

Appendix 1 Declaration from the manufacturer of the cosmetic product

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

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.

Manufacturer
Product's function/type (e.g. shampoo, soap, lotion, wet wipes, toothpaste)

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

- Ingoing substances: All substances in the Nordic Swan Ecolabelled cosmetic product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoing substances.
- Impurities: Residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the Nordic Swan Ecolabelled cosmetic product in concentrations less than 100 ppm in the rinse-off product and less than 10 ppm in the leave-on product.
- Impurities in the raw materials exceeding concentrations of ≥ 1000 ppm are always regarded as ingoing substances, regardless of the concentration in the Nordic Swan Ecolabelled cosmetic product.

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

Foil that is not removed before use of the product is considered as part of the formulation/recipe.

O2: SCCS Opinions		YES	NO
Is the product a cosmetic product that does <i>not</i> comply with SCCS Opinions?			
O4: Palm oil/palm kernel oil		YES	NO
Does the product contain renewable raw materials from palm oil or palm kernel oil? This includes by-products, residues, and waste fractions from palm oil industries, such as palm fatty acid distillate and palm effluent sludge			
If yes, is this palm oil/palm kernel oil RSPO certified and what is the tracability level? (tick below)			
No traceability			
Identity Preserved			
Segregated			
Mass Balance			
Book & Claim			
O5: Does the product contain substances classified with any of the hazard phrases below? <i>Incl. all classification variants. For example, H350 also covers classification H350i.</i>		YES	NO
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			
Acute Tox. (oral) 1 or 2 H300			
ED HH 1			
ED HH 2			
ED ENV 1			
ED ENV 2			
PBT			
vPvB			
PMT			
vPvM			

O6: Does the product contain any of the following excluded substances?	YES	NO
Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS No. 25013-16-5), alkylphenol ethoxylates (APEO), and other alkylphenol derivatives (APD) <i>An exemption is made for BHT (CAS No. 128-37-0) in perfumes in the amount of ≤ 100 ppm, provided that the amount in the cosmetic product is ≤ 1 ppm.</i>		
Bisphenols and bisphenol derivatives 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).		
Benzalkonium chloride (CAS No. 63449-41-2)		
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		
Halogenated and / or aromatic solvents		
Microplastics: Synthetic polymer microparticles as defined in the Restriction List (entry 78) of the amended Annex XVII to the REACH Regulation (EC) No 1907/2006 <i>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. 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> <i>Applies to ingoing substances and impurities present at ≥ 0,010% in the cosmetic rinse-off or leave-on product.</i>		
Nanomaterials/-particles, as defined in the cosmetic products regulation ((EC) No 1223/2009) <i>Exemptions are made for:</i> <i>a) Synthetic amorphous silica (SAS) used as an abrasive in toothpaste.</i> <i>b) Titanium dioxide (TiO2) used as a UV-filter approved in SCCS opinion SCCS/1516/13; i.e. TiO2 may not be photocatalytic, coating must be stable and TiO2 may not be included in spray products</i>		
Nitro musks and polycyclic musk compounds		
Organic chlorine compounds, hypochlorous acid and hypochlorite		
Parabens (4-Hydroxybenzoic acid and its salts and esters)		
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/pbt/-/dislist/details/0b0236e1889ab857		
Per- and polyfluorinated substances (PFAS)		
Phthalates (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: https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu List II: https://edlists.org/the-ed-lists/list-ii-substances-under-eu-investigation-endocrine-disruption List III: https://edlists.org/the-ed-lists/list-iii-substances-identified-as-endocrine-disruptors-by-participating-national-authorities		
Quaternary ammonium compounds, which are not aerobically or anaerobically biodegradable** (such as DTDMAC, DSDMAC, DHTDMAC and DADMAC).		
Salicylic acid (CAS No. 69-72-7) and its salts (CAS No. 824-35-1 / 18917-89-0 / 59866-70-5 / 54-21-7 / 578-36-9 / 2174-16-5), benzyl salicylate (CAS No. 118-58-1), and ethyl-hexyl salicylate (CAS No. 118-60-5)		

