About Nordic Swan Ecolabelled

Disposable bags, tubes and accessories for health care

Version 2.0

Background to ecolabelling

Draft for consultation 28 February 2019

Nordic Ecolabelling

Content

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Addresses

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
Danish Standards Foundation
Göteborg Plads 1, DK-2150 Nordhavn
Fischersgade 56, DK-9670 Løgstør
Tel: +45 72 300 450
info@ecolabel.dk
www.ecolabel.dk

Iceland
Ecolabelling Iceland
Norræn Umhverfismerking
á Íslandi
Suðurlandsbraut 24
IS-108 Reykjavik
Tel: +354 591 20 00
ust@ust.is
www.svanurinn.is

Finland
Ecolabelling Finland
Urho Kekkosen katu 4-6 E
FI-00100 Helsinki
Tel: +358 9 61 22 50 00
joutsen@ecolabel.fi
www.ecolabel.fi

Norway
Ecolabelling Norway
Henrik Ibsens gate 20
NO-0255 Oslo
Tel: +47 24 14 46 00
info@svanemerket.no
www.svanemerket.no

Sweden
Ecolabelling Sweden
Box 38114
SE-100 64 Stockholm
Tel: +46 8 55 55 24 00
info@svanen.se
www.svanen.se

1 Summary

The main objective of these criteria is to label products that are an alternative to products of softened PVC. The criteria are designed to promote the development of products that do not use substances that are harmful to health or the environment. The material PVC needs plasticizers 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 is a source to harmful chemicals for humans and in nature. The criteria set general requirements to additives to the plastic, and will therefore also handle possible harmful additives also in other types of plastic than PVC.

The production of PVC has several environmental aspects related to all the three stages; chlorine production, the production of the monomer VCM and finally polymerisation into PVC. The chlor-alkali industry is energy-intensive and all three cell techniques (mercury, diaphragm and membrane) may give rise to emissions of chlorine to air and release of substances like free chlorine, heavy metals, organic compounds and halogenated organic compounds to waste water. The mercury cell technique has been a significant source of environmental pollution for many years. For plants using asbestos, there can be emissions of asbestos to the surroundings, but also a potential workspace problem. The membrane technology is considered the most environmentally aware method. However, the use of PFAS-coated membrane is a possible source of these substances into the environment. The production of VCM and PVC can also release hazardous substances to the environment.

Medical disposable products are mainly sent for incineration. Incineration of chlorinated plastics such as PVC can be a possible source to the release of dioxins and other harmful substances to the environment, although the problems related to this are reduced in Europe due to strict regulations. Due to the waste problems with PVC, Denmark has specific national legislation on this matter.

PVC is still widely used in the medical industry for disposable products. There are alternatives to the use of PVC in many types of disposable products in the health care sector, so there is potential and possibility to make changes.

The main changes in the revision from generation 1 to generation 2 are changes in the product group definition, new requirements to the materials latex and silicone and a general ban on phthalates. In the product group definition it is now emphasized that the products that can be labelled must be alternatives to products made of softened PVC and it is extended with blood bags. Latex is not allowed to use in the products, as latex itself can cause allergic reactions. There is also a new requirement to the content of the cyclic siloxanes D4, D5 and D6 in silicone material. These substances are now on the EU's Candidate List.

2 Basic facts about the criteria

Products that can be labelled

The product group definition has been slightly changed from the previous generation. The product group now also comprises blood bags, as there has been a project for many years aiming to develop PVC-free blood bags[1]. It is also pointed out that the products must be an alternative to products made of softened PVC on the market.

The products that can be labelled must be single-use products included under the Regulation (EU) 2017/745 on medical devices with subsequent amendments and adaptations and/or the EU Medicinal Products Directive (2001/83/EC). It is emphasized that Nordic Ecolabelling do not put any requirements to the medicinal product, but it is important that the medicinal product is according to the regulations and relevant directives. The products that can be labelled are:

- intravenous (IV) infusion treatment
- blood bags
- peritoneal dialysis (PD) treatment
- treatment of urinary retention and incontinence
- ostomy pouches and accessories for treatment following ileostomy, colostomy, or ureterostomy surgery

The materials that can replace softened PVC are mainly soft plastic, but also silicone or rubber is possible replacements. Products in hard plastic will not be a natural replacement for softened PVC, but some products need to contain products/parts in hard plastic to make the product work properly, for instance connections between the different parts of the products (tube and bag). All the products/parts necessary for the function of the ecolabelled product, can be included in the license.

These criteria are developed for products that are an alternative to products made of softened PVC, the environmental aspects related to disposable products made of other materials as the main material, like hard plastic or metals are not evaluated and hence cannot be ecolabelled within the scope of these criteria.

Products that cannot be labelled

Basically, only product types mentioned specifically in the product group definition can be labelled. Other relevant disposable health care products that are not mentioned above may be included in the product group if they are alternative products to products made of PVC softened with plasticisers and if they are governed by the aforementioned regulation and directive. This means that a large proportion of the products on the market must be based on PVC as a material. This is because the environmental impact for these products are closely related to the material PVC and the different plasticizers used in PVC, see also chapter 5.2.1. Nordic Ecolabelling will decide which new products may be included in the product group based on information about the product and market situation.

