Nordic Ecolabelling for

Cosmetic products

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CONSULTATION

Nordic Ecolabelling

Content

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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What is a Nordic Swan Ecolabelled cosmetic product?

All cosmetic products covered by the EU Cosmetics Regulation with subsequent amendments, wet wipes, animal care products, and lubricants can be Nordic Swan Ecolabelled.

Nordic Swan Ecolabelled cosmetic products are some of the products that have the lowest impact on their environment in their category and they meet both environmental and health requirements. Requirements are set on the environmental properties and health properties of the ingoing substances and on the packaging.

The products go down the drain after use, either directly such as soap, shampoo, and toothpaste, or indirectly by washing bodies, hair, or clothes, such as lotions, creams, hairstyling products and make-up. Properties like biodegradability, bioaccumulability and aquatic toxicity are therefore essential for all ingredients.

Cosmetic products come into direct contact with the body. Therefore Nordic Ecolabelling also sets strict requirements on the substances with potentially effects that are harmful to health.

Sustainable extraction of renewable raw materials is a vital global issue with a major environmental impact. Nordic Ecolabelling raises awareness of this issue via the requirement for sustainably produced palm oil, which contributes to the production of more sustainable raw materials.

The packaging requirements ensure a high filling degree and stimulate resource efficiency and circular economy by limiting the use of packaging materials. Requirements on packaging design ensure packaging that is recyclable.

Nordic Swan Ecolabel cosmetic products:

- Meet strict requirements concerning chemicals that pose a health hazard, including a ban on substances classified to cause cancer, as toxic to reproduction or to potentially damage genetic material, substances that are identified or potential endocrine disruptors on up-to-date lists from EU and national authorities or by classification, PFAS and various other specifically problematic substances.
- Contain no microplastics.
- Contain no fragrances if intended for babies or children.
- Meet strict requirements concerning environmentally hazardous chemicals to avoid long-term, negative effects in nature (biodegradability), to avoid harmful chemicals accumulating in animals and humans (bioaccumulation), and to avoid substances that are toxic to, for example, fish and crustaceans (ecotoxicity).
- Responsible sourcing of renewable raw materials is promoted, and any palm oil or palm kernel oil in the product is RSPO certified.

- Have packaging that contributes to a circular economy by ensuring that the amount of packaging is low, and that design and material composition promote recycling.
- Wet wipes contain no plastic fibres.

Why choose the Nordic Swan Ecolabel?

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

What can carry the Nordic Swan Ecolabel?

All cosmetic products covered by the EU Cosmetics Regulation with subsequent amendments, such as skin care products, hair care products, decorative cosmetics, perfumes, and hygiene products can be Nordic Swan Ecolabelled.

According to the Regulation, “cosmetic product” means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

Wet wipes are included in the definition of the product group, as the liquid on the wipe is intended for functions as described above.

Washing up liquid with added skin protection, perfumed toilet paper or tissues with lotion, for example, do not meet the above criteria and are not included in the definition.

Mix-it-yourself products (cosmetics kits), in which all the ingredients together with instructions for mixing the product are sold as a combined unit/single

product are covered by the Cosmetics Regulation and can be Nordic Swan Ecolabelled.

In addition to products within the scope of the cosmetic products regulation, the product group also includes a number of other product types.

Lubricants for medical purposes (such as medical examinations with or without e.g. an ultrasound probe) as well as lubricants marketed as “sex products” (such as lube, anal creams, and orgasm gels) can be Nordic Swan Ecolabelled when their formulations are similar to cosmetic products. Lubricants for medical purposes are part of the scope of the Medical Device Regulation, which can also be the case for “sex products”.

Products for animals, but otherwise corresponding to cosmetic products for human use, can be Nordic Swan Ecolabelled when their formulations are similar to cosmetic products.

Products within the scope of the Medicinal Products Regulation (EC) No 726/2004 or the Biocides Regulation 528/2012 cannot be Nordic Swan Ecolabelled. Products that are marketed as being antibacterial, antimicrobial, antiseptic and/or disinfectant or claim to have ingredients that have these properties cannot be Nordic Swan Ecolabelled, as this does not comply with the Biocides Regulation 528/2012.

The product group includes both products for consumers and for professional use.

How to apply

Application and costs

For information about the application process and fees for this product group, please refer to the respective national web site, see first in this document.

What is required?

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

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

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

✉ Enclose

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

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 extended or adjusted, in which case the licence is automatically extended, and the licencee informed.

Revised criteria shall be published at least one year prior to the expiry of the present criteria. The licencee 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 information first in this document. Further information and assistance (such as calculation sheets or electronic application help) is available. Visit the relevant national website for further information.

1 Requirements

1.1 Definition of the product group

All cosmetic products covered by the EU Cosmetics Regulation with subsequent amendments, such as skin care products, hair care products, decorative cosmetics, perfumes, and hygiene products can be Nordic Swan Ecolabelled.

According to the Regulation, “cosmetic product” means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours. Wet wipes are included in the definition of the product group, as the liquid on the wipe is intended for functions as described above. Washing up liquid with added skin protection, perfumed toilet paper or tissues with lotion, for example, do not meet the above criteria and are not included in the definition.

Mix-it-yourself products (cosmetics kits), in which all the ingredients together with instructions for mixing the product are sold as a combined unit/single product are covered by the Cosmetics Regulation and can be Nordic Swan Ecolabelled.

Wet wipes can be Nordic Swan Ecolabelled even if there is only lotion in the product, which is covered by the Cosmetics Regulation. Animal care products can be Nordic Swan Ecolabelled although these are not covered by the Cosmetics Regulation.

Lubricants for medical purposes (such as medical examinations with or without e.g. an ultrasound probe) as well as lubricants marketed as "sex products" (such as lube, anal creams, and orgasm gels) can be Nordic Swan Ecolabelled when their formulations are similar to cosmetic products. Lubricants for medical purposes are part of the scope of the Medical Device Regulation, which can also be the case for "sex products".

Products covered by the Biocides Regulation 528/2012 cannot be Nordic Swan Ecolabelled. Products that are marketed as being antibacterial, antimicrobial, antiseptic and/or disinfectant or claim to have ingredients that have these properties cannot be Nordic Swan Ecolabelled, as this does not comply with the Biocides Regulation 528/2012.

1.2 Other definitions

For the purpose of this document, the following definitions shall apply.

Definition	Description
Rinse-off product	A cosmetic product marketed as intended to be removed with water after use in normal conditions. This includes products that according to the usage instructions are rinsed off with water immediately after use (e.g. shampoo, conditioner, soaps, shaving cream, bath foam and scrubs, cleansing products/gels, hair treatments and peels). Solid shampoo/conditioner and shower bars are also included. Note that toothpaste is considered rinse-off but must meet requirement O19 Biodegradability and aquatic toxicity instead of O17 aNBO and O18 CDV.
Leave-on product	A cosmetic product marketed as not intended to be removed with water after use in normal conditions. This includes products stay on the skin (e.g. creme, lotion, perfumes). Products that according to the usage instruction are rinsed off with cotton wool, cotton pads etc. are also included (e.g. cleansing lotion, eye make-up remover). Note that lubricants are considered leave-on.
Ingoing substances	All substances in the 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 cosmetic product in concentrations less than 100 ppm for rinse-off products and 10 ppm for leave-on products if no other limit is stated in the requirement. Impurities in the raw materials exceeding concentrations of 1000 ppm are always regarded as ingoing substances, regardless of the concentration in the 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. The impurity limits apply to each individual substance that is excluded, i.e., Impurities with the same classification in different raw materials shall not be summed up to comply with the limit. The same contaminants in different raw materials also do not need to be summed.
DID-list	The DID-list (Detergent Ingredient Database) part A contains information on toxicity and degradability of several substances that are used in cosmetic products. If an ingoing substance is included on the DID-list, the data from the DID-list must be used for calculations of the amount of aerobic/anaerobic non-biodegradable organics, the critical dilution value and biodegradability and toxicity. If a substance is not included on the DID-list, or data is missing, the methods described in part B of the DID-list must be used. For this criteria generation, the DID-list dated 2023 or later versions apply. See

	further details in Appendix 6. The DID-list can be obtained from the Nordic Swan Ecolabelling websites.
Wet wipes	Pre-wetted cloths of non-wowen fabric, where the lotion is covered by the EU Cosmetic Products Regulation.
Animal care product	Any product intended to be placed in contact with animal hair or skin to clean them or to improve the condition of it, such as shampoos and conditioners for animals
Sex lubricants	Lubricants with formulations similar to cosmetic products, that are marketed as "sex products" (such as lube, anal creams, and orgasm gels).
Medical lubricants	Lubricants with formulations similar to cosmetic products, that are marketed for medical purposes such as medical examinations with or without e.g. an ultrasound

1.3 General requirements

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 exempted from the requirements.

O1 Description of the product

The applicant must give detailed information on the cosmetic products to which the application relates. The following information is required:

- Description of the product
- A complete recipe for the product. The recipe must, if possible, include for each ingoing substance:
    - Trade name
    - Chemical name
    - INCI name (International Nomenclature of Cosmetic Ingredients)
    - Amount (both with and without solvents, e.g., water)
    - CAS No. and/or EC number
    - DID number for substances that can be placed in the DID-list dated 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 6 for a detailed description.*

Description of the product, e.g., label or other documentation.

Complete recipe in line with the requirement, Nordic Ecolabelling's calculation sheet for cosmetic products can be used.

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).

O2 SCCS

Recommendations from the EU's Scientific Committee on Consumer Safety, SCCS Opinions[1], must be complied with where there is an unambiguous

[1] https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs_en

conclusion from SCCS. In cases where there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies.

Appendix 1 or equivalent declaration completed and signed.

O3 Supply chain policy and code of conduct

The licence holder must have a) supply chain policy and b) a code of conduct for responsible sourcing of minerals and renewable raw materials* used in the Nordic Swan Ecolabelled cosmetic product. The supply chain policy and code of conduct must be both public and communicated to the supply chain. Licence holders that are micro companies with maximum 10 employees are exempted.

a) The supply chain policy must include the following:

- A policy statement committing the licence holder to respect human rights and the environment within its operations and supply chain; this includes a commitment to support suppliers' compliance with the supplier code of conduct by engaging in responsible purchasing practices.
- Commitment to comply with all appliable local, national- and international environmental laws and regulations, as well as all applicable health and safety regulations.
- A description for governance processes in place for due diligence; this includes routines for assessing biodiversity and deforestation risk along the whole supply chain.

b) The supplier Code of Conduct must inform all suppliers along the whole supply chain what is expected of them with respect to the Licencee's own supply chain policy regarding human rights and protecting the environment.

