the product contains enzymes and that its handling and use may require special safety measures.

**** See also requirement O7 (Excluded substances) for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.

- T Safety data sheet for all ingoing substances in line with prevailing European legislation (Annex II to REACH Regulation, 1907/2006/EC).
- T Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.
- For products containing enzymes: Copy of label or accompanying product sheet demonstrating that the product is not a spray.
- For products containing enzymes: Copy of label or accompanying product sheet demonstrating that the product contains enzymes and that its handling and use may require special safety measures.

Background to requirement O3 Classification of ingoing substances

Excluding carcinogenic, mutagenic, reproduction toxic (CMR), sensitizing substances and specific target organ toxicity, repeated exposure STOT RE 1 is an important parameter from a health perspective. Excluding substances that are hazardous to the ozone layer is an important parameter from an environmental perspective.

Complexing agents of the MGDA and GLDA type may contain NTA impurities in the raw material. NTA as an impurity in complexing agents is therefore, exempted from the requirement, but with the restriction that the concentration must be less than 0.2% in the raw material and less than 0.1% in the product which is best practice in the industry.

The rationale for exempting enzymes is that they can improve product efficacy, and enzymes in liquid form or solid granulate form are not expected to cause allergies in the user as the ingredients of the enzyme are included in the product and do not exist as "free dust". However, the exemption does not apply to any type of spray product, as these generally pose a greater risk of exposure. According to the Detergent Regulation (EC 648/2004), it is mandatory to declare the presence of enzymes in a product, regardless of concentration. In many cases, enzymes must also be listed in the product's Safety Data Sheet, as required by REACH Annex II. However, this does not apply to all types of enzymes or at all concentrations. A study by the UK Health and Safety Executive² found that personnel using enzyme-containing products were generally unaware that the products contained enzymes, that enzymes pose a risk of allergy, or of the necessary procedures and safety measures to prevent exposure and contact. Therefore, Nordic Ecolabelling consider it appropriate to require that users are made aware that the product contains enzymes and that special safety measures may be necessary when handling and using the product.

MI (methylisothiazolinone, CAS no. 2682-20-4) and MI/CMIT 3:1 (5-Chloro-2-methyl-4isothiazolin-3-one, CAS No. 26172-55-4) are classified as H317 and are therefore excluded from use in Nordic Swan Ecolabelled products according to this requirement.

² Health and Safety Executive (2013). A survey of exposure to enzymes in cleaning solutions used to clean endoscopes. RR972 Research Report. <u>http://www.hse.gov.uk/research/rrpdf/rr972.pdf</u> (Accessed 2025-02-11)

The requirement has changed compared to generation 2 of the criteria regarding the following:

The Nordic Swan Ecolabel has included the new EUH CLP classifications to align with the European Green Deal's goal of a toxic-free environment. This inclusion reflects the need to establish hazard identification for endocrine disruptors and addresses criteria for environmental toxicity, persistency, mobility and bioaccumulation. By incorporating these classifications, Nordic Swan Ecolabel ensures that the criteria relate to up-to-date scientific understanding and regulatory compliance. Additionally, the inclusion of PMT and vPvM substances is crucial due to their persistence, mobility and potential impact on water quality. The Nordic Swan Ecolabel aims for comprehensive hazard identification and protection of the environment and human health.

Additionally, hazard classes for specific target organ toxicity, repeated exposure (STOT RE 1), and substances that are hazardous to the ozone layer have been added to the prohibited classifications.

O4 Surfactants

All surfactants must be readily biodegradable according to Test No. 301 A–F, Test No. 306 or Test No. 310 in OECD Guidelines for the Testing of Chemicals or other equivalent test methods evaluated by an independent body and controlled by Nordic Ecolabelling.

All surfactants must be anaerobically biodegradable in accordance with ISO 11734, ECETOC No 28, Test No. 311 in OECD Guidelines for the Testing of Chemicals or equivalent testing methods evaluated by an independent body and controlled by Nordic Ecolabelling.

Reference to the DID list dated 2023 or later versions. For substances not on the DID list, or where data on the DID list is missing, the associated documentation must be submitted. See Appendix 3 for test requirements.

Background to requirement O4 Surfactants

Surfactants are used in large quantities in cleaning agents for use in the food industry, making the products functional and effective. Many surfactants are hazardous to aquatic organisms. The Detergent Regulation³ generally requires that all surfactants must be readily biodegradable. If a substance does not meet this requirement and is intended solely for professional use, an exemption can be requested, allowing the substances to only be potentially biodegradable. The requirement for anaerobic biodegradability is considered a baseline, in line with the position of Nordic Ecolabelling, which asserts that environmentally harmful substances should be capable of degrading regardless of the environment they end up in. This is deemed relevant as surfactants have been found in sludge intended for use as fertilizer on land. The presence of these substances suggests that degradation in sludge or soil is not guaranteed, even though they may be biodegradable in aerobic aquatic environments. Since these criteria apply only to professional use and an exemption from the Detergent Regulation can be requested for such products, it is relevant to require both aerobic and anaerobic biodegradability for surfactants.

Date

³ Regulation (EC) No 648/2004, 2004.

The requirement excludes linear alkylbenzene sulphonates (LAS) as they are not anaerobically biodegradable.

The requirement is unchanged compared with generation 2 of the criteria.

O5 Preservatives

All preservatives in the product must not be bioaccumulative in line with the testing methods in Appendix 3 having a BCF (Bioconcentration Factor) less than 500 or log Kow (octanol-water partition coefficient) less than 4.

Preservatives are permitted solely for the preservation of products or raw materials and must not be used to impart antibacterial or disinfecting properties.

See also requirement O7 (Excluded substances) for additional requirements for preservatives.

- T Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

Background to requirement O5 Preservatives

Preservatives are typically harmful to aquatic organisms and can cause sensitivity and allergic reactions. Many products within this category do not need preservatives because they are acidic or basic. Still, preservatives are added to neutral, liquid products to prevent the growth of bacteria. Preservatives are essential for extending the shelf life of these products.

Preservatives may be included in both the final product and the ingoing substances, provided they are not bioaccumulative.

The requirement has changed since generation 2 of the criteria, and a Challenge test is no longer required. This is line with the Nordic Ecolabelling policy on preservatives.

O6 Phosphorus

The total amount of phosphorus from phosphates, phosphonates and other phosphorus compounds may not exceed 0.50 g P/litre in-use solution.

The calculation must be based on the highest recommended dosing stated on the product label or accompanying product sheet.

Please note that aminopolyphosphonates must not be present in the product according to requirement O7 (Excluded substances).

Be aware of national legislation on phosphorus where the product will be sold/marketed. In Norway, phosphorus is regulated in sections 2-12 in Regulation on Detergents and Cleaning Products.

- Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.
- T Calculation of the added amount of phosphorus, calculated as elementary phosphorus (P), per litre in-use solution.

Background to requirement O6 Phosphorus

Phosphorus and nitrogen are the primary nutrients driving eutrophication. This process depletes oxygen in lakes, oceans, and watercourses, leading to the formation of dead zones. In addition, phosphorus is a non-renewable resource facing continuously rising demand, and it can only be sourced from phosphorite, which is found in only a few countries—many of which have unstable regimes. Aside from Morocco, several of these countries are already nearing depletion of extractable phosphorus⁴.

Nordic Ecolabelling has reviewed licensed products and consulted with the industry, finding that phosphorus in these products primarily comes from phosphate, phosphonate, and phosphoric acids. Feedback from the industry and license data confirm that the limit value of 0.50 g P/litre of in-use solution is reasonable and supports the production of effective ecolabelled products.

The requirement is unchanged compared to criteria generation 2.

O7 Excluded substances

The following substances or substance groups must not be present as ingoing substances in the product.

- Alkylphenols (AP) (e.g. butylated hydroxy anisole (BrHA, CAS No. 25013-16-5), alkylphenol ethoxylates (APEO), and other alkylphenol derivates (APD)
- Aminopolyphosphonates
- Aromatic solvents

Solvents are defined as in Commission Directive 1999/13/EC: organic substances with a vapour pressure of at least 0.01 kPa at 20 °C.

