Nordic Ecolabelling for

Medical devices in plastic or silicone

Version 3.0 • date – date

CONSULTATION

Nordic Ecolabelling

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Contact information

In 1989, the Nordic Council of Ministers decided to introduce a voluntary official ecolabel, the Nordic Swan Ecolabel. These organisations/companies operate the Nordic Ecolabelling system on behalf of their own country's government. For more information, see the websites:

Denmark

Ecolabelling Denmark

www.svanemaerket.dk

Iceland

Ecolabelling Iceland

www.svanurinn.is

Finland

Ecolabelling Finland

www.joutsenmerkki.fi

Norway

Ecolabelling Norway

www.svanemerket.no

Sweden

Ecolabelling Sweden

www.svanen.se

1 Environmental communication guideline for Nordic Swan Ecolabel Medical devices in plastic or silicone

The overall environmental impact in the lifecycle of this product group and Nordic Swan Ecolabel identification of where ecolabelling can have the greatest effect is described in section 6 “Environmental impact of Medical devices in plastic or silicone”.

A Nordic Swan Ecolabelled Medical device in plastic or silicone does not contain PVC or phthalates. The products fulfil strict chemical requirements for surface treatment, adhesive and additives in plastic and silicon. The packaging must be of materials and be designed to promote recycling. EU legislation in the area is extensive and imposes strict requirements as to the safety of the products.

Nordic Swan Ecolabel Medical devices in plastic or silicone:

- Are free from halogenated plastics and rubbers.
- Meet strict environmental and health requirements for substances in materials and surface treatments. The following are for example not allowed:
    - Phthalates
    - PFAS
    - Bisphenols
    - Identified and potential endocrine disruptors on up-to-date lists from EU and national authorities
    - Harmful siloxanes (D4, D5 and D6) in silicone
- Have packaging design and materials that promote recycling.
- In addition, for products mainly made of silicone (min. 80 wt%): Emissions into air and water are limited during manufacturing, including limits for emission of greenhouse gases in production of silicones.

2 What can carry the Nordic Swan Ecolabel?

Product group definition

Products that may carry the Nordic Swan Ecolabel are mainly (min. 90 wt%) made of plastic or silicone and are for storage, transfer or transport of fluid, gas or medicine; or for preventing leakage of fluids from the body. The products must be included under the Regulation (EU) 2017/745 on medical devices or EU Medicinal Products Directive (2001/83/EC). The products can either be single-use or reusable.

Products included are:

Masks: Masks or other devices used to deliver for example oxygen and anaesthetic gases: Oxygen mask, anaesthesia mask, oxygen halter and breathing balloon set.

Flexible tubes: Flexible tubes used for removal of gas or fluids, maintaining open airways, delivering oxygen, other gases, medication or nutrition: Urine catheter, vein catheter, umbilical catheter, intravenous infusion treatment, intestinal tube, gastric tube, duodenal tube, tracheal tube, pharyngeal tube, nasal tube, suction hose and drainage.

Bags: Bags or pouches used for storage and transfer of fluids: Blood bag, urine bag, drainage bag, suction bag, ostomy pouch and dialysis treatment bag.

Plugs: Utilities used for preventing leakage from the body: Anal plug, continence support and prolapse ring.

Syringes: Includes empty syringes and syringes prefilled with salt water or water.

If a product is a combination of different subcomponents mentioned above, it is also included within these criteria. For example, bags, catheters and tubes in a peritoneal dialysis (PD) treatment set.

Accessories as clamps, stoppers, connectors, caps etc. can be approved as stand-alone products, but only if they originally are a part of and sold in connection with an Ecolabelled main product.

In addition to those specified above, relevant medical devices in plastic or silicone may be included in the product group upon request. This applies only to products mainly (min. 90 wt%) made of plastic or silicone and are for storage, transfer and transport of fluid, gas or medicine; or for preventing leakage of fluids from the body, and which are included under the Regulation (EU) 2017/745 on medical devices or EU Medicinal Products Directive (2001/83/EC). Nordic Ecolabelling will decide which new products may be included in the product group.

Some products for medical use, not included in these criteria can be Nordic Swan Ecolabelled under the criteria for Protective and Absorbent Hygiene Products, for example plasters, compresses, mattress covers/protectors, draw sheets, surgical gowns, patient gowns/patient covers, surgical masks and caps.

2.1 Justification of the product group definition

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

<u>Further background for the product group definition:</u>

Only the product types (e.g. “anaesthesia mask”) which are listed under each group (e.g. “masks”) in the product group definition can be labelled.

The wt% of plastic and silicone in the products must be calculated without fluids such as dialysate in dialysis treatment bags and salt water in prefilled syringes.

For generation 3 of the criteria there were a wish from public procurement and manufactures to expand the product types that are included in the criteria. Relevant environmental impacts in the life cycle of these product types were investigated by using the tools MECO and RPS,

see section 6. If a product type showed environmental hotspots in the MECO, the RPS was medium/high and fits into the product group definition (see section 2) then the new product type could be included in the criteria.

Some wishes for new product types were not included, due to different reasons.

Nordic Ecolabelling are conducting a pre study to evaluate if there is basis to make a new criteria set for gloves (e.g. examination gloves).

Hazardous waste containers, needle buckets, dosing box, medicine cup, washset bowl, sampling tubes and bowls/bottles/jars/tubes for laboratory culture/tests showed low RPS and were therefore not included in the criteria.

Prefilled syringes with other than salt water or water (e.g. medicine) are not included. This is because it may be perceived that the content (e.g. medicine) is also Nordic Swan Ecolabelled, and this risk of this misunderstanding do Nordic Ecolabelling want to avoid.

Bottle teats are normally not included in Regulation (EU) 2017/745 on medical devices, even though bottle teats may be if they are part of a specialized feeding system for medical conditions.

CPAP masks (Continuous Positive Airway Pressure) are not included in the criteria, because PVC is not commonly used in modern CPAP masks.

Autoclave bags are not covered by Regulation (EU) 2017/745 on medical devices or EU Medicinal Products Directive (2001/83/EC) and are therefore not included in the criteria.

3 How to read this criteria document

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

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

- Upload
- Requirement checked on site

To be awarded a Nordic Swan Ecolabel licence:

- All obligatory requirements must be fulfilled.
- Nordic Ecolabelling must inspect the site.

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

4 Summary

The criteria set requirements for the materials in the medical device, the additives used in polymer materials, chemicals in adhesive and surface treatment but also to packaging.

Changes and updates from generation 2 to 3

The most important changes are described below. See also table of overview of changes in section 4.1.

Product group definition and name of criteria:

Several new product types e.g. types of masks and syringes have been added, see section 2 for a complete list of new product types. Information about these product types were collected. Hereafter, relevant environmental impacts in the life cycle of these product types were investigated by using the tools MECO and RPS, see section 6 "Environmental impact of Medical devices in plastic or silicone". If a product type showed environmental hotspots in the MECO, the RPS was medium/high and fits into the product group definition then the new product type was included in the criteria, see more details in section 2.1.

The name of the criteria has been changed to "Medical devices in plastic or silicone", to better suit the new product types that can be ecolabelled.

Requirements for materials:

Halogenated butyl rubber (O3): A new requirement forbidding halogenated butyl rubber in products is introduced.

Silicone (O5): Has been tightened. The level of impurities of D4, D5 and D6 must not exceed 100 ppm for all parts and must be tested. The silicone must be medical-grade silicone.

Silicone production (O6-O8): New requirements for products made of min. 80 wt% silicone.

Requirements for chemicals (O9-O14):

The requirements for chemicals have been tightened and are divided into section for “Additives in polymer materials” and section for “Adhesive and surface treatment”. Requirements for surface treatment are new.

Now the only option is that declarations must be completed by the manufacturer/supplier of the polymer material, adhesive or surface treatment.

Several new classifications and substances have been banned.

New requirement for impurities of D4, D5 and D6 in silicone and siloxanes used in adhesives or surface treatment.

Packaging requirements (O15-O16):

The requirements for packaging are new, beside that halogenated plastics also were forbidden in packaging in generation 2.

Requirement on safety (O17):

Is tightened by adding that the CE marking shall be visible on the label followed by the identification number of the notified body.

4.1 Changes compared to previous generation

Below is an overview of changes from criteria generation 2 to 3.

Table A. Overview of changes to criteria for medical devices in plastic or silicone generation 3 compared with previous generation 2.

Requirement generation 3	Requirement generation 2	Same requirement	Change	New requirement	Comments
Name of criteria	Name of criteria		X		Changed to fit also new added product types.
Product group definition	Product group definition		X		Updated to fit also new added product types. The product must be made of min. 90 wt% plastic and/or silicone.
O1	O1		X		Updated text and appendix 2 regarding information about the product.
O2	O2	X			
O3	-			X	
O4	O3	X			
O5	O4		X		Tightened. Max 100 ppm for impurities of D4, D5 and D6 regardless of which part in product. In addition, the level of D4, D5 and D6 must now be tested. And the silicone must be medical-grade silicone.
O6	-			X	
O7	-			X	
O8	-			X	
O9	O6		X		Tightened with added classifications. Exemption deleted for: • TiO2 • TMP • Dye with H317 (O5 in gen. 2)
O10	O7		X		Tightened with added substances. Potential or identified endocrine disruptors updated regarding definition of these.
O11	O5		X	X	New req. for surface treatment. Loosened for additives in polymer materials where this req. has been deleted. Tightened with added classifications.

O12	O6		X	X	New req. for surface treatment. Tightened with added classifications.
O13	O7		X	X	New req. for surface treatment. Tightened with added substances. Potential or identified endocrine disruptors updated regarding definition of these.
O14	-			X	
O15	O2		X		Tightened by added req. to other packaging materials than halogenated plastics.
O16	-			X	
O17			X		Tightened by added that the CE marking, and the identification number of the notified body shall be on the label.
O18	O11		X		Updated to new general req. for Nordic Swan Ecolabelled products.
O19	O14		X		Updated to new general req. for Nordic Swan Ecolabelled products.
-	O9, O10, O12, O13, O15				The requirements are deleted because this is now included in the application form.

5 Requirements and justification of these

5.1 Definitions

Terms	**Definition**
Ingoing substances	All substances* in the chemical product/additive regardless of amount, including additives (e.g., preservatives and stabilizers) in the raw materials. Substances released from ingoing substances (e.g., biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances. ** N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance (Unknown or Variable composition, Complex reaction products or of biological materials) are also regarded separately, and all known constituents must be regarded.*
Impurities *(See additional information about ingoing substances and impurities below this table)*	Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials, that remain in the chemical product or additive in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%). *Examples of impurities: Background environmental pollutants from feedstock, as well as contaminants and residues from production such as reactants (incl. monomers), reagents, catalysts, by-products, scavengers, detergents for production equipment, carry-over from other or previous production lines.* Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the chemical product or additive.
Surface treatment	Surface treatment is usually added to improve the function of the product. This could for example be lubricants and coatings whose main purpose is to ease insertion or improve the user experience. The surface treatment is often used as a barrier between the materials in the product and the human body or medicinal liquids.

Primary packaging	Primary packaging means the packaging of the product that is necessary until the point of user. In the case of sterile products, primary packaging is designed to maintain the sterility of the product resulting in one piece of the specific product per primary packaging. Non-sterile products can be packed in primary packaging per product, in a certain number of products or without any primary packaging. It depends on the product types and their need for protection.
Secondary packaging	Secondary packaging means the packaging of a certain number of products in their primary packaging (if used) for protection during transport and storage.
Tertiary packaging	Tertiary packaging means the outer layer of packaging in which the product is distributed during their initial dispatch from the manufacturer of the product. Auxiliary packaging as wrapping film etc. for transportation pallets are excluded. Other packaging used in downstream distribution, including transport between distribution centres, retailers, or final customers is excluded.
Packaging component	A component is a component that is easily separable from other components without the use of tools. Examples are bottles, jars and detachable lids.

Additional information about ingoing substances and impurities:

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

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of Biological materials) have a composition of constituents that is not completely known or is variable from time to time. For substances registered under REACH as UVCBs, all constituents are considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

5.2 Description of the product and manufacturing process

O1 Description of the product and manufacturing process

The product must be made of min. 90 wt% plastic and/or silicone.

The applicant must provide the following information about the product and the manufacturing process:

- Trade name of the product.
- Product category according to product group definition, product type, and product data sheet.
- That the product is included in the Regulation (EU) 2017/745 or EU Medicinal Products Directive (2001/83/EC).
- Total weight of the product (in grams).
- Information whether the product is surface treated and/or if any adhesives are used in the product.
- Information about the different components in the product (like bag for solutions, tubes, connectors etc.) and what materials* the different components are made of. The information shall for each component include the following information:

a) Component of the product/trade name, code/item number corresponding to the flowchart and material type(s).
b) Supplier of the component including information on production site with full address.
c) Safety data sheet for each material.
d) Weight of each material in the component (in grams).
e) Whether the material(s)* and/or the component has a surface treatment.

- A flowchart showing an overview of the product and the manufacturing process of the product, including information on what components are bought from external manufacturers and what processes are done externally and internally. An example of a flowchart is shown in Appendix 1.

** Materials can be different plastics such as polypropylene (PP) and polyethylene terephthalate (PET) as well as other kind of materials such as thermoplastic elastomers (TPE), silicone and steel.*

- Description of the product and its components as described in the requirement.
- Product data sheet of the product.
- Safety data sheets for all materials.
- Flowchart as described in the requirement.
- Appendix 2 completed and signed by the manufacturer of the product.

Background to O1 Description of the product

The product must be made of min. 90 wt% plastic and/or silicone, because the main environmental hotspots in the criteria are alternatives to PVC and for silicone the hotspots number of harmful monomers and production of silicone raw material, see more details in section 6.

It is important that this information is entered correctly, as it determines which requirements are relevant for the applied product.

To gain an overview of the production chain of the applied product, the applicant is required to provide information about suppliers, production sites, overview of manufacturing processes etc. This is important to be able to assess which requirements in the criteria must be documented for each product.

5.3 Materials in the product

O2 Halogenated plastics

Halogenated plastics, e.g., polyvinyl chloride (PVC), polyvinyl dichloride (PVDC) and polytetrafluoroethylene (PTFE), are not allowed in the product.

- Appendix 2 completed and signed by the manufacturer of the product.

Background to O2 Halogenated plastics

Halogenated plastics such as PVC are not allowed to reduce problems in waste handling and to reduce the risk of health-related problems. PVC has long been in focus in the environmental debate. Some of the environmental problems of PVC are due to the molecule itself – or more precisely the organic bound chlorine in the PVC molecule both in the production and waste handling. In other cases, the problems concern additives in the PVC which are harmful to the environment and to health.

Soft PVC, in contrast to other polymers, requires a significant amount of plasticiser, which has the potential to migrate and enter a patient's body. If PVC ends up in the landfill, the leakage of plasticisers like phthalates is a source for these chemicals into the environment.

Read more about Nordic Ecolabelling's position on PVC here: PVC.

O3 Halogenated butyl rubber

Halogenated butyl rubbers, e.g., chlorobutyl rubber and bromobutyl rubber, are not allowed in the product.

- Appendix 2 completed and signed by the manufacturer of the product.

Background to O3 Halogenated butyl rubber

Halogenated butyl rubber is commonly used for the plunger stopper in syringes but may also be used in other kinds of medical devices.

Halogenated butyl rubber waste has many of the same issues as PVC waste. Incineration can release halogenated toxicants such as dioxins and furans, which are harmful to both human health and the environment[1].

Modern incineration plants in Europe have effective incineration, and the emissions of PAHs, benzo-a -pyrene, dioxins and furans have been significantly reduced. However, solid waste is generated during the process of neutralization the air pollution [2].

O4 Natural rubber latex

Natural rubber latex is not allowed in the product.

- Appendix 2 completed and signed by the manufacturer of the product.