** Renewable raw materials compose of biomass and that can be continually replenished for example wood, crops, marine products, organic waste or be recycled raw materials*

Submit supply chain policy according to the requirement or reference to info on webpage.

Submit supplier code of conduct according to the requirement or reference to info on webpage.

Submit information on how the supply chain policy and supplier code of conduct are public and communicated to the supply chain.

O4 Certified raw materials from oil palms

If renewable raw materials from palm oil are used in the product, the palm oil/palm kernel oil must be RSPO certified. This also includes by-products, residues, and waste fractions from palm oil industries, such as palm fatty acid distillate and palm effluent sludge. Tracability must be ensured by Mass Balance, Segregated, or Identity Preserved. Book and Claim are not accepted. The requirement does not include raw materials < 1% in the final product.

A valid RSPO Supply Chain certificate from all relevant raw material manufacturers/suppliers.

The manufacturer of the Nordic Swan Ecolabelled product must submit invoices/delivery notes/order confirmation that the palm oil purchased is RPSO

certified and information about traceability system (Mass Balance, Segregated or Identity Preserved accepted).

In cases where the applicant is RSPO chain of custody certified: a third party-controlled balance sheet showing RSPO certified raw materials being accounted/recorded to the Nordic Swan Ecolabelled product(s).

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

O5 Classification of ingoing substances

Ingoing substances must not be classified with the hazard codes described in the table below.

Table 1 Classification of ingoing substances

Hazard class	Hazard class and category	Hazard code
Carcinogenicity*, **	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity*	Muta. 1A or 1B Muta. 2	H340 H341
Reproductive toxicity*	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Respiratory or skin sensitisation***	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
Acute toxicity****	Acute Tox. (oral) 1 or 2	H300
Hazardous to aquatic environment	Aquatic Chronic 1	H410, M>1******
Endocrine disruption for human health*****	ED HH 1 ED HH 2	EUH380 EUH381
Endocrine disruption for the environment*****	ED ENV 1 ED ENV 2	EUH430 EUH431
Persistent, Bioaccumulative and Toxic properties***** Very Persistent, Very Bioaccumulative properties*****	PBT vPvB	EUH440 EUH441
Persistent, Mobile, and Toxic properties Very Persistent, Very Mobile properties	PMT vPvM	EUH450 EUH451

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

** Titanium dioxide (CAS 13463-67-7) is exempted from the requirement until 2024-12-31 on the following conditions:

- The product must not be loose powder, spray form, toothpaste, or lip products (lip balm, lipstick, lip gloss, lipliner, and similar)
- Titanium dioxide in powder form must be added 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 reduce the dust or completely remove the dust from the raw materials (e.g., exhaust ventilation, personal protective equipment and clear safety instructions)

*** The following substances are exempted:

- Enzymes that are in liquid form or in solid form as granulates (including stabilisers in the enzyme raw material) and not used in spray products.
- Fragrance can be included in the final product according to the fragrance requirements O8-O10
- Tocopherol and tocopherol acetate (DID no. 2618)
- Amidoamines in betaine raw materials, such as cocamidopropyl betaine (CAPB): max. 1% of the betaine active content in the raw material, e.g., max. 0.3% amidoamine in raw materials with 30% betaine.

**** Only applies to lip products, toothpaste, oral hygiene products, and nipple cream. All other products are exempted.

***** See also O6 Excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances

****** M is the multiplying factor used for substances classified as chronic aquatic toxicity category 1, as stated in the CLP Regulation (EC) No 1272/2008.

Safety data sheet for all ingoing substances in line with prevailing European legislation (Annex II to REACH Regulation, 1907/2006/EC).

Appendix 1 or equivalent declaration completed and signed.

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

O6 Excluded substances

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

Please note that exemptions to the definition of ingoing substances and impurities are specifically indicated in some cases.

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

  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.
- 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 enducrine disruptors for the environment of for human health, or that can be identified as toxic for reproduction[2]
- 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*

[2] Assesment of regulatory needs: Bisphenols, ECHA, 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed: https://echa.europa.eu/documents/10162/c2a8b29d-0e2d-7df8-dac1-2433e2477b02

- Microplastics**

  Exemption to the definition of ingoing substances and impurities: Applies to ingoing substances and impurities present at ≥ 0,010% in the cosmetic rinse-off or leave-on product.

- Nanomaterials/-particles, as defined according to the Cosmetic Products Regulation ((EC) No 1223/2009)***

  Exemptions are made for:

  a) Synthetic amorphous silica (SAS) used as an abrasive in toothpaste.

  b) Titanium dioxide (TiO_2) used as a UV-filter approved in SCCS opinion SCCS/1516/13; i.e. TiO_2 may not be photocatalytic, coating must be stable and TiO_2 may not be included in spray products

- Nitro musks and polycyclic musk compounds
- Organic chlorine compounds, hypochlorous acid and hypochlorite
- Parabens (4-Hydroxibenzoic 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

  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 exception is those substances on sublist II which were evaluated under a regulation or directive which doesn't have provisions for identifying EDs (e.g. the cosmetic products regulation). For those substances, ED properties may still have been confirmed or suspected. 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, 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

  Exemptions are made for linear siloxanes in in leave-on products.

- Silver, colloidal silver and nanosilver

- Substances on the REACH Candidate list of SVHC substanceshttps://www.echa.europa.eu/candidate-list-table
- Titanium dioxide (TiO_2, CAS No. 13463-67-7)

  Exemptions apply until 2024-12-31 for product that are not loose powder, in spray form, toothpaste, or lip products (lip balm, lipstick, lip gloss, lipliner, and similar)

  Titanium dioxide in powder form must be added 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)

* 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

** 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:), 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".

*** Nanomaterials/-particles is defined as insoluble or biopersistent and intentionally manufactured materials with one or more external dimensions or an internal structure in the region of 1-100 nm. Nordic Ecolabelling reserves the

right to adopt a newer definition, should the Cosmetic Products Regulation ((EC) No 1223/2009) implement an adjusted definition.

**** 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.

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

O7 Surfactants

All surfactants in the Nordic Swan Ecolabelled cosmetic product, irrespective of their function in the product must live up to the following requirements:

- Be readily biodegradable (aerobically) and anaerobically biodegradable in line with the testing methods in Appendix 6.
- Impurities of 1,4-dioxane (CAS No. 123-91-1) must not exceed 1,0 ppm in the surfactant active matter.
- Sodium lauryl sulphate (SLS) is not allowed in toothpaste.

- Reference to the DID* list dated 2023 or later versions. Substances not on the DID list must be calculated based on the guidance in part B of the DID list and associated data must be presented.

  ** DID list: "Detergents Ingredients Database" list, see Appendix 6 for a more detailed description.*
- Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all relevant raw material manufacturers/suppliers.

O8 IFRA

All fragrances in the Nordic Swan Ecolabelled cosmetic products must be added in line with the IFRA's guidelines. The IFRA's (International Fragrance Association) guidelines can be read at https://ifrafragrance.org/.

- IFRA certificate according to the current amendments to the IFRA standards.
- Appendix 1 or equivalent declaration completed and signed.

O9 Fragrance free products for babies and children

Fragrance substances/perfumes/flavourings/aromas/fragrance substances in plant extracts must not be added to baby and children's products*.

Exemption: Flavourings are allowed in children's toothpaste, see requirement O20 Oral products: Flavourings, colours, and preservatives.

** Baby/children's products are products that are marketed for or have words such as infant, baby and/or children or pictures of children under the age of 12 years on the label.*

- Recipe.

Appendix 1 or equivalent declaration completed and signed.

Label.

O10 Fragrance allergens

All fragrance substances/ flavourings/aromas/fragrance substance in plant extract in the Nordic Swan Ecolabelled cosmetic products must live up to the following requirements:

- Substances with the hazard statement H317 and/or H334 or fragrance allergens listed in Annex III of the Cosmetic Regulation may be included at a maximum of 0.001% (10 ppm) in leave-on products and a maximum of 0.01% (100 ppm) in rinse-off products.
- The following fragrance allergens are prohibited: Oak moss extract (Evernia prunastri) and Tree moss extract (Evernia furfuracea).

Appendix 1 or equivalent declaration completed and signed.

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

Fragrance allergens list.

O11 Organic colorants

All organic colorants in the Nordic Swan Ecolabelled cosmetic product must live up to the following requirements:

- Must not bioaccumulative line with the testing methods in Appendix 6, having a BCF (bioconcentration factor) < 500 or log Kow (logarithmic octanol-water partition coefficient) < 4. Alternatively, the colorant must be approved for use in food.
- Carbon black is prohibited.

Appendix 1 or equivalent declaration completed and signed.

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

O12 Preservatives

All preservatives in the Nordic Swan Ecolabelled cosmetic products must be:

- Readily aerobically degradable in line with the testing methods in Appendix 6.
- Not bioaccumulative in line with the testing methods in Appendix 6, having a BCF < 500 or log Kow < 4.

Documentation showing that the substance is readily aerobically degradable. Safety data sheet in line with prevailing European legislation (Annex II to REACH Regulation, 1907/2006/EC) or reference to the DID* list dated 2023 or later versions can be used.

** DID list: "Detergents Ingredients Database" list, see Appendix 6 for a more detailed description.*

Appendix 1 or equivalent declaration completed and signed.

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

O13 UV filter

All UV filters in the Nordic Swan Ecolabelled cosmetic product must live up to the following requirements:

- UV filters may only be added to leave-on products and only to protect the user, not the product.
- All organic UV filters contained in the product must not be bioaccumulative in line with the testing methods in Appendix 6, having a BCF < 500 or log Kow < 4 or must have a lowest toxicity with NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l.

Nano UV filters, with exemption to nano TiO_2, are prohibited under requirements O6 Excluded substances.

Appendix 1 or equivalent declaration completed and signed.

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

O14 Residual monomers in polymers

For each synthetic polymer in the Nordic Swan Ecolabelled cosmetic product, the quantity of residual monomers in newly produced polymers and its classifications must be stated. The polymer raw material may not contain more than 100 ppm residual monomer in of each classification listed in the table below.