- Benzalkonium chloride (CAS No. 63449-41-2)
- Bisphenols and bisphenol derivatives, defined as the 34 bisphenols that have been identified by ECHA⁵ for further EU regulatory risk management because they are known or potential endocrine disruptors for the environment or for human health, or can be identified as toxic for reproduction.
- Boric acid, borates, and perborates
- Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts
- Fragrances

⁴ Når det er tomt her - er verden ille ute | DN (Accessed on 25 October 2024).

⁵ EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA).

^[1] Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed <u>https://echa.europa.eu/documents/10162/5e60f2fe-12d0-7f6b-5868-f199cfd7f984</u>

Halogenated organic compounds

Nordic Ecolabelling

Consultation document

- LAS (linear alkylbenzene sulphonates)
- NTA (nitrilotriacetic acid, CAS-no. 139-13-9) and its salts

Exemption: 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 final product is below 0.1%.

- Organic chlorine compounds, hypochlorous acid and hypochlorite
- PBT and vPvB substances in accordance with REACH Annex XIII, including substances under investigation according to the ECHA PBT assessment list <u>https://echa.europa.eu/da/pbt</u>
- Per- and polyfluoroalkyl substances (PFAS)

PFASs are defined as fluorinated substances containing at least one fully fluorinated methyl or methylene carbon atom (without any H / CI / Br / I atom attached to it), i.e., with a few listed exceptions, all chemicals with at least one perfluorinated methyl group ($-CF_3$) or a perfluorinated the methylene group ($-CF_2$ -) is a PFAS as described in the OECD recommendations.

- Phthalates (i.e., esters of phthalic acid CAS No. 88-99-3)
- Potential or identified endocrine disruptors, according to any of the following EU member state initiative "Endocrine Disruptor Lists" List I, II and III

Exemption: MEK (Methyl ethyl ketone, CAS No. 78-93-3).

Please be aware that the exemption for MEK may be revised following further investigation by Nordic Ecolabelling.

N.B. A substance which is transferred to one of the corresponding sublists called "Substances no longer on list" and no longer appears on any of List I-III, is no longer excluded. The exemption is those substances on sublist II which were evaluated and where concern for endocrine disruption may still remain. Nordic Ecolabelling will evaluate the circumstances case-by-case, based on the background information indicated on sublist II.

 Quaternary ammonium compounds, which are not aerobically or anaerobically biodegradable* such as DTDMAC (CAS No. 61789-80-8), DSDMAC (CAS No. 107-64-2), DHTDMAC (CAS No. 61789-72-8) and DADMAC (CAS No. 7398-69-8).

* According to test method 301 (A-F) or 310 in OECD guidelines for testing of chemicals or other equivalent methods evaluated by an independent body and controlled by Nordic Ecolabelling.

- Siloxanes D4, D5, D6 and HMDS
- Substances on the REACH Candidate list of SVHC substances
 <u>https://www.echa.europa.eu/candidate-list-table</u>
- Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.

Background to requirement O7 Excluded substances

This requirement generally prohibits substances that Nordic Ecolabelling knows, or suspects have negative effects on health and the environment. Some of the substances are also prohibited in other requirements but are included here for the sake of clarity and to minimize the risk of misunderstandings.

The requirement is updated compared to generation 2 of the criteria.

APEO and APD Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS No. 25013-16-5), alkylphenol ethoxylates (APEO), and other alkylphenol derivates (APD)

Alkylphenols is a group of mainly non-ionic surfactants that are produced in large volumes and their use leads to widespread release to the aquatic environment. APEOs are highly toxic to aquatic organisms and degrade to more environmentally persistent compounds (APDs). Ethoxylated nonylphenol and several other alkylphenols are included in the Candidate List due to endocrine disrupting properties. Other alkylphenols are polyalkylated phenols such as butylated hydroxytoluene (BHT) and butylated hydroxyanisole (BHA) which have antioxidant properties. APEO and APD are also excluded from use through requirement O4 (Surfactants). The requirement is updated compared to generation 2 of the criteria.

Aminopolyphosphonates

Aminopolyphosphonates are for example used in laundry detergents. An analysis hypothesize that glyphosate may also be a transformation product of aminopolyphosphonates. Glyphosate is suspected of causing genetic damage. Glyphosate is acutely toxic to fish and birds and can kill beneficial insects and soil organisms that maintain ecological balance. Laboratory studies have identified adverse effects of glyphosate-containing products in all standard categories of toxicological testing. <u>Glyphosate contamination in European rivers not from herbicide application? - ScienceDirect</u> This is a new requirement in generation 3 of the criteria.

Aromatic solvents (see definition in the requirement)

Halogenated solvents are harmful to health, often not readily biodegradable and can have negative effects on the earth's ozone layer. Some halogenated solvents are suspected of causing cancer. The requirement is unchanged compared to criteria generation 2.

Benzalkonium chloride (CAS No. 63449-41-2)

Benzalkonium chlorides (BACs) is part of a group of chemicals with wide applications due to their antimicrobial properties against bacteria, fungi and viruses. There is a risk that frequent and widespread use of BACs in commercial products can generative selective environments for microbes and contribute to resistance to antibiotics. Furthermore, there is a risk to consumer exposure due to their toxicity and allergenic properties. The requirement is unchanged compared to criteria generation 2.

Bisphenols and bisphenol derivatives belonging to the group of 34 substances that have been identified by ECHA for further EU regulatory risk management that are known or

potential endocrine disruptors for the environment of for human health, or that can be identified as toxic for reproduction

Several bisphenols with the general bisphenol structure and 'bisphenol derivatives' which have constituents with structural properties common to bisphenols are now prohibited. Based on the potential for widespread use and available information on potential endocrine disruptors, reproductive toxicity and PBT/vPvB properties, 34 substances (see in the requirement) were identified in need for further regulatory risk management in EU. This is a new requirement in generation 3 of the criteria.

Boric acid, borates, and perborates

Perborates are sometimes used as bleaching agents. Many perborates are classified as toxic for reproduction. Nordic Ecolabelling wishes to continue listing these as prohibited, despite them also being banned under requirement O3 (Classification of ingoing substances). This is a new requirement in generation 3 of the criteria.

Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and Diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts

EDTA, DTPA and their salts are not readily degradable, furthermore, they are both classified toxic for reproduction and poses a risk to consumers. for EDTA, the EU's risk assessment states that under the conditions at municipal water treatment plants EDTA is either not broken down or only breaks down to a slight degree. To-date in Europe, EDTA has been replaced in virtually all consumer products by readily biodegradable alternatives such as MGDA (methylglycine diacetic acid) and GLDA (glutamic acid diacetic acid). The requirement is unchanged compared to criteria generation 2.

Fragrances

Fragrance substances are often not easily biodegradable and many are ecotoxic and sensitizing. The requirement is unchanged compared to criteria generation 2.

Halogenated Organic compounds

Halogenated organic compounds is a large group of substances that are harmful to both the environment and human health. They are often carcinogenic, highly toxic to aquatic organisms and very persistent to degradation.

LAS (linear alkylbenzene sulphonates)

Linear alkylbenzene sulphonates (LAS) are toxic to aquatic organisms and are not biodegradable in an anaerobic environment. LAS is already excluded through requirements for surfactants, but for the sake of clarity it is now also included in this requirement.

NTA (nitrilotriacetic acid, CAS-no. 139-13-9) and its salts

NTA is classified as Carc cat. 2 (EU, 2008b) and is thus already prohibited in requirement O4 due to its classification. However, complexing agents that replace NTA (GLDA and MGDA) contain small quantities of NTA as residues from raw material production (as attested in various safety data sheets for the raw materials). To encourage a transition to

MGDA and GLDA, they may contain NTA impurities in the raw material in concentrations of less than 0.2% if the concentration of NTA in the product is below 0.1%. This is a new requirement in generation 3 of the criteria.

