About Nordic Ecolabelling for

Medical devices and medicinal products in plastic and silicone

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Nordic Ecolabelling

Contents

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

Finland
Ecolabelling Finland
www.joutsenmerkki.fi

Sweden
Ecolabelling Sweden
www.svanen.se

Iceland
Ecolabelling Iceland
www.svanurinn.is

Norway
Ecolabelling Norway
www.svanemerket.no

1 Justification of the product group definition

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

Further background for the product group definition:

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 w% of plastic and silicone in the products must be calculated without fluids such as dialysate in dialysis treatment bags and saline 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 4. If a product type showed environmental hotspots in the MECO, the RPS was medium/high and fits into the product group definition (see section "What can carry the Nordic Swan Ecolabel?" in the criteria) then the new product type could be included in the criteria.

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

Nordic Ecolabelling has conducted a pre-study to evaluate if there is basis to make a new separate criteria set for gloves (e.g. examination gloves). Based on the pre-study it was in 2026 decided to develop a criteria set for gloves.

Hazardous waste containers, needle buckets, dosing box, medicine cup, wash set 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 saline 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 Nordic Ecolabelling wants to avoid this risk of this misunderstanding.

Bottle teats are normally not included in Regulation (EU) 2017/745 on medical devices, therefore they are not included in the criteria. However, there are some rare exemptions if the bottle teat is part of a specialized feeding system for medical conditions.

CPAP masks (Continuous Positive Airway Pressure) are not included in the criteria, because the materials and the amount silicone that are commonly used in modern CPAP masks will give a low RPS (see about RPS in section 4).

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.

2 Summary

Nordic Ecolabelling criteria for medical devices and medicinal products in plastic and silicone have been revised for generation 3. The criteria contain requirements in those areas in the life cycle that have been found to have potential to reduce the environmental impact. These

areas are materials, chemicals harmful to the environment and health, energy consumption and packaging, see details in section 4.

The focus of the revised criteria has been to expand the product types covered by the criteria, so that it will include more product types for healthcare in public procurement. The new added product types were selected based on suggestion from public purchasers and which also showed high RPS, see section 4. The product group definition was updated, and the name of the criteria have been changed to fit the new product types.

The focus was also to set requirements to surface treatment, which is a new area in the revised criteria. Also in focus, was to update the chemical requirements for additives in polymer materials and adhesives, and the documentation for these. In the revised criteria the only option is that declarations for chemicals must be completed by the manufacturer/supplier of the polymer material, adhesive or surface treatment.

For materials halogenated butyl rubbers has been forbidden in the revised criteria. Halogenated butyl rubbers can for example be used in the plunger stopper of syringes, which are new product types covered by the criteria.

The new product group for plunges is made of mainly or 100% silicone. To have strong requirements for these products, new requirements is set for silicone production regarding emissions of dust and chlorides to air, emissions of copper and zinc to water and information about energy sources and consumption. These requirements apply for products containing min. 80 w% silicone.

New requirements for packaging are added in the revised criteria. The definition of primary packaging, secondary packaging and tertiary packaging have been done in close collaboration with licensee to fit the industry. The requirements cover packaging material and design for recycling.

A new requirement for energy mapping and an action plan for reduces energy consumption at the manufacturing sites that preform sterilization of the final product is set, which will have a potential for energy saving.

An overview of chances compared to previous generation can be seen in Table A in section 2.1.

2.1 Changes compared to previous generation

All changes and updates to the requirements in generation 3 compared to previous generation 2 are summarized in Table A below.

Further information about:

Product group definition and name of criteria:

Several new product types e.g. types of masks and syringes have been added, see section 1.1 and section "What can carry the Nordic Swan Ecolabel?" in the criteria 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 4 "Environmental impact of Medical devices and medicinal products in plastic and 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 1.1.

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

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.