Table 2 Classification of monomers

Hazard class	Hazard class and category	Hazard code
Carcinogenicity	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity	Muta. 1A or 1B Muta. 2	H340 H341
Reproductive toxicity	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
Specific target organ toxicity	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Acute toxicity	Acute Tox. (oral) 1 Acute Tox. (oral) 2 Acute Tox. (dermal) 1 or 2 Acute Tox. (dermal) 3 Acute Tox. (inhalation) 1 Acute Tox (inhalation) 2	H300 H301 H310 H311 H330 H331
Endocrine disruption for human health*	ED HH 1 ED HH 2	EUH380 EUH381

* Other potential or identified endocrine disruptors, as defined in requirement O6 Excluded substances are also restricted according to this requirement.

Appendix 1 or equivalent declaration completed and signed.

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

O15 Aluminium

In Nordic Swan Ecolabelled cosmetics products, aluminium (corresponding to % elemental Al) may be present at the maximum concentration limits stated for each product type in the table below.

If a product type is not included in the table, the following maximum limit applies: 17.5%

Table 3 Maxiumum concentration limits of Aluminium in specific product categories.

Product category	Conentration (%) limits Alumunium
After Shave	2.5
Bar Soap	4
Body Lotion	3.81
Body Spray	1.18
Deo Gel	6.18
Deo RollOn	5.63
Deo Stick	7.73
Deo Wipes	0
Deo Spray	4.88
Deo Spray (anti-perspirant)	3.24
Eau de Parfum, Eau de Toilette	0.05
Eye Shadow	43.62
Eyeliner	15.76
Face Moisturizer	10.59
Hair Spray	0.15
Hair Styling	6.7
Hand Cream	0.86
Lip Care Products	0.606
Lip Stick	14.62
Liquid Hand Soap	0.89
Liquid Make Up Foundation	23
Make Up Remover	10.59
Mascara	3.13
Mouthwash	0
Conditioner	7.14
Shampoo	7.14
Shaving Products	0.094
Shower Gel	0.89
Sun Screen Lotion	8.403
Sun Screen Spray	0.332
Talc	2
Toothpaste	3.18

Formulation and calculation of aluminium content corresponding to elemental Al

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

1.4 Biodegradability and aquatic toxicity

O16 Environmentally hazardous substances (C_{total})

The total weighted quantity of ingoing substances classified as environmentally hazardous according to Regulation 1272/2008/EEC (C_{total}) in the Nordic Swan Ecolabelled cosmetic products must not exceed the limits indicated in the table below, when calculated as the total weighted quantity:

$$C_{total} = 100 \cdot C_{H410} + 10 \cdot C_{H411} + C_{H412}$$

C_{H41X} is the fraction of the product, measured in percentage by weight, made up of the H410, H411 or H412 classified substances.

Ingoing substances must not be classified with the hazard code H410 if the associated multiplying factor as described in the CLP Regulation (EC) No 1272/2008 M>1 according to requirement O5 Classification of ingoing substances.

Table 4 Limit values for total weighted quantity of environmental hazards

Type of product	C_{total} (wt. %)
Liquid soap, shower gel	10.0
Other cosmetic products	2.0

- Calculation of the weighted quantity (percentage by weight) of H410, H411, and H412 classified substances. If data is missing on a substance, it is assessed according to a worst-case scenario (H410). Nordic Ecolabelling's calculation sheet for cosmetic products can be used.
- Appendix 1 or equivalent declaration completed and signed.
- Appendix 2 or equivalent declaration completed and signed by all raw material manufacturers/suppliers.

Rinse-off products

O17 aNBO (aerobic non-biodegradable organics) and anNBO (anaerobic non-biodegradable organics)

Organic substances in the Nordic Swan Ecolabelled cosmetic product that are not readily biodegradable according to Appendix 6, must not exceed the limits indicated in the table below. For foam soap it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in O18 CDV.

Surfactants must be biodegradable, see requirement O7 Surfactants.

Exemption to the definition of ingoing substances and impurities: Impurities in raw material ≤ 1.0 w% will not be included in calculations.

Table 5 Limit values for aNBO and anNBO

Type of product	aNBO (mg/g AC*)	anNBO (mg/g AC*)
Solid hand soap, shampoo bar, conditioner bar, shower bar.	5	5
Other rinse-off products	14	14

Type of product	aNBO (mg/dose**)	anNBO (mg/dose**)
Foam soap	2.5	2.5

** Active content (AC) refers to the amount (weight) of all organic substances in the product excluding the water content of the ingredients. Abrasives in handwash and exfoliants are not included. However, see requirement O6 Excluded substances for requirements on microplastics.*

*** One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designed for the product. If the product is not sold with a particular dispenser, a standardised dose of 0.75 g is used*

- Calculation of the quantity (mg) of aNBO and anNBO/g AC or mg/dose for the product. Nordic Ecolabelling's calculation sheet for cosmetic products can be used.

- Reference to the DID list 2023 or later versions. For substances not on the DID list or for which data is missing on DID-list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented. See Appendix 9 for further details on biodegradability, toxicity, potential for bioaccumulation and bioavailability.

O18 Critical dilution volume (CDV)

The Nordic Swan cosmetic product's critical dilution volume (CDV) must not exceed the threshold values in the table below. CDV is calculated according to the formula:

$$CDV_{chronic} = \Sigma(DF_i \cdot C_i / TF_i \text{ (chronic)})$$

DF_i is the degradation factor for substance i.
C_i is the amount in l of substance i per g active content or per dose
TF_i is the toxicity factor for substance i.

The calculation of CDV is based on information provided regarding the toxicity and biodegradability of the individual substances in an aquatic environment and must be obtained from the DID list 2023 or later versions. For substances not on the DID list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented.

For foam soap it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in O17 aNBO and anNBO.

For concentrated products incl. powder products, which must be mixed with water by the consumer before use, the calculation is carried out on the use solution.

Exemptions to the definition of ingoing substances and impurities: Impurities in raw material ≤ 1.0 w% will not be included in calculations.

Table 6 Limit values for CDV

Type of product	$CDV_{chronic}$ (l/g AC*)
Solid hand soap, shampoo bar, conditioner bar, shower bar.	2000
Other rinse-off products	9000

Type of product	$CDV_{chronic}$ (l/dose**)
Foam soap	1000

** Active content (AC) refers to the amount (weight) of all organic substances in the product excluding the water content of the ingredients. Abrasives in handwash and exfoliants are not included. However, see requirement O6 Excluded substances for requirements on microplastics.*

*** One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designed for the product. If the product is not sold with a particular dispenser, a standardised dose of 0.75 g is used*

Calculation of the $CDV_{chronic}$ l/g AC or l/dose for the product. Nordic Ecolabelling's calculation sheet for cosmetic products can be used.

Reference to the DID list 2023 or later versions. For substances not on the DID list or for which data is missing on DID-list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented. See Appendix 9 for further details on biodegradability, toxicity, potential for bioaccumulation and bioavailability. If chronic values are available, they must be used instead of acute ones.

Leave-on products

O19 Biodegradability and aquatic toxicity

At least 96% by weight of the total content of organic ingoing substances in the Nordic Swan Ecolabelled cosmetic product must be:

- Readily biodegradable (OECD 301 A-F), and/or
- Lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioaccumulative (log Kow < 4 or BCF < 500), and/or
- Lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or
- Lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol).

Exemptions to the definition of ingoing substances and impurities: Impurities in raw material ≤ 1.0 w% will not be included in calculations.

UV filters are exempted.

Surfactants must be biodegradable, see requirement O7 Surfactants.

Calculation of the quantity (percentage by weight) of substances that fulfil the listed requirements. Nordic Ecolabelling's calculation sheet for cosmetic products can be used.

Reference to the DID list 2023 or later versions. For substances not on the DID list or for which data is missing on DID-list, the parameters must be calculated

based on the guidance in part B of the DID list and associated documentation must be presented. See Appendix 9 for further details on biodegradability, toxicity, potential for bioaccumulation and bioavailability. If chronic values are available, they must be used instead of acute ones.

1.5 Specific additional requirements relating to certain product types

Lip products, toothpaste, oral hygiene products, and nipple cream

O20 Flavourings, colours and preservatives

Flavourings, colours, and preservatives in Nordic Swan Ecolabelled lip products, toothpaste, oral hygiene products, and nipple cream must live up to the following requirements:

- Must be approved for use in foodstuff under Regulation 1333/2008 for food additives and Regulation (EC) No 1334/2008 for flavourings.
- Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in lip care products must comply with the recommendations by Cosmetic Europe for mineral oils: https://cosmeticseurope.eu/download/N08vNnB0TUhMbWpwQmlqVk9UZzdwZz09
- Water-soluble Zinc salts in mouthwash is only allowed up to 0,1%.

Appendix 1 or equivalent declaration completed and signed.

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

Flavourings: Specification of FL-number*.

** FL-numbers are available at the European Commission's Food flavourings database https://ec.europa.eu/food/food-feed-portal/screen/food-flavourings/search and Annex I of Regulation (EC) No 1334/2008.*

O21 Fluoride

Nordic Swan Ecolabelled toothpaste and mouthwash products must contain fluoride in line with the national recommendations on fluoride content.

Recipe.

Appendix 1 or equivalent declaration completed and signed.

Decorative cosmetics and hair dyes

O22 Heavy metals in colourants

Traces of the following heavy metals cannot exceed the following limits in the Nordic Swan Ecolabelled decorative cosmetic product or hair dye product:

- Arsenic 1 ppm
- Antimony 1 ppm
- Cadmium 1 ppm

- Chromium 10 ppm
- Cobalt 1 ppm
- Lead 1 ppm
- Mercury 1 ppm
- Nickel 10 ppm

Colours that are approved for use in food in Regulation 1333/2008 may be used without further documentation of the metals listed above.

In addition, the following requirement applies to decorative cosmetics:

- Bismuth Oxychloride (CAS 7787-59-9) is prohibited.

Analysis results and/or material specification of the colourant.

Appendix 2 or equivalent declaration completed and signed with calculations of the amount of the specific metals in the Nordic Swan Ecolabelled product.

Alternatively, test report showing that the quantities in the Nordic Swan Ecolabelled product meet the requirement.