Organic chlorine compounds, hypochlorous acid and hypochlorite

Organic chlorine compounds, hypochlorite and hypochlorous acid can be used as disinfecting and antibacterial substances and as bleaching agents. Chlorine-based substances generally have undesirable health and environmental properties. Both hypochlorite and hypochloric acid can lead to formation of organic chlorine compounds and byproducts that are toxic and bioaccumulative, like trihalomethanes and haloacetic acids. Hypochlorous acid is not classified, and hypochlorite have the classification Very toxic to aquatic life (H400) and thus, they are not covered by the general requirement concerning environmentally hazardous substances. However, both pose an environmental risk due to the possibility of organic chlorine compounds forming. The requirement is unchanged compared to criteria generation 2.

PBT and vPvB substances in accordance with REACH Annex XIII, including substances under investigation according to the ECHA PBT assessment list https://echa.europa.eu/da/pbt

PBT and vPvB are abbreviations for substances that are persistent, bioaccumulative and toxic, and very persistent and very bioaccumulative, respectively, in accordance with REACH Annex XIII. This means that they are not biodegradable and that they accumulate in living organisms. Based on these adverse characteristics they pose a threat to the environment and human health. They are prohibited in all Nordic Swan Ecolabel products.The requirement is updated compared to criteria generation 2.

Per- and polyfluoroalkyl substances (PFAS)

Per- and polyfluoroalkyl substances (PFAS) are a group of substances with undesirable properties. The substances are persistent and are readily absorbed by the body. PFASs are defined as fluorinated substances containing at least one fully fluorinated methyl or methylene carbon atom (without any H / Cl / Br / I atom attached to it), i.e., with a few listed exceptions, all chemicals with at least one perfluorinated methyl group (–CF3) or a perfluorinated the methylene group (–CF2–) is a PFAS as described in the OECD recommendations⁶.

This is a new requirement in generation 3 of the criteria.

Phthalates (i.e., esters of phthalic acid CAS No. 88-99-3)

Several phthalates are identified as endocrine disruptors and some of them are classified as reprotoxic. For these reasons several phthalates are included in the Candidate list. Based on their hazardous properties, phthalates pose a threat to the environment and human health and there is a ban on this group of substances. The requirement is unchanged compared to criteria generation 2.

⁶ <u>Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and practical Guidance</u>, OECD 2021.

Potential or identified endocrine disruptors

Endocrine disruptors (EDs) are chemicals that alter the functioning of the endocrine (hormone) system and consequently cause adverse health effects. The hormone system regulates many vital processes in living organisms and when normal signalling is disturbed, adverse effects may result. EDs raise high concern for their risk of causing serious negative impact on the environment as well as on human health specifically. Special concern is raised for effects on reproduction and development and about possible links to increases in public health diseases. While effects in wildlife populations have been confirmed, evidence is pointing to effects also in humans. By excluding both identified and prioritised potential EDs which are under evaluation, Nordic Ecolabelling ensures a restrictive policy on EDs.

The ED lists I-III on <u>https://edlists.org/</u> are dynamic, and the companies are responsible for keeping track of updates, in order to keep labelled products compliant with the requirement throughout the validity of the licences. Nordic Ecolabelling acknowledges the challenges associated with new substances being introduced on particularly List II and III, and in some cases also List I. We will evaluate the circumstances and possibly decide on a transition period on a case-by-case basis.

MEK (Methyl ethyl ketone, CAS 78-93-3) is exempted from the requirement because it is allowed in the EU-recipe for fully denatured ethanol. The requirement is updated compared to criteria generation 2.

Quaternary ammonium compounds, which are not aerobically or anaerobically biodegradable such as DTDMAC (CAS No. 61789-80-8), DSDMAC (CAS No. 107-64-2), DHTDMAC (CAS No. 61789-72-8) and DADMAC (CAS No. 7398-69-8).

Quaternary ammonium compounds (QACs) are usually surface-active agents where some of them precipitate or denature proteins and destroy micro-organisms. QACs are toxic to a lot of aquatic organisms including fish, daphnids, algae, rotifer and microorganisms employed in wastewater treatment systems. The requirement is unchanged compared to criteria generation 2.

Siloxanes D4, D5, D6 and HMDS

Siloxanes are a group of substances with molecular weights from a few hundreds to several hundred thousand. Many of them are substances with PBT and/or vPvB properties and gives rise to specific concern based on their potential to accumulate in the environment. Therefore, siloxanes with known problematic properties are excluded, more specifically D4, D5, D6 and HMDS. Other siloxanes or silicones are not included on the list of substances prohibited in the product under this requirement; however, they are restricted under requirement O11 (Biodegradability) and requirement O12 (Critical dilution volume (CDV)). This is a new requirement in generation 3 of the criteria.

Substances on the REACH Candidate list of SVHC substances <u>https://www.echa.europa.eu/candidate-list-table</u>

The Candidate List identifies substances of very high concern which fulfil the criteria in article 57 of the REACH Regulation (EC 1907/2006). The list includes carcinogenic; mutagenic; and reprotoxic substances (CMR, categories 1A and 1B in accordance with the CLP Regulation); and PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent

and very bioaccumulative) substances (as defined in REACH Annex XIII). In addition, two more substance groups are included if they are of equivalent level of concern (ELoC) as the ones previously mentioned. These are endocrine disruptors and substances which are environmentally hazardous without fulfilling the requirements for PBT or vPvB. Based on these adverse characteristics, Nordic Ecolabelling prohibits substances on the Candidate List. This means that we act ahead of the legislation and ban the substances before they are subject to authorisation and restriction in accordance with REACH. The requirement is unchanged compared to criteria generation 2.

070/3.0

O8 Microplastics

Microplastics* must not be present as ingoing substances in the cleaning agent for use in the food industry and must not be added to the product during manufacturing.

Nordic Ecolabelling reserves the right to change the requirement when more guidance from the EU on the restriction of synthetic polymer microparticles in REACH is published.

* Microplastics are synthetic polymer microparticles as defined in REACH Regulation ((EC) No 1907/2006), Annex XVII, Entry no. 78: Synthetic polymer microparticles: polymers that are solid, and which fulfil both of the following conditions:

- a) are contained in particles and constitute at least 1% by weight of those particles; or build a continuous surface coating on particles.
- b) at least 1% by weight of the particles referred to in point (a) fulfil either of the following conditions:
- (i) all dimensions of the particles are equal to or less than 5 mm.
- (ii) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3.

The following polymers are excluded from this designation:

- a) polymers that are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted, which are not chemically modified substances.
- b) polymers that are biodegradable as proved in accordance with Appendix 15 [to REACH, Regulation (EC) No 1907/2006].
- c) polymers that have a solubility greater than 2 g/L as proved in accordance with Appendix 16 [to REACH, Regulation (EC) No 1907/2006].
- d) polymers that do not contain carbon atoms in their chemical structure.

N.B. The following "Conditions of restriction" paragraphs apply: 1 (concentration limit in mixtures), 2 (definitions), 3 (particle size limits). The remaining points do not apply, e.g. 4 (Paragraph 1 shall not apply to the placing on the market of:), e.g. 4(a) "synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites", 5 (derogations), e.g. 5 (b) "synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry".

- $\overline{1}$ Appendix X or equivalent declaration from the manufacturer of the product.
- Appendix X or equivalent declaration from the manufacturer/supplier of each raw material.

Background to requirement O8 Microplastics

Microplastics⁷ are very small fragments of plastic material, less than 5 mm. They can be harmful to health and the environment due to their size, surface properties, resistance to degradation and because they can carry harmful chemicals. In nature, microplastics come from pellets, paint, tires, textiles, personal care products and various plastic items. They have been found all over the world, at sea, in freshwater, sediments, sludge from wastewater treatment plants and agricultural soil. Microplastics have been detected in various aquatic organisms across the food chain, from zooplankton to vertebrates and in human tissues and organs such as blood and placenta. The Nordic Swan Ecolabel uses the precautionary principle and strives to limit the use and release of microplastics wherever possible.