[1] http://www.pvcfreebloodbag.eu/ (available 2019-01-08)

Medical gloves can be made of PVC, but a large proportion is also made of other materials like latex and nitrile. Nordic Ecolabelling has evaluated to set requirements for gloves specifically, but have concluded to not include gloves in the product group definition. Both latex (natural) and nitrile have issues with allergy, and Nordic Ecolabelling see it as problematic to label gloves that could give an allergic reactions, either in form of the material itself (natural latex) or chemicals used in the production process, like accelerators. There is possible to make so-called accelerator-free gloves of nitrile, but at the moment these gloves make up a very little proportion of the market, around 1%. The total evaluation is therefore that Nordic Ecolabelling does not use resources to develop criteria for such a small proportion of the market.

The exact product group definition in the criteria is:

Disposable products that can be labelled must be single-use products included under the Regulation (EU) 2017/745 on medical devices with subsequent amendments and adaptations and/or EU Medicinal Products Directive (2001/83/EC) as applicable. It is emphasized that Nordic Ecolabelling do not put any requirements to the medicinal product, but it is important that the medicinal product is according to the regulations and relevant directives.

The disposable product must be an alternative to products of softened PVC on the market. Products that can be labelled are:

- intravenous (IV) infusion treatment,
- blood bags
- peritoneal dialysis (PD) treatment
- treatment of urinary retention and incontinence
- ostomy pouches and accessories for treatment following ileostomy, colostomy, or ureterostomy surgery

Other relevant disposable health care products that are not mentioned above may be included in the product group if they are an alternative to products made of softened PVC and if they are governed by the aforementioned regulation and directive. Nordic Ecolabelling will decide which new products may be included in the product group.

Some disposable products for medical use that are not included in this criteria can be labelled under the criteria for sanitary products, for example plasters, compresses, mattress covers/protectors, draw sheets, surgical gowns, patient gowns/patient covers, surgical masks and caps.

Justification for Nordic Ecolabelling

The motive for starting ecolabeling of disposable products for the medical industry in 2007 was a potential for improvements in the waste cycle and for health by excluding PVC and harmful phthalates which are common to use as plasticizers. Production of PVC also have negative impacts on the environment. These aspects are still relevant today. Plastic materials other than PVC can also contain additives with a possible negative impact on the environment and health. As of today, Nordic Ecolabelling considers that purchasers of hospital products have a desire and need for a simple guide to a good environmental choice.

Version and validity of the criteria

The generation 1 of the criteria were published the first time on December 13, 2007. Generation 1 have been changed three times where a minor limit has been introduced for environmentally hazardous substances, a change regarding mandatory text together with the Nordic Ecolabel and updating of the chemical requirements according to REACH. and CLP. The criteria have also been extended with catheters and ostomy bags. Generation 1 of the criteria has been prolonged 6 times. Generation 2 of the criteria was decided xx.xx.2019 and are valid until xx.xx.20xx.

Nordic Swan Ecolabel licences in the Nordic Market

There is today 1 license that is valid in all the Nordic countries. The license is for equipment for the treatment of peritoneal dialysis and comprises bags, tubing and different accessories in different sizes.

3 The Market

The medical devices industry is extensive and global, with a large number of international manufacturers often represented at the national level either through subsidiaries or trading companies. In the Nordic market there is a consolidation with fewer operators on the market in the last years. In Sweden there are for example only two suppliers for equipment for peritoneal dialysis, Fresenius Medical Care and Baxter.

Of the total use of PVC in the world, it is estimated that a little less than 1% is used in medical devices. The consumption of PVC for medical devices in Europe is approximately 85.000 tons every year and almost one third of plastic based medical devices are made from PVC[2]. In Denmark the import of PVC for medical devices was estimated to 850 tons in 2017.[3] The two main application areas for medically approved PVC compounds are flexible containers and tubing to be used in for instance containers for blood or urine or for ostomy products, tubing used for blood taking and blood giving sets, haemodialysis set and catheters.

There are PVC-free alternatives available today on the market in nearly all areas of use (except for blood bags). However, the project "PVC-free blood bags" has resulted in a successful result. Karolinska University hospital are working together with two European companies to establish contact with a partner who can launch PVC-free blood bags on the market[4]. Hopefully, these blood bags will soon be on the market.

A driving force in Europe for increased environmental focus in the health care sector is the organization Healthcare Without Harm. Among other things, they have focused on the use of PVC products that contain harmful phthalates and have prepared the report Non-toxic Healthcare: Alternatives to Phthalates and Bisphenol A in Medical Devices[5] in 2014. When it comes to PVC and phthalate

[2] http://www.pvc.org/en/p/health (available 2019-01-08)
[3] Kortlægning af PVC I Danmark 2018, Miljøstyrelsen november 2018, Miljøprojekt nr. 2049
[4] https://www.karolinska.se/en/karolinska-university-hospital/about-karolinska/environment-and-sustainability/pvc-free-blood-bag/(available 2019-01-08)
[5] Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, 31. Desember 2014, Health Care Without Harm

DEHP, they write that there are alternatives in many product areas such as gloves and IV solution bags. For gloves, latex and nitrile are mentioned and HDPE is mentioned for bags. Alternatives to other soft PVC products such as tubes are silicone, ethylene vinyl acetate (EVA), polyester, elastomers and various polyolefins.