Specification of E-number for colorants approved for food. Appendix 2 can be used.

O23 Hair dyes

The following hair dyes are prohibited in Nordic Swan Ecolabelled hair dye products:

- Lawsone (CAS No. 83-72-7)
- Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (CAS No. 928659-47-5 and CAS No. 73793-79-0)
- Hair dyes judged to be sensitising and/or allergenic by the SCCS is prohibited even if they do not meet the classification of H317 and/or H334

Appendix 1 or equivalent declaration completed and signed.

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

Wet Wipes

O24 Wipe material

Wipe carrier material used in Nordic Swan Ecolabelled wet wipes must live up to the following requirements:

- Must not be based on fossil raw materials and must be plastic free. Chemically modified natural polymers, and biodegradable/bio-based plastics are also considered plastic, as specified in the guidelines on the Single-Use Plastic directive[3].

[3] Commission guidelines on single-use plastic products in accordance with Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment (2021/C 216/01)

- Wipe carrier material or fibre type must meet relevant requirements under one (not all) of the criteria documents listed in the table below. For cellulose-based pulp and fluff pulp used in carrier material of wipes, the requirements in the Appendix 7 can also be applied.

Table 7 Requirements for wipe carrier material.

Wipe carrier material	EU Ecolabel, Absorbent hygiene products 2023/1809/EU	Nordic Swan Ecolabel, Textiles version 5.4 or later	Nordic Swan Ecolabel, Tissue paper version 6.0 or later	EU Ecolabel Tissue paper 2019/70/EU
Regenerated cellulose*	Criterion 2,7	Fibres must be licenced or fulfil requirements O23-O27 O30-O31 O33-O41	***	***
Cellulose-based pulp/fluff pulp**	Criterion 1,7	***	***	***
Cotton and other natural cellulosic fibres	Criterion 3,7	Fibres must be licenced or fulfil requirements O14 O30-O31 O33-O41	***	***
Flax, bamboo, hemp and bast fibres	***	Fibres must be licenced or fulfil requirements O16-O17 O30-O31 O33-O41	***	***
Tissue paper made off cellulose-based pulp	***	***	Paper must be licenced	Paper must be licenced

* Regenerated cellulose fibres, also known as man-made cellulose fibres, means fibres produced from the raw material cellulose which include viscose, modal, lyocell, cupro and triacetate.

** For cellulose-based pulp and fluff pulp, the requirements in the Appendix 7 can be applied as an alternative to the mentioned criteria document in the table.

*** The criteria document is not applicable to the material type, select another of the alternative criteria documents.

If wipe carrier material or fibre type is licenced or used in a licenced product, valid licence number must be stated. Otherwise, documentation for the relevant requirements in the chosen criteria document must be provided.

O25 Process water

Sensitising substances with H317 and/or H334 can be used in the process water of the wet wipe material production only if the concentration in the carrier material/wipe is < 0.10 ppm per sensitising substance.

Signed declaration of the use of sensitising substances in the process water for material in wet wipes. Appendix 3 can be used.

If sensitising substances are used, an analysis report is to be enclosed showing < 0.10 ppm for each sensitising substance.

O26 User information

Nordic Swan Ecolabelled wet wipes must be marked on the front side of the packaging with the following information:

- “Do not flush” pictogram defined in guidelines for the EU Single-Use Plastic (SUP) Directive:

- "Use re-usable washcloths instead of single-use products like wet wipes whenever possible"

Label or packaging sample

Sunscreen products

O27 Efficacy and UV protection claims

The efficacy of Nordic Swan Ecolabelled sunscreen product's protection against UVB and UVA radiation must comply with the EU Commission Recommendation (2006/647/EC), Section 3 Minimum efficacy:

- UVB protection of minimum SPF 6
- UVA protection factor of minimum 1/3 of UVB SPF
- Critical wavelength of minimum 370 nm

Test methods

The test methods used to verify the efficacy shall be among those established by the European Committee for Standardization (CEN). The methods currently include:

- EN ISO 24444:2020 "Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF) (ISO 24444:2019)"
- EN ISO 24443:2021 "Cosmetics - Determination of sunscreen UVA photoprotection in vitro (ISO 24443:2021, Corrected version 2022-02)"
- EN ISO 24442:2022 "Cosmetics - Sun protection test methods - In vivo determination of sunscreen UVA protection (ISO 24442:2022)"

Currently under drafting:

- prEN ISO 23675 "Cosmetics - Sun protection test Methods - In Vitro determination of Sun Protection Factor"

Labelling

The labelling of the Nordic Swan Ecolabelled sunscreen product must comply with Section 4 Simple and meaningful claims of efficacy:

- Claims indicating the efficacy shall be simple, unambiguous, meaningful, and coherent with the results from the above-mentioned efficacy testing of the product.
- Claims on the protection efficacy shall be indicated by categories “low”, “medium”, “high”, “very high”, according to the SPF intervals tabled in the Commission Recommendation.
- The claimed SPF shall be one of the “labelled sun protection factor” tabled in the Commission Recommendation, in accordance with the results of the efficacy testing.
- The protection efficacy category shall be indicated at least as prominently as the SPF.

Test reports including description of the tests methods used and the results obtained.

Product label.

Products outside the scope of the cosmetic products regulation

O28 Animal care products

Nordic Swan Ecolabelled animal care products must live up to the following requirements:

- Fragrance and colourants are prohibited
- The product shall comply with the following parts of the EU regulation on cosmetic products ((EC) No 1223/2009):
  - Article 14 Restrictions for substances listed in the Annexes
  - Article 15 Substances classified as CMR substances
  - Article 19 Labelling
  - Article 20 Product claims
- The product must not be classified as hazardous to the aquatic environment corresponding to any of the codes H400, H410, H411, H412 or H413, according to the EU CLP regulation ((EC) No 1272/2008).

Safety data sheet (MSDS) of the product in accordance with the EU REACH regulation ((EC) No 1907/2006, Annex II).

Appendix 1 or equivalent declaration completed and signed.

Product label.

O29 Sex lubricants

Nordic Swan Ecolabelled sex lubricant products must live up to the following requirements:

- Fragrance and colourants are prohibited
- The product shall comply with the following parts of the EU regulation on cosmetic products ((EC) No 1223/2009):
  - Article 3 Safety
  - Article 8 Good manufacturing practise

- Article 10 Safety assessment
- Article 14 Restrictions for substances listed in the Annexes
- Article 15 Substances classified as CMR substances
- Article 19 Labelling
- Article 20 Product claims

- The safety assessment must be conducted by a specialist with documented qualifications required for cosmetic product safety assessment. Additionally, in case the product manufacturer doesn't manufacture cosmetic products, the safety assessor must be an independent third party
- The product must not be classified as hazardous to the aquatic environment corresponding to any of the codes H400, H410, H411, H412 or H413, according to the EU CLP regulation ((EC) No 1272/2008).

In cases where the product is within the scope of the EU regulation on medical devices (MDR, (EU) 2107/745)), compliance with it must be shown. The product then doesn't need to comply with articles 3, 8, and 10 of the cosmetic products regulation.

Safety data sheet (MSDS) of the product in accordance with the EU REACH regulation ((EC) No 1907/2006, Annex II) (not for products within the scope of the MDR).

Safety assessment report and declaration of the qualifications of the safety assessor (not for products within the scope of the MDR).

EU declaration of conformity with the MDR (only for products within the scope of the MDR).

Appendix 1 or equivalent declaration completed and signed.

Product label (with CE conformity mark if the product is within the scope of the MDR).

O30 Medical examination lubricants

Nordic Swan Ecolabelled medical lubricant products must live up to the following requirements:

- Fragrance and colourants are prohibited
- The product shall be within the scope of, and compliant with, the EU regulation on medical devices (MDR, (EU) 2017/745)
- The product shall comply with the following parts of the EU regulation on cosmetic products (CPR, (EC) No 1223/2009) (where the CPR is stricter than the MDR, the former applies):
  - Article 14 Restrictions for substances listed in the Annexes
  - Article 15 Substances classified as CMR substances
  - Article 19 Labelling
  - Article 20 Product claims

EU declaration of conformity from the notified body, in accordance with the MDR.

Appendix 1 or equivalent declaration completed and signed.

Product label, with CE conformity mark.

1.6 Packaging requirements

Packaging is a focus area in circular economy, an one of the most important parameters in reducing the climate burden. Nordic Ecolabelling wants to set strict requirements on packaging to ensure the best possibilities for recycling and to reduce the material consumption and transport of packaging.

The packaging requirements target the primary packaging*. Only the packaging materials described in requirement O31 Packaging and materials can currently be used. Please note that glass packaging is no longer permitted. If you are interested in another packaging type (or e.g., another label type), please contact Nordic Ecolabelling to find out whether the criteria can be extended to include your format.

** In accordance with EU Directive 94/62/EC on packaging and packaging waste, the term "primary packaging" is defined as consumer packaging, i.e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of sale.*

O31 Packaging and materials

The following material types must be used in primary packaging*:

- Plastic (see requirements O32)
- Paper-based, e.g. cardboard and corrugated board (see requirements O33)
- Aluminium can be used only for the following types of products, if the container does not contain any other metals and is not based on aluminium alloys:
  - Product sizes < 100 ml
  - Spray bottles/propellant bottles for hairstyling products and shaving foam in all sizes

The following packaging and material types must not be used:

- Miniature bottles sold to the HoReCa sector**.
- Glass
- Metal

  Exemptions for:
  - Aluminium for the product types described above
  - Small metal parts, e.g. parts of a hand pump or sealing foil across small openings on e.g. tubes, are permitted up to 1% of the total weight of the packaging
  - Decorative cosmetics up to 15% of the total weight of the packaging. Mirrors are not permitted as part of the packaging

** In accordance with EU Directive 94/62/EC on packaging and packaging waste, the term "primary packaging" is defined as consumer packaging, i.e., packaging conceived to constitute a sales unit to the final user or consumer at the point of sale.*

*** Hotel, restaurant, and catering sector.*

- Specification of materials, including description of all components (cap, pump, lid, etc.). Appendix 4 Declaration from the manufacturer/supplier(s) of the primary packaging component can be used as part of the documentation.
- Declaration from the applicant that products with a volume lower than 100 ml is not sold to the HoReCa sector. Appendix 1 can be used.
- If primary packaging of aluminium: Declaration that no other metals, alloys or labels are used. Appendix 4 Declaration from the manufacturer/supplier(s) of the primary packaging component can be used.
- If decorative cosmetic: Account of the content of metal in packaging for decorative cosmetics.