Background to O4 Natural rubber latex

Latex is a possible alternative to PVC in medical devices[3]. However, natural rubber latex may cause allergic reactions of Type I (e.g. anaphylaxis) and Type IV (e.g. allergic contact dermatitis) as well as

[1] https://onlinelibrary.wiley.com/doi/pdf/10.1002/tcr.202500022
[2] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/circular-economy-and-resource-efficiency/pvc/
[3] Maria José Amaral, Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, HealthcareWithoutHarm, 31. Dcember 2014

non-allergic irritant contact dermatitis[4]. This issue is also mentioned in the report for Health care Without Harm. Nordic Ecolabelling does not wish to label products where the material itself can cause allergic reactions. Also, it is important for Nordic Ecolabelling to secure that renewable materials are sourced sustainably. Tapping of raw latex from the rubber tree (Hevea brasiliensis) occurs almost exclusively in tropical areas, where there may be a risk of deforestation to make plantations. Most natural rubber comes from plantations in South and Southeast Asia. About 75% of the total volume of natural rubber production comes from the five countries Thailand, Indonesia, Malaysia, India and Vietnam[5]. The global demand for natural rubber is growing and drives the expansion of rubber plantations across the tropics. Natural rubber was also considered by the EU Commission to be on the limit of being a critical raw material[6].

O5 Silicone

For silicone and siloxanes used in adhesive or surface treatment (e.g. silicone oil) see requirements in section 5.5.

- Must be medical-grade silicone.
- Octamethylcyclotetrasiloxane, D4, (CAS 556-67-2), decamethylcyclopenta-siloxane, D5, (CAS 541-02-6) or dodecamethylcyclohexasiloxane, D6, (CAS 540-97-6) must not form part of the silicone material. The requirement does not apply to D4, D5 and D6 contained as impurities* up to a limit of 100 ppm for each substance. The number of impurities must be tested according to test method for silicone elastomer products from CES-Silicones Europe[7] and the analysis laboratory shall fulfil the general requirements of standard EN ISO/IEC 17025 or have official GLP status.

** Impurities of D4, D5 and D6 are defined as residual products from the raw material production that can be found in the silicone material.*

- Appendix 3 or equivalent, completed and signed by the manufacturer/supplier of the silicone.
- Test report showing the amount of D4, D5 and D6 in the silicone material according to test method for silicone elastomer products from CES-Silicones Europe.
- Documentation for that the analysis laboratory fulfils the general requirements of standard EN ISO/IEC 17025 or have official GLP status.

Background to O5 Silicone

Silicone may be an alternative material to PVC in for instance catheters and dialysis machines[8]. Silicones can also be used in small parts, for instance as sealing. D4 (octamethylcyclotetrasiloxane, CAS No. 556-67-2), D5 (decamethylcyclopentasiloxane, CAS No. 541-02-6), D6 (dodecamethylcyclohexasiloxane, CAS No. 540-97-6) can be residues

[4] https://www.naaf.no/fokusomrader/allergi-og-overfolsomhet/lateksallergi/ (Available 2019-01-09).
[5] Brochure from FSC, 2017: FSC®-certified natural rubber: Deforestation free, socially responsible.
[6] The European Critical Raw Materials review: http://europa.eu/rapid/press-release_MEMO-14-377_en.htm (Available 2019-01-26).
[7] Quantification-of-Residual-Amounts-of-Cyclic-Volatile-Methyl-Siloxanes-in-Silicone-Elastomers_final-002.pdf
[8] Maria José Amaral, Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, HealthcareWithoutHarm, 31. Dcember 2014

from polymerisation of silicone. D4, D5 and D6 are on the Candidate List[9] and are toxic to human health and with PBT and/or vPvB properties and gives rise to specific concern based on their potential to accumulate in the environment.

D4, D5 and D6 are restricted in REACH Annex XIII Entry 70[10] to less than 0.1 wt% of the respective substance after 6 June 2031 for devices defined in Article 1(4) of Regulation (EU) 2017/745. Devices for the care of stoma are derogated in REACH Annex XIII Entry 70. Hereby, the requirement goes beyond the regulation in EU.

CES-Silicones Europe has described methods for testing the amount of D4, D5 and D6 in silicone fluids, silicone elastomer products and fully formulated Personal Care Products, respectively[11]. The test for silicone elastomer products is relevant here and CES-Silicones Europe write[12]: "The purpose of this document is to provide a robust analytical method for quantification of low levels (~0.1%) of Cyclic Volatile Methyl Siloxanes (cVMS) in cured and uncured silicone elastomers. It is broadly applicable to one-part and two-part pastes, sealants, heat cured elastomers, liquid silicone rubbers and room temperature vulcanized silicones in their cured and uncured states. This method uses common laboratory reagents, solvents, and equipment and should be easy to install in a laboratory equipped with a Gas Chromatograph with a Flame Ionization Detector (FID)". In the test method is describe that method is expected to work over a range of concentrations between 0.01 to 0.5%. RISE (Research Institutes of Sweden) also refer to the test method from CES-Silicones Europe[13].

5.3.1 Silicone production

Requirements in this section only applies to products made of min. 80 wt% silicone.

O6 Emissions of dust and chlorides to air

1. Emissions of dust

1a) The storage and handling of the elemental silicon raw material shall use at least one of the following techniques:

- Storing of elemental silicon in silos (after grinding).
- Storing of elemental silicon in covered areas protected from rain and wind (after grinding).
- Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding).
- Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.

1b) The yearly average of channelled emissions of dust shall be below 5 mg/Nm^3. The dust emissions should be continuously monitored.

[9] https://echa.europa.eu/da/-/ten-new-substances-added-to-the-candidate-list
[10] REACH Annex XIII Entry 70: 0ac1f453-ad41-4010-e837-a68273b896ca
[11] New analytical methods quantify siloxanes in silicone products - Silicones Europe Visited 25 September 2025.
[12] Quantification-of-Residual-Amounts-of-Cyclic-Volatile-Methyl-Siloxanes-in-Silicone-Elastomers_final-002.pdf Visited 25 September 2025.
[13] Analysis of siloxanes (D4, D5, D6) in textile and plastics | RISE Visited 25 September 2025.

Methods accepted are EN 15267-1, EN 15267-2, EN 15267-3, EN 15267-4, EN 13284-1 and EN 13284-2. The measurement shall cover grinding, storage and handling of elemental silicon as a minimum.

2. Emissions of chlorides

The off gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process.

- From the silicone manufacturer:

  1a) describe the technique used on site.

  1b) results of the dust measurements taken on site, together with the yearly average of the dust emission.

  2) details on the processing of the off gases from the methyl chloride, direct synthesis and distillation steps.

- Appendix 4 completed and signed by the manufacturer of the silicone.

Background to O6 Emissions of dust and of chlorides to air

Requirements O6 - O8 only apply when the product is made of a comprehensive proportion of silicone (80 wt% or more), whereby the silicone production will be a significant environmental impact of the product.

Background for this requirement is presented only shortly as more information can be found from EU Ecolabel's Technical Report for Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups[14].

Requirement for emissions to air aims at minimising the emissions of dust and chlorides during production of silicon. Dust is emitted during i.e. elemental silicon grinding, storage and handling. Different measures such as filtering can be used to decrease these emissions. A Best Available Technique-Associated Emission Levels (BAT-AEL) for channelled emissions of dust in all chemical plants is 1-5 mg/Nm^3. Therefore, a 5 mg/Nm^3 dust emission level is set as a limit value (yearly average).

During silicone material production, chlorides emissions occur during the methyl chloride synthesis, the direct synthesis and the distillation process steps. The off-gases from these processes shall undergo thermal oxidation followed by scrubbing. Thermal oxidation step is to minimise the risk of polychlorinated dibenzodioxins/furans (PCDD/Fs) formation.

O7 Emissions of copper and of zinc to water

The water effluents from the polydimethylsiloxane (PDMS) production step shall be pre-treated by precipitation or flocculation under alkaline conditions, followed by sedimentation and filtration. This shall include:

[14] Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197. JRC Publications Repository - Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products)

a) dewatering of the sludge before disposal; and

b) recovering of the solid metal residues in metal recovery plants.

The concentration of copper in the treated effluent shall be below 0.5 mg/l, while the concentration of zinc shall be below 2 mg/l.

- Description of how the effluent is treated.
- Results for copper and zinc measurements in the treated effluent and test reports for these.
- Appendix 4 completed and signed by the manufacturer of the silicone.

Background to O7 Emissions of copper and of zinc to water

Background for this requirement is presented only shortly as more information can be found from EU Ecolabel's Technical Report for Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups[15].

Inorganic impurities in wastewater arise from the use of different catalysts and other additives during silicon production. The main inorganic compounds present in the wastewater are copper and zinc. To minimise the concentration of copper and zinc in the effluent, the wastewater from PDMS production can be treated in two steps: a pre-treatment by precipitation/flocculation, and a sedimentation step to remove heavy metals.

O8 Emissions of CO_2

Emissions of CO_2 from the production of the silicone shall not exceed 6.58 kg per kg silicone, including emissions from the production of electricity (whether on-site or off-site).

CO_2 emissions shall include all sources of non-renewable energy used during the production of the silicone (whether on-site or off-site). CO_2 emission factors for other energy sources can be found in Annex VI to Regulation (EU) 2018/2066, whereas the CO_2 emission factors for grid electricity shall be calculated by factor 210 g CO_2/kWh. However, if the greenhouse gas emission intensity of electricity generation given by European Environment Agency* indicates a higher emission calculation factor for the country where the manufacturing is located, this shall be used.

* https://www.eea.europa.eu/en/analysis/indicators/greenhouse-gas-emission-intensity-of-1

- Data and detailed calculations for the CO_2 emissions from the production of silicone, showing the fulfilment of the requirement.
- Appendix 4 completed and signed by the manufacturer of the silicone.

[15] Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197. JRC Publications Repository - Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products)

Background to O8 Emissions of CO_2

Background for this requirement is presented only shortly as more information can be found from EU Ecolabel's Technical Report for Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups[16].

The production of silicone is related to significant amounts of energy; therefore, GHG emissions are one of the most important sustainability parameters. This requirement thus aims at reducing the emissions of CO_2 occurring during the production of the raw material (silicone). CO_2e emissions related to electricity are calculated by factor 210 g CO_2/kWh. However, if the greenhouse gas emission intensity of electricity generation given by European Environment Agency indicates a higher emission calculation factor for the country in which the manufacturing is located, this shall be used. The factor of 210 g CO_2/kWh is based on Greenhouse gas emission intensity of electricity generation in Europe[17].

5.4 Additives in polymer materials

This section covers requirements to additives, e.g., plasticisers, colourants/pigments and antioxidants, added to the masterbatch or compound. The requirement does not include the polymer production itself. Polymer materials are e.g. plastics (e.g. PP, PET), thermoplastic elastomers (TPE), silicone, synthetic latex and other rubbers.

The requirements in this section and accompanying appendices apply to all ingoing substances in the additives. Impurities are not regarded as ingoing substances and are exempt from the requirements. Ingoing substances and impurities are defined in section 5.1 Definitions, unless stated otherwise in the requirements.

Polymer materials used in adhesive or surface treatment are not covered by this section but are covered by section 5.5.

O9 Classification of ingoing substances in additives

Ingoing substances* in the additives used in the materials must not be classified with any of the hazards from CLP Regulation (EC) No 1272/2008 listed below.

** See definition in section 5.1.*

[16] Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197. JRC Publications Repository - Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products)

[17] https://www.eea.europa.eu/en/analysis/indicators/greenhouse-gas-emission-intensity-of-1

Table 1 Excluded hazards

Hazard Class	Hazard Category	Hazard Statement Code
Hazardous to the ozone layer	Ozone	H420
Specific target organ toxicity: Single or repeated exposure	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
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
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

*** Includes all classification variants (e.g. H350 also covers H350i).*

*** See also requirement O10 Excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.

Exemption applies to:

- When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, exemption is given to antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the part at maximum 0.5 % and assessed as safe and not detectable in an ISO 10993 evaluation.

- A safety data sheet (SDS) for all additives, prepared in accordance with Annex II of REACH Regulation (EC) No 1907/2006.

- Appendix 5 completed and signed by the manufacturer/supplier of the polymer material.

- Exemption for antioxidants classified as H361 in polyisoprene parts:
  - Data from licensee confirming that a replacement is required for regulatory reasons due to release of n-nitrosamine impurities from polyisoprene part(s).
  - Data from supplier showing that the level of such antioxidant does not exceed 0.5% in the polyisoprene material.
  - An evaluation according to ISO 10993 concluding that the use of an antioxidant (classified as above) in the polyisoprene part is safe, and that the antioxidant is

not released in detectable amounts from the medicinal product and medical device.

Background to O9 Classification of ingoing substances in additives

Nordic Ecolabelling strives to ensure that the health and environmental impact of the products are as low as possible. The requirements therefore make it clear that ingoing substances with the following classifications cannot be used in the Nordic Swan Ecolabelled product: Hazardous to the ozone layer, causes damage to organs, sensitising, carcinogenic, mutagenic, toxic for reproduction, endocrine disruptors, and persistent, bio accumulative/mobile and toxic.

The new CLP classifications for endocrine disruptors, PBT/vPvB and PMT/vPvM (environmental toxicity, persistency, mobility and bioaccumulation) are included. The inclusion of PMT and vPvM substances is crucial due to their persistence, mobility and potential impact on water quality. The new rules are in force as of 20 April 2023. From this day on, the Member States can make proposals for harmonized classification and labelling (CLH) with the new hazard classes and manufacturers, importers, downstream users and distributors can self-classify their substances and mixtures accordingly.

There are transitional periods from the entry into force of the Delegated Regulation, during which manufacturers, importers, downstream users and distributors are not yet required to classify their substances or mixtures according to the new hazard classes. During these periods, the new hazard classes can be applied on a voluntary basis. If applied to an ingoing substance it is excluded in these criteria.

The requirement is intended to exclude problematic substances that are not necessarily found in products on the market today.

When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, an exemption has been made for antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the polyisoprene part at maximum 0.5 % and assessed as safe and not detectable in an ISO 10993 evaluation. N-nitrosamines can be classified as e.g. carcinogenic cat 2. There are international safety regulations for n-nitrosamines with safety limits for daily exposure levels from medical devices. To fulfil the regulations for n-nitrosamines, antioxidants classified as toxic to reproduction cat 2 (H361) can be needed as additive in polyisoprene parts of the product. Although it is not desirable to replace one harmful substance with another, it is unfortunately seen as necessary in this case. However, it is important to note that the product part must be assessed as safe and that the antioxidants are not released in detectable amounts in an ISO 10993 evaluation.

O10 Excluded substances in additives

The following substances or substance groups must not be present as ingoing substances* in the additives used in the materials.

** See definition in section 5.1.*

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

  For D4, D5 and D6 in silicone polymers, see O5.

- PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt
- Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III

  Note: Substances moved to "Substances no longer on list" and not present on Lists I-III, are no longer excluded, except for those on sublist II where concern remains. Nordic Ecolabelling will assess these on a case-by-case basis.
- Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid)
- Azo dyes that may release aromatic amines with carcinogenic, reproductive toxicity or mutagenic properties listed in Regulation (EC) No 1907/2006, Annex XVII, Appendix 8
- Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA[18] for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity
- Per- and polyfluoroalkyl substances (PFAS)

  Defined as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).
- Halogenated organic compounds

  Exemption for: Pigments that meet the EU's requirement concerning colourants in food packaging under Resolution AP (89) point 2.5.

  Please note: Per- and polyfluoroalkyl substances (PFAS) are covered by their own bullet and are not included in the exemption.
- Heavy metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), zinc (Zn), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)

- Appendix 5 completed and signed by the manufacturer/supplier of the polymer material.