Nordic Ecolabelling is concerned about consequences when microplastics are released into the environment. Thus, we do not apply the derogations in paragraph 4 and 5 of Annex XVII to the REACH Regulation (EC) No 1907/2006 when excluding microplastics.

The requirement is new for this generation of the criteria.

O9 Nanomaterials

Nanomaterials/-particles* must not be added or be present in the product.

* Nanomaterials/-particles are defined according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01): 'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions:

(a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm;

(b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;

(c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

- $\overline{\mathbf{t}}$ Appendix X or equivalent declaration from the manufacturer of the product.
- Appendix X or equivalent declaration from the manufacturer/supplier of each raw material.

Background to requirement O9 Nanomaterials

Nanomaterials⁸ are a diverse group of materials under the size of 100 nm. Due to their small size and large surface area nanoparticles are often more reactive and may have other properties compared to larger particles of the same material. Further, different sizes, shapes, surface modifications and coatings can also change their physical and chemical properties. Nanoparticles can cross biological membranes and thus be taken up by cells and organs.

⁸ <u>https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/chemicals-nano-and-microplastics/nanomaterials/</u>

⁷ <u>https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/chemicals-nano-and-microplastics/microplastics/</u>

One of the main concerns are linked to free nanoparticles, as some of these – when inhaled – can reach deep into the lungs, where the uptake into the blood is more likely.

There is concern among public authorities, scientists, environmental organisations, and others about the insufficient knowledge regarding the potential detrimental effects on health and the environment⁹,¹⁰,¹¹. Nordic Ecolabelling takes these concerns seriously and applies the precautionary principle to exclude potentially hazardous nanomaterials from products.

The requirement is new for this generation of the criteria.

5.2 Biodegradability and aquatic toxicity

O10 Long-term environmental effects

The use of ingoing substances which are classified* with any of the hazard codes $H_{410},\,H_{411}$ or H_{412} is limited as follows:

 $M^{*}100^{*}C_{H410} + 10^{*}C_{H411} + C_{H412} < 40$ grams / litre in-use solution, where M is the multiplying factor for H_{410} as described in the CLP Regulation (EC) No 1272/2008).

 C_{H410} = Concentration of substances with H_{410} in grams / litre in-use solution

 C_{H411} = Concentration of substances with H_{411} in grams / litre in-use solution

 C_{H412} = Concentration of substances with H_{412} in grams / litre in-use solution

The calculation must be based on the highest recommended dosing stated on the product label or accompanying product sheet.

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.

* Please note that in order to assess the classification, all the available data must have been evaluated, including data in ECHA databases.

- Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.
- Calculation to show that the requirement is fulfilled. Nordic Ecolabelling's calculation sheet for Cleaning agents for use in the food industry can be used. It is available from Nordic Ecolabelling's websites.

¹⁰ Parliamentary Assembly of the Council of Europe (2013) Nanotechnology: balancing benefits and risks to public health and the environment.

http://assembly.coe.int/CommitteeDocs/2013/Asocdocinf03 2013.pdf

¹¹ SCCS (Scientific Committee on Consumer Safety) (2019) Guidance on the Safety Assessment of Nanomaterials in Cosmetics. SCCS/1611/19.

https://ec.europa.eu/health/sites/health/files/scientific committees/consumer safety/docs/sccs o 233.pdf

⁹ UNEP (2017) Frontiers 2017 Emerging Issues of Environmental Concern. United Nations Environment Programme, Nairobi. <u>https://wedocs.unep.org/bitstream/handle/20.500.11822/22255/Frontiers_2017_EN.pdf</u>

Background to requirement O10 Long-term environmental effects

A Nordic Swan Ecolabelled product must not be classified as environmentally hazardous, see requirement O2 (Classification of the product). To further minimise potential problems for the aquatic environment, a limit has been set for the highest permitted content of environmentally hazardous substances in a product.

The requirement has been changed compared to generation 2 of the criteria, removing the exemption for surfactants classified as H411 and H412. The exemption for protease/subtilisin regarding the H411 classification has also been removed, as it is not harmonized under H411. However, the intention has been to maintain the same level of the requirement. In addition, the multiplying factor M, for H410 as stated in CLP, is included in the calculation.

O11 Biodegradability

The quantity of organic substances that are aerobically non-biodegradable (aNBO) must not exceed 0.20 g/ litre in-use solution.

The quantity of organic substances that are anaerobically non-biodegradable (anNBO) must not exceed 0.40 g/ litre in-use solution.

The calculation must be based on the highest recommended dosing stated on the product label or accompanying product sheet.

Please note that all surfactants must be aerobically and anaerobically biodegradable under requirement O4 (Surfactants).

See also the exemption from the requirement of anaerobic biodegradability for substances which are not surfactants in Appendix 3, item 7, Anaerobic biodegradability.

- Reference to the DID list, version 2023 or later. 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.
- Calculation of the product's content of organic substances that are either not aerobically or anaerobically biodegradable. Nordic Ecolabelling's calculation sheet for Cleaning agents for use in the food industry can be used. It is available from Nordic Ecolabelling's websites.

Background to requirement O11 Biodegradability

The persistence of substances in nature is an important environmental parameter. The extent to which substances degrade in aquatic environments indicates how long they may impact the ecosystem. Degradation in water depends on the presence of oxygen in the receiving environment, which is why Nordic Ecolabelling distinguishes between aerobic (with oxygen) and anaerobic (without oxygen) degradability.

The proportion of non-aerobically or anaerobically degradable substances varies across different products. Industrial cleaning and degreasing agents may contain limited amounts of organic compounds that are neither aerobically nor anaerobically degradable. By restricting the content of such substances in chemicals, Nordic Ecolabelling ensures that no more substances are released into the environment than necessary.

070/3.0

O12 Critical dilution volume (CDV)

The critical dilution volume (CDV) of the product must not exceed 20 000 litres/ in-use solution.

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

 $CDV_{chronic} = \Sigma CDV_i = \Sigma$ (dose_i x DF_i x 1000 / TF_i chronic), where

dose_i = the input quantity of the individual substance in g/ litre 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.

The calculation must be based on the highest recommended dosing stated on the product label or accompanying product sheet.

- Reference to the DID list, version 2023 or later. 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.
- Calculation of the product's CDV_{chronic}. Nordic Ecolabelling's calculation sheet can be used. It is available from Nordic Ecolabelling's websites.
- Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.

Background to requirement O12 Critical dilution volume (CDV)

CDV is a theoretical value that takes account of each substance's toxicity and biodegradability in the environment. The method was developed together with the EU Ecolabel. Setting a maximum limit for CDV ensures that the Nordic Swan Ecolabelled products have a minimal impact on the receiving water. CDV is calculated for all ingoing substances in the product.

The CDV limit is only stated with chronic values. The use of chronic data is generally preferable, since long-term toxicity data is considered of higher quality and to give more precise/reliable estimates of potential environmental effects compared with acute toxicity data. The limit values have been set on the basis of licence data.

The requirement has been changed compared with generation 2 of the criteria in terms of: The limit value has been tightened, and the separate limit value for ready-to-use products has been removed.

Date

Date

5.3 Performance

O13 Performance

The product's efficacy must be documented through a user test that meets the requirements outlined below:

- The product must have been used by at least three independent users within its area of application over a period that reflects the product's usage frequency (i.e., the product must have been used repeatedly). More than one test report from the same company is accepted if they apply to different applications or test locations.
- The product must be tested at the dosage recommended on the product label or accompanying product sheet.
- All users must rate the product as either sufficiently effective or very effective.
- The user must complete Appendix 4. All appendices must be submitted to Nordic Ecolabelling.
- A test report detailing the user test, including a summary of the results, must be prepared.
- Appendix 4 from all users who have tested the product.
- Test report describing the user test, including summary of the results.

Background to requirement O13 Performance

Performance testing is primarily a quality requirement to ensure that a Nordic Swan Ecolabelled product delivers effective cleaning results for its intended areas of use at the specified dosage. A product that performs well reduces the risk of overdosing.