O32 Plastic packaging: Recyclability and design for recycling

To enable recycling, the following is required:

- The main materials* in the primary packaging must be possible to recycle** in today's existing material recirculation systems in the Nordic countries.
- All parts of the packaging of products for domestic use that are comprised of different materials must be possible to be sorted separately without using a tool (including sorting into different plastic types). Mixed materials that cannot be separated must not be used.

  An exemption is made for small metal parts in pumps (e.g. springs) up to 1% of the total weight of the packaging, labels, pressurised containers (including airless) and packaging for decorative cosmetic products.

The primary packaging must have a design that enables material recovery, and therefore must live up to the following requirements:

- The container and closure must be made from monomaterial of either polyethylene (PE), polypropylene (PP) or polyethylene terephthalate (PET). However, up to 5% of PE in PP material and up to 1% of PP in PE material is permitted from masterbatch. Recycled material, which is purchased as one type of polymer, e.g. PP, is considered monomaterial.

  An exemption is made for small metal parts in pumps (e.g. springs) up to 1% of the total weight of the packaging.
- For rigid plastic packaging: Packaging and closures must be compatible with each other, in accordance with the following:
  - PET packaging: PE or PP closure with a density < 1.0 g/cm^3.
  - PE packaging: PP/OPP-closures must not be used unless the following text or similar is stated on the packaging: "Take the cap/closure off prior to recycling to improve recycling".
- Pigments must not be added to PET. Coloured, recycled PET granulate where the pigment originates from the recycled material is allowed.
- Carbon black pigments must not be added to container or closure.
- Fillers (such as $CaCO_3$) must not be included in PE or PP containers or closures at a level that the density of the plastic exceeds 0.995g / cm^3.
- Barriers are not allowed in rigid plastic packaging. Barrier coatings in flexible plastic pouches can only be of EVOH (ethylene vinyl alcohol) and constitute max 5% of the total weight.

- Silicone is not allowed in closures.
- The primary packaging must not be surface treated with PFAS, either on the inside or on the outside.

Container means e.g., bottle, tube, jar, flexible plastic pouches including spout fixed to the plastic pouch.

Closure means e.g., cap, lid, pump, spout, dosing device, oblate, seal. Please note that a spout that is fixed to the container counts as part of the container.

** Labels, pumps, and spray nozzles are not considered main materials.*

*** Incineration with energy recovery is not considered to be material recycling. In case of doubt about the actual recyclability in the current Nordic systems, Nordic Ecolabelling may request the applicant to obtain additional substantiation about the recyclability from one of the Nordic Producer Responsibility organisations.*

Documentation showing that the primary packaging is recyclable: List the used materials in Appendix 4 and define how each component should be recycled.

Statement from one of the Nordic Producer Responsibility organisations, if specifically requested by Nordic Ecolabelling.

A picture/description of how the lid/pump can be taken apart without tools.

Packaging specifications (including all components, such as container and closure, label etc.) or certificate showing the materials used, component weights, density of PE or PP components, and which pigments have been added. Appendix 4 Declaration from the manufacturer/supplier(s) of the primary packaging component can be used as part of the documentation.

Label showing text regarding instruction to remove the cap before recycling, where applicable.

O33 Paper-based packaging: Recycled material and design for recycling

To enable recycling of the cardboard and corrugated board packaging, the following is required:

- The main materials* in the primary packaging must be possible to recycle** in today's existing material recirculation systems in the Nordic countries.
- Cardboard packaging must contain at least 90% paper/paperboard.
- A minimum of 90% by weight of the wood raw material that is used in the paper/cardboard must be made of recycled material***.
- The remaining proportion of wood raw material (that is not recycled material) must be covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources).
- Two-sided plastic laminate is not permitted.
- PVC or plastic based on other types of halogenated plastics must not be used in the packaging (container and closure).
- Solid coloured cardboard is not permitted, except for white solid coloured cardboard, which is permitted.

** Labels, pumps, and spray nozzles are not considered main materials.*

*** Incineration with energy recovery is not considered to be material recycling. In case of doubt about the actual recyclability in the current Nordic systems, Nordic Ecolabelling may request the applicant to obtain additional substantiation about the recyclability from one of the Nordic Producer Responsibility organisations.*

**** Recycled material is defined in accordance with ISO 14021 in the following two categories:*

- Material in the pre-consumer phase: Material that has been taken from the waste flow during the manufacturing process. The exception is the re-use of material that is generated in a process, e.g., waste that can be recycled within the same process that generated it.
- Material in the post-consumer phase: Material generated by households or by trade, industry, or institutional facilities in their role as end-users of a product that can no longer be used for its intended purpose. This includes the return of materials from the distribution chain.

Description of the packaging from the packaging producer showing. Appendix 4 can be used:

- percentage (by weight) of paper/paperboard material, and percentage of recycled material in wood raw material
- percentage (by weight) of any barrier material; material type and description showing whether the barrier is one- or two-sided
- percentage (by weight) of other materials that might be present in elements such as closure, handles etc. and material type.

Declaration that any non-recycled wood raw material is covered by the FSC/PEFC control schemes.

Declarations that PVC and other plastic based on other types of halogenated plastics has not been used. Appendix 4 can be used.

Declarations that aluminium and other metals has not been used. Appendix 4 can be used.

If labels are used: Specification from the manufacturer showing that the label is made of paper and that the adhesive is water soluble.

O34 Labels for all packaging materials: Design for recycling of packaging

To enable recycling of the packaging, the following is required for the labels*:

- Containers in polyethene (PE) and polypropene (PP): The label must be of the same material as the packaging.

  Cross-over labels are exempted from this requirement.
- Containers in polyethylene terephthalate (PET):
  - The label must be of PP or PE with a density < 1.0 g/cm^3.
  - The label must not cover more than 50% of the packaging surface for sizes ≤ 500 ml and 70% for sizes > 500 ml.**
- For aluminium packaging: Labels must not be used.
- For all plastic packaging: Paper labels must not be used.

- For paper/cardboard packaging: Paper labels can be used, but other types of labels must not be used. The label glue must be water soluble.
- Labels of polyvinyl chloride (PVC) and other halogenated plastics must not be used.
- Metallized labels/shrink film labels must not be used.
- Direct print on the container is not permitted except for date codes, batch codes and UFI (Unique Formula Identifier).

  An exemption is made for tubes, flexible plastic pouches, paper-based packaging and containers made from aluminium.

** Label means "traditional label", shrink film label/sleeve, direct print etc.*

*** 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 the packaging are of different size, the maximum percentage shall be fulfilled for each side separately. For a cylindrical bottle, the calculation can also be based on the three-dimensional profile excluding the bottom and top of the bottle.*

Label specifications showing the material used and density. Appendix 4 Declaration from the manufacturer/supplier(s) of the primary packaging component can be used as part of the documentation.

Declarations that PVC and other halogenated plastics, aluminium and other metals have not been used. Appendix 4 can be used.

For labels of different material on PET packaging: Calculation of label size compared to the surface of the container.

Declaration from the applicant that direct print is not used except for date codes, batch codes and UFI.

O35 Amount of packaging: Weight-Utility Ratio (WUR)

To limit the use of an unnecessarily large amount of material, the primary packaging must meet the following calculation. See more information and calculation examples in Appendix 5.

$$\frac{\sum(mf_i \cdot W_{material\_i}) - \frac{W_{pump}}{2}}{t} \leq a \cdot Vol_{product} + b$$

mf_i = Material factor for type of material divided into the following three materials:

$mf_{paper/cardboard} = 0.4$

$mf_{plastic} = 1.0$

$mf_{plastic\ laminate} = 1.0$

$mf_{aluminium} = 2.1$

$W_{material\ i}$ = Weight of the packaging component (including label + information sheet) in grams

W_{pump} = Weight of pump (if applicable) in grams.

t = Reuse factor (t=1 for packaging, which is not reused for the same purpose, t > 1 if the product is sold with a refill or for the purpose of multiple refills, e.g. t = 5 if the amount of refills is 4.)

$Vol_{product}$ *= Volume of the product in ml*

a and b are constants that vary for different packaging types:

Packaging type	a	b
Pump bottle incl."Airless"	0.05	22
Tube	0.1	6.4
Bottle	0.065	15
Jar	0.08	35
Stick + roll on	0.5	8
Wet wipes*	0.98	8
Propellant bottles	0.4	10
Solid soaps, shampoo etc.	0.025	0.4

For decorative cosmetics** the following applies:

$$\frac{\sum W_{packaging,i}}{W_{product,total}} \leq 0.9$$

$W_{packaging,\ i}$ *= the weight of the packaging component i*

$W_{product,\ total}$ *= the weight of the end product (packaging plus content)*

** Wet wipes use the same equation as above, but volume of the product is replaced by the number of wet wipes in the packaging.*

*** Decorative cosmetics are mascara, eye liner, eye primer, eyebrow pencil, eyeshadow, powder/blusher, concealer, primer, nail varnish, lipstick, lip gloss and similar products.*

Declaration/documentation from the packaging manufacturer stating the type of material in the packaging components (e.g., closure (cap, spray nozzle etc.), bottle and labels). Appendix 4 can be used.

Calculation of weight-utility ratio (WUR) and required documentation on reuse of the packaging component. Nordic Ecolabelling's WUR calculation sheet for cosmetic products can be used.

If t >1: Documentation in the form of sales statistics or similar showing how many refills are sold per original packaging.

O36 Dosability / Dosing systems and emptying level

To avoid over-dosing, the following is required:

- For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press
- The following products must have an emptying level* of 90% or be able to be taken apart without tools in order to be able to empty the packaging further:
  - Bottles for conditioner and cream
  - Bottles with a pump, incl. dispenser bottles and bag-in-box dispenser systems

Pump products with an "airless" system are exempted from this requirement

** Emptying level must be calculated according to the formula and taking into account the emptying methods in Appendix 5.*

For liquid hand soap: Description of dosing system and weighing results per full press.

For conditioner and cream bottles, bottles with a pump, incl. dispenser bottles, and bag-in-box products: Documentation of emptying level in accordance with Appendix 5 or a picture/description of how the lid/pump can be taken apart without tools.