Background to O10 Excluded substances in additives

Substances on the REACH Candidate list of SVHC

The Candidate List identifies substances of very high concern which fulfil the criteria in article 57 of the REACH Regulation (EC 1907/2006). The list includes carcinogenic; mutagenic; and reprotoxic substances (CMR, categories 1A and 1B in accordance with the CLP Regulation); and PBT (persistent, bio accumulative and toxic) and vPvB (very persistent and very bio accumulative) substances (as defined in REACH Annex XIII). In addition, two more substance groups are included if they are of equivalent level of concern (ELoC) as the ones previously mentioned. These are endocrine disruptors and substances which are

[18] EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA).
[1] Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed https://echa.europa.eu/documents/10162/5e60f2fe-12d0-7f6b-5868-f199cfd7f984

environmentally hazardous without fulfilling the requirements for PBT or vPvB. Based on these adverse characteristics, Nordic Ecolabelling prohibits substances on the Candidate List. This means that we act ahead of the legislation and ban the substances before they are subject to authorisation and restriction in accordance with REACH.

PBT and vPvB substances in accordance with REACH Annex XIII

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

Potential or identified endocrine disruptors according to any of the EU member state initiative "Endocrine Disruptor Lists" List I; II; and III

Endocrine disruptors (EDs) are chemicals that alter the functioning of the endocrine (hormone) system and consequently cause adverse health effects. The term potential EDs is used for chemicals with properties that make them suspected to be E.Ds. The hormone system regulates many vital processes in living organisms and when normal signalling is disturbed, adverse effects may result. EDs raise high concern for their risk of causing serious negative impact on the environment as well as on human health specifically. Special concern is raised for effects on reproduction and development and about possible links to increases in public health diseases. While effects in wildlife populations have been confirmed, evidence is pointing to effects also in humans.

Phthalates

A number of phthalates are identified as endocrine disruptors and some of them are classified as reprotoxic. For these reasons several phthalates are included in the Candidate list.

Based on their hazardous properties, phthalates pose a threat to the environment and human health and there is a ban on this group of substances.

Azo dyes that may release aromatic amines with carcinogenic, reproductive toxicity or mutagenic properties

Aromatic amines released by azo dyes may be carcinogenic, reproductive toxicity or mutagenic. The aromatic amines are listed in Regulation (EC) No 1907/2006, Annex XVII, Appendix 8[19].

[19] Appendix 8: Entry 43 - Azocolourants - List of aromatic amines - ECHA

Bisphenols and bisphenol derivatives

Several bisphenols with the general bisphenol structure and 'bisphenol derivatives' which have constituents with structural properties common to bisphenols are now prohibited. Based on the potential for widespread use and available information on potential endocrine disruptors, reproductive toxicity and PBT/vPvB properties, 34 substances were identified in need for further regulatory risk management in EU[20].

Per- and polyfluoroalkyl substances (PFAS)

Per- and polyfluoroalkyl substances (PFAS) are used in many types of products due to their water and dirt repellent properties. These compounds constitute a group of substances that have highly problematic intrinsic hazardous properties. They are extremely persistent and accumulate in the body. They are spread all over the globe, from the large oceans to the Arctic, and are found in e.g. wild birds and fish and their eggs. Also, shorter chain compounds (2–6 carbon atoms) have been discovered in nature. The substances in this group are suspected to be endocrine disruptors, carcinogenic and to have a negative impact on the human immune system.

Halogenated organic compounds

Halogenated organic compounds, including short-chain chlorinated paraffins (C10-C13), medium-chain chlorinated paraffins (C14-C17), chlorophenols and dimethyl fumarate derivates, is a large group of substances that are harmful to both the environment and human health. They are often carcinogenic, highly toxic to aquatic organisms and very persistent to degradation. Halogenated flame retardants are included in this requirement.

Heavy metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), zinc (Zn), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)

Heavy metals refer to heavy and particularly environmentally harmful metals as specified in the requirement. They are prohibited/restricted because they are toxic to people and other organisms, both on land and in the aquatic environment[21,22,23]. Chromium VI is classified as: very toxic, CMR and harmful to the environment.

[20] Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed https://echa.europa.eu/documents/10162/5e60f2fe-12d0-7f6b-5868-f199cfd7f984
[21] Government official investigations: https://www.regeringen.se/49bbb3/contentassets/c0f10a5d57534a48b9b8641aba971a1e/bilagorna-6-9 (visited 2022-06-01)
[22] Government official investigations: https://www.regeringen.se/49bbb3/contentassets/c0f10a5d57534a48b9b8641aba971a1e/bilagorna-6-9 (visited 2022-06-01)
[23] Toxicity, mechanism and health effects of some heavy metals: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4427717/ (visited 2022-06-01)

5.5 Adhesive and surface treatment

This section covers requirements to adhesives and surface treatments used in or on the products and the various parts/components of the product. There are no requirements for chemicals used for maintenance of machines or in the production processes (such as lubricants, cleaning chemicals etc.).

The requirements in this section do not apply to adhesive or surface treatment used for packaging unless the packaging is part of the product.

The requirements in this section and accompanying appendices apply to all ingoing substances in the adhesives and surface treatments. Impurities are not regarded as ingoing substances and are exempt from the requirements. Ingoing substances and impurities are defined in section 5.1 Definitions, unless stated otherwise in the requirements.

O11 Classification of adhesive and surface treatment

Adhesives and surface treatments used in or on the product and the various parts/components of the product must not be classified with any of the hazards from CLP Regulation (EC) No 1272/2008 listed below.

Table 2 Excluded hazards

Hazard Class	Hazard Category	Hazard Statement Code
Hazardous to the aquatic environment	Aquatic Acute 1 Aquatic Chronic 1 Aquatic Chronic 2 Aquatic Chronic 3 Aquatic Chronic 4	H400 H410 H411 H412 H413
Hazardous to the ozone layer	Ozone	H420
Acute toxicity	Acute Tox. 1 or 2 Acute Tox. 1 or 2 Acute Tox. 1 or 2 Acute Tox. 3 Acute Tox. 3 Acute Tox. 3	H300 H310 H330 H301 H311 H331
Specific target organ toxicity: Single or repeated exposure	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
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

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

** Includes all classification variants (e.g. H350 also covers H350i).*

Exemptions apply to:

- The classifications "Hazardous to the aquatic environment" and H317 (Skin sens 1, 1A and 1B) is exempted if used in UV-cured acrylates-based adhesives cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.
- H317 is exempted for the hardener in 2-component adhesives that do not come into contact with the medicinal solution or the patient during treatment.

- A safety data sheet (SDS) for the adhesive and surface treatment, prepared in accordance with Annex II of REACH Regulation (EC) No 1907/2006.
- Appendix 6 completed and signed by the manufacturer/supplier of the adhesive or surface treatment.
- Exemption for UV-cured acrylates-based adhesives: Description of the application system and how workers are protected from exposure.

Background to O11 Classification of adhesive and surface treatment

The requirement concerns the classification of the adhesives and surface treatment used in the product and is set to reduce the use of chemical products that have a negative impact on the environment or to health. Adhesives can for instance be used between different layers of plastic materials in a bag or between different plastic components in an infusion treatment set. If the raw material is not by definition an adhesive but has the function of mellowing the materials for two parts to adhere to each other, it is interpreted as an adhesive within the scope of these criteria.

Surface treatment refers to all liquids that comes into direct contact with the product and is usually added to improve the function of the product. This could for example be lubricants and coatings whose main purpose is to ease insertion or improve the user experience. The surface treatment is often used as a barrier between the materials in the product and the human body or medicinal liquids. This means that it needs to fulfil strict health requirements to affect human health in the least possible way. Medicinal solutions that are not primarily added to improve the user experience of the product but are intended for injection or in any other way intended for medicinal treatment, is not included in this requirement.

UV-cured adhesives may be acrylates-based, and there is an increasing number of acrylates that are being classified as environmentally hazardous and skin sensitizing. During the curing process, the acrylates monomers react with each other, so they do not pose an environmental or health hazard in the finished cured adhesive nor in the final product. Therefore, an exemption has been made for UV-cured acrylates-based adhesives, but the exemption only applies if the classified chemical is used in a closed production system,

where there is no direct contact/exposure between worker and the chemical product. Using UV-curing have several advantages as it provides durable products and does not require solvents (low VOC-content).

H317 for the hardener in the 2-component adhesives that do not come into contact with the medicinal solution or the patient during treatment are exempted. In the cured state, this classification is no longer relevant, and hence the exposure risk is reduced. The requirement concerns the classification of the adhesive and not to classification of ingoing substances in the adhesive.

O12 Classification of ingoing substances in adhesive and surface treatment

Ingoing substances* in the adhesives and surface treatments used in or on the product and the various parts/components of the product must not be classified with any of the hazards from CLP Regulation (EC) No 1272/2008 listed below.

** See definition in section 5.1.*

Table 3 Excluded hazards

Hazard Class	Hazard Category	Hazard Statement Code
Hazardous to the ozone layer	Ozone	H420
Specific target organ toxicity: Repeated exposure	STOT RE 1	H372
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
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
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

** Includes all classification variants (e.g. H350 also covers H350i).*

*** See also requirement O13 Excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.*

Exemptions apply to:

- The classification H317 (Skin sens 1, 1A and 1B) is exempted if used in UV-cured acrylates-based adhesives cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.

- H317 is exempted for the hardener in 2-component adhesives that do not come into contact with the medicinal solution or the patient during treatment.
- Exemption is given for 2-component adhesives with isocyanates (classified H351), if the workers are not exposed during the production of the product and the isocyanates are cured in the finished product. Legislation for working environment must be fulfilled.
- Exemption is given to photoinitiators classified as H350 or H361 in UV-cured acrylates-based adhesives or in UV-cured surface treatment, if the chemical product is cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.

- Appendix 6 completed and signed by the manufacturer/supplier of the adhesive or surface treatment.
- Exemption for UV-cured acrylates-based adhesives: Description of the application system and how workers are protected from exposure.
- Exemption for 2-component adhesives with isocyanates (classified H351), a description of how the workers are protected and how the legislation for working environment is fulfilled.
- Exemption for photoiniators in UV-cured acrylates-based adhesives: Description of the application system and how workers are protected from exposure.

Background to O12 Classification of ingoing substances in adhesive and surface treatment

Nordic Ecolabelling strives to ensure that the health and environmental impact of the products are as low as possible. The requirements therefore make it clear that ingoing substances with the above-mentioned classifications cannot be used in the Nordic Swan ecolabelled product.

The new CLP classifications for endocrine disruptors, PBT/vPvB and PMT/vPvM (environmental toxicity, persistency, mobility and bioaccumulation) are included. The inclusion of PMT and vPvM substances is crucial due to their persistence, mobility and potential impact on water quality. The new rules are in force as of 20 April 2023. From this day on, the Member States can make proposals for harmonized classification and labelling (CLH) with the new hazard classes and manufacturers, importers, downstream users and distributors can self-classify their substances and mixtures accordingly.

There is an exemption for classification H317 in UV-cured acrylates-based adhesives and 2-component adhesives, see background under O11.

There is an exemption in the requirement for 2-component adhesives with isocyanates classified as H351. The exemption is given if the workers are not exposed during the production of the product, meaning that current legislation of working environment must be fulfilled, and the isocyanates are cured in the finished product. Emissions of isocyanate compounds or residues thereof in adhesives after curing will result in minimal exposure. However, it is important to emphasise that Nordic Swan Ecolabelled products must always meet the regulatory requirements for, among other things, the working environment which is of great importance when using isocyanate-containing products.

An exemption has been made for photoinitiators classified as H350 or H361. Photoinitiators are compounds that produce radicals when exposed to UV light. Then, these react with monomers and/or oligomers to initiate polymer chain growth. They are essential ingredients of all "modern" UV-curable adhesives, and the industry has not yet found substances that can replace them. The same technique is used for photoinitiators in UV-cured surface treatment; thus the exemption also applies to that. However, the exemption only applies if the classified chemical is used in a closed production system, where there is no direct contact/exposure to the chemical product.

O13 Excluded substances in adhesive and surface treatment

The following substances or substance groups must not be present as ingoing substances* in adhesives or surface treatment chemicals.

** See definition in section 5.1.*

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

  For D4, D5 and D6 in silicone polymers, see O14.

- PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt
- Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III

  Note: Substances moved to "Substances no longer on list" and not present on Lists I-III, are no longer excluded, except for those on sublist II where concern remains. Nordic Ecolabelling will assess these on a case-by-case basis.

- Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid)
- Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS No. 25013-16-5), butylated hydroxytoluene (BHT, CAS No. 128-37-0), alkylphenol ethoxylates (APEOs) and other alkylphenol derivates (APD)
- Per- and polyfluoroalkyl substances (PFAS)

  Defined as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).

- Halogenated organic compounds
- Heavy metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), zinc (Zn), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)
- Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA[24] for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity

[24] EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA).
[1] Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed https://echa.europa.eu/documents/10162/5e60f2fe-12d0-7f6b-5868-f199cfd7f984

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

  ** According to OECD test method 301 (A-F) or 310 or equivalent methods evaluated by an independent body and controlled by Nordic Ecolabelling.*

- Volatile aromatic compounds (VAC) (volatile organic compounds containing one or more benzene rings)
- Nanomaterials/-particles

  Nanomaterials/-particles are defined according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01)10: 'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

- Appendix 6 completed and signed by the manufacturer/supplier of the adhesive or surface treatment.

Background to O13 Excluded substances in adhesive and surface treatment

Substances on the REACH Candidate list of SVHC

The Candidate List identifies substances of very high concern which fulfil the criteria in article 57 of the REACH Regulation (EC 1907/2006). The list includes carcinogenic; mutagenic; and reprotoxic substances (CMR, categories 1A and 1B in accordance with the CLP Regulation); and PBT (persistent, bio accumulative and toxic) and vPvB (very persistent and very bio accumulative) substances (as defined in REACH Annex XIII). In addition, two more substance groups are included if they are of equivalent level of concern (ELoC) as the ones previously mentioned. These are endocrine disruptors and substances which are environmentally hazardous without fulfilling the requirements for PBT or vPvB. Based on these adverse characteristics, Nordic Ecolabelling prohibits substances on the Candidate List. This means that we act ahead of the legislation and ban the substances before they are subject to authorisation and restriction in accordance with REACH.

PBT and vPvB substances in accordance with REACH Annex XIII

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

Potential or identified endocrine disruptors according to any of the EU member state initiative "Endocrine Disruptor Lists" List I; II; and III

Endocrine disruptors (EDs) are chemicals that alter the functioning of the endocrine (hormone) system and consequently cause adverse health effects. The term potential EDs is used for chemicals with properties that make them suspected to be EDs. The hormone system regulates many vital processes in living organisms and when normal signalling is disturbed, adverse effects may result. EDs raise high concern for their risk of causing serious negative impact on the environment as well as on human health specifically. Special concern is raised for effects on reproduction and development and about possible links to increases in public health diseases. While effects in wildlife populations have been confirmed, evidence is pointing to effects also in humans.

Phthalates

A number of phthalates are identified as endocrine disruptors and some of them are classified as reprotoxic. For these reasons several phthalates are included in the Candidate list.

Based on their hazardous properties, phthalates pose a threat to the environment and human health and there is a ban on this group of substances.

Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS No. 25013-16-5), butylated hydroxytoluene (BHT, CAS No. 128-37-0), alkylphenol ethoxylates (APEO) and other alkylphenol derivates (APD)

The non-ionic APEO group of surfactants are produced in large volumes and their uses lead to widespread release to the aquatic environment. APEOs are highly toxic to aquatic organisms and degrade to more environmentally persistent compounds (APDs). Ethoxylated nonylphenol and several other alkylphenols are included in the Candidate List due to endocrine disrupting properties.

Per- and polyfluoroalkyl substances (PFAS)

Per- and polyfluoroalkyl substances (PFAS) are used in many types of products due to their water and dirt repellent properties. These compounds constitute a group of substances that have highly problematic intrinsic hazardous properties. They are extremely persistent and accumulate in the body. They are spread all over the globe, from the large oceans to the Arctic, and are found in e.g. wild birds and fish and their eggs. Also, shorter chain compounds (2–6 carbon atoms) have been discovered in nature. The substances in this group are suspected to be endocrine disruptors, carcinogenic and to have a negative impact on the human immune system.