In general, the purchase of disposable products for health care is mainly done through public procurement. There has traditionally been a focus on quality and safety as well as price in the health care sector. However, there is more and more interest in the environment and health aspect in the public health sector, although this varies between the Nordic countries and within each country. Several actors in the public health care sector in Sweden have long focused on phasing out the use of products containing PVC. The Region of Västra Götaland decided in 2014 that no gloves purchased for the health care sector should be PVC[6]. Stockholms Läns Landsting (SLL) also has a strong focus on phasing out PVC and products containing harmful chemicals. In their action plan for 2012-2016, it was stated that products containing different phtalates such as DBP, DEHP, DINP and DNOP or products, like catheters and urine bags made of PVC should either be phased out or reduced[7].

4 Environmental impact of the product group

The main objective of these criteria is to label products that are an alternative to PVC. The material PVC needs plasticisers to make it flexible and soft, and many of these additives have problematic properties related to the environment and health. The main plasticisers used in PVC are phthalates. Many of these phthalates, particularly DEHP, BBP, DBP and DIBP, has been a focus point the last decades due to their reproductive and endocrine disrupting effects. As the plasticisers are not bound to the polymer, they can leak out and is a source to harmful chemicals for humans and the environment. As the products that can be ecolabelled are in close contact with the body it is important that they do not contain substances with a possible harmful effect.

The material PVC is also linked to other environmental problems related to the production process and waste handling. The main problem in the production process of PVC is related to chlorine. PVC is manufactured in three separate stages: chlorine production, the production of the monomer VCM and finally polymerisation into PVC. All these processes can lead to chlorine pollution. Also the production of the chlorine also can lead to emissions of mercury and asbestos, as well as PFAS.[8]

Medical disposable products are mainly sent for incineration as recycling is difficult as such products very often have been in contact with medicinal products or body fluids. Chlorinated plastics such as PVC produce hydrochloric acid when they are incinerated and needs expensive equipment to neutralise the acid. The

[6] http://www.upphandlingsmyndigheten.se/hallbarhet/varfor_upphandling/goda-exempel/kemikalier/pvc-fria-handskar-i-vastra-gotalandsregionen/ (tilgjengelig 10.01.2017)
[7] https://www.sll.se/globalassets/6.-om-landstinget/hallbarhet/miljo/stockholms-lans-landstings-utfasningslista-2012-2016.pdf (available 2019-01-15)
[8] Chlorine and Building Materials: A Global Inventory of Production Technologies, Markets, and Pollution, Phase 1: Africa, The Americas, and Europe

neutralising process generates a large amount of problematic residue in the incineration plant, and this residue must be deposited under special conditions. Incineration of halogenated plastic like PVC can cause release of harmful substances like dioxins. However, it is difficult to relate this to halogenated plastic alone, as there is chlorine from many other sources in municipal waste. Also, due to strict EU regulations and national legislation the problems related to this are reduced in Europe.

There are alternatives to the use of PVC in many types of disposable products in the health care sector, so there is potential and possibility to make changes. Several reports focus on the replacement of PVC and harmful plasticisers in the health care sector[9],[10],[11]. More detailed information is given in chapter 5 under the different requirements.

5 Justification of the requirements

This chapter presents proposals for new and revised requirements, and explains the background to the requirements, the chosen requirement levels and any changes compared with generation 1. The appendices referred to are those that appear in the criteria document “Nordic Swan Ecolabelling of disposable bags, tubes and accessories for health care".

5.1 General requirements

O1 Description of the product and production process

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

- Trade name of the product
- Function of the product
- That the product is included in the regulation 2017/745 and/or 2001/83/EC
- Information about the different components and their function (like bag for solutions, tubes, connectors etc.) and what materials* the different components are made of.
- A flowchart showing the production of the product, including information on what components are bought from external manufacturers and what processes are done externally and internally

**materials can be different plastics like PE, PET, PA as well as other kind of materials like silicone.*

✉ Description in accordance with the requirement and flowchart that shows the production of the product (from the components to finalized product). Appendix 1 (applicant's declaration) and appendix 2 (for the manufacturer of the product) can be used.

[9] Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, 31. Desember 2014, Health Care Without Harm
[10] Alternatives to classified phthalates in medical devices, Danish Ministry of the Environment Environmental Project No. 1557, 2014
[11] Alternativa mjukgörare I sjukvården, Swetox, mars 2016

Background for the requirement

The requirement is basically not changed, but it is stated more clearly what information that must be given and that a flowchart showing the production process, including information on what kind of components that are bought from external manufacturers, and what processes that are done externally and internally, must be given. It is important to have general information about the product to make sure that the product is covered by the product group definition, that it follows the relevant regulations and directives and to get a better understanding of the production of the product.

5.2 Environmental and health requirements

This chapter covers both requirements to the materials in the product, and to chemicals added to the plastic material or used in or on the different components and product, like adhesive.