1.7 Disposal information requirements

Correct disposal of cosmetic products is an important factor in reducing the environmental impact.

O37 Disposal information

- All cosmetic products must have a label that includes the correct pictogram(s) in accordance with the common Nordic system of waste symbols, showing how the packaging should be sorted by the consumer. See details in the design guidelines for packaging: Unified pictogram system for recycling[4]. For products that are not sold in the nordic countries, national symbols or phrases can be used instead.
- The product types mentioned in the table below must bear the texts stated or equivalent information/pictogram on the label:

Table 8 Consumer information on label

Product	Cleansing lotion	Eye make-up remover	Nail polish	Nail polish remover	Aerosol spray cans
"Do not discard product, cotton wool or paper carrying this product in the lavatory or drain. Dispose in a waste bin instead"	X	X			
"Do not discard cotton wool or paper carrying this product in the lavatory or drain. Dispose in a waste bin instead"				X	
"Do not throw out-of-date/unwanted product in the lavatory, drain or waste bin. Please leave at a collection point for hazardous waste instead"			X	X	

[4] Design guidelines for packaging: Unified pictogram system for recycling: https://www.eupicto.com/media/khlbx4hb/eupicto_design-guidelines-for-packaging_final-5-skrivskyddad.pdf

"Do not discard product in a waste bin. Please leave at a collection point for hazardous waste instead"					X

Label or packaging sample

1.8 Licence maintenance

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

O38 Customer complaints

The licencee must guarantee that the quality of the Nordic Swan Ecolabelled product or service does not deteriorate during the validity period of the licence. Therefore, the licencee must keep an archive over customer complaints. Note that the original routine must be in one Nordic language or in English.

Upload your company's routine for handling and archiving customer complaints.

O39 Traceability

The licencee must be able to trace the Nordic Swan Ecolabelled 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.

Upload your traceability routine or a description.

Regulations for the Nordic Ecolabelling of products

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

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

Follow-up inspections

Nordic Ecolabelling may decide to check whether the products fulfil 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 licencee.

Criteria version history

Nordic Ecolabelling adopted version 4.0 of the criteria for cosmetic products on *DAY MONTH YEAR*. The criteria are valid until *DAY MONTH YEAR*.

New criteria

In the next version of the criteria, the following should be reviewed:

- The possibility for setting a requirement for the maximum allowed content of raw materials based on fossils.
- The possibility for requiring that palm oil/palm kernel oil must be RSPO certified with traceability level Segregated or Identity Preserved, and no longer allowing Mass Balance (or Book and Claim).
- The possibility for setting a requirement for the maximum allowed content of viscose in wet wipes.
- The possibility for setting a requirement for the use of recycled plastics for packaging.

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 *not* 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? *Incl. all classification variants. For example, H350 also covers classification H350i.*	**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 derivates (APD) *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.*		
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 *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".* *Applies to ingoing substances and impurities present at ≥ 0,010% in the cosmetic rinse-off or leave-on product.*		
Nanomaterials/-particles, as defined in the cosmetic products regulation ((EC) No 1223/2009) *Exemptions are made for:* *a) Synthetic amorphous silica (SAS) used as an abrasive in toothpaste.* *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*		
Nitro musks and polycyclic musk compounds		
Organic chlorine compounds, hypochlorous acid and hypochlorite		
Parabens (4-Hydroxibenzoic 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 *Exemptions are made for linear siloxanes in in leave-on products.*		
Silver, colloidal silver and nanosilver		
Substances on the REACH Candidate list of SVHC https://www.echa.europa.eu/candidate-list-table		
Titanium dioxide (TiO2, CAS No. 13463-67-7) *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, lipliner, and similar)*		
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? *An exemption is made for children's toothpaste*		
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 (Evernia prunastri) or tree moss extract (Evernia furfuracea).		
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: *Incl. all classification variants. For example, H350 also covers classification H350i.*	**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 Devises Regulation?		

Is the product an animal care product, sex lubricant, or medical lubricant that does not 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**

Appendix 2 Declaration from the manufacturer/supplier of the raw material

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.

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

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.

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, 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:

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.

O4: Palm oil/palm kernel oil		**YES**	**NO**
Does the raw material contain 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? *Incl. all classification variants. For example, H350 also covers classification H350i.*	**YES**	**NO**
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 raw material 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 derivates (APD) *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.*		
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*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".*		

Nanomaterials/-particles, as defined in the cosmetic products regulation ((EC) No 1223/2009) *Exemptions are made for:* *a) Synthetic amorphous silica (SAS) used as an abrasive in toothpaste.* *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*		
Nitro musks and polycyclic musk compounds		
Organic chlorine compounds, hypochlorous acid and hypochlorite		
Parabens (4-Hydroxibenzoic 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, that are cyclic		
Siloxanes, that are linear		
Silver, colloidal silver and nanosilver		
Substances on the REACH Candidate list of SVHC https://www.echa.europa.eu/candidate-list-table		
Titanium dioxide (TiO2, CAS No. 13463-67-7) *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, lipliner, and similar)*		
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 raw material contain surfactants with impurities of 1,4-dioxane (CAS 123-91-1) > 1 ppm in the surfactant active matter?		
Does the raw material contain sodium lauryl sulphate (SLS)?		
O8-010: Fragrances	**YES**	**NO**
Does the raw material contain fragrances that are not added in line with the IFRA guidelines		
Is the product intended for babies/children and contain fragrances? *An exemption is made for children's toothpaste*		

Does the raw material contain fragrances that are H317/H334 classified or are fragrance allergens listed in Annex III of the Cosmetics Regulation?		
Does the raw material contain the fragrance allergens oak moss extract (Evernia prunastri) or tree moss extract (Evernia furfuracea).		
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 raw material contain preservatives? **If yes**, state log KoW/BCF:		
Does the raw material contain preservatives that are not readily aerobic biodegradable?		
O13: UV filters	**YES**	**NO**
Does the raw material contain UV filters? **If yes**, state log KoW/BCF or lowest available NOEC/EC/LC50:		
O14: Does the raw material contain synthetic polymers with one or more residual monomers of the following properties > 100 ppm: *Incl. all classification variants. For example, H350 also covers classification H350i*	**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 raw material contain aluminium? **If yes**, state the amount of aluminium corresponding to elemental %Al:		
O16: Environmentally hazardous substances	**YES**	**NO**
Does the raw material contain substances classified H410, H411 or H412?		
O20-O21: Oral products	**YES**	**NO**
Does the raw material contain colourants, preservatives, or flavourings? **If yes**, state the E-number of colorants and preservatives: **If yes**, state the FL-number of flavourings:		
Does the raw material contain mineral oil saturated hydrocarbons (MOSH) or mineral oil aromatic hydrocarbons (MOAH)?		
Does the raw material contain water-soluble zinc salts? **If yes**, state the content:		
Does the raw material contain flouride? **If yes**, state the content:		
O22-O23: Decorative cosmetics and hair dyes	**YES**	**NO**
Does the raw material contain heavy metals? **If yes**, state type and content:		
Does the raw material contain 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)?		

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 raw material, 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**

Appendix 3 Declaration on sensitising substances in the process water for wet wipe carrier material

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/supplier
Wet wipe material (tradename and composition)

O25: Process water	**YES**	**NO**
Are sensitising substances with H317 and/or H334 used in the process water of the wet wipe material		
If yes, does the concentration in the carrying material/wipe exceed 0.10 ppm per sensitising substance? Enclose an analysis report.		
If no, which preservative is used in the process water?		

In the event of any change to the above stated, 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**

Appendix 4 Declaration from the manufacturer/supplier of the primary packaging component

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.

Please note that small amounts of impurities when using recycled materials are possible and do not affect fulfilment of the requirements.

Manufacturer/supplier
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.

How should the packaging component be recycled? (E.g. as plastic packaging, cardboard etc.) (O32)

O31: Aluminium packaging	**YES**	**NO**
Is the packaging made from aluminium that contains other metals?		
Is the packaging made from aluminium that contains aluminium allooys?		

Is the packaging made from aluminium and have a label?		
O32: Plastic packaging	**YES**	**NO**
Does the component contain metal seals or other metal parts? *An exemption is made for small metal parts in pumps and sealing foil across small openings on tubes etc, up to 1% of the total weight of the packaging.*		
Is the component made from monomaterial of either PE, PP or PET? *An exemption is made for ≤ 5% PE in PP and ≤ 1% PP in PE from masterbatch and small metal parts in pumps up to 1% of the total weight of the packaging.*		
If made of PET: Have any pigments/colours been added? *Exemption for recycled PET granulate where the pigment originated from the recycled material.*		
Has carbon black been added to the component?		
Are fillers used in the component? **If yes**, state the density of the packaging component [g/cm3]:		
Are any barriers used in the component? **If yes**, please state barrier type and percentage (weight %):		
For closures: Does the component contain silicone?		
Is the component treated with PFAS?		
O33: Paper-based packaging	**YES**	**NO**
Does the packaging contain recycled material*? * Recycled material is defined in accordance with ISO 14021 in the following two categories: Material in the pre-consumer phase. Material that has been taken from the waste flow during the manufacturing process. The exception is the re-use of material that is generated in a process, e.g. waste that can be recycled within the same process that generated it. Material in the post-consumer phase. Material generated by households or by trade, industry, or institutional facilities in their role as end-users of a product that can no longer be used for its intended purpose. This includes the return of materials from the distribution chain.		
With reference to the percentage PCR in the wood raw material above: Is the remaining proportion of wood raw material covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources)?		
Is the packaging a cardboard packaging?		
Is the packaging a corrugated board packaging?		
Is the packaging laminated with any barrier material? **If yes**, please state the barrier material type: **If yes**, is the laminate on one side only?		
Does the packaging contain PVC (polyvinyl chloride) or other types of halogenated plastics?		
Is the packaging material solid coloured?		
Does the packaging contain metal seals or other metal parts?		
O34: Labels	**YES**	**NO**
Please specify the label material and its density in g/cm3:		
Is there Polyvinyl chloride (PVC) or other halogenated plastics present in the labels?		
Does the label contain metal?		

For plastic packaging: Is the label made of paper?		
For paper-based packaging: Is the label made of plastic?		
For paper-based packaging: Is the label glue water soluble?		