Since no standardized tests exist and professional users have high demands, Nordic Ecolabelling considers user tests the most reliable way to document the product's performance. Due to the demanding nature of user tests in the food industry - requiring long test periods, large product quantities, and strict hygiene standards - Nordic Ecolabelling has decided to only require three test sites unlike other chemical-technical product groups where more test sites are usually required.

The test period length is not strictly defined, as it depends on how the product is used. It is reasonable for products used daily to have a different test duration than those used weekly. The product must be used multiple times during the test period. A four-week test period is generally a good guideline.

The requirement is unchanged compared with generation 2 of the criteria.

5.4

O14 User information

The product label or accompanying product sheet must include the information below.

• Product type and area of use.

Packaging and user information

The product's area of use must align with the application for which it was tested in requirement O11 (Performance).

• For products that require dilution before use: Recommended dosage for regular use and typical soiling.

The recommended dosage can be stated in units such as dl, pumps, or caps, for example.

- Description of how the user can avoid coming into contact with the product, for example, by using personal protective equipment.
- T Copy of label and/or product sheet.

Background to requirement O14 User information

Incorrect use and overdosing of products result in an unnecessary increased environmental impact. To mitigate this, Nordic Ecolabelling requires that the product label or accompanying product sheet includes clear information on the intended use and correct dosage.

To ensure safe use of the product, there must be a description of how the user can avoid coming into contact with the product.

The requirement is unchanged compared to criteria generation 2.

O15 Packaging

Packaging up to 20 litres must consist of either PE, PP or PET according to the following requirements.

PE and PP packaging

 The container and closure must be made of minimum: 99% polyethene (PE) or 95 % polypropene (PP).

The remaining % must not be of biodegradable or any other material than PE or PP.

- Colours: Carbon black pigments must not be added to the packaging.
- Labels: Must be made of the same material as of the packaging component they are placed on.

PET packaging

- The container and closure must be made of minimum: 98% polyethylene terephthalate (PET).
- Colours: Transparent and transparent colours without carbon black are allowed.
- Labels: Must be made of PE or PP.

- The label must not cover more than 50% of the packaging surface for sizes ≤ 500 ml and 70% for sizes > 500 ml.
- Appendix 5 or equivalent declaration completed and signed.
- For labels on PET packaging: Declaration from the applicant regarding the size of the label compared to the container.

Background to requirement O15 Packaging

The Nordic recycling manuals for plastic packaging¹² are the base for the requirement stating that plastic bottles/containers and closures must be made from PE, PP or PET. These are the best plastics from a recycling perspective. Biodegradable plastics are not suitable in today's recycling systems and can cause problems in the material recovery process.

PE and PP containers must have labels of the same plastic material, in order to facilitate correct sorting by the NIR sensor.

PET containers must have labels made of PE or PP. Labels for sizes > 500 ml must not cover more than 70% of the container, and maximum 50% sizes \leq 500 ml. The calculation of the percentage shall be based on the two-dimensional profile of the container i.e., the area of the top and bottom of the packaging and the sides of a box/container/bottle/can shall not be included in the calculation. If the label on the front of pack and back of pack are of different size, the maximum percentage of (50% or 70%) shall be fulfilled for each side separately. For a cylindrical bottle, the calculation can also be based on the three-dimensional profile exclusive bottom and top of the bottle.

The permitted sizes of labels of material other than the container come from ReCyclass' recommendations. These are the sizes they have tested and can vouch for in relation to NIR sorting. Swedish authorities' national Eco design guidelines have chosen to say 60% for all sizes. We have not been able to find a basis for that decision and have therefore chosen to go with what has been tested.

The requirement is new for this generation of the criteria.

Suomen Uusiomuovi Oy: Opas kierrätyskelpoisen muovipakkauksen suunnitteluun

https://plast.dk/wp-content/uploads/2018/11/Design-manual-ENG-Forum-for-Circular-Plastic-Packaging-NOVEMBER-2018.pdf, https://plast.dk/wp-content/uploads/2018/06/Bilag-A-designmanual.pdf;

¹² "Plastförpackningar – En återvinningsmanual från FTI, version 0.7,

http://www.uusiomuovi.fi/document.php/1/130/packdes_painos_1/442070829017fd4aa7d7e00bf960978b (visited 2019-04-30)

<u>https://www.grontpunkt.no/media/2777/report-gpn-design-for-recycling-0704174.pdf</u> (Accessed 2020-08-12); http://norden.diva-portal.org/smash/get/diva2:1364632/FULLTEXT01.pdf (Accessed 2020-08-12);

5.5 Licence maintenance

The purpose of the licence maintenance is to ensure that fundamental quality assurance is dealt with appropriately.

O16 Customer complaints

The licensee must guarantee that the quality of the Nordic Swan Ecolabel product or service does not deteriorate during the validity period of the licence. Therefore, the licensee must keep an archive over customer complaints.

Note that the original routine must be in one Nordic language or in English.

T Upload your company's routine for handling and archiving customer complaints.

Background to requirement O16 Customer complaints

Nordic Ecolabelling requires that your company has implemented a customer complaint handling system. To document your company's customer complaint handling, you must upload your company's routine describing these activities. The routine should be dated and signed and will normally be part of your company's quality management system.

If your company does not have a routine for customer complaint handling, it is possible to upload a description of how your company perform these activities. During the on-site visit, Nordic Ecolabelling will check that the customer complaint handling is implemented in your company as described. The customer complaints archive will also be checked during the visit.

O17 Traceability

The licensee must be able to trace the Nordic Swan Ecolabel products in the production. A manufactured / sold product should be able to trace back to the occasion (time and date) and the location (specific factory) and, in relevant cases, also which machine / production line where it was produced. In addition, it should be possible to connect the product with the actual raw material used.

You can upload your company's routine or a description of the actions to ensure traceability in your company.

 $\overline{1}$ Please upload your routine or a description.

Background to requirement O17 Traceability

Nordic Ecolabelling requires that your company has implemented a traceability system. To document your company's product traceability, you must upload your company's routine describing these activities. The routine should be dated and signed and will normally be part of your company's quality management system.

If your company does not have a routine for product traceability, it is possible to upload a description of how your company perform these activities. During the on-site visit, Nordic Ecolabelling will check that the product traceability is implemented in your company as described.

6 Environmental impact of cleaning agents for use in the food industry

The relevant environmental impacts found in the life cycle of cleaning agents for use in the food industry are set out in a MECO scheme, see section 6.2. A MECO describes the key areas that have impact on the environment and health throughout the life cycle of the product – including consumption of materials/resources (M), energy (E), chemicals (C) and other impact areas (O).

Nordic Ecolabelling sets requirements concerning the topics and processes in the life cycle that have a high environmental impact – also called hotspots. Based on the MECO analysis, an RPS tool is used to identify where ecolabelling can have the greatest effect. R represents the environmental relevance, P is the potential to reduce the environmental impact and S is the steerability on how compliance with a requirement can be documented and followed up. The criteria contain requirements in those areas in the life cycle that have been found to have high RPS, since there is potential to achieve positive environmental gains.

Degradability and toxicity to aquatic organisms, exposure of chemicals harmful to health, eutrophication from phosphorous compounds, user information, dosing and performance and packaging stand out as key parameters in the MECO analysis. See section 6.1 for a RPS scheme on these parameters.

Life cycle stages	Area and assessment of R, P, S (high, medium or low)	Comments
Raw material		
	It is not identified any environmental hotspots during the raw material phase.	
Production		
	It is not identified any environmental hotspots during the production phase.	
Use phase		
	Professional users' exposure to allergens and other hazardous chemicals	R is high due to professional users being exposed to allergens and other hazardous chemicals.
	R: High P: High S: High RPS: High	P is high as there is a potential to prohibit or limit allergens and other hazardous chemicals. There is also a potential to ensure safe use of the product.
		S is high as requirements to prohibit or limit allergens and other hazardous chemicals can be set. In addition, Nordic Ecolabelling can require that the product label or accompanying product sheet include a description of how the user can avoid coming into contact with the product. For certain products, the packaging design may also be required to demonstrate that users do not come into contact with the product.