Halogenated organic compounds

Halogenated organic compounds, including short-chain chlorinated paraffins (C10-C13), medium-chain chlorinated paraffins (C14-C17), chlorophenols and dimethyl fumarate

derivates, is a large group of substances that are harmful to both the environment and human health. They are often carcinogenic, highly toxic to aquatic organisms and very persistent to degradation. Halogenated flame retardants are included in this requirement.

Heavy metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), zinc (Zn), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)

Heavy metals refer to heavy and particularly environmentally harmful metals as specified in the requirement. They are prohibited/restricted because they are toxic to people and other organisms, both on land and in the aquatic environment[25, 26, 27]. Chromium VI is classified as: very toxic, CMR and harmful to the environment.

Bisphenols and bisphenol derivatives

Several bisphenols with the general bisphenol structure and 'bisphenol derivatives' which have constituents with structural properties common to bisphenols are now prohibited. Based on the potential for widespread use and available information on potential endocrine disruptors, reproductive toxicity and PBT/vPvB properties, 34 substances were identified in need for further regulatory risk management in EU[28].

Quaternary ammonium compounds, which are not readily aerobic biodegradable such as DTDMAC (CAS No. 68783-78-8), DSDMAC (CAS No. 107-64-7), DHTDMAC (CAS No. 61789-80-8) and DADMAC (CAS No. 7398-69-8)

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

Volatile aromatic compounds (VAC)

Volatile aromatic compounds (VACs) have a chemical structure with one or more benzene rings within the molecule, e.g. toluene, benzene and xylene. Some VACs are very stable and have a specific impact on the environment and human health, including damage to DNA. They are used as additives in plastics or as monomers in production of binders for paints (e.g., styrene).

[25] Government official investigations: https://www.regeringen.se/49bbb3/contentassets/c0f10a5d57534a48b9b8641aba971a1e/bilagorna-6-9 (visited 2022-06-01)
[26] Government official investigations: https://www.regeringen.se/49bbb3/contentassets/c0f10a5d57534a48b9b8641aba971a1e/bilagorna-6-9 (visited 2022-06-01)
[27] Toxicity, mechanism and health effects of some heavy metals: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4427717/ (visited 2022-06-01)
[28] Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed https://echa.europa.eu/documents/10162/5e60f2fe-12d0-7f6b-5868-f199cfd7f984

Nanomaterials/-particles

Nanomaterials[29] are a diverse group of materials under the size of 100 nm. Due to their small size and large surface area nanoparticles are often more reactive and may have other properties compared to larger particles of the same material. Further, different sizes, shapes, surface modifications and coatings can also change their physical and chemical properties. Nanoparticles can cross biological membranes and thus be taken up by cells and organs. One of the main concerns are linked to free nanoparticles, as some of these – when inhaled – can reach deep into the lungs, where the uptake into the blood is more likely.

There is concern among public authorities, scientists, environmental organisations, and others about the insufficient knowledge regarding the potential detrimental effects on health and the environment[30, 31 ,32]. Nordic Ecolabelling takes these concerns seriously and applies the precautionary principle to exclude potentially hazardous nanomaterials from products.

O14 Silicone in adhesive and surface treatment

This requirement applies to silicone and siloxanes used in adhesive or surface treatment, e.g. silicone oil.

Octamethylcyclotetrasiloxane, D4, (CAS 556-67-2), decamethylcyclopenta-siloxane, D5, (CAS 541-02-6) and dodecamethylcyclohexasiloxane, D6, (CAS 540-97-6) must not form part of the silicone material. The requirement does not apply to D4, D5 and D6 contained as impurities* up to a limit of 100 ppm for each substance. The amount of impurities must be tested according to test method for silicone fluids from CES-Silicones Europe[33] and the analysis laboratory shall fulfil the general requirements of standard EN ISO/IEC 17025 or have official GLP status.

** Impurities of D4, D5 and D6 are defined as residual products from the raw material production that can be found in the silicone material.*

- Appendix 6 or equivalent, completed and signed by the manufacturer/supplier of the silicone.
- Test report showing the amount of D4, D5 and D6 in the silicone material according to test method for silicone fluids from CES-Silicones Europe.
- Documentation for that the analysis laboratory fulfils the general requirements of standard EN ISO/IEC 17025 or have official GLP status.

[29] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/chemicals-nano-and-microplastics/nanomaterials/
[30] UNEP (2017) Frontiers 2017 Emerging Issues of Environmental Concern. United Nations Environment Programme, Nairobi. https://wedocs.unep.org/bitstream/handle/20.500.11822/22255/Frontiers_2017_EN.pdf
[31] Parliamentary Assembly of the Council of Europe (2013) Nanotechnology: balancing benefits and risks to public health and the environment.
http://assembly.coe.int/CommitteeDocs/2013/Asocdocinf03_2013.pdf
[32] SCCS (Scientific Committee on Consumer Safety) (2019) Guidance on the Safety Assessment of Nanomaterials in Cosmetics. SCCS/1611/19.
https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_233.pdf
[33] Quantification-of-residual-amounts-of-Volatile-Siloxanes-in-silicone-products_final.pdf

Background to O14 Silicone in adhesive and surface treatment

Silicone may be an alternative material to PVC in for instance catheters and dialysis machines[34]. Silicones can also be used in small parts, for instance as sealing. D4 (octamethylcyclotetrasiloxane, CAS No. 556-67-2), D5 (decamethylcyclopentasiloxane, CAS No. 541-02-6), D6 (dodecamethylcyclohexasiloxane, CAS No. 540-97-6) can be residues from polymerisation of silicone. D4, D5 and D6 are on the Candidate List[35] and are toxic to human health and with PBT and/or vPvB properties and gives rise to specific concern based on their potential to accumulate in the environment.

D4, D5 and D6 are restricted in REACH Annex XIII Entry 70[36] to less than 0.2 wt% of the respective substance in mixture after 6 June 2031 for devices defined in Article 1(4) of Regulation (EU) 2017/745. Devices for the care of stoma are derogated in REACH Annex XIII Entry 70. Hereby, the requirement goes beyond the regulation in EU.

CES-Silicones Europe has described methods for testing the amount of D4, D5 and D6 in silicone fluids, silicone elastomer products and fully formulated Personal Care Products, respectively[37]. The test for silicone fluids is relevant here and CES-Silicones Europe write[38]: "The purpose of this document is to provide a robust analytical method for quantification of low levels (~0.1%) of Cyclic Volatile Methyl Siloxanes (cVMS) in a variety of silicone products. This method uses common laboratory reagents, solvents, and equipment and should be easy to install in a laboratory equipped with a Gas Chromatograph with a Flame Ionization Detector (FID)". RISE (Research Institutes of Sweden) also refer to the test method from CES-Silicones Europe[39].

5.6 Packaging

O15 Packaging materials

The requirement applies to primary, secondary and tertiary packaging* unless otherwise stated.

Small parts such as stables, plastic strips, closure clips and cords are exempt from the requirement.

** See definition in section 5.1.*

Description of the packaging:

Description of all the materials (including type of polymer e.g. PP) in the primary, secondary and tertiary packaging including container, lid and label, respectively.

[34] Maria José Amaral, Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, HealthcareWithoutHarm, 31. Dcember 2014
[35] https://echa.europa.eu/da/-/ten-new-substances-added-to-the-candidate-list
[36] REACH Annex XIII Entry 70: 0ac1f453-ad41-4010-e837-a68273b896ca, Paragraph 6 (c).
[37] New analytical methods quantify siloxanes in silicone products - Silicones Europe Visited 25 September 2025.
[38] Quantification-of-residual-amounts-of-Volatile-Siloxanes-in-silicone-products_final.pdf Visited 25 September 2025.
[39] Analysis of siloxanes (D4, D5, D6) in textile and plastics | RISE Visited 25 September 2025.

Plastic:

Halogenated plastics (e.g. polyvinyl chloride (PVC) and polyvinylidene chloride (PVDC)), oxo-degradable plastic and biodegradable plastic must not be used in the packaging or labels.

Board and paper:

A minimum of 70 wt% of the wood raw material in the paper- and board packaging must be recycled* or must come from forests that are managed in accordance with sustainable forestry management principles established by FSC- or PEFC-schemes.

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

Metal:

Metals must not be used.

For primary packaging is exception of metal layer for barrier purposes to preserve a sterile barrier, minimize evaporation and/or improve product shelf life.

- Description of all the materials in the primary, secondary and tertiary packaging container, lid and label respectively.
- Appendix 7 completed and signed by the applicant.
- Appendix 8 completed and signed by the packaging manufacturer/supplier.
- For board and paper: Documentation showing that the quantity of certified wood raw material or recycled material is met, and the remaining proportion is covered by FSC/PEFC's control schemes (FSC controlled wood/PEFC controlled sources). This shall be specified in e.g. invoices or delivery notes from suppliers.

Background to O15 Packaging materials

Nordic Ecolabelling sets requirements for materials used in primary packaging, secondary packaging and tertiary packaging. Requirements are e.g. set for restriction of materials that hinder recycling and to promote a transition to materials with a lesser impact on the climate.

Halogenated plastics, such as polyvinyl chloride (PVC) and polyvinylidene chloride (PVDC) must not be used because of emissions of harmful organic chemicals from the entire production chain and challenges with waste management during production and end of life. Read more about Nordic Ecolabelling's position on PVC here: PVC.

Oxo-degradable and biodegradable plastics must not be used since they "contaminate" the other recycled plastics streams in the Nordic region. Read more about Nordic Ecolabelling's position on biodegradable plastics here: Biodegradable plastics. Bio-based plastic in PET, PE and PP can be recycled in the same way as fossil-based plastic in PET, PE, and PP.

For cardboard and paper minimum 70% by weight must be post-consumer recycled material or the packaging must be FSC-/PEFC-certified. The remaining proportion of wood raw material must be covered by the FSC/PEFC control schemes For more information about FSC, PEFC and Nordic Swan Ecolabelling's approach on forest, click here.

Metal must not be used for packaging as metal production is associated with a large climate and environmental impact. Exceptions are for any staples that can be used to staple cardboard or plastic together.

For primary packaging is exception of metal layer for barrier purposes to preserve the sterile barrier, minimize evaporation and/or improve product shelf life.

O16 Packaging design for recycling

Requirements for secondary packaging and tertiary packaging*:

The packaging must fulfil that:

- All components* 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. Different materials must not be glued or welded together.
- Must not contain intentionally added PFAS**, nor be surface treated with PFAS, either on the inside or on the outside of the packaging.
- Be marked with pictograms for recycling according to one of the following:
  - EUPicto (eupicto.com)
  - European standards (e.g. DIN 6120-2)
  - Mobius loop including material code
  - Recommendations from national recycling systems (such as Grønt Punkt)
  - From August 2028 (or 24 months from the date of entry into force***) pictograms according to Regulation (EU) 2025/40 must be used.
- If the packaging consists of several material types, it must be informed on the packaging that material types must be separated before sorting for recycling.

In addition, for plastic packaging:

- Carbon black pigments must not be added to plastic materials.

Requirement for primary packaging*:

Must not contain intentionally added PFAS**, nor be surface treated with PFAS, either on the inside or on the outside of the packaging.

** See definition in section 5.1.*

*** PFAS: as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).*

**** Regulation (EU) 2025/40 on packaging and packaging waste (Chapter III): "From 12 August 2028 or 24 months from the date of entry into force of the implementing acts adopted pursuant to paragraphs 6 or 7 of this Article, whichever is the latest …".*

For secondary packaging and tertiary packaging:

- Picture/artwork of packaging and description of how the packaging's components of different materials can be separated without using tools.
- Appendix 7 completed and signed by the applicant.
- Appendix 8 completed and signed by the packaging manufacturer/supplier.

For primary packaging:

- Declaration that the packaging has not been added nor treated with PFAS. Appendix 7 completed and signed by the applicant and Appendix 8 completed and signed by the packaging manufacturer/supplier.

Background to O16 Packaging design for recycling

The EU has adopted a circular economy action plan[40] that has a clear focus on recovery and recycling, particularly with regards to packaging material. Recyclability is an important step in shifting towards a circular economy. The requirement states that all parts of the packaging that consist of different materials must be possible to be separate without using a tool and sorted separately, to not hinder recycling.

Surface treatment of the sales packaging with PFAS or contents with PFAS can occur. PFAS constitute a group of substances that have highly problematic intrinsic hazardous properties. Therefore, such surface treatment and intentionally added PFAS is prohibited in packaging of Nordic Swan Ecolabelled products.

Marking of plastic parts is aimed at helping with sorting and recycling at end-of life. Marking helps correct sorting at the first line of the recycling process when end-users have to sort the discarded packaging.

The pictograms for recycling according to EUPicto (eupicto.com) is developed in the Nordic countries. DIN 6120-2 is a standard for marking of packaging and packaging materials for recycling purposes. Mobius loop is described in ISO 14021 and the material code can be according to e.g. EU Decision 97/129/EC[41]. Pictograms recommended by national recycling systems are also accepted, e.g. Grønt Punkt from Norway[42]. Näringslivets Producentansvar (NPA AB) from Sweden recommends using EUPicto[43]. EU are about to implement mandatory pictograms through Regulation (EU) 2025/40 on packaging and packaging waste[44] (Chapter III) from August 2028 or 24 months from the date of entry into force. After this date pictograms through Regulation (EU) 2025/40 must be used.

At the sorting facility manual sorting is in many cases replaced by a sorting technology using infrared light or sorting by density separation using a float/sink process. Carbon black causes problems in automated sorting plants for plastic, as the NIR (near infrared reflectance) detector cannot identify dark colours produced with carbon black.

[40] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Closing the loop – An EU action plan for the Circular Economy, COM(2015) 614 final, https://eur-lex.europa.eu/resource.html?uri=cellar:8a8ef5e8-99a0-11e5-b3b7-01aa75ed71a1.0012.02/DOC_1&format=PDF (Accessed 2023-11-24)
[41] Decision - 97/129 - EN - EUR-Lex
[42] https://www.grontpunkt.no/emballasjedesign/emballasjemerking
[43] https://npa.se/vart-erbjudande/mark-dina-forpackningar
[44] Regulation - EU - 2025/40 - EN - EUR-Lex

5.7 Safety

O17 Safety

Both product and parts must be safe to use and function well according to the EU Medical Devices Regulation (2017/745) or EU Medicinal Products Directive (2001/83/EC) with subsequent amendments and adaptations, as applicable.

For medical devices the CE marking shall be visible on the label followed by the identification number of the notified body.

- Medical device: Copy of the approval/certificate from a notified body.
- Medicinal product: Copy of the market authorisation from the reference member state or national authority.
- Medical device: The label showing CE marking and the identification number of the notified body.

Background to O17 Safety

For reasons of credibility, the applicant is required to submit documentation for compliance with the legislation regarding the safety and correct functioning of the medical device. The documentation is a copy of the approval/certificate from a notified body.

Products included in the EU Medical Devices Regulation (2017/745) shall bear the CE marking to indicate their conformity with the regulation and their adequacy to be sold in the European market. The notified body, responsible for the evaluation of the products compliance with the regulation, has an identification number that shall be included together with the CE marking on the label. For products included in the EU Medicinal Products Directive (2001/83/EC), CE marking is not applicable and therefore excluded from this part of the requirement.

5.8 Licence maintenance

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

O18 Customer complaints

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

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

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

Background to O18 Customer complaints

Nordic Ecolabelling requires that your company has implemented a customer complaint handling system. To document your company’s customer complaint handling, you must

upload your company's routine describing these activities. The routine should be dated and signed and will normally be part of your company's quality management system.

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

O19 Traceability

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

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

- Please upload your routine or a description.

Background to O19 Traceability

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

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

6 Environmental impact of medical devices in plastic or silicone

The relevant environmental impacts found in the life cycle of medical devices in plastic or silicone are set out in a MECO scheme (see below). A MECO describes the key areas that have impact on the environment and health throughout the life cycle of the product – including consumption of materials/resources (M), energy (E), chemicals (C) and other impact areas (O).

