

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

To be submitted with an application for a Nordic Swan Ecolabel licence.

This declaration is based on the best available knowledge at the time of the application, including test results. If new information or scientific findings become available, please inform Nordic Ecolabelling 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 ≤ 50 ppm (≤ 0.0050 w%).

Examples of impurities: 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.

- **Impurities in the raw materials** in concentrations $\geq 10\,000$ ppm (≥ 1.0000 w%) are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled product.

Additional information concerning definitions of ingoing substances and impurities

Limit values: The limit for excluded ingoing substances is 0 ppm (unless otherwise stated), while there's a specific defined limit for impurities. The impurity limit applies separately to each individual excluded substance, from each individual raw material. Concentrations of different impurities with the same excluded classification or substance group characteristics shall not be summed up to meet the impurity limit in the labelled product. Also, concentrations of an individual impurity, originating from different raw materials, shall not be summed.

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of Biological materials) have a composition of constituents that is not completely known or is variable from time to time. For substances registered under REACH as UVCBs, all constituents that are known must be declared in the Nordic Swan Ecolabel raw material appendix based on the best available knowledge. All constituents are considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

However, in the requirements concerning environmentally hazardous substances, aNBO, anNBO and CDV, the UVCB substance can be considered as one ingoing substance and placed in a single row in the calculation sheet. If the UVCB substance can be assigned a DID-number, the data on the DID-list must be used.

Please list the ingoing substances in the raw material in the table below and indicate 'yes' or 'no' as to whether each substance is registered in REACH as a UVCB substance.

If the raw material contains impurities that are listed under excluded substances or has any of the classifications mentioned in this appendix, write the amount in the box 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.

Name of raw material ingredient	Chemical name	CAS No.	Amount in weight %	Function of the raw material/ingredient	Suggested DID No.	UVCB substance?

Please note that:

The DID-list (Detergents Ingredients Database) is available on the Nordic Ecolabelling websites.

DID-list Part A: https://www.svanen.se/49baaa/siteassets/att-svanenmarka/kriterier/did-listan/did_list_2023.pdf

DID-list part B: https://www.svanen.se/49bfd4/siteassets/att-svanenmarka/kriterier/did-listan/didlist_2023_partb.pdf

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

The information provided in this declaration will be shared internally with the Nordic Ecolabelling certification personnel for the purpose of evaluating license applications.

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 derivatives (APD))		
Aminopolyphosphonates		
Aromatic solvents <i>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.</i>		
Benzalkonium chloride (CAS No. 8001-54-5, 63449-41-2 and others)		
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		
Isothiazolinones (e.g. methylisothiazolinone (MIT), CAS No. 2682-20-4, methylchloroisothiazolinone (CMIT), CAS No. 26172-55-4, C(M)IT/MIT (3:1), CAS No. 55965-84-9, benzisothiazolinone (BIT), CAS No. 2634-33-5, octylisothiazolinone (OIT), CAS No. 26530-20-1 and dichlorooctylisothiazolinone (DCOIT), CAS No. 64359-81-5)		
Halogenated organic compounds		
LAS (linear alkylbenzene sulphonates)		
NTA (nitrilotriacetic acid, CAS-no. 139-13-9) and its salts		
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) <i>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.</i>		
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 <i>Exemption: MEK (Methyl ethyl ketone, CAS No. 78-93-3).</i> <i>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.</i>		

Quaternary ammonium compounds, which are not aerobically or anaerobically biodegradable* such as DTDAC (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 Microplastics

	Yes	No
<p>Does the raw material contain microplastics?</p> <p><i>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:</i></p> <ul style="list-style-type: none"> a) <i>are contained in particles and constitute at least 1% by weight of those particles; or build a continuous surface coating on particles.</i> b) <i>at least 1% by weight of the particles referred to in point (a) fulfil either of the following conditions:</i> <ul style="list-style-type: none"> (i) <i>all dimensions of the particles are equal to or less than 5 mm.</i> (ii) <i>the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3.</i> <p><i>The following polymers are excluded from this designation:</i></p> <ul style="list-style-type: none"> a) <i>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.</i> b) <i>polymers that are biodegradable as proved in accordance with Appendix 15 [to REACH, Regulation (EC) No 1907/2006].</i> c) <i>polymers that have a solubility greater than 2 g/L as proved in accordance with Appendix 16 [to REACH, Regulation (EC) No 1907/2006].</i> d) <i>polymers that do not contain carbon atoms in their chemical structure.</i> <p><i>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".</i></p>		

O9 Nanomaterials

	Yes	No
<p>Does the raw material contain nanomaterials/-particles?</p> <p><i>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:</i></p> <ul style="list-style-type: none"> (a) <i>one or more external dimensions of the particle are in the size range 1 nm to 100 nm;</i> (b) <i>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;</i> (c) <i>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.</i> 		

O10 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 regarding ingoing substances or impurities is Yes, please provide the following information for each relevant substance: CAS No. (where possible), chemical name, concentration (in ppm, % by weight or mg/kg). Also state whether the substance is present as an ingoing substance or impurity.

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If the raw material composition changes, a new declaration confirming compliance with the requirements must be submitted to Nordic Ecolabelling.

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