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

Req. gen. 3	Req. gen. 2	Same req.	Change	New req.	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 w% plastic and/or silicone.
O1	O1		X		Updated text and appendix 2 regarding information about the product.
O2	O2	X			
O3	-			X	Halogenated butyl rubbers, e.g., chlorobutyl rubber and bromobutyl rubber, are not allowed in the product.
O4	O3	X			
O5	O4		X		The requirement is tightened. Small parts are now defined. The silicone must be medical-grade silicone or tested according to ISO 10993 or USP class VI. In addition, the level of D4, D5 and D6 must be tested.
O6	-			X	For products consisting of min. 80% silicone: Emissions of dust and chlorides to air from silicone production.
O7	-			X	For products consisting of min. 80% silicone: Emissions of copper and zinc to water from silicone production.
O8	-			X	For products consisting of min. 80% silicone: Information about energy consumption for silicone production.
O9	O6		X		The requirement is tightened with added classifications for: • Hazardous to the ozone layer (H420) • Specific target organ toxicity (H370, H371, H372, H373) • Respiratory or skin sensitisation (H334, H317) • Endocrine disruption for human Health and environment (EUH380, EUH381, EUH430, EUH431)

					• Persistent, Bioaccumulative and Toxic properties (EUH440) • Very Persistent, Very Bioaccumulative properties (EUH441) • Persistent, Mobile and Toxic properties (EUH450) • Very Persistent, Very Mobile properties (EUH451) Exemptions are removed for: • TiO_2 • TMP • Dye with H317 (O5 in gen. 2)
O10	O7		X		Requirement is tightened with added substances: • Azo dyes (with CRM properties) • Bisphenols and bisphenol derivatives • PFAS • Halogenated organic compounds • Heavy metals and metalloids Potential or identified endocrine disruptors updated regarding definition of these.
O11	O5		X	X	New requirement for surface treatment. Loosened for additives in polymer materials where this req. has been deleted. Tightened with added classifications: • Hazardous to the ozone layer (H420) • Endocrine disruption for human Health and environment (EUH380, EUH381, EUH430, EUH431) • Persistent, Bioaccumulative and Toxic properties (EUH440) • Very Persistent, Very Bioaccumulative properties (EUH441) • Persistent, Mobile and Toxic properties (EUH450) • Very Persistent, Very Mobile properties (EUH451) Exemption for photo initiators in UV-cured acrylates-based adhesives and 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.
O12	O6		X	X	New requirements for surface treatment. Tightened with added classifications: • Hazardous to the ozone layer (H420) • Specific target organ toxicity: Repeated exposure (H372) • Respiratory or skin sensitisation (H334, H317) • Endocrine disruption for human Health and environment (EUH380, EUH381, EUH430, EUH431) • Persistent, Bioaccumulative and Toxic properties (EUH440) • Very Persistent, Very Bioaccumulative properties (EUH441) • Persistent, Mobile and Toxic properties (EUH450) • Very Persistent, Very Mobile properties (EUH451)
O13	O7		X	X	New requirement for surface treatment. Requirement in former generation (gen. 2) is tightened with added substances: • Alkylphenols (AP) and other alkylphenol derivates (APD) • PFAS

					• Halogenated organic compounds • Metals and metalloids • Bisphenols and bisphenol derivatives • Quaternary ammonium compounds, which are not readily aerobic biodegradable • VAC • Nanomaterials/-particles Potential or identified endocrine disruptors updated regarding definition of these.
O14	-			X	Level and test for D4, D5 and D6 in silicone in adhesive and surface treatment.
O15	-			X	New requirement for energy management at manufacturing sites that preform sterilization of the final product.
O16	O2		X		Requirement is tightened. More packaging materials are included.
O17	-			X	Packaging design for recycling.
O18			X		Requirement is tightened. CE marking shall be on the label and manufacturing site of the final product must be certified according to ISO 13485 or EN ISO 13485.
O19	O11		X		Updated to new general requirement for Nordic Swan Ecolabelled products.
O20	O14		X		Updated to new general requirement for Nordic Swan Ecolabelled products.
-	O9, O10, O12, O13, O15				The requirements are deleted because the information needed, is included in the application form.

3 Justification of requirements

3.1 Description of the product and manufacturing process

Background to O1 Description of the product

The product must be made of min. 90 w% plastic and/or silicone, because the main environmental hotspots in the criteria are alternatives to PVC and production of silicone raw material, see more details in section 4.

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 that must be documented for each product.