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

RPS scheme (Main)

Life cycle stages	Area and assessment of R, P, S (high, medium or low)	Comments
Raw materials		
Halogenated plastics (e.g. PVC)	Halogenated plastics (e.g. PVC): R: High P: Medium to high S: High	High RPS for requirements for halogenated plastics. Relevance: Halogenated plastics are typically used in the product types covered by the criteria. Plastic production is energy and resource intensive. The main problem in the production process of PVC is related to chlorine. PVC is manufactured in three separate stages: chlorine production (via the energy demanding chlor-alkali process), the production of the vinyl chloride monomer (VCM) and finally polymerisation into PVC. There are different methods for the final polymerisation into PVC. All PVC production is responsible for the generation of a certain number of emissions and waste streams[45], but use of best available techniques (BAT)[46] minimize the quantity of e.g. chlorine and halogenated organic compounds released to air and water. Technology employing mercury or asbestos are not BAT. The membrane cell technology is the preferred method from an environmental point of view. Halogenated plastics often contain plasticisers (e.g. phtalates) to make it flexible and soft, and many of these additives have problematic properties related to the environment and health. As the plasticisers are not bound to the polymer, they can leak out and be a source to harmful chemicals for humans and in nature. Halogenated plastics waste: Modern incineration plants in Europe have effective incineration, and the emissions of PAHs, benzo-a -pyrene, dioxins and furans have been significantly reduced. Nevertheless, not all the Nordic countries allow the incineration of used PVC due to the amount of air pollution control products needed for neutralization and the resulting solid waste generated during this process[47]. Potential: In many cases it is possible to replace halogenated plastic with other plastic types in the products. However, there may be product types where this is not possible (at least for now). There is therefore a medium to high potential for setting requirement that forbid the use of halogenated plastics. Steerability: The manufacturers have information if halogenated plastics are used in their products. Hereby there is a high steerability for that halogenated plastics are not used.
Other polymers (e.g. Polypropylene (PP), Polyethylene (PE) and Thermoplastic	Polymers (other than halogenated plastics): R: Medium to high P: Medium to high S: Medium	Medium to high RPS for requirements for polymers (other than halogenated plastics). Relevance: Different types of plastics are normally used in the product types covered by the criteria. Polymer/plastic production is energy and resource intensive.

[45] https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/JRC109279_LVOC_Bref.pdf
[46] https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/pol_bref_0807.pdf
[47] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/circular-economy-and-resource-efficiency/pvc/

elastomers (TPE))		Plastics contains additives, of which some can have problematic properties related to the environment and health. Potential: In most cases it will probably not be possible to replace one type of polymer with another (e.g. which has a lower energy consumption), because each type of polymer has specific properties needed in the product. However, there is potential for limiting harmful additives added to polymers/plastic. There is therefore a medium to high potential for setting requirements for additives. Steerability: The manufacturers of plastic know which additives are used in their products. However, this information is relative far back in the production chain and the plastic manufacturers may be unwilling to give this information. Therefore, there is a medium steerability for setting requirement for additives.
Biobased polymers (PP, PE and TPE)	Biobased polymers (other than halogenated plastics): R: Low to medium P: Low S: High	Low to medium RPS for requirements for biobased polymers. Relevance: There are a few examples of that biobased polymers used in the products[48]. Biobased polymers have reduced climate impact compared to virgin plastic. Social aspects and ethical aspects of agricultural raw material for biobased polymers (e.g. sugarcane) extraction. Potential: At present, biobased polymers are only used to a very limited extent in products. There is therefore a low potential for setting requirements for use of biobased polymers. Steerability: That polymers are biobased can be documented with various certification systems. Therefore, there is a high steerability for setting requirement for biobased polymers.
Natural rubber latex	Natural rubber latex: R: High P: Medium to high S: High	High RPS for requirements for natural rubber latex. Relevance: Natural rubber latex may be used in the product types covered by the criteria. Natural rubber latex may cause type I allergy. Land use for cultivation of natural rubber latex (e.g. may cause deforestation in the rainforest). Social aspects and ethical aspects of agricultural natural rubber latex extraction. Potential: In many cases it is possible to replace natural rubber latex with other polymer types in the products. There is therefore a medium to high potential for setting requirement that forbid the use of natural rubber latex. Steerability: The manufacturers know if natural rubber latex is used in their products. Hereby there is a high steerability for that natural rubber latex is not used.
Silicone	Silicone: R: High P: Medium to high S: Medium to high	Medium to high RPS for requirements for silicone. Relevance: Silicone may be used in the product types covered by the criteria. Silicone production is related to significant amounts of energy; therefore, GHG emissions are one of the most important sustainability parameters. Other main environmental issues

[48] Redefining Syringes: Carbon Footprint Reduction with RAUMEDIC's Green Syringe – RAUMEDIC

		associated with the production of silicones are dust and chlorides emissions to air, as well as emission of copper and zinc to water. Silicone may contain D4, D5 and D6, which are toxic to human health and the environment having PBT and/or vPvB properties. <u>Potential:</u> It is possible to produce silicone with technologies and treatments that reduce the environmental impacts. There is therefore a medium to high potential for setting requirement to silicone production. It is possible to make silicone of a quality with less D4, D5 and D6. There is therefore a high potential for setting requirement to the level of D4, D5 and D6 in silicone. <u>Steerability:</u> Production of silicone is fare back in the production chain of the medical device products, and therefore there is a medium steerability for setting requirement to silicone production. The manufacturers of silicone can document the amount of D4, D5 and D6 in the silicone. Hereby there is a high steerability for setting requirement that limits the amount of D4, D5 and D6.
Production		
Chemicals harmful to the environment and health	Chemical: R: High P: Medium to high S: Medium to high	<u>High RPS</u> for requirements for chemicals. <u>Relevance:</u> Halogenated plastics (e.g. PVC): Halogenated plastics often contain plasticisers (e.g. phtalates) to make it flexible and soft, and many of these additives have problematic properties related to the environment and health[49]. As the plasticisers are not bound to the polymer, they can leak out and be a source to harmful chemicals for humans and in nature. Halogenated plastics also contain other additives that may be harmful[50]. Other polymers (than halogenated plastics): Plastics contains additives, of which some can have problematic properties related to the environment and health. Silicon: Silicone may contain D4, D5 and D6, which are toxic to human health and the environment having PBT and/or vPvB properties. Coating/surface treatment and adhesive: Chemical treatments and adhesive used in or on the various parts/components of the product can have problematic properties related to the environment and health, e.g. PFAS. <u>Potential:</u> There is potential for limiting harmful chemical substances in materials used in the products. There is also potential for limiting harmful substances in chemical treatments and adhesive used in or on the various parts/components of the product. There is therefore a medium to high potential for setting requirements to reduce harmful chemicals. <u>Steerability:</u> The manufacturers of polymers/plastic know which additives are used in their products. However, this information is relative far back in the production chain and the plastic manufacturers may be unwilling to give this information. The manufacturers of coating/surface treatment and adhesive know which substances are in their products. Therefore, there is a medium to high steerability for setting requirements to reduce harmful chemicals.

[49] Rapport, The use of PVC in the context of a non-toxic environment, EU Kommisionen 2022
[50] Rapport, The use of PVC in the context of a non-toxic environment, EU Kommisionen 2022.

Energy consumption	Energy consumption: R: Low to medium P: Low S: Low to medium	Low RPS for requirements for energy consumption during manufacturing of products. The primary energy consumption is probably in the raw material phase. Knowledge about energy consumption during manufacturing of the products is low, but energy consumption at this phase is expected not to have a significant environmental impact. Potential: The potential is low to medium because of the expected relative low energy consumption. In addition, the product types covered by the criteria are very diverse which will make it very difficult to set a specific limit for energy consumption per product. Steerability: The steerability is low to medium because of difficult to separate energy consumption used for manufacturing from other activities at production sites.
Packaging design (materials and volume)	Packaging design: R: High P: Medium S: Medium	Medium to high RPS for requirements for packaging design. Design of packaging is relevant because it affects the amount of resources used for materials and transport. Materials that can be recycled will limit the consumption of energy and fossil resources. Potential: The potential is medium because design for recycling is seen as areas that can be improved. However, it is important that the products are still packed in a way that keep them safe from physical damage and contamination, and to obtain this will vary depending on the product type. Steerability: The steerability is medium because information about materials and combinations of materials are information that are known and for volume can be calculated. However, the function of the packaging and legislation for Medical devices must be fulfil limiting the possibility to change the packaging.
Use phase		
Chemicals harmful to the health	Chemical: R: High P: High S: Medium to high	High RPS for requirements for chemicals. Relevance: Potential exposure in case of migration of chemicals from polymers or from e.g. coating/surface treatments chemicals to human body or medicine. Halogenated plastics (e.g. PVC): Halogenated plastics often contain plasticisers (e.g. phtalates) to make it flexible and soft, and many of these additives have problematic properties related to the environment and health[51]. As the plasticisers are not bound to the polymer, they can leak out and be a source to harmful chemicals for humans and in nature. Halogenated plastics also contain other additives that may be harmful[52]. Other polymers (than halogenated plastics): Plastics contains additives, of which some can have problematic properties related to the environment and health. Silicon: Silicone may contain D4, D5 and D6, which are toxic to human health and the environment having PBT and/or vPvB properties. Coating/surface treatment and adhesive:

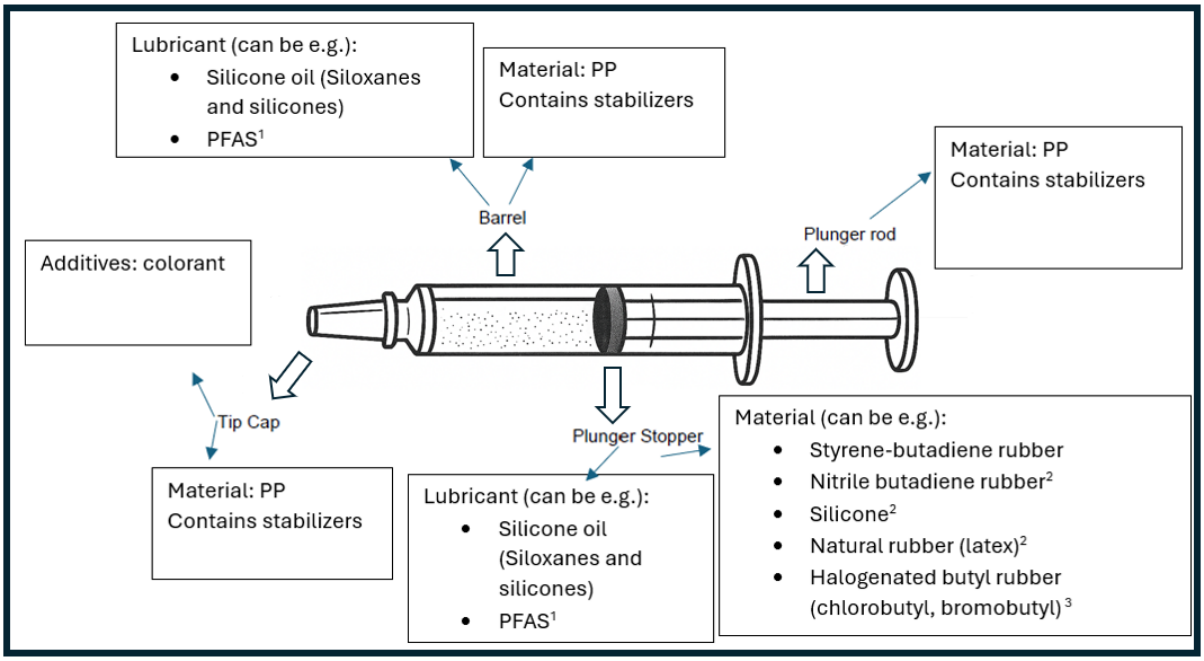
[51] Rapport, The use of PVC in the context of a non-toxic environment, EU Kommisionen 2022
[52] Rapport, The use of PVC in the context of a non-toxic environment, EU Kommisionen 2022.

		Chemical treatments and adhesive used in or on the various parts/components of the product can have problematic properties related to the environment and health, e.g. PFAS. Potential: There is potential for limiting harmful chemical substances in materials used in the products and in chemical treatments and adhesive used in or on the various parts/components of the product. There is therefore a high potential for setting requirements to reduce harmful chemicals. Steerability: The manufacturers of polymers/plastic know which additives are used in their products. However, this information is relative far back in the production chain and the plastic manufacturers may be unwilling to give this information. The manufacturers of coating/surface treatment and adhesive know which substances are in their products. Therefore, there is a medium to high steerability for setting requirements to reduce harmful chemicals.
End of life		
Halogenated plastics waste	Halogenated plastics (e.g. PVC): R: High P: Medium to high S: High	High RPS for requirements for halogenated plastics. Halogenated plastics waste: General are medical devices covered by these criteria are incinerated after use, regardless of which materials the consist of. Modern incineration plants in Europe have effective incineration, and the emissions of PAHs, benzo-a -pyrene, dioxins and furans have been significantly reduced. Nevertheless, not all the Nordic countries allow the incineration of used PVC due to the amount of air pollution control products needed for neutralization and the resulting solid waste generated during this process[53]. This also applies to halogenated butyl rubber (e.g. chlorobutyl, bromobutyl). Potential: In many cases it is possible to replace halogenated plastic with other plastic types in the products. However, there may be product types where this is not possible (at least for now). There is therefore a medium to high potential for setting requirement that forbid the use of halogenated plastics. Steerability: The manufacturers know if halogenated plastics are used in their products. Hereby there is a high steerability for that halogenated plastics are not used.
Recycling of packaging materials	Materials in the packaging R: High P: Medium to high S: High	High RPS for requirements for packaging design. Design of packaging is relevant because it affects the amount of resources used for materials. Materials that can be recycled will limit the consumption of energy and fossil resources. Potential: The potential is medium to high because design for recycling is seen as areas that can be improved. However, it is important that the products are still packed in a way that keep them safe from physical damage and contamination, and to obtain this will vary depending on the product type. Steerability: The steerability is high because information about materials and combinations of materials are information that are known.

[53] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/circular-economy-and-resource-efficiency/pvc/

RPS scheme for syringes

Figure A Prefilled syringe



1: https://www.efpia.eu/media/52ipvgfi/annex-1-efpia_sea_pfas_final.pdf

2: https://www.lindepolymer.com/products/syringe-plunger-stopper/

3: https://pda.org/docs/default-source/posters/universe-of-pre-filled-syringes-and-injection-devices/bredel-taras.pdf?sfvrsn=1a226092_3

The plunger stopper normally constitutes about 19 wt% of the syringe (when not filled).

RPS scheme for syringes

Life cycle stages	Area and assessment of R, P, S (high, medium or low)	Comments
Raw materials		
Silicone	Silicone: R: High P: Medium to high S: Medium to high	Medium to high RPS for requirements for silicone. (See details in Main-RPS)
Natural latex	Natural latex: R: High P: Medium to high S: High	High RPS for requirements for natural latex. (See details in Main-RPS)
Halogenated butyl rubber (e.g. chlorobutyl, bromobutyl)	Halogenated butyl rubber (e.g. chlorobutyl, bromobutyl): R: High P: High S: High	High RPS for requirements for halogenated butyl rubber. Halogenated butyl rubber waste has many of the same issues as PVC waste. See under “End of life”.