In the event of any change to the composition of component, 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**

Appendix 5 Packaging calculations

1. Amount of packaging

The amount of packaging compares the amount of packaging material with the content using the following formula:

$$\frac{\sum(mf_i \cdot W_{material\_i}) - \frac{W_{pump}}{2}}{t} \leq a \cdot Vol_{product} + b$$

mf_i = Material factor for type of material divided into the following three materials:

$mf_{paper/cardboard} = 0.4$

$mf_{plastic} = 1.0$

$mf_{aluminium} = 2.1$

$W_{material\ i}$ = Weight of the packaging component (including label + information sheet) in grams

$Weight_{pump}$ = Weight of pump (if applicable) in grams.

t = Reuse factor (t=1 for packaging which is not reused for the same purpose, t > 1 if the product is sold with a refill or for the purpose of multiple refills, e.g. t = 5 if the amount of refills is 4.)

$Vol_{product}$ = Volume of the product in ml

a and b are constants that vary for different packaging types:

Packaging type	a	b
Pump bottle incl. ”Airless”	0.05	22
Tube	0.1	6.4
Bottle	0.065	15
Jar	0.08	35
Stick + roll on	0.5	8
Wet wipes**	0.98	8
Propellant bottles	0.4	10
Solid soaps, shampoo etc.	0.025	0.4

Example calculation for a 200 ml product with a pump that is not sold with a refill (pump = 12 g, plastic packaging weighs 37 g in total):

$$\frac{\sum(mf_i \cdot W_{material\_i}) - \frac{W_{pump}}{2}}{t} \leq 0.04 \cdot Vol_{product} + 30$$

$$\frac{\sum(1.0 \cdot 37g) - \frac{12g}{2}}{1} \leq 0.05 \cdot 200 + 22$$

$$\frac{37g - 6g}{1} \leq 10 + 22$$

$$31.55 \leq 32 \Rightarrow OK$$

2. Emptying level

The amount of product remaining in the packaging (R), which must be less than 10% is calculated using the following formula:

$$R = \frac{(m_2 - m_3)}{m_1 - m_3} \cdot 100\%$$

where:

m_1= mass of primary packaging and product (g)

m_2= mass of primary packaging and remainder of product in normal conditions (g)

m_3= mass of empty and clean primary packaging (g)

Normal conditions of use are defined as:

- Pump bottle: Repeatedly press the mouth of the pump. If nothing has come out of the packaging after 5 presses in a row, the packaging is considered to be empty. The mouth of the pump may not be taken apart and water must not be introduced in the packaging.
- Vials/flasks: The vial is turned upside down, with the cap in the downward position and is pressed as it would usually be pressed when using the product. After the trickle is not continuous, the bottle is left in the same position for a maximum of 24 hours. The bottle can also be hit on the table which corresponds to normal consumer behaviour. Neither the cap is dismantled, nor water is introduced inside the packaging.

The packaging is approved if an average of 3 tests come in below the limit. The same test can be used for products that are similar but have different perfumes or colours. The products must be the same viscosity.

Appendix 6 Analysis laboratory and test methods

1. Requirements for analysis laboratory

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

The applicant's own analysis laboratory/test procedure may be approved for analysis and testing if one of the following is fulfilled:

- The authorities monitor the sampling and analysis process
- The manufacturer has a quality management system encompassing sampling and analysis and has been certified to ISO 9001 or ISO 9001
- The manufacturer can demonstrate agreement between a first-time test conducted at the manufacturer's own laboratory and testing carried out in parallel at an independent test institute, and that the manufacturer takes samples according to a set sampling plan.

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 that must be used are stated below.

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.

* *The Commission prohibited animal testing of ingredients for cosmetic products from March 2009 onwards. To determine aquatic toxicity, however, the prohibition only concerns testing with fish (does not include invertebrates). As such, OECD test guideline no. 203 (acute toxicity – fish), 210, 215 and 229 (chronic toxicity – fish) cannot be used to document acute/chronic toxicity in the future. The results of acute/chronic toxicity testing using fish produced before March 2009 may still be used, however.*

4. Bioaccumulation

Unless otherwise proven, substances are considered bioaccumulating if log Kow ≥ 4.0 in OECD test methods no. 107 or 117. Such a substance may be tested on fish in line with the OECD test methods 305 A-E*.

If the substance has a biological concentration factor (BCF) ≥ 500 the substance is considered to be bioaccumulative, and if the BCF < 500 the substance is considered not to be bioaccumulative. If there is a measured BCF value, it is

always the highest measured BCF that is used in assessing a substance's bioaccumulative potential.

OECD test method 107 cannot be applied to surfactants which have both fat and water-soluble 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.

Data models (such as BIOWIN) are accepted, 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.

** The Commission prohibited animal testing of ingredients for cosmetic products from March 2009 onwards. As such, OECD test guideline no. 305 (bioconcentration factors), cannot be used to document bioaccumulation in the future. Results produced before March 2009 may still be used, however.*

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 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 7 Requirements for cellulose-based pulp/fluff pulp in wet wipe carrier material

Cellulose-based pulp/fluff pulp

The manufacturer of wipe carrier material shall provide information regarding the pulp: state the name and type of the pulp/fluff pulp - manufacturer, trade name, production site, type of pulp (such as ECF, TCF, CTMP etc., market pulp or not).

The following requirements must be met:

- Only virgin fibres shall be used in the pulp/fluff pulp used to manufacture wet wipes.
- The cellulose-based pulp/fluff must not be bleached with chlorine gas (Cl2).
- Optical brightener or fluorinated chemicals must not be added to the cellulose-based pulp/fluff.
- The cellulose-based pulp/fluff must not have a growth inhibiting effect on microorganisms, under test method EN 1104.
- Chemicals added to the finished cellulose-based pulp/fluff to provide specific properties* must fulfil the chemical requirements O1-O2** in the Chemical Module, version 3 or later.

** Softeners that contain quaternary imidazoline (CAS No. 72749-55-4) are exempt from classification as Aquatic acute 1 H400, Aquatic chronic 1 H410, Aquatic chronic 2 H411 and Aquatic Chronic 3 H412 in the requirement O1 in the Chemical Module, version 3 or later.*

*** Production chemicals used during the production of the cellulose pulp are not included in the requirement.*

- The manufacturer of the wipe carrier material must state name and manufacturer of the purchased cellulose based pulp/fluff that are used in the wet wipe.
- The pulp manufacturer shall enclose duly completed and signed Appendix 8.
- If chemicals are added to the finished pulp/fluff:
  - The pulp manufacturer shall submit a list of the chemical products added to the finished pulp/fluff including name, manufacturer, function, and amount used (kg/ADt). Product safety data sheets for chemical products shall be included upon request. Appendix 8 can be used.
  - The manufacturer/supplier of the chemical product shall demonstrate compliance with the requirement in the web-based application tool.

Cellulose-based pulp/fluff pulp, fibre raw material

The requirement consists of four parts that all must be fulfilled by the pulp manufacturer:

1. Virgin tree species listed on Nordic Ecolabelling's list of restricted tree species* must not be used in pulp.

The list consists of tree species listed on:

i. CITES (Appendices I, II and III)

ii. IUCN red list, categorized as CR, EN and VU

iii. Rainforest Foundation Norway´s tree list

iv. Siberian larch (originated in forests outside the EU)

Exemptions: Eucalyptus and Acacia used for pulp and paper production are exempted from the list (note **).

Tree species listed on either ii, iii or iv may be used if it meets all the following requirements: • the tree species does not originate from an area/region where it is IUCN red listed, categorized as CR, EN or VU.

- The tree species does not originate from Intact Forest Landscape (IFL), defined in 2002 http://www.intactforests.org/world.map.html.
- The tree species shall originate from FSC or PEFC certified forest/plantation and shall be covered by a valid FSC/PEFC chain of custody certificates documented/controlled as FSC or PEFC 100% through the FSC transfer method or PEFC physical separation method. Tree species grown in plantation shall in addition originate from FSC or PEFC certified forest/plantation, established before 1994.

* *The list of prohibited tree species is located on the website: www.nordic-ecolabel.org/wood/*

** *Regarding pulp, fibre raw material from eucalyptus/acacia must be a minimum of 70% certified.*

2. The manufacturer of cellulose-based pulp/fluff must state the name (species name/scientific name) of the fibre raw material used in the production of pulp.

3. The pulp manufacturer must be Chain of Custody certified in accordance to FSC or PEFC. All fibres shall be covered by valid chain of custody certificates issued by FSC or PEFC.

4. On an annual basis/the latest 12 months, a minimum of 70 weight-% of all fibre raw material used in the cellulose-based pulp/fluff, must origin from forestry certified under the FSC or PEFC schemes or 70% of the wood raw material in the pulp must be wood shavings or sawdust or a combination of certified and wood shavings/sawdust. If the pulp contains both certified fibres and wood shavings or sawdust, the sum of these fibres shall in total be a minimum of 70%.

The remaining proportion of fibre raw material must be covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources).

If several pulps are mixed, the certification percentage must be fulfilled for the finished pulp/fluff in the product. The proportion of fibre raw material in the pulp taken from certified sources and wood shavings or sawdust, is calculated as a weighted total of the proportion in each constituent pulp.

- Declaration from the pulp manufacturer that tree species listed on i-iv) are not used. Regarding acacia/eucalyptus, documentation showing that the quantity of certified fibre in pulp is met. Appendix 8 can be used.
- If species from the lists ii), iii) or iv) is used:
- The pulp manufacturer/supplier are required to present a valid FSC/PEFC Chain of Custody certificate that covers the specific tree species and demonstrate that the tree is controlled as FSC or PEFC 100% through the FSC transfer method or PEFC physical separation method.
- The pulp manufacturer/supplier are required to document full traceability back to the forest/certified forest unit thereby demonstrating that:
  - The tree does not originate from an area/region where it is IUCN red listed, categorized as CR, EN or VU
  - The tree species does not originate from Intact Forest Landscape (IFL), defined in 2002 http://www.intactforests.org/world.webmap.html
  - For plantations the applicant/manufacturer/supplier are required to document that the tree species does not originate from FSC or PEFC certified plantations established after 1994.
- Pulp manufacturer shall describe name (species name) on the fibre raw material used in the pulp/fluff.
- Pulp manufacturer must present a valid FSC/PEFC Chain of Custody certificate covering all fibre raw material used in the pulp (e.g. via link to website).
- Pulp manufacturer shall enclose documentation such as audited accounting documents showing the amount of certified fibre raw material in the pulp/fluff is met. For the uncertified fibre raw material, proof that it is controlled wood covered by a verification system. Nordic Ecolabelling may request further documents to examine whether the requirements are fulfilled.