3.2 Materials in the product

Background to O2 Halogenated plastics

Nordic Ecolabelling acknowledges that much has been done by industry to reduce the environmental and health impact of PVC manufacturing and PVC products within the last 10 years. However, Nordic Ecolabelling consider that the use of PVC as a material in plastic products in medical technology is problematic for the following reasons:

- Although the recyclability of PVC and PVC products is undeniable, and PVC recycling systems are under development, it is still a challenge for the industry to collect, sort and process the material so that it does not contaminate new products with harmful legacy chemicals.
- Although the use of the most problematic phthalates is now restricted in the EU, other additives hazardous to the environment and health (e.g., plasticizers and stabilizers) can still be used in PVC as well as in other plastics[1]. The recent ECHA's work on an investigation report on the use of PVC and its additives, is in line with Nordic Ecolabelling's specific concerns with PVC and additives[2],[3].
- The environmental problems caused by PVC-production, e.g. where the mercury cell method is used to produce chlorine gas from salt (NaCl). Despite major reductions in emissions, mercury is still normally emitted to water and air. However, the mercury cell method has been phased out most places and are not used in Europe anymore. On the other hand, the acetylene route of PVC production (which also uses mercury) is growing. In China, 83% of PVC production uses the acetylene route. In Asia as a whole 63% of PVC production uses the acetylene route.
- Although mercury cells are not used in Europe anymore, the replacing membrane technology requires the use of harmful substances (PFAS) to produce the chlorine gas needed in PVC and other chemicals/plastics production[4],[5]. How much PFAS are released to the environment throughout the service life of the membrane and how the membrane is disposed afterwards as waste, are issues in need of more investigation.

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

Polyvinyl dichloride (PVDC) shares the same issues as PVC in the end-of-life phase.

Polytetrafluoroethylene (PTFE) has several environmental issues in its lifecycle. During manufacturing per- and polyfluoroalkyl substances (PFAS) compounds may be emitted. Over time PTFE can break down into trifluoroacetate (TFA) - a persistent pollutant toxic to plants and stable in water and soil. Incineration of PTFE may create additional harmful fluorinated byproducts[6].

[1] https://echa.europa.eu/sv/mapping-exercise-plastic-additives-initiative
[2] https://echa.europa.eu/documents/10162/17233/mandate_pvc_and_additives_rev_en.pdf/a860fd87-4231-5ed4-157b-f6cda1ee5832?t=1655721970555
[3] https://echa.europa.eu/documents/10162/7d64f1d7-b29f-94ec-4477-9bcebf737a82
[4] https://eippcb.jrc.ec.europa.eu/reference/production-chlor-alkali-0
[5] https://www.eurochlor.org/publication/fluoropolymers/
[6] What Are The Environmental Concerns Associated With Ptfe Manufacturing? Assessing The Full Lifecycle Impact - Kintek. https://kintek-solution.com/faqs/what-are-the-environmental-concerns-associated-with-ptfe-manufacturing

Background to O3 Halogenated butyl rubber

Halogenated butyl rubbers, especially chlorobutyl rubber and bromobutyl rubber, are commonly used for the plunger stopper in syringes but may also be used in other kinds of medical devices.

Halogenated butyl rubber is derived from butyl rubber by introducing halogen atoms (typically bromine or chlorine) to enhance vulcanization and compatibility with other rubbers[7]. Halogenated butyl rubbers are very persistent to degradation and incineration of halogenated butyl rubber waste may release halogenated toxicants such as dioxins and furans, which are harmful to both human health and the environment[8].

Background to O4 Natural rubber latex

Latex is a possible alternative to PVC in medical devices[9]. 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 non-allergic irritant contact dermatitis[10]. 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[11]. 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[12].

Background to O5 Silicone

Silicone may be an alternative material to PVC in for instance catheters and dialysis machines[13]. Silicones can also be used in small parts, for instance as sealing.

Silicone used in medical devices must meet strict biocompatibility standards to ensure it is safe for contact with human tissue. Therefore, the silicone must be medical-grade or be tested according to ISO 10993 or USP Class VI, which are recognized standards for evaluating silicone’s biological safety are.