5.2.1 Materials

O2 Halogenated plastics

Halogenated plastics such as PVC are not allowed in the product or packaging.

Packaging refers to any inner and outer packaging of the product, including transport packaging.

✉ Duly completed and signed appendix 2 by the manufacturer of the product. Equivalent documentation can be approved.

Background for the requirement

The requirement is not changed and forbid the use of halogenated plastics such as PVC in the product and the packaging. In this case packaging refers to any inner packaging around the products that are ecolabelled, and any outer packaging, like transport packaging. The decision to exclude halogenated plastics such as PVC was made in the light of Nordic Ecolabelling's objective to reduce problems in waste handling and to reduce the risk of health-related problems. PVC has long been in focus in the environmental debate. Some of the environmental problems of PVC are due to the molecule itself – or more precisely the organic bound chlorine in the PVC molecule both in the production and waste handling. In other cases, the problems concern additives in the PVC which are harmful to the environment and to health.

Production

PVC is manufactured in three separate stages: chlorine production, the production of the monomer VCM and finally polymerisation into PVC. The raw materials for PVC are 57% salt (NaCl) and 43% ethylene (oil or natural gas). There are three electrolysis processes used to derive chlorine from salt: the mercury method, the diaphragm method and the membrane process. The mercury method and the diaphragm method using asbestos are the oldest technologies. The two newer technologies use diaphragms or membranes coated with per- and polyfluoroalkyl substances (PFAS).

According to the BAT-report[12] on the chlor-alkali industry there are several environmental aspects related to the industry. It is energy-intensive and consumes large amounts of electricity during the electrolysis process. All three cell techniques (mercury, diaphragm and membrane) may give rise to emissions of chlorine to air and substances emitted to waste water include free chlorine, chlorate, bromate, chloride, sulphate, heavy metals, sulphite, organic compounds and halogenated organic compounds. The mercury cell technique has been a significant source of environmental pollution for many years, and mercury can be released to air, water, products and wastes. For plants using asbestos, there can be emissions of asbestos to the surroundings, but also a potential workspace problem.

Most chlorine produced in Europe and Africa comes from PFAS-coated membrane technology. However, in Europe, exemptions to regulations that otherwise prohibit asbestos and mercury-based technologies allow the largest chlor-alkali plant to continue to use asbestos, and at least five other locations will continue using mercury into the foreseeable future[13]. The main chlor-alkali producers in Africa do not use mercury cells or asbestos diaphragms. In the Americas 8 of 12 largest plants use asbestos, which constitute approximately 45% of chlorine production capacity. Asbestos diaphragm technology plants supply 7 of 16 US PVC resin plants, including 3 of the 5 largest plants in US. In China, that have 41% of the chlor-alkali industry[14] many plants still use mercury.

The membrane technology is considered the most environmentally aware method. However, the use of PFAS-coated membrane is a possible source of these substances into the environment. Emissions to air or water of the PFAS chemicals are not regulated at the chlorine manufacturing plant. PFAS are highly toxic and long-lived chemicals and have been detected in the effluent from the main US manufacturer of membranes used in chlorine plants[13]. Therefore, this technology also has possible negative impacts on the environment and health.

The production of VCM and PVC can also release hazardous substances to the environment. According to the report from Healthy Building Network, most chlorinated pollution is associated with the production of EDC, VCM, and PVC resins either from the chlor-alkali process or the further production of VCM and PVC. This includes emissions of chlorine gas, carbon tetrachloride, dioxins and PCBs, VCM (vinyl chloride monomer). Carbon tetrachloride is a greenhouse gas and affects the ozone layer. Vinyl chloride monomer is released primarily during the production of PVC resins. The Australian and European PVC industries have established voluntary standards for residual VCM in PVC resins and VCM release rates from production, but this has not been done in the US[13].

Waste handling

Medical disposable products are mainly sent for incineration. Recycling is difficult as such products very often have been in contact with medicinal products or body fluids, and are therefore regarded as contaminated waste. Some of the

[12] Best Available Techniques (BAT),Reference Document for the Production of Chlor-alkali, 2014
[13] Chlorine and Building Materials: A Global Inventory of Production Technologies, Markets, and Pollution, Phase 1: Africa, The Americas, and Europe
[14] Best Available Techniques (BAT),Reference Document for the Production of Chlor-alkali, 2014

products that can be ecolabelled will be waste from the hospitals, but some of the products are used at home, like equipment for peritoneal dialysis. These products will not be sorted, but end up in the residual waste that in general is sent for incineration.

Denmark has specific national legislation (Affaldsbekendtgørelsens § 33) [15] for PVC waste that sets out the rules concerning the handling of end-of-life PVC:

- The local municipality must establish a collection system for PVC waste. The system must be designed such that a substantial proportion of both recyclable and non-recyclable PVC waste is collected.
- The municipality must ensure that a substantial proportion of the collected recyclable PVC waste is recycled, and that a substantial proportion of the non-recyclable PVC waste is sent to landfill.