Production		
Chemicals harmful to the environment and health	Chemical: R: High P: Medium to high S: Medium to high	High RPS for requirements for chemicals. Relevance: Additives: Plastics and silicone contain additives, of which some can have problematic properties related to the environment and health. Silicon: Silicone may contain D4, D5 and D6, which are toxic to human health and the environment having PBT and/or vPvB properties. Coating/surface treatment and adhesive: Chemical treatments used in or on the various parts/components of the product can have problematic properties related to the environment and health, e.g. PFAS. Potential: There is potential for limiting harmful chemical substances in materials used in the products. There is also potential for limiting harmful substances in chemical treatments used in or on the various parts/components of the product. There is therefore a medium to high potential for setting requirements to reduce harmful chemicals. Steerability: The manufacturers of polymers/plastic know which additives are used in their products. However, this information is relative far back in the production chain and the plastic manufacturers may be unwilling to give this information. The manufacturers of coating/surface treatment and adhesive know which substances are in their products. Therefore, there is a medium to high steerability for setting requirements to reduce harmful chemicals.
Energy consumption	Energy consumption: R: Low to medium P: Low S: Low to medium	Low RPS for requirements for energy consumption during manufacturing of products. (See details in Main-RPS)
Packaging design (materials and volume) (Same for all product types)	Packaging design: R: High P: Medium S: Medium	Medium to high RPS for requirements for packaging design. (See details in Main-RPS)
Use phase		
Chemicals harmful to the environment and health	Chemical: R: High P: High S: High	High RPS for requirements for chemicals. Relevance: Silicone may contain D4, D5 and D6, which are toxic to human health and the environment having PBT and/or vPvB properties. Coating/surface treatment: Lubricants can be use on the plunger stopper and the inside of the barrel of the syringes. These lubricants can have problematic properties related to the environment and health, e.g. PFAS or D4, D5 and D6 from silicone oil. Potential: There is potential for limiting harmful chemical substances in silicone used in the products. There is also potential for limiting harmful substances in lubricants used on parts of

		the syringe There is therefore a medium to high potential for setting requirements to reduce harmful chemicals. Steerability: The amount of D4, D5 and D6 in the silicone can be tested. The manufacturers of lubricant know which substances are in their products. Therefore, there is high steerability for setting requirements to reduce harmful chemicals.
End of life		
Halogenated butyl rubber (e.g. chlorobutyl, bromobutyl)	Halogenated butyl rubber (e.g. chlorobutyl, bromobutyl): R: High P: High S: High	High RPS for requirements for halogenated butyl rubber. Relevance: Halogenated butyl rubber waste has many of the same issues as PVC waste. Toxic emissions during Incineration: Disposal via incineration can release halogenated toxicants such as dioxins and furans, which are harmful to both human health and the environment[54]. Modern incineration plants in Europe have effective incineration, and the emissions of PAHs, benzo-a -pyrene, dioxins and furans have been significantly reduced. However, solid waste is generated during the process of neutralization the air pollution [55]. Potential: In many cases it is possible to replace halogenated butyl rubber with other polymer types in the products. There is therefore a high potential for setting requirement that forbid the use of halogenated butyl rubber. Steerability: The manufacturers know if halogenated butyl rubber is used in their products. Hereby there is a high steerability for that halogenated butyl rubber are not used.
Recycling of packaging materials (Same for all product types)	Materials in the packaging R: High P: Medium to high S: High	High RPS for requirements for packaging design. (See details in Main-RPS)

RPS scheme for silicone products

Life cycle stages	Area and assessment of R, P, S (high, medium or low)	Comments
Raw materials		
Silicone	Silicone: R: High P: Medium to high S: Medium to high	Medium to high RPS for requirements for silicone. Relevance: Some product types covered by the criteria are mainly made of silicone (e.g. plugs). Silicone production is related to significant amounts of energy; therefore, GHG emissions are one of the most important sustainability parameters. Other main environmental issues associated with the production of

[54] https://onlinelibrary.wiley.com/doi/pdf/10.1002/tcr.202500022
[55] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/circular-economy-and-resource-efficiency/pvc/

		silicones are dust and chlorides emissions to air, as well as emission of copper and zinc to water Silicone may contain D4, D5 and D6, which are toxic to human health and the environment having PBT and/or vPvB properties. Silicones are produced in different qualities. Medical-grade silicone is non-toxic and highly biocompatible. Up to 0,1% (1000 ppm) of D4, D5 and D6 in products is allowed by EU legislation (applies from 6 June 2031) (Regulation (EU) 2017/745 on medical devices[56] and EU REACH Regulation (Annex XVII, Entry 70[57])). Potential: It is possible to produce silicone with technologies and treatments that reduce the environmental impacts. There is therefore a medium to high potential for setting requirement to silicone production. It is possible to make silicone of a quality with less D4, D5 and D6. There is therefore a high potential for setting requirement to the level of D4, D5 and D6 in silicone. There is therefore a high potential for setting requirement that the silicone is medical-grade silicone. Steerability: Production of silicone is fare back in the production chain of the medical device products, and therefore there is a medium steerability for setting requirement to silicone production. The amount of D4, D5 and D6 in the silicone can be tested. Hereby there is a high steerability for setting requirement that limits the amount of D4, D5 and D6. The manufacture of the silicone can declare that it is medical-grade silicone and include intended use (e.g. for implants, catheters, or medical devices) can be stated in the Technical Data Sheets (TDS) of the silicone material.
Production		
Chemicals harmful to the environment and health	Chemical: R: High P: Medium to high S: Medium to high	High RPS for requirements for chemicals. Relevance: Silicone may contain D4, D5 and D6, which are toxic to human health and the environment having PBT and/or vPvB properties. Silicone products may contain harmful additives. PFAS may be use as release agent during moulding of the silicone products. Potential: There is potential for limiting harmful chemical substances (D4, D5, D6, PFAS and additives) in silicone used in the products. There is also potential for limiting harmful substances in surface treatments and adhesive used in or on the various parts/components of the product. There is therefore a medium to high potential for setting requirements to reduce harmful chemicals. Steerability: The amount of D4, D5 and D6 in the silicone can be tested. The manufacturers of silicone know which additives are used in their products. However, this information is relative

[56] REGULATION (EU) 2017/ 745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - of 5 April 2017 - on medical devices, amending Directive 2001/ 83/ EC, Regulation (EC) No 178/ 2002 and Regulation (EC) No 1223/ 2009 and repealing Council Directives 90/ 385/ EEC and 93/ 42/ EEC
[57] Liste over begrænsninger - ECHA

		far back in the production chain and the silicone manufacturers may be unwilling to give this information. The amount of left over PFAS on the products can be tested for or have procedures (e.g. washing) to eliminate. Therefore, there is a medium to high steerability for setting requirements to reduce harmful chemicals.
Energy consumption	Energy consumption: R: High P: Medium to high S: Medium to high	Low RPS for requirements for energy consumption during manufacturing of products. The primary energy consumption is in the raw material phase. Knowledge about energy consumption during manufacturing of the products is low, but energy consumption at this phase is expected not to have a significant environmental impact. Energy used for production of silicone as raw material is relatively high. In addition, for medical-grade silicone specific production methods must be used, which use additional energy. See details under “Raw material”.
Packaging design (materials and volume) (Same for all product types)	Packaging design: R: High P: Medium S: Medium	Medium to high RPS for requirements for packaging design. (See details in Main-RPS)
Use phase		
Chemicals harmful to the health	Chemical: R: High P: High S: Medium to high	High RPS for requirements for chemicals. Relevance: Silicone may contain D4, D5 and D6, which are toxic to human health and the environment having PBT and/or vPvB properties. Silicone products may contain harmful additives. Chemical treatments and adhesive used in or on the various parts/components of the product can have problematic properties related to the environment and health. Lubricants are often used on intravaginal incontinence aid and anal plugs, and dissolvable film may also be used on the surface of the products[58]. These lubricants and dissolvable film do normally not contain harmful substances, but by including these in the requirements also very small amounts of harmful substances are excluded which are not covered by regulations. Potential: There is potential for limiting harmful chemical substances in materials used in the products and in chemical treatments and adhesive used in or on the various parts/components of the product. There is therefore a high potential for setting requirements to reduce harmful chemicals. Steerability: The amount of D4, D5 and D6 in the silicone can be tested. The manufacturers of silicone know which additives are used in their products. However, this information is relative far back in the production chain and the silicone manufacturers may be unwilling to give this information. The manufacturers of lubricant/coating/surface treatment and adhesive know which substances are in their products. Therefore, there is a medium to high steerability for setting requirements to reduce harmful chemicals.

[58] Products for faecal incontinence

End of life		
Silicone waste	Silicone: R: Low P: Low S: Low	Low RPS for requirements for silicone. Silicone waste: Loss of resources: Medical disposable products are mainly sent for incineration due to contaminated waste. Potential: Lack of widespread recycling infrastructure for silicone waste. There is therefore a low potential for setting requirement that silicone waste shall be recycled or that recycled silicone shall be used in the products. Steerability: There is a low steerability because of lack of recycling infrastructure for silicone waste and that end-user send used products to material recycling.
Recycling of packaging materials (Same for all product types)	Materials in the packaging R: High P: Medium to high S: High	High RPS for requirements for packaging design. (See details in Main-RPS)

MECO scheme (Main)

	Raw material	Production	Use	End of life
Material	Extraction of fossil raw materials lead to GHG emissions, land use change, pollution and biodiversity loss. [59] **Halogenated plastics (e.g. PVC)[60]** Ethylene (crude oil/natural gas), salt (NaCl). Fossil raw material. **Natural latex** Latex sap tapped from the rubber tree.[61] Non-fossil raw material. **Silicone** Silica [SiO_2] (quartz sand), methyl chloride. Mix of fossil and non-fossil raw material. Octamethylcyclotetrasiloxane, D4, decamethylcyclopentasiloxane, D5 and dodecamethylcyclohexasiloxane, D6 can be residues from polymerisation of silicone. D4, D5 and D6 are on the Candidate List.[62] **Polypropylene (PP)** Byproduct of petroleum refining and natural gas processing, polymerized to form polypropylene.[63] Fossil raw material. **Polyethylene (PE)** Produced by cracking hydrocarbons like naphtha or ethane, then polymerized to form polyethylene. Fossil raw material. **Thermoplastic elastomers (TPE)** Styrenic Block Copolymers (e.g., SBS, SEBS): styrene and butadiene or isoprene monomers. Often fossil raw material. Thermoplastic Polyolefins (TPOs): Blends of polypropylene (PP) and rubber. Fossil raw material.	(Polymers and additives are manufactured into desired shapes/sizes).	Mostly single-use due to sterility requirements (a few product types are reusable).	Loss of resources: Medical disposable products are mainly sent for incineration due to contaminated waste. Material recycling is at present non-existent but may be possible in the future.

[59] Riskanalys för Medicintekniska förbrukningsartiklar | Upphandlingsmyndigheten
[60] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/circular-economy-and-resource-efficiency/pvc/
[61] Hevea Brasiliensis - an overview | ScienceDirect Topics
[62] All news - ECHA
[63] The Synthetic Rubber Production Process | Aquaseal Rubber

<table>
<tr>
<td></td>
<td>Biobased polymer (e.g. PP, PE and TPE)
Renewable resources like sugarcane or corn, converted into ethylene or propylene for polymerization into biobased plastics. Non-fossil raw material.
Rubber (other than natural latex and TPE)
Petrochemical monomers if synthetic (fossil). Plant-derived if natural rubber (non-fossil).

Packaging:
Common materials for packaging are board and plastic (e.g. PP, PE, PET). Some primary packaging in plastic may need metal layer for barrier purposes to preserve a sterile barrier, minimize evaporation and/or improve product shelf life.</td>
<td></td>
<td></td>
<td>Packaging:
Packaging can be designed so that a large proportion of the materials can be recycled.</td>
</tr>
<tr>
<td>Energy</td>
<td>Plastic manufacturing is energy-intensive and if the energy comes from fossil sources manufacturing has a major negative climate impact.[64]
Energy for extraction/production of raw materials[65]:
<table>
<tr><th>Material</th><th>CO_2-eq [kg]</th><th>Energy [MJ]</th></tr>
<tr><td>PVC</td><td>2.62</td><td>51.42</td></tr>
<tr><td>PP</td><td>3.14</td><td>80.60</td></tr>
<tr><td>PE (HDPE)</td><td>2.86</td><td>77.80</td></tr>
<tr><td>TPE*</td><td>3.14</td><td>80.60</td></tr>
<tr><td>Silicone (PDMS)</td><td>9.53</td><td>98.77</td></tr>
<tr><td>Natural latex</td><td>2.67</td><td>83.38</td></tr>
<tr><td>Other rubber (synthetic)</td><td>3.25</td><td>80.59</td></tr>
</table>
*The database does not contain any independent “thermoplastic elastomer production”. PP granules have therefore been chosen as the closest mass-produced analogue.</td>
<td>Energy source (renewable/fossil) effects footprint.

Electricity/energy of the manufacturing processes[6] (extrusion/calendering):

PVC
<table>
<tr><th>Process</th><th>CO_2-eq [kg]</th><th>Energy [MJ]</th></tr>
<tr><td>extrusion, plastic pipes</td><td>0.48</td><td>5.83</td></tr>
<tr><td>calendering, rigid sheets</td><td>0.49</td><td>6.20</td></tr>
<tr><td>injection moulding</td><td>1.43</td><td>20.70</td></tr>
</table>
PP
<table>
<tr><th>Process</th><th>CO_2-eq [kg]</th><th>Energy [MJ]</th></tr>
</table></td>
<td>(No energy use during use phase).</td>
<td>Loss of resources: Medical disposable products are mainly sent for incineration due to contaminated waste. However, when plastic components are incinerated, the released energy can be recovered and utilized for heat and electricity generation.</td>
</tr>
</table>

[64] Riskanalys för Medicintekniska förbrukningsartiklar | Upphandlingsmyndigheten
[65] Based on Ecoinvent - APOS Cumulative LCIA v 3.11 (reference flow = 1 kg)

		injection moulding 1.43 20.70 extrusion, plastic film 0.61 7.61 blow moulding 1.49 20.00 extrusion of plastic sheets & thermoforming, inline 0.90 11.33 stretch blow moulding 1.95 24.45 **PE (HDPE)** Process / CO_2-eq [kg] / Energi [MJ] extrusion, plastic pipes 0.48 5.83 blow moulding 1.49 20.00 injection moulding 1.43 20.70 extrusion, plastic film 0.61 7.61 **TPE (proxy)** Process / CO_2-eq [kg] / Energi [MJ] injection moulding 1.43 20.70 extrusion, plastic film 0.61 7.61 **Silicone (PDMS)** Process / CO_2-eq [kg] / Energi [MJ]		

	Packaging: Metal	injection moulding (generic) 1.43 20.70 extrusion, plastic pipes (generisk proxy) 0.48 5.83 There are no silicone-specific extrusion datasets in v 3.11; the generic plastic processes are used as a best alternative. **Natural rubber latex** Process / CO_2-eq [kg] / Energi [MJ] seal production, natural rubber based (proxy for latex-dypning/formning) 2.43 73.09 **Synthetic "Other rubber"** Process / CO_2-eq [kg] / Energi [MJ] seal production, natural rubber based (proxy) 2.43 73.09 injection moulding (generisk) 1.43 20.70 **Packaging:** Metal has a high energy consumption.		**Packaging:** Metal can be recycled.
Chemicals	Emissions during extraction and refining processes of raw materials e.g. VOC, SO_x, NO_x.	Polymer manufacturing: Emissions/contents of VOCs, monomers (e.g., styrene, 1,3-butadiene, acrylonitrile, D4, D5, D6), PAHs, solvents, and additives (e.g. plasticizers). **Plastic granules:** Emissions/contents of VOCs, particulate matter, acid gases and lubricants.	Health and environment issues: Exposure of chemicals from ingoing substances (phthalates, CMR substances) and impurities can harm both	Emissions from incineration: Particulates, PAHs and VOCs. Especially for PVC: Higher degree of air

			environment and health.[66] Natural latex can cause allergic reactions.[67]	pollution (PAHs, benzo-a-pyrene, dioxins, furans) during incineration.[68]
Other	Social aspects and ethical aspects of agricultural raw material (e.g. natural latex, sugarcane for biobased polymers) and fossil raw material extraction. **Agricultural of raw material for biobased plastics (natural latex, biobased polymers etc.) can lead to:[69]** - Landuse change (e.g. from food production to production of agricultural raw material for biobased polymers) - Loss of biodiversity (e.g. deforestation of native rainforest to produce agricultural raw materials) - Non sustainable agriculture (e.g. use of pesticides, artificial fertilizer and water)	**Transports:** Global supply chains contribute to climate change.[70] Transportation results in emissions of SOx, NOx, CO_2.		