D4 (octamethylcyclotetrasiloxane, CAS NO. 556-67-2), D5 (decamethylcyclopentasiloxane, CAS NO. 541-02-6), D6 (dodecamethylcyclohexasiloxane, CAS NO. 540-97-6) can be

[7] https://page-one.springer.com/pdf/preview/10.1007/978-94-009-8108-9_6
[8] https://onlinelibrary.wiley.com/doi/pdf/10.1002/tcr.202500022
[9] Maria José Amaral, Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, HealthcareWithoutHarm, 31. Dcember 2014
[10] https://www.naaf.no/fokusomrader/allergi-og-overfolsomhet/lateksallergi/ (Available 2019-01-09).
[11] Brochure from FSC, 2017: FSC®-certified natural rubber: Deforestation free, socially responsible.
[12] The European Critical Raw Materials review: http://europa.eu/rapid/press-release_MEMO-14-377_en.htm (Available 2019-01-26).
[13] Maria José Amaral, Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, HealthcareWithoutHarm, 31. December 2014

residues from polymerisation of silicone. D4, D5 and D6 are on the Candidate List[14] 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[15] to less than 0.1 w% 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.

This general rule has an exemption for small parts that weight maximum 2 grams and that are not introduced into the patient during treatment, then the silicone does not have to be medical-grade and up to 1000 ppm of D4, D5 or D6 are allowed. For these small parts tests do not have to be performed but can instead be declared by the manufacturer/supplier of the silicone.

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[16]. The test for silicone elastomer products is relevant here and CES-Silicones Europe write[17]: "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 the test 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[18]. Also, any ISO/IEC 17025-validated GC-MS method achieving LOQs (lowest quantifiable amount) at or below 100 ppm can be used for testing.

3.2.1 Silicone production

Requirements in this section only applies to products made of min. 80 w% 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 w% or more), whereby the silicone production will be a significant environmental impact of the product.

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

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[19].

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, which are toxic and persistent organic pollutants (POPs).

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[20].

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.

The limits of below 0.5 mg/l for copper and below 2 mg/l for zinc is the same limits as set for EU Ecolabel reusable menstrual cups, which is based on BREF to produce Speciality Inorganic Chemicals[21].

Background to O8 Energy consumption

Manufacturing of silicone have a high energy consumption compared to other polymers (see MECO in section 4). To support continuous improvement and enable more targeted and impactful criteria development, Nordic Ecolabelling has a requirement to collect detailed

[19] 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)

[20] 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)

[21] JRC, 2007, Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Production of Speciality Inorganic Chemicals. Available at: https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/sic_bref_0907.pdf

energy data. Reported data will be utilized and will serve as a foundation for future criteria generations, enabling Nordic Ecolabelling to better address climate impact and further promote the transition toward more sustainable production practices.

3.3 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 4.1 Definitions in the criteria, 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 3.4.

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 were 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 since no other technically and regulatory safe alternatives are available at this point. 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.

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 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 (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid)) 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[22].

Bisphenols and bisphenol derivatives

Several bisphenols with the general bisphenol structure and 'bisphenol derivatives' which have constituents with structural properties common to bisphenols are 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[23].

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 halogenated 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.

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

[23] 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

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

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[24,25,26]. Chromium VI is classified as: very toxic, CMR and harmful to the environment.

3.4 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 4.1 Definitions in the criteria, unless stated otherwise in the requirements.

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 is a broad term that refers to all treatments 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

[24] Government official investigations: https://www.regeringen.se/49bbb3/contentassets/c0f10a5d57534a48b9b8641aba971a1e/bilagorna-6-9 (visited 2022-06-01)
[25] Government official investigations: https://www.regeringen.se/49bbb3/contentassets/c0f10a5d57534a48b9b8641aba971a1e/bilagorna-6-9 (visited 2022-06-01)
[26] Toxicity, mechanism and health effects of some heavy metals: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4427717/ (visited 2022-06-01)

for injection or in any other way intended for medicinal treatment, is not included in this requirement.

UV-curing adhesives are widely used in medical devices because they can make manufacturing faster and cleaner while still achieving strong, precise bonds. UV-curing also have the advantages that it provides durable products and does not require solvents (low VOC-content). 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 H317. UV-cured adhesives contain photo initiators which may give the adhesives classifications such as H360 and H361, see more under O12. 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.

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.

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. For 2-component adhesives also H334 is exempted because in the cured state, this classification is no longer relevant, and hence the exposure risk is reduced. 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 photo initiators. Photo initiators may have classifications such as H350, H360, H361 and H372. Photo initiators 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 photo initiators in UV-cured surface treatment; thus, the exemption also applies to that. However, the exemption only applies if the photo initiators are used in a closed production system, where there is no direct contact/exposure to the chemical product.