An important reason for introducing a regulatory framework that requires the sorting of PVC waste was that it was not suitable for incineration in the available waste incineration plants. The PVC waste accounted for a dominant share of the chlorine load in the plants, which resulted in undesirable formation of hydrochloric acid with e.g. resulting in corrosion. PVC combustion with dry flue gas cleaning gives rise to very large volumes of flue gas cleaning residues, whereby waste disposal costs become high. In Sweden, which mainly has waste incineration plants equipped with wet flue gas cleaning, these problems are not so severe[16].

Historically, incineration of PVC has been a source to hazardous substances in the environment. Incineration of PVC leads to the risk of accidental release of hazardous substances such as polyaromatic hydrocarbons (PAH), benzo-a-pyrene, dioxins and furans.[13] These substances can be formed by incomplete combustion of organic matter and in the presence of chlorine. According to WHO (World Health Organization), uncontrolled waste incinerators for solid waste and hospital waste is the main source of dioxins to the environment globally, due to incomplete burning[17]. However, it is important to point out that it is difficult to relate the release of dioxins specifically to incineration of halogenated plastics, because there is normally always chlorine from other sources in municipal waste. Due to the issues related to chlorine from halogenated plastics and municipal waste in general, Europe has strict regulations in both EU directives and national legislation. The problems related to incineration of PVC in Europe have therefore been severely reduced.

Even though incineration of PVC is not desired in Denmark, a lot of products made of PVC will end in the waste fraction sent for incineration, also disposable products for medical health care To increase the recycling of PVC from the medical sector in Denmark, there is dialogue with the different regions to include sorting of the soft PVC as an own fraction at the hospitals. There is however, a problem around contamination and a potential need for disinfection. There is an

[15] https://www.retsinformation.dk/pdfPrint.aspx?id=144826 (available 2019-01-09)
[16] Avfall och särskilt farliga ämnen: Kartläggning och analys av avfallsströmmar som bör hanteras på särskilt sätt Naturvårdsverket 2016
[17] https://www.who.int/news-room/fact-sheets/detail/dioxins-and-their-effects-on-human-health (available 2019-01-15)

ongoing project "Safe and efficient recycling of soft PVC from medical devices by environmentally friendly supercritical carbon dioxide (scCO2)". The purpose of the project is to develop and demonstrate new possibilities for utilizing soft PVC from high quality medical equipment in recycling through safe removal of plasticizers and additives using environmentally friendly supercritical carbon dioxide (scCO2) technologies[18].

Halogenated plastics other than PVC are probably not used in medical devices or medicinal products packaging at this time, so the requirement is intended to ensure that halogenated plastics are not used as an alternative to PVC in the future. Other plastics do not generate acid to the same extent in waste incineration plants and therefore are less problematic.

Plasticisers

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

A precautionary approach is therefore to avoid such polymers. See more about plasticisers and other additives in chapter 5.2.2.

O3 Latex

Latex (natural) are not allowed in the product or packaging.

✉ Duly completed and signed appendix 2 by the manufacturer of the product. Equivalent documentation can be approved.

Background for the requirement

The requirement is new. Latex is a possible alternative to PVC in medical devices[19]. 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[20]. 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 in order to build 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[21]. 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[22].

[18] Kortlægning af PVC I Danmark 2018, Miljøstyrelsen november 2018, Miljøprojekt nr. 2049
[19] Maria José Amaral, Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, HealthcareWithoutHarm, 31. Dcember 2014
[20] https://www.naaf.no/fokusomrader/allergi-og-overfolsomhet/lateksallergi/ (available 2019-01-09
[21]Brochure from FSC, 2017: FSC®-certified natural rubber: Deforestation free, socially responsible
[22] The European Critical Raw Materials review: http://europa.eu/rapid/press-release_MEMO-14-377_en.htm (available 2019-01-26)

O4 Silicone

For products made of silicone, like a tube or catheter:

Octamethyl cyclotetrasiloxane, D4, (CAS 556-67-2), decamethyl cyclopentasiloxane, D5, (CAS 541-02-6) and dodecamethyl cyclohexasiloxane, D6, (CAS 540-97-6) must not form part of the silicone material. The requirement does not apply to D4, D5 and D6 contained as impurities* up to a limit of 100 ppm.

For small parts of silicone, like sealing:

Octamethyl cyclotetrasiloxane, D4, (CAS 556-67-2), decamethyl cyclopentasiloxane, D5, (CAS 541-02-6) and dodecamethyl cyclohexasiloxane, D6, (CAS 540-97-6) must not form part of the silicone material. The requirement does not apply to D4, D5 and D6 contained as impurities* up to a limit of 1000 ppm.

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

✉ Duly completed and signed appendix 4, Silicones in the product or appendix 5 for small parts of silicone. Equivalent documentation can be approved.