6.1 RPS scheme

	Professional satisfaction influenced by product quality, effectivity, and shelf life R: High P: High S: High RPS: High Reduced wastage based on dosing instructions and design R: High P: High S: Medium RPS: High	R is high because a poorly performing product may lead to overdosing, resulting in unnecessary and increased environmental impact. P is high as there is a potential to ensure that the product performs well. S is high as Nordic Ecolabelling can set up performance requirement. R is high because overdosing of products result in an unnecessary increased environmental impact. P is high as there is a potential to ensure correct use of the product and to limit overdosing. S is medium as Nordic Ecolabelling can require that the product label or accompanying product sheet includes clear instructions for use and recommended dosage for products that require dilution before use. However, it is the user who decides whether the information is followed.
End of life		
	Loss of the material value if packaging is incinerated (higher impact) vs. recycled (lower impact) R: Medium P: Medium S: High RPS: Medium	R is medium due to consumption of energy and fossil resources. P is medium as the packaging sizes generally are large (> 20 litres) and they are commonly reused. However, there are smaller packaging where there is potential to promote design for recycling. S is high as requirements concerning the packaging's recyclability can be set for smaller packaging.
	Wastewater emissions of chemicals toxic to aquatic organisms R: High P: High S: High RPS: High Emissions of phosphorous compounds	R is high as the product end up in a water treatment plant and then the water recipient. The product therefore risks to harm both aquatic organism and the ecosystem, depending on the inherent properties of the ingredients. P is high as there is a potential to reduce the content of environmentally hazardous ingredients such as substances toxic to aquatic organism, non-degradable substances, microplastics, endocrine disruptors etc in the products. S is high as requirements to prohibit or limit problematic substances can be set. R is high because phosphorus is a driver of
	that cause eutrophication R: High P: High S: High RPS: High	eutrophication. P is high as there is potential to prohibit or limit the content of phosphorus in the products. S is high as requirements to prohibit or limit phosphorous in the products can be set.

6.2 MECO scheme

	Raw material	Production	Use	End of life	Transport
Material	Extraction of oil, gas, metals, and minerals for non- renewable raw materials Agricultural production for renewable raw materials Forestry for paper-based packaging Water consumption in raw material production		Water consumption in use	Loss of the material value if packaging is incinerated (higher impact) vs. recycled (lower impact)	
Energy	Energy consumption to extract/cultivate and process raw materials for product and packaging (15-30% GWP in LCA, with higher water content reducing raw chemical contribution but increasing packaging contribution)	Energy consumption to produce product and packaging (ca 5% GWP in LCA for liquids; ca 10% for powder or solid products due to energy for drying)	Energy for heating water for product use (50-75% GWP in LCA, if applicable)	Energy from wastewater treatment and solid waste handling (5-20% GWP in LCA)	Energy use of transport vehicles (ca 5% in LCA)
Chemicals	Agricultural chemicals including pesticides and fertilizers Exposure to hazardous chemicals in the work environment or nearby communities	Exposure to hazardous chemicals in the work environment or nearby communities	Professional users' exposure to allergens and other hazardous chemicals	Wastewater emissions of chemicals toxic to aquatic organisms Emissions of phosphorous compounds that cause eutrophication	Air pollution from transport vehicles
Other	Biodiversity and ecosystem impacts from resource extraction, forestry, and agriculture Conflicts arising due to land right disputes and impacts on local and indigenous communities		Professional satisfaction influenced by product quality, effectivity, and shelf life Reduced wastage based on dosing instructions and design	Biodiversity and health impacts from hazardous chemicals from sewage sludge leaching to land and water Emissions of microplastics or nanomaterial (due to	Particulate matter from transport vehicles

Nordic Ecolabelling Consultation document

Sources for MECO

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7 Future criteria generation

Points will be added after the consultation.

8 Criteria version history

Criteria version history will be added after the consultation.

9 How to apply and regulations for the Nordic Ecolabelling

Application and costs

For information about the application process and fees for this product group, please refer to the respective national website. For contact information see the beginning of this document.

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

Licence validity

The Nordic Swan Ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be prolonged or adjusted, in which case the licence is automatically prolonged, 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 on-site inspection visit/-s 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 contact info in the beginning of this document. Further information and assistance (such as calculation sheets or electronic application help) is available. Visit the relevant national website for further information.

Follow-up inspections

Nordic Ecolabelling may decide to check whether the product 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 product 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.

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 <u>www.nordic-swan-ecolabel.org/regulations</u>

To be used in conjunction with an application for a licence for the Nordic Swan Ecolabel of cleaning agents 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.

Product name:	
Product type and area of use:	

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 product including additives (e.g. preservatives and stabilisers) from the raw materials. Substances released from ingoing substances (e.g. biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances.

*N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance (Unknown or Variable composition, Complex reaction products or of Biological materials) are also regarded separately, and all known constituents shall be regarded.

Impurities: Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials that remain in the product in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%). Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.

Examples of impurities are: Background environmental pollutants from feedstock, as well as contaminants and residues from production such as reactants (incl. monomers), reagents, catalysts, by-products, scavengers,

detergents for production equipment, carry-over from other or previous production lines.

O2 Classification of the product		
Is the product classified with any of the hazard phrases below? Incl. all classification variants. For example, H350 also covers classification H350i.	Yes	No
If the answer to all the classifications below is No, mark here		
Carc. 1A or 1B H350		
Carc. 2 H351		
Muta. 1A or 1B H340		
Muta. 2 H341		
Repr. 1A or 1B H360		
Repr. 2 H361		
Lact. H362		
Resp. Sens. 1, 1A or 1B H334		
Skin Sens. 1, 1A or 1B H317		
EUH208: "Contains (name of sensitising substance). May cause an allergic reaction."		
Acute Tox. 1 or 2 H300		
Acute Tox. 1 or 2 H310		
Acute Tox. 1 or 2 H330		
Acute Tox. 3 H301		
Acute Tox. 3 H311		
Acute Tox. 3 H331		
Acute Tox. 4 H302		
Acute Tox. 4 H312		
Acute Tox. 4 H332		
Aquatic Acute 1 H400		
Acute Chronic 1 H410		
Aquatic Chronic 2 H411		
Aquatic Chronic 3 H412		
Aquatic Chronic 4 H413		
Ozone H420		
STOT SE 1 H370		
STOT SE 2 H371		

STOT RE 1 H372	
STOT RE 2 H373	
STOT RE 2 H373	
Asp. Tox. 1 H304	
Flam. Aer. 1 H222	
Flam. Aer. 2 H223	
Flam. Aer. 3 H229	
Flam. Liq. 1 H224	
Flam. Liq. 2 H225	
Flam. Liq. 3 H226	
ED HH 1 EUH380	
ED HH 2 EUH381	
ED ENV 1 EUH430	
ED ENV 2 EUH431	
PBT EUH440	
vPvB EUH441	
PMT EUH450	
vPvM EUH451	

O3 Classification of ingoing substances		
Does the product contain substances classified with any of the hazard phrases below? Incl. all classification variants. For example, H350 also covers classification H350i.	Yes	No
If the answer to all the classifications below is No, mark here		
Carc. 1A or 1B H350		
Carc. 2 H351		
Muta. 1A or 1B H340		
Muta. 2 H341		
Repr. 1A or 1B H360		
Repr. 2 H361		
Lact. H362		
Resp. Sens. 1, 1A or 1B H334		
Skin Sens. 1, 1A or 1B H317		
STOT RE 1 H372		
Ozone H420		
ED HH 1 EUH380		

ED HH 2 EUH381	
ED ENV 1 EUH430	
ED ENV 2 EUH431	
PBT EUH440	
vPvB EUH441	
PMT EUH450	
vPvM EUH451	

O5 Preservatives		
	Yes	No
Does the product contain preservatives?		
If yes, state the BCF (Bioconcentration Factor) and/or log Kow (octanol-water partition coefficient):		

O6 Phosphorus		
	Yes	No
Does the product contain phosphorus?		