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 (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid)) 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 halogenated 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.

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

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[27,28,29]. 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[30].

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).

Nanomaterials/-particles

Nanomaterials[31] 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.

[27] Government official investigations: https://www.regeringen.se/49bbb3/contentassets/c0f10a5d57534a48b9b8641aba971a1e/bilagorna-6-9 (visited 2022-06-01)
[28] Government official investigations: https://www.regeringen.se/49bbb3/contentassets/c0f10a5d57534a48b9b8641aba971a1e/bilagorna-6-9 (visited 2022-06-01)
[29] Toxicity, mechanism and health effects of some heavy metals: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4427717/ (visited 2022-06-01)
[30] 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
[31] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/chemicals-nano-and-microplastics/nanomaterials/

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[32,33,34]. Nordic Ecolabelling takes these concerns seriously and applies the precautionary principle to exclude potentially hazardous nanomaterials from products.

Background to O14 Silicone in adhesive and surface treatment

Silicone may be an alternative material to PVC in for instance catheters and dialysis machines[35]. 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[36] 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[37] to less than 0.2 w% 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[38]. The test for silicone fluids is relevant here and CES-Silicones Europe write[39]: "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[40]. Also, any ISO/IEC 17025-validated GC-MS method achieving LOQs (lowest quantifiable amount) at or below 100 ppm can be used for testing.

[32] 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
[33] 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
[34] 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
[35] Maria José Amaral, Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, HealthcareWithoutHarm, 31. Dcember 2014
[36] https://echa.europa.eu/da/-/ten-new-substances-added-to-the-candidate-list
[37] REACH Annex XIII Entry 70: 0ac1f453-ad41-4010-e837-a68273b896ca, Paragraph 6 (c).
[38] New analytical methods quantify siloxanes in silicone products - Silicones Europe Visited 25 September 2025.
[39] Quantification-of-residual-amounts-of-Volatile-Siloxanes-in-silicone-products_final.pdf Visited 25 September 2025.
[40] Analysis of siloxanes (D4, D5, D6) in textile and plastics | RISE Visited 25 September 2025.

3.5 Energy

Background to O15 Energy management

The requirement only applies to manufacturing sites that preform sterilization of the final product. It the product is not sterilised then the requirement does not apply.

There is a potential to achieve significant energy saving by mapping and working systematically with energy savings. Manufacturers of the final product/assembly of the final product must actively work with energy savings by either being certified according to ISO 50001, ISO 14001 (including extended energy review corresponding to part 6.3 of ISO 50001 upon recertification) or audit according to EN 16247 within the last 4 years or audit according to a national implementation of the Energy Efficiency Directive (2012/27/EU, article 8) within the last 4 years.

Through energy mapping and energy audits, energy action plans can be developed and implemented to identify and actively work with issues related to low energy efficiency. These plans also enable the setting of clear, measurable targets for energy reduction which can be followed over time.

3.6 Packaging

Background to O16 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, and is therefore allowed.

For labels the only requirement is that they must not be made of halogenated plastics (e.g. PVC and PVDC), oxo-degradable plastic or biodegradable plastic.

For board and paper, a minimum of 70% by weight must be post-consumer recycled material or the wood raw material in the packaging must be FSC-/PEFC-certified. The remaining proportion of wood must meet the requirements of FSC controlled wood or PEFC controlled sources. The requirement limit, a minimum of 70% of all wood raw material (virgin or recycled), corresponds to the FSC and PEFCs requirement limits for use of the respective on-products labels, such as "FSC100%/-mix/-recycled" and "PEFC certified/recycled" The purchase shall be documented through invoices/delivery notes from suppliers which prove that the paper/board is certified e.g., name of tree species, license/CoC code, FSC/PEFC

claim and quantities of paper/board. Pictures of product packaging with a clear FSC/PEFC logo can also be included in the documentation.

Recycled materials not covered by FSC/PEFC's Chain of Custody certification, can also be used in the packaging.

The requirement for board and paper must be documented as purchased amount annually.

The paper part of protective blister in primary packaging is exempt from the requirement for board and paper. This part in the packaging is often paper and plastic blend to have more protection and is not PSC or PEFC certified.