Background for the requirement

The requirement is new. Silicone may be an alternative material to PVC in for instance catheters and dialysis machines[23]. Silicones can also be used in small parts, for instance as sealing. Octamethyl cyclotetrasiloxane, D4, decamethyl cyclopentasiloxane, D5 and dodecamethyl cyclohexasiloxane, D6 can be residues from polymerisation of silicone. D4, D5 and D6 are now on the Candidate List[24]. As these substances are not actively added, but impurities from the production of silicone, these substances will not be covered by the chemical requirements, and therefore there is a separate requirement to these substances. As the requirement is new, Nordic Ecolabelling has limited information about the level of impurities in medical silicone materials. In a report from Kemikalieinspektionen from 2018[25], the level of different silicone polymers was analysed in menstrual cups. The level of D4, D5 and D6 varied between the different products, but in general the levels were low (between 3,7-10,1 ppm). However, one product had as much as 2778 ppm of D4, D5 and D6, with D6 making up the biggest part (around 2000 ppm). In breast implants made of silicone, levels of D4 varied from not detected to 134 ppm, D5 from not detected to 457 and D6 from not detected to 604[26]. This shows that it is possible to make products with a low level of these substances, and also that there is important to set requirements, as the levels can be high.

5.2.2 Chemicals

Chemicals like plasticisers and other additives like colourants/pigments and antioxidants, added to the plastic, and adhesive used in or on the various parts/components of the product must fulfil requirements O5-O7.

[23] Maria José Amaral, Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, HealthcareWithoutHarm, 31. Dcember 2014
[24] https://echa.europa.eu/da/-/ten-new-substances-added-to-the-candidate-list (available 2018-11-29)
[25] Kemikalieinspektionen: Kartläggning av farliga kemiska ämnen i intimhygienprodukter, rapport 3/18
[26] Opinion on The safety of Poly Implant Prothèse (PIP) Silicone Breast Implants
Update of the Opinion of February 2012, SCENIHR, 12th of May 2014

The requirements apply to additives added to soft and hard plastic to give the plastic different properties, like pigments or softeners. The requirement also applies if additives are added to any other material that might be a part of the product, like rubber and silicone. The requirements do not apply to rest monomers in the plastic material from the production process of the plastic. For D4, D5 and D6 as residual products from the production of silicone there is an own requirement, see O4.

No requirements are imposed on chemicals used for maintenance of machines or in the production processes (such as lubricants, cleaning chemicals etc.) without being added to the plastic material, unless otherwise stated.

No requirements are imposed on chemicals used on the transport packaging, for instance adhesives and printing inks used on a cardboard box for packaging of the final product.

The requirements in the criteria document and accompanying appendices apply to all ingoing substances in the chemical product, but not impurities unless stated otherwise in the requirements. Chemical product refers to for instance adhesives, softeners, colourants/pigments, antioxidants or other additives. Ingoing substances and impurities are defined below:

Ingoing substances: All substances in the chemical product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine) are also regarded as ingoing substances.

Impurities: Residuals, pollutants, contaminants etc. from production, including production of raw materials that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg).

Please note that the definition on ingoing substances and impurities only apply to requirement O6 and O7. O5 concerns the classification of the chemical product and not the classification of ingoing substances in the chemical product.

Information can be sent directly to Nordic Ecolabelling. Nordic Ecolabelling will provide confidentiality agreements if requested.

O5 Chemical products, classification

The requirement applies to:

- Plasticisers and other additives like colourants/pigments and antioxidants added to the plastic material
- Adhesives used in or on the various parts/components of the product

The plasticisers, other additives and adhesives cannot be classified according to table 1:

Table 1. Classification

Classification under CLP Regulation (EC) No 1272/2008		
Hazard class	Category	Hazard code
Hazardous to the aquatic environment*	Aquatic Acute 1 Aquatic Chronic 1 Aquatic Chronic 2 Aquatic Chronic 3 Aquatic Chronic 4	H400 H410 H411 H412 H413

Carcinogenic	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity	Muta. 1A eller 1B Muta. 2	H340 H341
Reproductive toxicity	Repr. 1A eller 1B Repr. 2 Lact.	H360 H361 H362
Acute toxicity	Acute Tox 1 or 2 Acute Tox 1 or 2 Acute Tox 1 or 2 Acute Tox 3 Acute Tox 3 Acute Tox 3	H300 H310 H330 H301 H311 H331
Specific target organ toxicity	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Aspiration hazard	Asp. Tox. 1	H304
Allergenic	Resp. sens 1 or Skin sens 1	H334 H317

**There is an exception of up to 0,1 % by weight of additives classified as hazardous for the environment (the pharmaceutical inside as well as box for secondary packaging and transport packaging shall not be included in the weight of the product)*

☒ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier.
Equivalent documentation with date and signature can also be approved.

O6 Chemical substances – CMR

The requirement applies to:

- Plasticisers and other additives like colourants/pigments and antioxidants added to the plastic material
- Adhesives used in or on the various parts/components of the product

Ingoing substances (apart from impurities) in the plasticisers, other additives and adhesives must not be classified as carcinogenic (Carc), mutagenic (Mut) and/or toxic for reproduction (Rep) according to CLP Regulation (EC) No 1272/2008 (see Table 2).

For definition of ingoing substances and impurities, see beginning of the section 2.2 Chemicals.

Table 2. Classification of CMR substances

Classification in line with CLP Regulation (EC) No 1272/2008	
Hazard class and category	H phrases (Code)
Carcinogenic Carc. 1A/1B Carc. 2	 H350 H351*
Mutagenic Muta. 1A/B Muta. 2	 H340 H341
Toxic for reproduction Repr. 1A/1B Repr. 2	 H360, H361 H362

** Exception is given for 2-component adhesives with isocyanates (classified H351), if the workers are not exposed during the production of the product and the isocyanates are cured in the finished product. Legislation for working environment must be fulfilled.*

✉ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier.
Equivalent documentation with date and signature can also be approved.