O7 Excluded substances		
Does the product contain any of the following substances?	Yes	No
Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS No. 25013-16-5), alkylphenol ethoxylates (APEO), and other alkylphenol derivates (APD)		
Aminopolyphosphonates		
Benzalkonium chloride (CAS No. 63449-41-2)		
Bisphenols and bisphenol derivatives, defined as the 34 bisphenols that have been identified by ECHA for further EU regulatory risk management because they are known or potential endocrine disruptors for the environment or for human health, or can be identified as toxic for reproduction.		
Boric acid, borates, and perborates		
Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts		
Fragrance		
Halogenated organic compounds		
Aromatic solvents		
Solvents are defined as in Commission Directive 1999/13/EC: organic substances with a vapour pressure of at least 0.01 kPa at 20 $^\circ$ C.		
LAS (linear alkylbenzene sulphonates)		

NTA (nitrilotriacetic acid, CAS-no. 139-13-9) and its salts Exemption: 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 final product is below 0.1%.	
Organic chlorine compounds, hypochlorous acid and hypochlorite	
PBT and vPvB substances in accordance with REACH Annex XIII, including substances under investigation according to the ECHA PBT assessment list https://echa.europa.eu/da/pbt	
Per- and polyfluoroalkyl substances (PFAS)	
PFASs are defined as fluorinated substances containing at least one fully fluorinated methyl or methylene carbon atom (without any H / Cl / Br / I atom attached to it), i.e., with a few listed exceptions, all chemicals with at least one perfluorinated methyl group (–CF3) or a perfluorinated the methylene group (–CF2–) is a PFAS as described in the OECD recommendations.	
Phthalates (i.e., esters of phthalic acid CAS No. 88-99-3)	
Potential or identified endocrine disruptors, according to any of the following EU member state initiative "Endocrine Disruptor Lists" List I, II and III Exemption: MEK (Methyl ethyl ketone, CAS No. 78-93-3).	
N.B. A substance which is transferred to one of the corresponding sublists called "Substances no longer on list" and no longer appears on any of List I-III, is no longer excluded. The exemption is those substances on sublist II which were evaluated and where concern for endocrine disruption may still remain. Nordic Ecolabelling will evaluate the circumstances case-by-case, based on the background information indicated on sublist II.	
Quaternary ammonium compounds, which are not aerobically or anaerobically biodegradable* such as DTDMAC (CAS No. 61789-80-8), DSDMAC (CAS No. 107-64-2), DHTDMAC (CAS No. 61789-72-8) and DADMAC (CAS No. 7398-69-8).	
* According to test method 301 (A-F) or 310 in OECD guidelines for testing of chemicals or other equivalent methods evaluated by an independent body and controlled by Nordic Ecolabelling.	
Siloxanes D4, D5, D6 and HMDS	
Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate- list-table	

O8 Long-term environmental effects		
	Yes	No
Does the product contain substances classified as H410, H411 or H412?		

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). Also, state whether the substance is contained in the form of an impurity or an ingoing 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
Responsible person	Signature of responsible person
Telephone	Email

Appendix 2 Declaration from the manufacturer/supplier of the raw material to the cleaning agent for use in the food industry

To be used in conjunction with an application for a licence for the Nordic Swan Ecolabel of cleaning agents 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. Please inform Nordic Ecolabelling if new knowledge arises and submit an updated declaration.

For suppliers: If you do not have knowledge about the complete composition of the raw material/ingredient, you are obliged to obtain this information from the manufacturer.

Manufacturer/Supplier	
Trade name of the raw material	

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 product including additives (e.g. preservatives and stabilisers) from the raw materials. Substances released from ingoing substances (e.g. biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances.

*N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance (Unknown or Variable composition, Complex reaction products or of Biological materials) are also regarded separately, and all known constituents shall be regarded.

Impurities: Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials that remain in the product in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%). Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.

Note that if the raw material contains impurities listed in this appendix, write the amount at the end of the appendix. The manufacturer of the Nordic Swan Ecolabelled product is responsible for calculating compliance with the requirements of the criteria.

Ingoing substances in the raw material/ingredient (chemical name, INCI name, CAS No., amount in weight-%):

Function of the raw material/ingredient(s), including all ingoing substances:

Please note that substances that are defined as surfactants according to Detergent Regulation (EC) No 648/2004, must always be reported with the function "surfactant".

Suggested DID-numbers for the raw material/ingredient(s), including all declared ingoing substances. The DID-list is available from the Nordic Ecolabelling web pages:

Please note that the information in this declaration is internally shared with certification personnel in Nordic Ecolabelling to be used in evaluation of applications of chemical technical products.

O3 Classification of ingoing substances		
Does the raw material contain substances classified with any of the hazard phrases below? Incl. all classification variants. For example, H350 also covers classification H350i.	Yes	No
If the answer to all the classifications below is No, mark here		
Carc. 1A or 1B H350		
Carc. 2 H351		
Muta. 1A or 1B H340		
Muta. 2 H341		
Repr. 1A or 1B H360		
Repr. 2 H361		
Lact. H362		
Resp. Sens. 1, 1A or 1B H334		
Skin Sens. 1, 1A or 1B H317		
STOT RE 1 H372		
Ozone H420		
ED HH 1 EUH380		
ED HH 2 EUH381		
ED ENV 1 EUH430		
ED ENV 2 EUH431		
PBT EUH440		
vPvB EUH441		
PMT EUH450		
vPvM EUH451		

O5 Preservatives		
	Yes	No
Does the raw material contain preservatives?		
If yes, state the BCF (Bioconcentration Factor) and/or log Kow (octanol-water partition coefficient):		

O6 Phosphorus		
	Yes	No
Does the raw material contain phosphorus?		
If yes, state the amount (%) of phosphorus?		

O7 Excluded substances		
Does the raw material contain any of the following substances?	Yes	No
Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS No. 25013-16-5), alkylphenol ethoxylates (APEO), and other alkylphenol derivates (APD)		
Aminopolyphosphonates		
Benzalkonium chloride (CAS No. 63449-41-2)		
Bisphenols and bisphenol derivatives, defined as the 34 bisphenols that have been identified by ECHA for further EU regulatory risk management because they are known or potential endocrine disruptors for the environment or for human health, or can be identified as toxic for reproduction.		
Boric acid, borates, and perborates		
Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts		
Fragrance		
Halogenated organic compounds		
Aromatic solvents Solvents are defined as in Commission Directive 1999/13/EC: organic substances with a vapour pressure of at least 0.01 kPa at 20 °C.		
LAS (linear alkylbenzene sulphonates)		
NTA (nitrilotriacetic acid, CAS-no. 139-13-9) and its salts		
Exemption: 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 final product is below 0.1%.		
Organic chlorine compounds, hypochlorous acid and hypochlorite		
PBT and vPvB substances in accordance with REACH Annex XIII, including substances under investigation according to the ECHA PBT assessment list https://echa.europa.eu/da/pbt		
Per- and polyfluoroalkyl substances (PFAS)		
PFASs are defined as fluorinated substances containing at least one fully fluorinated methyl or methylene carbon atom (without any H / Cl / Br / I atom attached to it), i.e., with a few listed exceptions, all chemicals with at least one perfluorinated methyl group (–CF3) or a perfluorinated the methylene group (–CF2–) is a PFAS as described in the OECD recommendations.		
Phthalates (i.e., esters of phthalic acid CAS No. 88-99-3)		
Potential or identified endocrine disruptors, according to any of the following EU member state initiative "Endocrine Disruptor Lists" List I, II and III		
Exemption: MEK (Methyl ethyl ketone, CAS No. 78-93-3).		
N.B. A substance which is transferred to one of the corresponding sublists called "Substances no longer on list" and no longer appears on any of List I-III, is no longer excluded. The exemption is those substances on sublist II which were evaluated and where concern for endocrine disruption may still remain. Nordic Ecolabelling will evaluate the circumstances case-by-case, based on the background information indicated on sublist II.		
Quaternary ammonium compounds, which are not aerobically or anaerobically biodegradable* such as DTDMAC (CAS No. 61789-80-8), DSDMAC (CAS No. 107-64-2), DHTDMAC (CAS No. 61789-72-8) and DADMAC (CAS No. 7398-69-8).		
* According to test method 301 (A-F) or 310 in OECD guidelines for testing of chemicals or other equivalent methods evaluated by an independent body and controlled by Nordic Ecolabelling		
Siloxanes D4, D5, D6 and HMDS		
Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate- list-table		

O8 Long-term environmental effects		
	Yes	No
Does the raw material contain substances classified as H410, H411 or H412?		