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.

Background to O17 Packaging design for recycling

The EU has adopted a circular economy action plan[41] 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.

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. Carbon black must not be added plastic material of the packaging, carbon black in ink for printing is not part of requirement O17.

Labels are not part of requirement O17.

[41] 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)

3.7 Safety

Background to O18 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. 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.

Certificate for the manufacturing site of the final product showing compliant with ISO 13485 or EN ISO 13485 “Medical devices – Quality management systems – Requirements for regulatory purposes” is needed so that management systems are in place to support living up to legislation. The legislation contains strict requirements as to the safety and function of the products.

3.8 Licence maintenance

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

Background to O19 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.

Background to O20 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.

4 Environmental impact of medical devices and medicinal products in plastic and silicone

The relevant environmental impacts found in the life cycle of medical devices and medicinal products in plastic and 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[42], but use of best available techniques (BAT)[43] 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

[42] https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/JRC109279_LVOC_Bref.pdf
[43] https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/pol_bref_0807.pdf

		control products needed for neutralization and the resulting solid waste generated during this process[44]. 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 elastomers (TPE))	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. 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[45]. 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.

[44] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/circular-economy-and-resource-efficiency/pvc/
[45] Redefining Syringes: Carbon Footprint Reduction with RAUMEDIC's Green Syringe – RAUMEDIC

		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 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. 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. 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 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	High RPS for requirements for chemicals. Relevance: 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[46]. 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[47]. 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:

[46] Rapport, The use of PVC in the context of a non-toxic environment, EU Kommisionen 2022
[47] 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. 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. 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 to medium S: Medium	Low to medium RPS for requirements for energy consumption during manufacturing of products. The primary energy consumption is probably in the raw material phase. However, knowledge about energy consumption during manufacturing of the products is low, and e.g. the process of sterilisation of products is probably quite energy consuming. Therefore, for products that are sterilised the RPS is medium. Potential: The potential is low to medium because of the expected relative low energy consumption at the manufacturing site of the final product, but higher if the products are sterilised. 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. However, energy mapping and action plan to reduce energy consumption at the manufacturing site that preform sterilization of the final product is possible. Steerability: The steerability is medium because of difficult to separate energy consumption used for manufacturing from other activities at production sites. However, it the total energy consumption at the manufacturing site is possible to measure.
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 number 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.

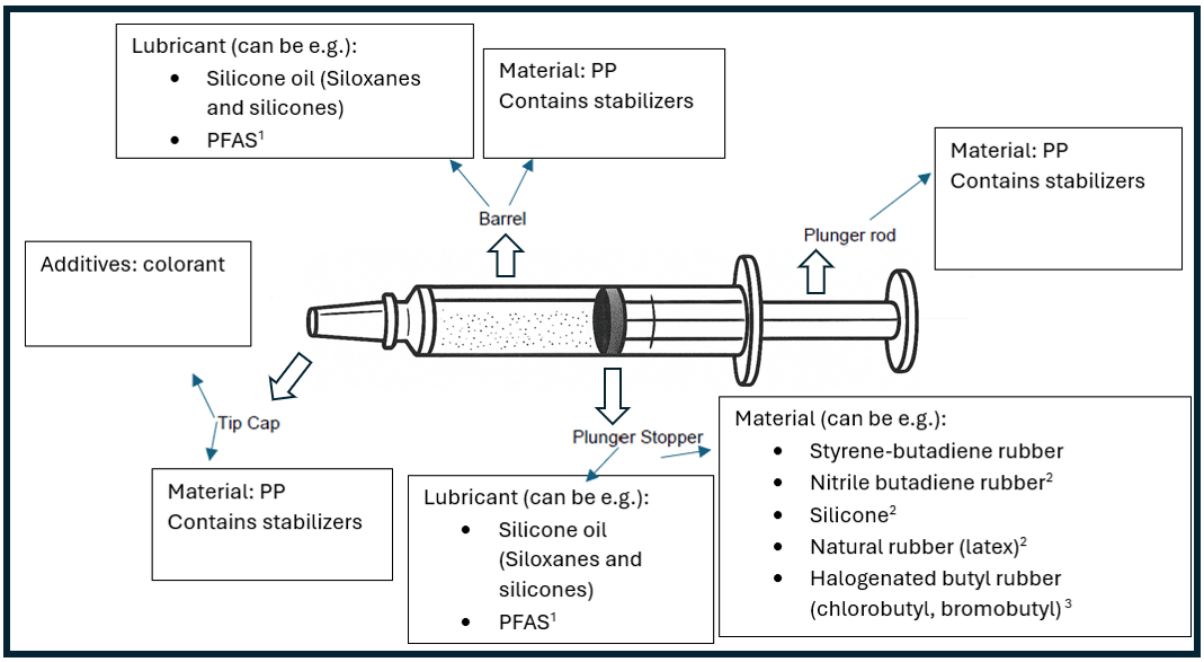
		Halogenated plastics (e.g. PVC): Halogenated plastics often contain plasticisers (e.g. phtalates) to make it flexible and soft, and many of these additives have problematic properties related to the environment and health[48]. As the plasticisers are not bound to the polymer, they can leak out and be a source to harmful chemicals for humans and in nature. Halogenated plastics also contain other additives that may be harmful[49]. 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 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. <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.
End of life		
Halogenated plastics waste	Halogenated plastics (e.g. PVC): R: High P: Medium to high S: High	<u>High RPS</u> 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[50]. This also applies to halogenated butyl rubber (e.g. chlorobutyl, bromobutyl). <u>Potential:</u> 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. <u>Steerability:</u> The manufacturers know if halogenated plastics are used in their products. Hereby there is a high steerability for that halogenated plastics are not used.