O7 Chemical substances – other excluded substances

The requirement applies to:

- Plasticisers and other additives like colourants/pigments and antioxidants added to the plastic material
- Adhesives used in or on the various parts/components of the product

Ingoing substances (apart from impurities) in the plasticisers, other additives and adhesives must not be from the list below.

For definition of ingoing substances and impurities, see beginning of the section 2.2 Chemicals.

List of excluded substances

- Substances of very high concern (SVHC)*
- Substances on the Candidate List**

D4, D5 and D6 in silicone polymers, see O4.

- Substances that have been evaluated in the EU to be PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative)***
- Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects****
- Phthalates*****

** Substances that meet the criteria in article 57 of the REACH Regulation*

***The Candidate List can be found on the ECHA website: http://echa.europa.eu/candidate-list-table*

****PBT and vPvB in accordance with the criteria in Annex XIII of REACH*

**** *Substances considered to be potential endocrine disruptors in category 1 or 2, see following link: http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf, see appendix L*

******Esters of phtalic acid (orthophthalic acid / phthalic acid /1,2-benzenedicarboxylic acid). The prohibition does not include polyethylene terephthalate (PET).*

✉ Safety data sheet in accordance with current European legislation and/or duly completed and signed appendix 3. The appendix can be filled out by the manufacturer of the ecolabelled product, the material supplier or the chemical supplier.
Equivalent documentation with date and signature can also be approved.

Background for the requirements O5-O7

It is important for Nordic Ecolabelling to have strict chemical requirements to the chemical products added to the plastic material or used in the production of the product like adhesive to protect both the user of the products and the environment.

By not allowing PVC, the risk of exposure to harmful phthalates is heavily reduced. However, almost all plastics contain additives to which humans or the environment may be exposed. It is also important to ensure that replacing PVC and phthalates do not lead to the use of other harmful chemicals, but to better alternatives for the environment and health.

Adhesives can for instance be used between different layers of plastic materials in a bag. Please note that the requirements do not apply to adhesives used on the outer transport packaging.

Classification of chemical products, O5

The requirement is not changed. The requirement concerns the classification of the chemical product added to the plastic to give it specific properties, like colourants/pigments, antioxidants, stabilizers and plasticizers or the adhesives used, and not to classification of ingoing substances in the chemical product. The requirement is set to reduce the use of chemical products that have a negative impact on the environment or to health.

Chemical substances – CMR, O6

The requirement is not changed. Nordic Swan Ecolabelling prohibits all CMR substances to increase reassurance and safety for the user. This will also exclude potentially mutagenic and/or toxic for reproduction effects in the environment. The new regulation on medical devices (2017/745) does have stricter requirements related to the use of hazardous substances than before. The use of substances that are classified as CMR of category 1A or 1B is still allowed, but the device shall only contain these substances in a concentration that is above 0,1 % weight by weight (w/w) where justified. This means that a justification for the use of the substance must be given (see 10.4 in the regulation). Where devices contain substances in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging. This has the potential to increase the substitution of substances that are CMR category 1A or 1B. The regulation is still quite new and there is also a transition period. The result of these new requirements is therefore still unknown. Nordic Ecolabelling also excludes substances in category 2, and also does not except any substances that are CMR and that are added with purpose regardless of quantity.

There is an exception in the requirement for 2-component adhesives with isocyanates classified H351. The exception 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 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.

Chemical substances – other excluded substances, O7

The requirement is not changed apart from a ban on all phtalates. Substances of Very High Concern (SVHC) cover substances that give grounds for caution due to their inherent properties. They meet the criteria in article 57 of the REACH Regulation, which defines SVHC as: substances that are CMR category 1A and 1B under the CLP Regulation, PBT substances, vPvB substances (see section below) and substances that have endocrine disruptive properties or are environmentally harmful without meeting the criteria for PBT or vPvB. A substance may meet the criteria for SVHC without being included on the Candidate List, so there is no direct equivalence between SVHC and the Candidate List. To avoid cross-references between PBT, vPvB, CMR and endocrine disruptors, instead of excluding SVHC (which does cover some CMR, PBT, vPvB, etc.) Nordic Ecolabelling chooses to exclude from use the substances on the Candidate List and to separately exclude PBT, vPvB and endocrine disruptors. This should still cover all SVHC substances.

"Persistent, bioaccumulative and toxic (PBT) organic substances" and "very persistent and very bioaccumulative (vPvB) organic substances" are substances whose inherent properties are not desirable in Nordic Swan Ecolabelled products. PBT and vPvB substances are defined in Annex XIII of REACH (Regulation (EC) No 1907/2006).