Cellulose-based pulp/fluff, production requirements

The cellulose-based pulp/fluff must fulfil the requirements O1-O6, O8-O16 in the Basic Module for Paper Products, version 3 and all the requirements in the Chemical Module, version 3, or corresponding requirements in later versions.

Fossil fuels

Fossil oil and coal must not be used as fuels* for production of process heat in the pulp/fluff mill.

Necessary use of fossil oil e.g. in planned maintenance stops, emergency maintenance stops, as a reserve and tip fuel (peak load fuel) or at start-ups for regulation of the combustion temperature in a heat and co-generation boiler is allowed.

* *Use of natural gas and liquefied petroleum gas (LPG) is allowed*

For the requirements concerning energy consumption and emissions, the following limits and reference values apply:

Energy

- $P_{electricity\_total} \leq 1.25z$

  $P_{fuel\_total} \leq 1.25$
- The reference values for cellulose pulp are found in the Basic Module, version 3 or later.
- The reference values for fluff pulp are $El_{reference}$ = 750 kWh/ADt and $Fuel_{reference}$ = 5400 kWh/ADt. For mechanical fluff pulp (CTMP) the reference values are $El_{reference}$ = 1650 kWh/ADt and $Fuel_{reference}$ = 900 kWh/ADt.

  A more detailed description of documentation requirements and calculation methods is provided in Appendix 4 of the Basic Module, generation 3 or later, in which $P_{electricity}$ and P_{fuel} are also defined.

Emissions of greenhouse gases

- Emissions of greenhouse gases from fuels and electricity used for production of process heat must not exceed 350 kg CO2/ADt. For mechanical fluff pulp (CTMP) the limit value for emissions of CO2 is 100 kg CO2/ADt.

  For pulp comprising a mixture of chemical pulps and mechanical pulps, a weighted limit value is calculated based on the proportion of each pulp type.

Emissions to water and air

Emissions of AOX from production of fluff/cellulose pulp must on average be ≤ 0.14 kg/ADt per pulp mixture. Emissions of AOX from the individual pulp must be ≤ 0.16kg/ADt.

Total emission points must be ≤ 4.0, and individual emission points must be ≤ 1.3. The reference values in the Basic Module shall be used*.

- $P_{emissions(total)} = PCOD + PP + PS + PNOx \leq 4$

To calculate the individual emission scores for PCOD, PP, PS, and PNox and for reference values for difference pulp types, please refer to the Basic Module, generation 3 or later (Appendix 5, Table 5.1).

** For unbleached chemical pulp used in manufacturing of fluff pulp, the reference value of phosphorus is 0.03 kg/ADt.*

A more detailed description of documentation requirements and calculation methods is provided in Appendix 4 of the Basic Module, generation 3 or later.

- Documentation from the producer of the pulp/fluff/ showing that the requirements are fulfilled. The pulp manufacturer shall use the spreadsheet provided by Nordic Ecolabelling.
- If the pulp/fluff has previously been approved by Nordic Ecolabelling, state the name of the pulp.

Background to the requirements

Environmental impact of wet wipes is highly related to raw materials used as carrier material in wipes. Cellulose pulp/fluff pulps are one of those raw materials that may be used in wipes. During the recent years, the focus in updating Nordic Swan Ecolabel requirements for paper related products has mainly been on reduced energy and greenhouse gas emissions and these requirements for pulp/fluff pulp used in wipe carrier material are also made more stringent than in the previous version of the Criteria for Cosmetics.

Compared with current requirements for pulp/fluff pulps, the following key changes have been introduced:

- Reference values for manufacturing of fluff pulp - consumption of fuel and electricity - have been tightened. Regarding fuel, from 6 000 kWh/ADt to 5400 kWh/ADt and for electricity from 900 kWh/ADt to 750 kWh/ADt.
- Reference values for the pulps in the Basic Module[5], generation 3 have been tightened.
- There is a new requirement for ban on fossil oil and coal used for production of process heat in the pulp/fluff pulp mill.
- The requirement for emissions of greenhouse gases has been changed. The greenhouse gas requirement only encompasses fuels used for production of process heat and not electricity as in the previous generation. The limit value is now set to 350 kWh/ADt.

The background document to the Basic Module, version 3 provides comprehensive information on the energy requirement and Appendix 4 in the Basic Module describes the calculations in detail. Nordic Ecolabelling also provides a spreadsheet that is to be used for these calculations.

Requirement for emissions to air and water and for fibre raw material are also tightened:

- Regarding emissions to water and air, limit value for individual point score has been tightened from 1.5 to 1.3. The reference values for all emission

[5] https://www.nordic-swan-ecolabel.org/490e0d/contentassets/7ead124e301748859ace02c8cbde539f/criteria-for-basic-module-3.0_005_tissue-paper-005_english.pdf

parameters, namely COD, P, S and NOx have been updated in the Basic Module. The weighted average value of AOX released from the mixed pulps must not exceed 0.14 kg/ADt pulp. AOX emissions from each individual pulp must not exceed 0.16 kg/ADt.

- Regarding the requirement for fibre raw material, the limit of certification has been increased from 30% to 70% in pulp.
- There is also an updated requirement for restricted tree species not to be used in pulp/fluff pulp. Eucalyptus and Acacia used for pulp are exempted from the list. However, fibre raw material originating from Acacia and Eucalyptus plantations must be a minimum of 70% certified.

Major changes in the Chemical Module[6], version 3 also affect the manufacturing of pulp/fluff pulp:

- The requirement for classification of chemical products (O1) has been expanded with hazard class and hazard statement Aquatic Chronic 3 -H412.
- There is a new requirement for prohibited substances (O2), such as substances on the Candidate list shall not be ingoing substances in chemical products used in the production of pulp. Subsequently, some former requirements are removed, such as the requirement concerning residual monomers, as these are now covered by the new requirement.
- The definition of ingoing substances and impurities in chemical products has been updated, the limit for impurities in the chemical product is 1000 ppm.

6 https://www.nordic-swan-ecolabel.org/490e0d/contentassets/7ead124e301748859ace02c8cbde539f/criteria-for-chemical-module-3.2_005_tissue-paper-005_english.pdf

Appendix 8 Declaration from the manufacturer of cellulose-based pulp/fluff pulp

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 as cellulose-based pulp/fluff pulp manufacturer have at the time of the application, 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
Pulp/fluff pulp (tradename and type)

O24: Wipe material	**YES**	**NO**
Is the cellulose-based pulp/fluff leached with chlorine gas (Cl_2)?		
Are optical brighteners or fluorinated organic chemicals added to the cellulose-based pulp/fluff?		
Does the cellulose-based pulp/fluff have a growth inhibiting effect on microorganisms, under test method EN 1104?		
Are recycled fibres used in pulp/fluff?		
Are chemicals added to the finished pulp/fluff? **If yes**, chemicals added to the finished cellulose-based pulp/fluff to provide specific properties* must fulfil the chemical requirements O1-O2** in the Chemical Module, version 3 or later***.		

* *Softeners that contain quaternary imidazoline (CAS No. 72749-55-4) are exempt from classification as Aquatic acute 1 H400, Aquatic chronic 1 H410, Aquatic chronic 2 H411 and Aquatic Chronic 3 H412 in the requirement O1 in the Chemical Module, version 3 or later.*

** *Production chemicals used during the production of the cellulose pulp/fluff are not included in the requirement.*

*** *Ask the manufacturer/supplier of the chemical product to demonstrate compliance with the requirement in the web-based application tool.*

O24: Wipe material: List of chemical products added to the finished pulp/fluff			
Name of the chemical product	**Function**	**Manufacturer/supplier**	**Amount used (kg/ADt)**

O24: Wipe material: Fibre raw material in pulp	YES	NO
Are tree species listed in the list of restricted tree species (Nordic Ecolabelling - Prohibited Wood*) used in the Swan Eclabelled product? * The list of prohibited tree species is located on the website: www.nordic-ecolabel.org/wood/ Eucalyptus and Acacia used for pulp and paper production is exempted from the list. Regarding pulp, fibre raw material from eucalyptus/acacia must be a minimum of 70% certified		
If tree species on the list of restricted tree species are used state scientific name of the tree species:		
Are the tree species listed on CITES list I,II and III?		
Is the following documentation for the tree species used provided? • A valid FSC/PEFC Chain of Custody certificate from the supplier or manufacturer of the Nordic Swan Ecolabelled product of the wood that covers the specific tree species and demonstrate that the tree is controlled as FSC or PEFC 100% through the FSC transfer method or PEFC physical separation method. • The applicant/manufacturer/supplier are required to document full traceability back to the forest/certified forest unit thereby demonstrating that; • The tree does not originate from an area/region where it is IUCN red listed, categorized as CR, EN or VU; • The tree species does not originate from Intact Forest Landscape (IFL), defined in 2002 http://www.intactforests.org/world.webmap.html; • For plantations the applicant/manufacturer/supplier are required to document that the tree species does not originate from FSC or PEFC certified plantations established after 1994.		
Used tree species? State the name (species name/scientific name) of the wood raw materials used in pulp:		
Eucalyptus/acacia pulps? State the name (species name/scientific name) of the wood raw materials used in pulp:		
Chain of Custody (CoC): Is the producer of the cellulose-based pulp/fluff Chain of Custody (CoC)-certified according to FSC or PEFC's schemes? Please attach valid CoC-certificate or state certificate number:		
Is the following documentation for the certified/uncertified fibres in the pulp provided? Pulp manufacturer shall enclose documentation such as audited accounting documents showing the amount of certified fibre raw material in the pulp/fluff is met. For the uncertified fibre raw material, proof that it is controlled wood covered by a verification system. Nordic Ecolabelling may request further documents to examine whether the requirements are fulfilled.		

We declare that the requirements have been met and that the information provided is correct. In the event of any change to the composition of the product, that impacts the product's fulfilment of the requirements, a new declaration of fulfilment of the requirements is to be submitted to Nordic Ecolabelling.

Pace and date	
Manufacturer	**Company name/stamp**
Responsible person	**Signature of responsible person**
Telephone	**Email**