[48] Rapport, The use of PVC in the context of a non-toxic environment, EU Kommisionen 2022
[49] Rapport, The use of PVC in the context of a non-toxic environment, EU Kommisionen 2022.
[50] https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/circular-economy-and-resource-efficiency/pvc/

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 number 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.

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 w% 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: Medium P: High S: High	Medium RPS for requirements for halogenated butyl rubber. Environmental impacts primarily arise from the halogenation process, which requires energy intensive production of halogen sources (chlorine, bromine) and can generate hazardous waste. Compared to unmodified butyl rubber, HBR leaches fewer harmful organic compounds, suggesting lower additive related toxicity.

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 to medium S: Medium	Low RPS for requirements for energy consumption during manufacturing of products, but medium RPS if sterilization is done. (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: Medium to high P: High S: High	Medium to high RPS for requirements for halogenated butyl rubber. Relevance: 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[51]. 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[52]. 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: Medium to high P: Medium to high S: High	Medium to high RPS for requirements for packaging design. (See details in Main-RPS)

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

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 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[53] and EU REACH Regulation (Annex XVII, Entry 70[54])). 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.

[53] 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
[54] Liste over begrænsninger - ECHA

		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 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[55]. 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

[55] Products for faecal incontinence

		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.
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.[56] **Halogenated plastics (e.g. PVC)**[57] Ethylene (crude oil/natural gas), salt (NaCl). Fossil raw material. **Natural latex** Latex sap tapped from the rubber tree.[58] 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.[59] **Polypropylene (PP)** Byproduct of petroleum refining and natural gas processing, polymerized to form polypropylene.[60] 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. **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.	(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 low but may be expanded in the future as several initiatives work on this. There is also development of take-back schemes, that may be further developed in the future.

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

<table>
<tr>
<td></td>
<td>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 paper 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.[61]
Energy for extraction/production of raw materials[62]:
<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/calendaring):

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>Calendaring, 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></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>

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

PP

Process	CO_2-eq [kg]	Energy [MJ]
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

<table>
<tr>
<td></td>
<td>Packaging:
Metal</td>
<td>
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 (generic 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.

Natural rubber latex
<table>
<tr><th>Process</th><th>CO_2-eq [kg]</th><th>Energi [MJ]</th></tr>
<tr><td>Seal production, natural rubber based (proxy for latex-dipping/forming)</td><td>2.43</td><td>73.09</td></tr>
</table>
Synthetic "Other rubber"
<table>
<tr><th>Process</th><th>CO_2-eq [kg]</th><th>Energi [MJ]</th></tr>
<tr><td>Seal production, natural rubber based (proxy)</td><td>2.43</td><td>73.09</td></tr>
<tr><td>Injection moulding (generic)</td><td>1.43</td><td>20.70</td></tr>
</table>
Packaging:
Metal has a high energy consumption.
</td>
<td></td>
<td>Packaging:
Metal can be recycled.</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>Polymer manufacturing:
Emissions/contents of VOCs, monomers (e.g., styrene, 1,3-butadiene, acrylonitrile, D4, D5, D6), PAHs, solvents, and additives (e.g. plasticizers).</td>
<td>Health and environment issues:
Exposure of chemicals from ingoing substances</td>
<td>Emissions from incineration: Particulates, PAHs and VOCs.</td>
</tr>
</table>