Potential endocrine disruptors are substances that may affect the hormone balance in humans and animals. The EU's strategy for endocrine disruptors[27] defines an endocrine disruptor as an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. Hormones control a number of vital processes in the body and are particularly important for development and growth in humans, animals and plants. Nordic Ecolabelling bans the use of substances that are considered to be potential endocrine disruptors, category 1 (there is evidence of a change in endocrine activity in at least one animal species) or category 2 (there is evidence of biological activity related to changes in hormone balance), in line with the EU's original report on "Endocrine disruptors"[28] or later studies. This entails a ban on substances such as several phthalates and certain alkylphenols.

Phthalates are also included as a separate point on the exclusion list to make it clear that no phthalates are permitted. This is changed from generation 1 that had a ban on some phthalates. The ban is on esters of phtalic acid (orthophthalic acid / phthalic acid /1,2-benzenedicarboxylic acid), and does not ban polyethylene terephthalate (PET). Nordic Ecolabelling excludes all phthalates as a precautionary approach. Many phthalates have negative effects on health and the environment. Some phthalates are inscribed on the EU's priority list of substances that should be investigated more closely for endocrine disruption – and some have already been identified as endocrine disruptors. Some phthalates can be found on the EU's Candidate List and some on the Danish "Listen over Uønskede Stoffer" (List of undesirable substances). The use of phthalates, particularly DEHP, BBP, DBP and DIBP, in consumer products with known

[27] http://ec.europa.eu/environment/chemicals/endocrine/definitions/endodis_en.htm (available 2019-01-15)
[28] http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf, see appendix L

human exposure, has been a focus point the last decades due to their reproductive and endocrine disrupting effects. These phthalates all have a harmonised classification stating that they may damage fertility (DEHP) or are suspected of damaging fertility (BBP, DBP, DIBP). All of these phthalates are classified "May damage the unborn child". Therefore, studies have been done trying to find alternatives to these substances, especially in products used for sensitive user groups, i.e. pregnant, neonatal and small children. A project in Denmark by the Danish Ministry of the Environment identified 10 possible alternatives to these phthalates in medical devices[29]. The conclusion in the report is that there are safer alternatives with a better toxicological profile. For some of the alternatives however, there is a lack of data. Also other reports focus on the replacement of PVC and harmful plasticisers in the health care sector[30],[31].

Documentation of the requirements

The requirements shall be documented by a material safety data sheet and/or a declaration that the requirements are fulfilled.

5.3 Safety requirement

O8 Safety

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

☒ Medical device: Copy of the approval / certificate from a notified body.
☒ Medicinal product: Copy of the market authorisation from the reference member state or national authority.

Background for the requirement

For reasons of credibility, the applicant is required to submit documentation for compliance with the legislation regarding the safety and correct functioning of a product. In the case of a medical device, it is a copy of the approval/certificate from a notified body. For a medicinal product, it is a copy of the market authorisation from the reference member state or national authority. The legislation contains strict requirements as to the safety and function of the products.

5.4 Quality and regulatory requirements

Quality and regulatory requirements are general requirements that are always included in Nordic Ecolabelling's product criteria. The purpose of these is to ensure that fundamental quality assurance and applicable environmental requirements from the authorities are dealt with appropriately. They also ensure compliance with Nordic Ecolabelling's requirements for the product throughout the period of validity of the licence.

[29] Alternatives to classified phthalates in medical devices, Danish Ministry of the Environment : Environmental Project No. 1557, 2014
[30] Non-toxic Healthcare:Alternatives to Phthalates and Bisphenol A in Medical Devices, 31. Desember 2014, Health Care Without Harm
[31] Alternativa mjukgörare I sjukvården, Swetox, mars 2016

To ensure that Nordic Ecolabelling requirements are fulfilled, the following procedures must be implemented.

O9 Responsible person and organisation

The company shall appoint individuals who are responsible for ensuring the fulfilment of the Nordic Ecolabelling requirements, for marketing and for finance, as well as a contact person for communications with Nordic Ecolabelling.

✉ Organisational chart showing who is responsible for the above.

O10 Documentation

The licensee must archive the documentation that is sent in with the application.

🔑 Checked on site as necessary.

O11 Quality of the disposable article

The licensee must guarantee that the quality of the Nordic Swan Ecolabelled product does not deteriorate for its defined shelf-life during the validity period of the licence.

✉ Procedures for archiving claims and, where necessary, dealing with claims and complaints regarding the quality of the Nordic Swan Ecolabelled disposable article.

🔑 The claims archive is checked on site.

O12 Planned changes

Written notice must be given to Nordic Ecolabelling of planned changes in products and markets that have a bearing on Nordic Ecolabelling requirements.

✉ Procedures detailing how planned changes in products and markets are handled.

O13 Unplanned nonconformities

Unplanned nonconformities that have a bearing on Nordic Ecolabelling requirements must be reported to Nordic Ecolabelling in writing and journalled.

✉ Procedures detailing how unplanned nonconformities are handled.

O14 Traceability

The licensee must be able to trace the Nordic Swan Ecolabelled disposable product in the production.

✉ Description of/procedures for the fulfilment of the requirement.

O15 Legislation and regulations

The licensee shall ensure compliance with all applicable laws and provisions at all production facilities for the Nordic Swan Ecolabelled product, e.g. with regard to safety, working environment, environmental legislation and site-specific terms/permits.

✉ Signed application form.