Siloxanes <i>Exemptions are made for linear siloxanes in in leave-on products.</i>		
Silver, colloidal silver and nanosilver		
Substances on the REACH Candidate list of SVHC https://www.echa.europa.eu/candidate-list-table		
Titanium dioxide (TiO ₂ , CAS No. 13463-67-7) <i>Exemptions apply until 2024-12-31 on the conditions that the product must not be loose powder, spray form, toothpaste, or lip products (lip balm, lipstick, lip gloss, lip liner, and similar)</i>		
If Titanium dioxide powder is added, has it been done so in a closed system, in a suspension or by means of a method that promotes a "low dust" working environment, e.g. using protective equipment which heavily reduces the dust or completely removes the dust from the raw materials (e.g. exhaust ventilation, personal protective equipment and clear safety instructions).		
Triclosan (CAS No. 3380-34-5)		
O7: Surfactants	YES	NO
Does the product contain surfactants with impurities of 1,4-dioxane (CAS No. 123-91-1) > 1 ppm in the surfactant active matter?		
Is the product a toothpaste that contains sodium lauryl sulphate (SLS)?		
O8-010: Fragrances	YES	NO
Does the product contain fragrances that are not added in line with the IFRA guidelines?		
Is the product intended for babies/children and contain fragrances? <i>An exemption is made for children's toothpaste</i>		
Does the product contain fragrances that are H317/H334 classified or are fragrance allergens listed in Annex III of the Cosmetics Regulation?		
Does the product contain the fragrance allergens oak moss extract (<i>Evernia prunastri</i>) or tree moss extract (<i>Evernia furfuracea</i>).		
O11: Organic colorants	YES	NO
Does the product contain organic colourant? If yes , state log KoW/BCF or E-number:		
O12: Preservatives	YES	NO
Does the product contain preservatives? If yes , state log KoW/BCF		
Does the product contain preservatives that are not readily aerobic biodegradable?		
O13: UV filters	YES	NO
Does the product contain UV filters? If yes , state log KoW/BCF or lowest available NOEC/EC/LC50		
O14: Does the product contain synthetic polymers with one or more residual monomers of the following properties > 100 ppm: <i>Incl. all classification variants. For example, H350 also covers classification H350i.</i>	YES	NO
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 SE 1 or 2 H370-H373		
Acute Tox. (oral) 1 or 2 H300, H301		
Acute Tox. (dermal) 1 or 2 H310, H311		
Acute Tox. (inhalation) 1 or 2 H330, H331		
ED HH 1 or 2 EUH 380, EUH 381		
Acute Tox. (dermal) 1 or 2 H310, H311		
Acute Tox. (inhalation) 1 or 2 H330, H331		
O15: Aluminium	YES	NO
Does the product contain aluminium? If yes, state the amount of aluminium corresponding to elemental %Al:		
O16: Environmentally hazardous substances	YES	NO
Does the product contain substances classified H410, H411 or H412? If yes, state the amount (% by weight) pr. classification:		
O20-O21: Oral products	YES	NO
Is the product a lip product, toothpaste, oral hygiene product or nipple cream? If yes, state the E-number of colorants and preservatives: If yes, state the FL-number of flavourings:		
Is the product a lip product that contains mineral oil saturated hydrocarbons (MOSH) or mineral oil aromatic hydrocarbons (MOAH), and that does not comply with the recommendations by Cosmetic Europe for mineral oils?: https://cosmeticseurope.eu/download/N08vNnB0TUhMbWpwQmlqVk9UZzdWZz09		
Is the product a mouthwash that contains more than 0,1% water-soluble zinc salts?		
Is the product a toothpaste? If yes, state the content of fluoride:		
O22-O23: Decorative cosmetics and hair dyes	YES	NO
Is the product a decorative cosmetic or hair dye that contains more than the following amounts of heavy metals?: - Arsenic, antimony, cadmium, cobalt, lead, mercury: 1 ppm - Chromium, nickel: 10 ppm		
Is the product a decorative cosmetic or hair dye that contains lawsone (CAS No. 83-72-7), hydroxypropyl p-phenylenediamine or its dihydrochloride salt (CAS No. 928659-47-5 and CAS No. 73793-79-0) or hair dyes judged to be sensitising and/or allergenic by the SCCS (even if they do not meet the classification of H317 and/or H334)?		
O28-O30: Animal care products and lubricants	YES	NO
Is the product an animal care product, sex lubricant, or medical lubricant that contains fragrance or colorants?		
Is the product an animal care product or sex lubricant that is classified H400, H411, H412 or H413?		
Is the product a sex lubricant or medical lubricant, which is covered by the Medical Devices Regulation?		

Is the product an animal care product, sex lubricant, or medical lubricant that does <u>not</u> comply with the following parts of the EU regulation on cosmetic products: - Article 3 Safety (only applies to sex lubricants) - Article 8 Good manufacturing practise (only applies to sex lubricants) - Article 10 Safety assessment (only applies to sex lubricants) - Article 14 Restrictions for substances listed in the Annexes - Article 15 Substances classified as CMR substances - Article 19 Labelling - Article 20 Product claims		
O31: Packaging and materials	YES	NO
Is the product in miniature bottles and being sold to the HoReCa sector (hotels, restaurants, and catering)?		

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 added substance.

--

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

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