		Plastic granules: Emissions/contents of VOCs, particulate matter, acid gases and lubricants.	(phthalates, CMR substances) and impurities can harm both environment and health.[63] Natural latex can cause allergic reactions.[64]	Especially for PVC: Higher degree of air pollution (PAHs, benzo-a-pyrene, dioxins, furans) during incineration.[65]
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:[66]** - Land use 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.[67] 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.	(Polymers and additives are manufactured into desired shapes/sizes). Many modern rubber formulations employed in the pharmaceutical industry for closures (stoppers and	Mostly single use due to sterility requirements (a few product types are reusable).	Loss of resources: Medical disposable products are mainly sent for

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

	Halogenated butyl rubber 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[68]. These properties make HBR ideal for tire inner liners, pharmaceutical closures, and chemical-resistant linings. See more details for HBR production[69]. 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 sulphur cross-links to allow reprocessing is possible but technically challenging and not widely adopted[70].	plungers), employ halo butyl rubbers as the base. Halo butyl rubbers typically have lower levels of extractables compared to other rubbers, and excellent resistance to permeation by water and oxygen.	HBR's durability and impermeability reduce leakage and extend product life, which can be environmentally beneficial. However, extractables and leachable from rubber oligomers (especially halogenated ones) may pose toxicity risks in sensitive applications like drug packaging[71].	incineration due to contaminated waste. Material recycling is at present restricted but may be possible in the future.
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[72],[73].	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

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

	Total climate and energy output[74]: Material / CO_2-eq [kg]/kg / Energy [MJ]/kg HBR* / > 6 / > 100 Synthetic rubber* / 3.5 - 6.5 / 70–110 Natural rubber*[75] / 0,4 / 50-80 ** The numbers are uncertain since little specific or comparative LCA studies exist.*			and utilized for heat and electricity generation.
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.[76]	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[77].

[74] https://link.springer.com/article/10.1007/s13762-024-05678-6
[75] https://link.springer.com/article/10.1007/s13762-024-05678-6#:~:text=The%20uncertainty%20analysis%20reveals%20that,sensitive%20to%20changes%20in%20yield
[76] background-document_098_disposable-bags-tubes-and-accessories-for-health-care-098_english.pdf
[77] 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.[78] 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[79].	Mostly single use due to sterility requirements (a few product types are reusable). Catheters, implants, tubing, respiratory masks, hearing aids[80].	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)[81]. Lack of widespread recycling infrastructure for silicone waste. Accumulation in landfills may lead to long-term environmental pollution.

[78] All news - ECHA
[79] Medical Grade Silicone: A Comprehensive Guide - Lanxin
[80] Advancing the circular economy of healthcare plastics - A systematic_review_2025
[81] 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[82]:
<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[83].</td>
<td>Energy source (renewable/fossil) effects footprint.
Electricity/energy of the manufacturing processes[84] (extrusion/calendaring):

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 (generic 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[85].

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[86]
Exposure of chemicals from ingoing substances and impurities can harm both environment and health.[87]</td>
<td>Emissions from incineration: Particulates, monomers, gaseous emissions like VOC, SOx, NOx and CO_2.</td>
</tr>
</table>

[82] Based on Ecoinvent - APOS Cumulative LCIA v 3.11 (reference flow = 1 kg)
[83] Chemical Recycling of Silicones—Current State of Play (Building and Construction Focus)
[84] Based on Ecoinvent - APOS Cumulative LCIA v 3.11 (reference flow = 1 kg)
[85] 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)
[86] https://www.newtopsilicone.com/understanding-the-toxicology-and-health-impacts-of-silicones/
[87] background-document_098_disposable-bags-tubes-and-accessories-for-health-care-098_english.pdf

5 Areas without requirements

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.