MECO for Halogenated butyl rubber (Syringes)

	Raw material	Production	Use	End of life
Material	Extraction of fossil raw materials and raw material production lead to unwanted GHG emissions, land use change, water consumption, acidification, ecotoxicity, human toxicity and eutrophication. See more in other below. **Halogenated butyl rubber**	(Polymers and additives are manufactured into desired shapes/sizes). Many modern rubber formulations employed in the pharmaceutical industry for closures (stoppers and plungers), employ halobutyl rubbers as the base. Halobutyl rubbers	Mostly single-use due to sterility requirements (a few product types are reusable). HBR's durability and impermeability reduce	Loss of resources: Medical disposable products are mainly sent for incineration due to contaminated waste. Material recycling is at present restricted but may be possible in the future.

[66] background-document_098_disposable-bags-tubes-and-accessories-for-health-care-098_english.pdf
[67] Lateksallergi | NAAF
[68] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/circular-economy-and-resource-efficiency/pvc/
[69] Brochure from FSC, 2017: FSC®-certified natural rubber: Deforestation free, socially responsible
[70] Riskanalys för Medicintekniska förbrukningsartiklar | Upphandlingsmyndigheten

	Halogenated butyl rubber is derived from butyl rubber (IIR)—a copolymer of isobutylene and isoprene—by introducing halogen atoms (typically bromine or chlorine) to enhance vulcanization and compatibility with other rubbers. This modification improves: Gas impermeability, heat and chemical resistance, vulcanization speed and efficiency[71]. These properties make HBR ideal for tire inner liners, pharmaceutical closures, and chemical-resistant linings. See more details for HBR production[72]. Recycled halogenated butyl rubber: Mechanical Recycling: HBR can be shredded and reused in low-grade applications, but performance may degrade. Chemical Recycling: Techniques like pyrolysis can break down HBR into reusable components, but these methods are energy-intensive and costly. Devulcanization: Breaking sulfur cross-links to allow reprocessing is possible but technically challenging and not widely adopted[73].	typically have lower levels of extractables compared to other rubbers, and excellent resistance to permeation by water and oxygen.	leakage and extend product life, which can be environmentally beneficial. However, extractables and leachables from rubber oligomers (especially halogenated ones) may pose toxicity risks in sensitive applications like drug packaging[74].	
Energy	Energy Consumption: Halogenated butyl rubber is produced by halogenating butyl rubber, which itself is a copolymer of isobutylene and isoprene. The halogenation step (typically with chlorine or bromine) adds significant energy and environmental burdens: Energy Intensity: The production of HBR is energy-intensive, especially due to: Petrochemical feedstock extraction (isobutylene, isoprene). Halogenation reactions requiring controlled conditions and additional reagents. Stabilization and purification steps to prevent degradation. Climate emission profile for HBR and other rubbers[75],[76].	Energy source (renewable/fossil) effects footprint. Electricity/energy of the manufacturing processes.	(No energy use during use phase).	Loss of resources: Medical disposable products are mainly sent for incineration due to contaminated waste. However, when plastic components are incinerated, the released energy can be recovered and utilized for heat and electricity generation.

[71] https://page-one.springer.com/pdf/preview/10.1007/978-94-009-8108-9_6
[72] www.exxonmobilchemical.com
[73] https://www.sybutylseal.com/blog/how-to-dispose-of-used-butyl-rubber-strip-39346.html
[74] https://www.nelsonlabs.com/wp-content/uploads/2022/03/2022-03-31_5_Presentation-Piet-Christiaens_Rubber-Oligomers.pdf
[75] Rubber Chronicle 19: CO2e Emissions of Natural Rubber, Neoprene, Geoprene and SBR | YULEX®
[76] Towards sustainable Elastomers from CO2 Towards sustainable Elastomers from CO2 Utilization for Rubbers

	Total climate and energy output[77]: Material / CO_2-eq [kg]/kg / Energy [MJ]/kg HBR* / > 6 / > 100 Syntethic rubber* / 3.5 - 6.5 / 70–110 Natural rubber*[78] / 0,4 / 50-80 * The numbers are uncertain since little specific or comparative LCA studies exist.			
Chemicals	Emissions during extraction and refining processes of raw materials e.g. VOC, PAH, furans and dioxine, SO_x, NO_x.	Polymer manufacturing: Emissions/contents of VOCs, PAH's, furan, dioxin, solvents, additives and purification.	Health and environment issues: Exposure of chemicals from ingoing substances and impurities can harm both environment and health.[79]	Emissions from incineration: Particulates, PAHs and VOCs. Halogenated butyl rubber is not biodegradable, and its disposal typically involves landfilling or incineration. Toxic emissions during Incineration: Disposal via incineration can release halogenated toxicants such as dioxins and furans, which are harmful to both human health and the environment[80].

[77] https://link.springer.com/article/10.1007/s13762-024-05678-6
[78] https://link.springer.com/article/10.1007/s13762-024-05678-6#:~:text=The%20uncertainty%20analysis%20reveals%20that,sensitive%20to%20changes%20in%20yield
[79] background-document_098_disposable-bags-tubes-and-accessories-for-health-care-098_english.pdf
[80] https://onlinelibrary.wiley.com/doi/pdf/10.1002/tcr.202500022

MECO for Silicone

	Raw material	Production	Use	End of life
Material	Reliance on non-renewable resources like quartz and petrochemicals. **Silicone** Silica [SiO_2] (quartz sand), methyl chloride. Mix of fossil and non-fossil raw material. Octamethylcyclotetrasiloxane, D4, decamethylcyclopentasiloxane, D5 and dodecamethylcyclohexasiloxane, D6 can be residues from polymerisation of silicone. D4, D5 and D6 are on the Candidate List.[81] Packaging materials are not evaluated in this MECO but might have impact but to lesser extent.	(Polymers and additives are manufactured into desired shapes/sizes). The primary difference between the traditional silicone and the medical-grade silicone lies in the way they polymerize. The traditional silicone is generally made using Peroxide Curing System. This process results in an acidic by-product making the silicone non-biocompatible and harmful to the body. On the other hand, medical-grade silicone is made using the Addition Cure or Platinum Cure System. It uses platinum salts and thus forms a non-reactive, biocompatible, and hypoallergenic material. It does not generate any toxic byproducts and therefore is safe to use. Also, LSR injection moulding is the optimal choice when manufacturing medical-grade silicone. While the process is expensive, it ensures the silicone is safe and effective[82].	Mostly single-use due to sterility requirements (a few product types are reusable). Catheters, implants, tubing, respiratory masks, hearing aids[83].	Loss of resources: Medical disposable products are mainly sent for incineration due to contaminated waste. Reusable medical devices require the re-user (i.e., hospital, healthcare provider) to have sterilization equipment (as, e.g., autoclaves and ultrasonic equipment). In this case, the devices are cleaned onsite by the re-user and may be reused multiple times. Reprocessed medical devices are sterilized by a third-party located outside the point-of-use (Unger 2015)[84]. Lack of widespread recycling infrastructure for silicone waste. Accumulation in landfills may lead to long-term environmental pollution.

[81] All news - ECHA
[82] Medical Grade Silicone: A Comprehensive Guide - Lanxin
[83] Advancing the circular economy of healthcare plastics - A systematic_review_2025
[84] https://www.researchgate.net/publication/346347311_Assessment_of_the_environmental_impacts_of_medical_devices_a_review

<table>
<tr>
<td>Energy</td>
<td>High energy consumption during manufacturing contributes to greenhouse gas emissions.

Energy for extraction/production of raw materials[85]:
<table>
<tr><th>Material</th><th>CO_2-eq [kg]</th><th>Energy [MJ]</th></tr>
<tr><td>Silicone (PDMS)</td><td>9.53</td><td>98.77</td></tr>
</table>

Potential for chemical recycling. Chemical recycling involves the depolymerization of silicone waste into oligomers, which can then be used to produce virgin-grade silicone. While this sector of the recycling industry is still in its infancy—it is estimated that 35,000 to 45,000 metric tons of silicone waste will be chemically recycled worldwide in 2024—an increasing number of companies are beginning to explore the implementation of closed-loop systems to recycle silicones[86].</td>
<td>Energy source (renewable/fossil) effects footprint.
Electricity/energy of the manufacturing processes[87] (extrusion/calendering):
Silicone (PDMS)
<table>
<tr><th>Process</th><th>CO_2-eq [kg]</th><th>Energi [MJ]</th></tr>
<tr><td>injection moulding (generic)</td><td>1.43</td><td>20.70</td></tr>
<tr><td>extrusion, plastic pipes (generisk proxy)</td><td>0.48</td><td>5.83</td></tr>
</table>
There are no silicone-specific extrusion datasets in v 3.11; the generic plastic processes are used as a best alternative.</td>
<td>(No energy use during use phase).</td>
<td>Loss of resources: Medical disposable products are mainly sent for incineration due to contaminated waste. However, when plastic components are incinerated, the released energy can be recovered and utilized for heat and electricity generation.</td>
</tr>
<tr>
<td>Chemicals</td>
<td>Emissions during extraction and refining processes of raw materials e.g. VOC, SO_x, NO_x.</td>
<td>The environmental issues associated with the production of silicones are dust and chlorides emissions to air, as well as emission of copper and zinc to water[88].

Polymer manufacturing:
Emissions/contents of VOCs, monomers (e.g., D4, D5, D6), solvents and additives. Mercury emissions from production waste.</td>
<td>Health and environment issues: Monomers of D4, D5 and D6 pose a risk for endocrine disruption, reproductive toxicity and respiratory issues[89]
Exposure of chemicals from ingoing substances and impurities can harm both environment and health.[90]</td>
<td>Emissions from incineration: Particulates, monomers, gaseous emissions like VOC, SOx, NOx and CO2.</td>
</tr>
</table>

[85] Based on Ecoinvent - APOS Cumulative LCIA v 3.11 (reference flow = 1 kg)
[86] Chemical Recycling of Silicones—Current State of Play (Building and Construction Focus)
[87] Based on Ecoinvent - APOS Cumulative LCIA v 3.11 (reference flow = 1 kg)
[88] Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197. JRC Publications Repository - Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products)
[89] https://www.newtopsilicone.com/understanding-the-toxicology-and-health-impacts-of-silicones/
[90] background-document_098_disposable-bags-tubes-and-accessories-for-health-care-098_english.pdf

7 Areas without requirements

Energy requirements:

It has been investigated if it would be possible to set energy requirements but decided not to, except for products made mainly of silicone. The reason for this is that the main energy consumption seems to be in the raw material phase. Knowledge about energy consumption during manufacturing of the products is low, but energy consumption at this phase is expected not to have a significant environmental impact. Setting energy requirements on the raw material phase will be very difficult because it is long back in the manufacturing chain and the possibilities for the license applicant to influence or set demands regarding energy consumption is limited.

For products made mainly of silicone (80 wt% or more) it was decided to set requirements for CO_2 emissions, see requirement O8.

For more details about energy, please see RPS and MECOs in section 6.

Quality:

This was investigated if it could be possible to set quality requirements to the products. However, it was decided not to do so because good quality can be several different parameters depending on the product type and the specific function within a product type. Quality requirements may be investigated more in the next generation of the criteria.

8 Criteria version history

Nordic Ecolabelling adopted version X.X of the criteria for XX on DAY MONTH YEAR. The criteria are valid until DAY MONTH YEAR.

9 How to apply and regulations for the Nordic Ecolabelling

Application and costs

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

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

Licence validity

The Nordic Swan Ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be prolonged or adjusted, in which case the licence is automatically prolonged, and the licensee informed.

Revised criteria shall be published at least one year prior to the expiry of the present criteria. The licensee is then offered the opportunity to renew their licence.

Responsibility for Compliance with Applicable Legislation

When applying for the Nordic Swan Ecolabel, the applicant/licensee confirms compliance with all current regulatory requirements related to both the exterior and interior environment in connection with the production and handling of the product(s) covered by the application. Furthermore, the applicant declares that all applicable regulatory requirements within the Nordic region are met for the product(s). Compliance with these regulations is a prerequisite for obtaining a licence.

On-site inspection

In connection with handling of the application, Nordic Ecolabelling normally performs on-site inspection visit/-s to ensure adherence to the requirements. For such an inspection, data used for calculations, original copies of submitted certificates, test records, purchase statistics, and similar documents that support the application must be available for examination.

Queries

Please contact Nordic Ecolabelling if you have any queries or require further information. See contact info in the beginning of this document. Further information and assistance (such as calculation sheets or electronic application help) is available. Visit the relevant national website for further information.

Follow-up inspections

Nordic Ecolabelling may decide to check whether the medical device fulfils Nordic Ecolabelling requirements during the licence period. This may involve a site visit, random sampling, or similar test.

The licence may be revoked if it is evident that the medical device does not meet the requirements.

Random samples may also be taken in-store and analysed by an independent laboratory. If the requirements are not met, Nordic Ecolabelling may charge the analysis costs to the licensee.

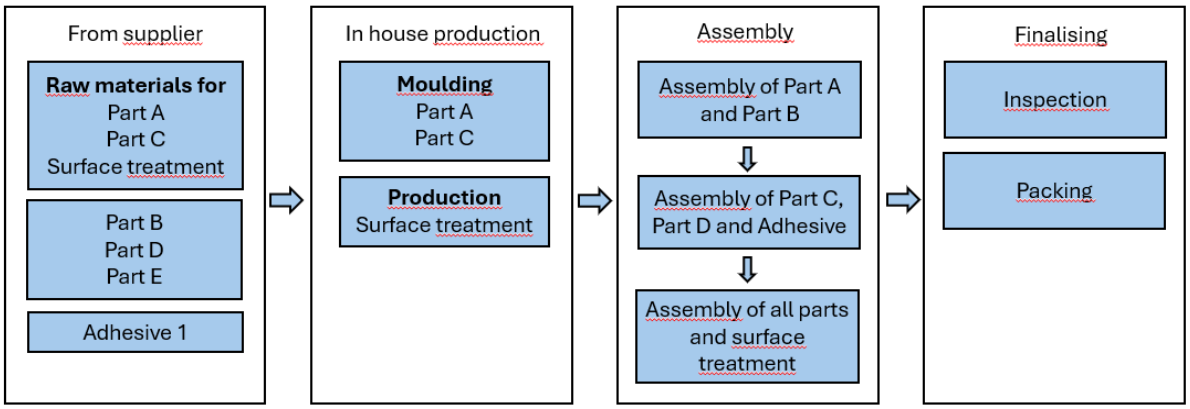
Regulations for the Nordic Ecolabelling of products

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

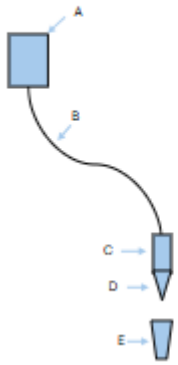
More information on graphical guidelines, regulations and fees can be found at www.nordic-swan-ecolabel.org/regulations

Appendix 1 Flowchart - Manufacturing process for the product

Example of flow chart:



Picture/drawing of the product



Code	Part of the product
Part A	
Part B	
Part C	
Part D	
Part E	
-	Adhesive
-	Surface treatment

Appendix 2 Manufacturers description of the product

General information of the product

O1 Description of the product and manufacturing process		
Trade name of the product:	Name:	
Product category (see product group definition):	Masks	
	Flexible tubes	
	Bags	
	Plugs	
	Syringes	
	Tubes	
Type of product (e.g. anaesthesia mask, tracheal tube, drainage bag):	Type:	

	YES	NO
Is the product in accordance with the EU Medical Devices Regulation (2017/745)?		
Is the product in accordance with the EU Medicinal Products Directive (2001/83/EC)?		
Is the product surface treated?		
Are any adhesives used in the product?		

Total weight of the product* (g): *Excluding weight of fluids in dialysis bags and prefilled syringes	Weight:

O2 Halogenated plastics	**YES**	**NO**
Does the product contain any halogenated plastics?		
O3 Halogenated butyl rubber		
Does the product contain any halogenated butyl rubber?		
O4 Natural rubber latex		
Does the product contain any natural rubber latex?		