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). Also, state whether the substance is contained in the form of an impurity or an ingoing 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
Responsible person	Signature of responsible person
Telephone	Email

Appendix 3 Analysis and test laboratories

1A Requirements on the analysis laboratory for ecotoxic effects

The analysis laboratory must be competent, impartial and shall fulfil the general requirements of standard EN ISO 17025 or have official GLP status.

1B Requirements on the analysis laboratory for performance

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

The applicant's own laboratory, and external testing institutes that do not meet EN ISO 17025 or do not have official GLP status, may be approved to carry out performance tests. In this case, the following conditions must be met:

- The organisation must be ISO 9001 certified or certified according to the International Features Standards (IFS) standard for Household and Personal Care.
- The test laboratory must be covered by the certification, and the performance test must be included in the quality management system.
- Nordic Ecolabelling is to be given access to all the raw data from the performance test.

The applicant's own laboratory may be approved to carry out performance tests even if the test laboratory and the performance test are not covered by ISO 9001 or IFS standard for Household and Personal Care certification. The following conditions must be met:

- The organisation must have a quality assurance system and an ISO 9001 or IFS standard for Household and Personal Care certification. The laboratory and the performance test do not have to be within the certification, but it needs to be described in that system. Nordic Ecolabelling is to be given access to all the raw data from the performance test.
- The laboratory must document that the test method used is suitable for differentiating between different products, and that the results achieved are reproducible.
- It must be possible for Nordic Ecolabelling to come and observe the performance of a test.

2. Approved test methods

International test methods (OECD Guidelines for Testing of Chemicals, ISBN 92-64-1222144) or equivalent methods must be used for documentation. If equivalent methods are used, these must be assessed by an independent body and approved by Nordic Ecolabelling to ensure that the results are equivalent. The relevant test methods are stated in the below sections. Calculations from data models (such as BIOWIN) are accepted, if they are assessed by an independent body, but if the results of the model calculations are close to the threshold values or if Nordic Ecolabelling has contradictory data, more certain information may be required.

3. Aquatic toxicity

For acute aquatic toxicity, test methods no. 201, 202, 203, and 212 in the OECD Guideline are used. For chronic aquatic toxicity test methods no. 210, 211, 215 and 229 in the OECD Guideline are used. OECD 201 can be used as chronic test if chronic endpoints are chosen.

OECD test guideline no. 249 (acute toxicity – fish) can be used as an alternative to OECD test guideline no. 203, but only if toxicity data for crustaceans and algae is also available.

4. Bioaccumulation

Unless otherwise proven, 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 \geq 4.0 according to method 107, 117 or 123 in the OECD Guidelines for the Testing of Chemicals or equivalent method. If the maximum measured BCF \leq 500, the substance is not considered bioaccumulating even if logKow \geq 4.0.

OECD test method 107 cannot be applied to surfactants which have both fat and watersoluble properties. Based on what is known today, for such substances it must be demonstrated with a high degree of certainty that they and their degradation products do not pose any risk to aquatic organisms over a longer time perspective.

5. Aerobic biodegradability

For aerobic biodegradability test method no. 301 (A to F), 306 or 310 in the OECD Guidelines are used.

6. Potential aerobic biodegradability

For potential (inherently) biodegradability test method no. 302 (A to C) in the OECD Guidelines are used.

7. Anaerobic biodegradability

For anaerobic degradability test method no. 311 in the OECD Guidelines, ISO 11734, or ECOTOC no. 28 (June 1988) are used.

Substances that are not surfactants and which are not included in the DID-list or for which data is missing on DID-list list may be exempt from the requirements on anaerobic degradability if they fulfil all the following requirements:

- Not toxic to aquatic organisms (NOEC/ECx > 0.1 mg/l or E/LC50 > 10 mg/l)
- Readily aerobically biodegradable
- Have low adsorption (A < 25%) or high desorption (D > 25%) or are not bioaccumulating

Testing for adsorption/desorption can be carried out under OECD guidelines 106 or under ISO CD 18749" Water quality - Adsorption of substances on activated sludge - Batch test using specific analytical methods".

8. DID-list

The DID-list, Detergent Ingredient Database has been developed to facilitate the ecolabel application process and is a tool to rank chemicals and thus make it easier for licence holders and producers to choose less environmentally harmful chemicals in their products. The list contains information on toxicity and degradability of several substances that are used in chemical products.

The substances on the DID-list cannot be seen as an overview of substances that are contained in ecolabelled products, and the DID-list cannot be used to document the toxicity of the individual substances in connection with the classification rules. Here, information from safety data sheets, literature or the raw materials producer must be used.

The DID-list can be obtained from the ecolabelling organisation or the website of the respective country. If a substance is not included on the DID-list, or biodegradability data is missing, the methods described in part B of the DID-list must be used. For these criteria, the DID-list dated 2023 or later versions apply.

Appendix 4 User test form

This appendix must be filled in by the user.

Information about the product

Product name:	
Manufacturer:	
Product type and area of use:	

Information about the test

The product must be tested within its area of application over a period that reflects the product's usage frequency (i.e., the product must have been used repeatedly).

The product must be tested at the dosage recommended on the product label or accompanying product sheet.

Dosage (g/litre in-use- solution)			
Is the product tested at the dosage recommended on the product label or accompanying product sheet?	Yes	No	
Test period	Start date: End date:		
How many times has the product been tested in the stated test period?			
In what types of enterprises was the product tested (e.g., bakeries, the food industry, xxx)?			

Performance of the product

The performance of the product must be visually assessed upon completion of the defined test period. Its performance is considered to be:

Not effective / not satisfactory	
Sufficiently effective / sufficiently satisfactory	
Very effective / very satisfactory	

Other comments to the assessment of the product:

Information about the site of testing performance

Place and date	Company name
Responsible person	Signature of responsible person
Telephone	Email

Appendix 5 Packaging

To be used in conjunction with an application for a licence for the Nordic Ecolabelling of cleaning agents 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.

Producer/distributor:
Part of the packaging (container, closure, label):
Packaging material (type of plastic, cardboard etc.) List all materials included in the packaging
component and the percentage of each material:

O13 Packaging: Container		
	Yes	No
Does the container consist of PE (polyethene)?		
If yes, how many % ?%	·	
Does the remaining % consist of biodegradable material or other material than PE or PP?		
Has carbon black been added to the component?		
Does the container consist of PP (polyethyleneterephtalate)?		
If yes, how many % ?%		
Does the remaining % consist of biodegradable material or other material than PE or PP?		
Has carbon black been added to the component?		
Does the container consist of PET (polypropene)?		
If yes, how many % ?%	·	•
Has carbon black been added to the component?		
Are the colour of the component transparent?		

O13 Packaging: Closure				
	Yes	No		
Does the closure consist of PE (polyethene)?				
If yes, how many % ?%				
Does the remaining % consist of biodegradable material or other material than PE or PP?				
Has carbon black been added to the component?				

Does the closure consist of PP (polyethyleneterephtalate)?	
If yes, how many % ?%	
Does the remaining % consist of biodegradable material or other material than PE or PP?	
Has carbon black been added to the component?	
	 •
Does the closure consist of PET (polypropene)?	
If yes, how many % ?%	
Has carbon black been added to the component?	
Are the colour of the component transparent?	

O13 Packaging: Label

Please specify which material the label consist of (PE (polyethene), PP (polypropene) or other material):

Place and date	Company name
Responsible person	Signature of responsible person
Telephone	Email