Components of the product

Code (from flow-chart)	Component of the product/trade name	Material type (e.g. PP, TPE, silicone)	Is the component produced internally or externally?	Is the component surface treated?	Name of manufacturer/supplier of the component and their address	Weight of each material in the component (g)

In the event of any changes of the information in this declaration, a new declaration must be submitted to Nordic Ecolabelling.

Signature of the manufacturer of the product:

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

Appendix 3 Declaration from the manufacturer of silicone

Manufacturer/supplier:
Trade name of the silicone material:

D4: Octamethylcyclotetrasiloxane, (CAS 556-67-2)

D5: Decamethylcyclopenta-siloxane, (CAS 541-02-6)

D6: Dodecamethylcyclohexasiloxane, (CAS 540-97-6)

	YES	NO
Is the silicone medical-grade silicone?		
Do D4, D5 or D6 form part of the silicone material?		
Please state number of impurities* of D4, D5 and D6 in the silicone material: D4: _____ ppm D5: _____ ppm D6: _____ ppm * Impurities of D4, D5 and D6 are defined as residual products from the raw material production that can be found in the silicone material.		
Is test report showing the amount of D4, D5 and D6 in the silicone material according to test method for silicone elastomer products from CES-Silicones Europe* attached? * Quantification-of-Residual-Amounts-of-Cyclic-Volatile-Methyl-Siloxanes-in-Silicone-Elastomers_final-002.pdf		

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

Appendix 4 Declaration from the manufacturer of silicone about production of silicone

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

Please note that for silicone Appendix 3 and Appendix 5 must also be completed.

Manufacturer:
Trade name of the silicone material:

Production of silicone

O37 Emission of dust and chlorides

The storage and handling of the elemental silicon raw material shall use at least one of the following techniques, see below, please specify which techniques are used.	**YES**	**NO**
Storing of elemental silicon in silos (after grinding)		
Storing of elemental silicon in covered areas protected from rain and wind (after grinding)		
Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding)		
Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.		
The yearly average of channelled emissions of dust shall be below 5 mg/Nm^3. The dust emissions should be continuously monitored. Attach test results of the dust measurements taken on site, together with the yearly average of the dust emission. Name of attachment: _____		
Is the yearly channelled dust emission on average below 5 mg/Nm^3?		
The off gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process. Attach details on the processing of the off gases from the methyl chloride, direct synthesis and distillation steps. Name of attachment: _____		

O38 Emissions of copper and of zinc to water	**YES**	**NO**
Are the water effluents from the polydimethylsiloxane (PDMS) production step pre-treated by precipitation or flocculation under alkaline conditions, followed by sedimentation and filtration? Including dewatering of the sludge before disposal and recovering of the solid metal residues in metal recovery plants? **Attach** description how the effluent is treated. Name of attachment:_____		
Is the concentration of zinc in the treated effluent below 2 mg/l? Attach test report for zinc measurements. Name of attachment: _____		
Is the concentration of copper in the treated effluent below 0.5 mg/l? Attach test report for copper measurements. Name of attachment: _____		
O39 Emissions of CO_2		
Do the emissions of CO_2 from the production of the silicone exceed 6.58 kg per kg silicone? Including emissions from the production of electricity whether on-site or off-site. Attach detailed calculations for the CO_2 emissions from the production of the silicone, name of attachment: _____ *CO_2 emissions shall include all sources of non-renewable energy used during the production of the silicone (whether on-site or off-site). CO_2 emission factors for other energy sources can be found in Annex VI to Regulation (EU) 2018/2066, whereas the CO_2 emission factors for grid electricity shall be calculated by factor 210 g CO_2/kWh. However, if the greenhouse gas emission intensity of electricity generation given by European Environment Agency* indicates a higher emission calculation factor for the country where the manufacturing is located, this shall be used.* *https://www.eea.europa.eu/en/analysis/indicators/greenhouse-gas-emission-intensity-of-1		

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

Appendix 5 Declaration from the manufacturer/supplier of plastic, silicone or rubber

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

This declaration is based on the best available knowledge at the time of the application, including test results. If new information or scientific findings become available, please inform Nordic Ecolabelling and submit an updated declaration. For suppliers: If you do not have knowledge about the complete composition of the additives in the polymer material, you are obliged to obtain this information from the manufacturer.

Manufacturer/supplier:
Trade name of the polymer material:
Type of polymer material (e.g. PP, PET, TPE, silicone):

This appendix covers requirements to additives, e.g., plasticisers, colourants/pigments and antioxidants, added to the masterbatch or compound. The requirement does not include the polymer production itself.

The requirements in this section and accompanying appendices apply to all ingoing substances in the additives. Impurities are not regarded as ingoing substances and are exempt from the requirements. Ingoing substances and impurities are defined as below, unless stated otherwise in the requirements.

Ingoing substances: All substances* in the chemical product/additive regardless of amount, including additives (e.g., preservatives and stabilizers) in the raw materials. Substances released from ingoing substances (e.g., biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances.

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

Impurities: Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials, that remain in the chemical product or additive in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%).

Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the chemical product or additive.

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

Additional information concerning definitions of ingoing substances and impurities:

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

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of Biological materials) have a composition of constituents that is not completely known or is variable from time to time. For substances registered under REACH as UVCBs, all constituents are considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

If the additives contain ingoing substances or impurities that are listed under excluded substances or has any of the classifications mentioned in this appendix, write the amount in the box at the end of the appendix. The manufacturer of the Nordic Swan Ecolabelled product is responsible for calculating compliance with the requirements of the criteria.

O6 Classifications according to CLP regulation 1272/2008		
Does the additive contain ingoing substances or impurities classified with any of the hazard codes below? Including all classification variants (e.g. H350 also includes H350i).	**YES**	**NO**
H420 – Ozone		
H370 – STOT SE 1		
H371 – STOT SE 2		
H372 – STOT RE 1		
H373 – STOT RE 2		
H350 – Carc. 1A or 1B		
H351 – Carc. 2		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2		

H362 – Lact.		
H334 – Resp. Sens. 1, 1A or 1B		
H317 – Skin Sens. 1, 1A or 1B		
EUH380 – ED HH 1		
EUH381 – ED HH 2		
EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		
O7 Excluded substances		
Does the additive contain any of the following as ingoing substances or impurities?	**Yes**	**No**
Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate-list-table *For D4, D5 and D6 in silicone polymers, use Appendix 3.*		
PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt		
Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III		
Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid)		
Azo dyes that may release aromatic amines with carcinogenic, reproductive toxicity or mutagenic properties listed in Regulation (EC) No 1907/2006, Annex XVII, Appendix 8		
Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity. *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)*		
Per- and polyfluoroalkyl substances (PFAS) *PFAS is defined as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it)*		
Halogenated organic compounds *Exemption for: Pigments that meet the EU's requirement concerning colourants in food packaging under Resolution AP (89) point 2.5.* *Please note: Per- and polyfluoroalkyl substances (PFAS) are covered by their own bullet and are not included in the exemption.*		
Heavy metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), zinc (Zn), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)		

If the answer to any of the above questions regarding ingoing substances or impurities is Yes, please provide the following information for each relevant substance: CAS No. (where

possible), chemical name, concentration (in ppm, % by weight or mg/kg). Also state whether the substance is present as an ingoing substance or impurity.

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

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

Appendix 6 Declaration from the manufacturer/supplier of adhesive or surface treatment

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

This declaration is based on the best available knowledge at the time of the application, including test results. If new information or scientific findings become available, please inform Nordic Ecolabelling and submit an updated declaration. For suppliers: If you do not have knowledge about the complete composition of the raw material/ingredient, you are obliged to obtain this information from the manufacturer.

Manufacturer/supplier:
Trade name of the adhesive or surface treatment:

The requirements in the criteria document and accompanying appendices apply to all ingoing substances in the adhesive or surface treatment. Impurities are not regarded as ingoing substances and are exempt from the requirements. Ingoing substances and impurities are defined as below, unless stated otherwise in the requirements.

Ingoing substances: All substances* in the adhesive or surface treatment regardless of amount in the raw materials. Substances released from ingoing substances (e.g., biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances.

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

Impurities: Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials, that remain in the chemical product or additive in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%).

Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the chemical product or additive.

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

Additional information concerning definitions of ingoing substances and impurities:

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

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of Biological materials) have a composition of constituents that is not completely known or is variable from time to time. For substances registered under REACH as UVCBs, all constituents are considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

If the adhesive or surface treatment contain ingoing substances or impurities that are listed under excluded substances or has any of the classifications mentioned in this appendix, write the amount in the box at the end of the appendix. The manufacturer of the Nordic Swan Ecolabelled product is responsible for calculating compliance with the requirements of the criteria.

O8 Classifications of the adhesive or surface treatment according to CLP regulation 1272/2008		
Is the adhesive or surface treatment classified with any of the hazard codes below? Including all classification variants (e.g. H350 also includes H350i).	**YES**	**NO**
H400 – Aquatic Acute 1		
H410 – Aquatic Chronic 1		
H411 – Aquatic Chronic 2		
H412 – Aquatic Chronic 3		
H413 – Aquatic Chronic 4		
H420 – Ozone		
H300 – Acute Tox. 1 or 2		
H310 – Acute Tox. 1 or 2		
H330 – Acute Tox. 1 or 2		
H301 – Acute Tox. 3		
H311 – Acute Tox. 3		
H331 – Acute Tox. 3		
H370 – STOT SE 1		
H371 – STOT SE 2		
H372 – STOT SE 3		
H373 – STOT SE 4		

H334 – Resp. Sens. 1, 1A or 1B		
H317 – Skin Sens. 1, 1A or 1B		
H350 – Carc. 1A or 1B		
H351 – Carc. 2		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2		
H362 – Lact.		
EUH380 – ED HH 1		
EUH381 – ED HH 2		
EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		
O9 Classifications of ingoing substances and impurities according to CLP regulation 1272/2008		
Does the adhesive or surface treatment contain ingoing substances or impurities classified with any of the hazard codes below? Including all classification variants (e.g. H350 also includes H350i).	**Yes**	**No**
H420 – Ozone		
H372 – STOT RE 1		
H334 – Resp. Sens. 1, 1A or 1B		
H317 – Skin Sens. 1, 1A or 1B		
H350 – Carc. 1A or 1B		
H351 – Carc. 2		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2		
H362 – Lact.		
EUH380 – ED HH 1		
EUH381 – ED HH 2		

EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		
O10 Excluded substances		
Does the adhesive or surface treatment contain any of the following as ingoing substances or impurities?	**Yes**	**No**
Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate-list-table		
PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt		
Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III		
Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid, CAS No. 88-99-3))		
Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS No. 25013-16-5), butylated hydroxytoluene (BHT, CAS No. 128-37-0), alkylphenol ethoxylates (APEOs) and other alkylphenol derivates (APD)		
Per- and polyfluoroalkyl substances (PFAS) PFAS is defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)		
Halogenated organic compounds		
Heavy metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), zinc (Zn), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)		
Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity. *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)*		
Quaternary ammonium compounds, which are not readily aerobic biodegradable such as DTDMAC (CAS No. 61789-80-8), DSDMAC (CAS No. 107-64-2), DHTDMAC (CAS No. 61789-72-8) and DADMAC (CAS No. 7398-69-8)		
Volatile aromatic compounds (VAC)		
Nanomaterials/-particles* ** Nanomaterials/-particles are defined according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01)10: 'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.*		

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

If the adhesive or surface treatment composition changes, a new declaration confirming compliance with the requirements must be submitted to Nordic Ecolabelling.

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

Appendix 7 Declaration from the applicant about packaging

To be completed by the applicant for a licence for the Nordic Swan Ecolabel.

Type of packaging	YES	NO
Primary packaging? *Primary packaging means the packaging of the product that is necessary until the point of user. In the case of sterile products, primary packaging is designed to maintain the sterility of the product resulting in one piece of the specific product per primary packaging. Non-sterile products can be packed in primary packaging per product, in a certain number of products or without any primary packaging. It depends on the product types and their need for protection.*		
Secondary packaging? *Secondary packaging means the packaging of a certain number of products in their primary packaging (if used) for protection during transport and storage.*		
Tertiary packaging? *Tertiary packaging means the outer layer of packaging in which the product is distributed during their initial dispatch from the manufacturer of the product. Auxiliary packaging as wrapping film etc. for transportation pallets are excluded. Other packaging used in downstream distribution, including transport between distribution centres, retailers, or final customers is excluded.*		

Packaging name and/or item number (write all the names/numbers this declaration covers):
Components of the packaging (container, closure, label):
Packaging material (type of plastic, board etc.). List all materials included in each component of the packaging:

For all packaging	YES	NO
Does the packaging contain halogenated plastics (e.g. PVC or PVDC), oxo-degradable plastic or biodegradable plastic?		
Does the packaging contain intentionally added PFAS*? ** PFASs are defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).*		
Is the packaging surface treated with PFAS*, either on the inside or on the outside of the packaging? * PFASs are defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).		
Is metal use in the packaging? Staples and other small parts are exempt.		

For primary packaging is exception of metal layer for barrier purposes to preserve a sterile barrier, minimize evaporation and/or improve product shelf life.		
For board and paper:		
Is the packaging marked with the FSC- or PEFC-logo? **If yes**, please attach documentation for certification.		
Does the packaging contain recycled wood raw material? If yes, please state amount (weight %):_____		
Does the packaging contain wood raw material from forests that are managed in accordance with sustainable forestry management principles established by FSC- or PEFC-schemes? **If yes**, please state amount (weight %):_____		
Does the packaging contain wood raw material covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources)? **If yes**, please state amount (weight %):_____		
For secondary packaging and tertiary packaging	**YES**	**NO**
Is the packaging made of monomaterial*? ** Monomaterial means one material type, e.g. cardboard or one type of plastic, e.g. PP. However, coloured packaging components made from PP are allowed to have up to 5% PE if it comes from the masterbatch.*		
If the packaging is not made of monomaterial: Is each packaging component made of monomaterial? Small parts such as plastic strips, closure clips and cords are exempt.		
If the packaging is not made of monomaterial: Can each packaging component be sorted separately without using a tool (including sorting into different plastic types)? Small metal parts (e.g. staples) are exempt.		
If the packaging is not made of monomaterial: Are packaging components made of different materials glued or welded together?		
If the packaging is not made of monomaterial: Is it stated on the packaging that different material types must be separated and sorted for recycling?		
Is each packaging component marked with pictograms for recycling? **If yes**, please state standard/system (e.g. DIN 6120, EUPicto):_____		
Has carbon black been added to any plastic components?		

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

Appendix 8 Declaration from the manufacturer/supplier of packaging

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

Manufacturer/supplier:
Packaging component name and/or item number (write all the names/numbers this declaration covers):
Component of the packaging (e.g. container, lid, label):
Packaging material (type of plastic, board etc.). List all materials included in the packaging component:

For all packaging	**YES**	**NO**
Does the packaging contain halogenated plastics (e.g. PVC or PVDC), oxo-degradable plastic or biodegradable plastic?		
Does the packaging contain intentionally added PFAS*? ** PFASs are defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).*		
Is the packaging surface treated with PFAS, either on the inside or on the outside of the packaging? ** PFASs are defined as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).*		
For board or paper packaging	**YES**	**NO**
Is the packaging marked with the FSC- or PEFC-logo? **If yes**, please attach documentation for certification.		
Does the packaging contain recycled wood raw material? **If yes**, please state amount (weight %):_____ **If yes**, please attach documentation, e.g. invoices or delivery notes from suppliers.		
Does the packaging contain wood raw material from forests that are managed in accordance with sustainable forestry management principles established by FSC- or PEFC-schemes? **If yes**, please state amount (weight %):_____		

If yes, please attach documentation, e.g. invoices or delivery notes from suppliers.		
Does the packaging contain wood raw material covered by the FSC/PEFC control schemes (FSC controlled wood/PEFC controlled sources)? **If yes**, please state amount (weight %):_____ **If yes**, please attach documentation, e.g. invoices or delivery notes from suppliers.		
For plastic packaging	**YES**	**NO**
Has carbon black been added to the component?		

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