Coloplast

Ostomy Care
Continence Care
Wound & Skin Care
Interventional Urology

Coloplast position on hazardous substances

Introduction

Coloplast products are biocompatible and safe for the intended purpose. Our company proactively wants to be in compliance and meet any potential concerns over human health and the environmental footprint. Coloplast is therefore highly committed to sustainable product design, product development and production, enabling sustainable product use and waste. Coloplast actively strives to reduce the health- and environmental impact of substances from the company's products and production process and stresses the importance of a substance ambition early in the design phase as well as in the production phase.
The reason Coloplast wants to eliminate hazardous substances, if any, is that

- We want to improve our environmental performance and reduce our footprint.
- We want to be proactive and ahead of the evolving legislation by designing and developing our product to not include hazardous substances
- We want to set an industry example and show transparency

Coloplast's position on hazardous[1] substances demands that the company adheres to the strictest global chemical regulatory requirements for substances used in its products. The regulatory requirements are based on stringent laws, and scientifically established threshold limit values, without compromising user safety as well as the clinical performance of the devices.

Scope

Coloplast position on hazardous substances is global, thereby applying the same standards and requirements regardless of the location of the production site or customers.

Governance

A quarterly process has been established to monitor the legislations mentioned on the "Coloplast Substance Requirement List" (CSRL), Appendix 1. The relevant changes and news are shared biannually in the Substance Substitution Group; a board of managers from Global Operations and Innovation (including R&D), which is anchored in Global Quality and Regulatory Affairs/Global Operations. If a hazardous substance has been identified, the Substance Substitution Group initiates a process to eliminate the substance from Coloplast devices.
Coloplast has set up a structured monitoring process to detect and identify changes in regulations, science and technology early on. This enables Coloplast to identify opportunities and risks at an early stage and proactively to substitute relevant substances if needed.

Coloplast substance requirement list

Coloplast's product requirements regarding the use of hazardous substance are captured in "Coloplast Substance Requirement List" (CSRL), Appendix 1. It combines legal, industry and voluntary requirements regarding chemical substances used in products and primary packaging material. It also prioritizes substances that have been identified as being of greatest concern by regulators across the globe. The CSRL list aims to control, reduce and eliminate

[1] Hazardous substances are in this context related to the substances regulated and evaluated as being of concern according to the CSRL list, Appendix 1.

harmful materials and their impact on the environment and human health, without compromising product safety or clinical performance.
Coloplast medical devices adhere to requirements stated by the European Medical Device Regulation (EU MDR), U.S. Food and Drug Administration (FDA) or other medical device regulations worldwide, ensuring compliance to the international standard EN ISO 10993-1:2020 Biological evaluation of medical devices – evaluation and testing within a risk management process". This standard includes a thorough evaluation of potential substances of concern demonstrating low and acceptable risk to the customer.
Coloplast proactively seeks to phase out or ban substances of concern before they are subject to any legal enforcement. Coloplast's substance position may therefore go beyond legislative compliance and stakeholder consultation. Decisions to seek substitutes on substances are based on an evaluation of the level of concern, commercial availability, and technical feasibility of potential alternatives.
The CSRL list includes substances, that:

- Are banned by law or by Coloplast in its products
- Need to be monitored due to regulatory requirements, or
- Coloplast wants to monitor out of precaution

The CSRL list covers many jurisdictions worldwide, with the most important ones being Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), The Stockholm Convention on Persistent Organic Pollutants (POP), EU MDR, Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP) and the California Proposition 65 list (Cal prop 65) (Appendix 1).

SCIP database

The Substances of Concern in articles or Products (SCIP) database is part of a global trend towards increased transparency in the supply chain. The database ensures that the information on articles containing REACH Candidate List substances is available throughout the whole lifecycle of products and materials, including waste stage. The information in the database is made available to waste operators and consumers. Coloplast completed their relevant 17 SCIP submissions in January 2021. The list will be updated as substitution projects will be finalised. See Appendix 2 for more information.

Process for monitoring and eliminating hazardous substances

If a hazardous substance according to the CSRL list is identified in Coloplast products, the Substance Substitution Group will review the substance and initiate a plan to investigate potential alternatives or eliminate the substance.

- In raw materials: Coloplast suppliers of raw materials used for products and primary packaging must comply with the substance requirements as defined in the CSRL, which will become an integral part of any commercial agreement between Coloplast and its suppliers. This is the case unless it can be documented that the safety and clinical performance of the device will be compromised.
- In product design: During the design phase of any new product development, Coloplast seeks to avoid any use of substances with the requirements defined in the CSRL in both products and production.
- In production and processing aids: Coloplast has initiated projects to reduce the amount of ethylene oxide gas with 50% during sterilization of the sterile devices where irradiation sterilization is not possible. Use of hazardous substances in production is carefully considered during product and process design.
- Additional monitoring: Restriction of Hazardous Substances (RoHS) and Waste from Electrical and Electronic Equipment (WEEE) will be monitored. Renewable and recyclable materials in packaging. Environmental impact of substances at end of life.

Communication and reporting

Coloplast´s position on hazardous substances will be visible in the updated Instruction for Use (IFU) and labels, as well as in a short update in the Sustainability Report. SCIP notifications, regarding substances with environmental

impact according to the waste framework directive, is externally communicated and will be updated regularly (Appendix 2).

1. Appendix 1. Coloplast Substance Requirement List (CSRL)

Legislation or regulation that the requirement relates to	Restricted or declarable	Minimum concentration of declaration limit (6)
REACH candidate- or Authorization listed substances (1)	Declarable	1000 ppm
REACH restricted substances (2)	Restricted	Case by case
Cal Prop 65 substances (3)	Restricted	MADL or NSRL exposure limit that requires label warning on the device
Substances classified as Persistent Organic Pollutants (POP) according to allowable limits set in the Stockholm Convention (4)	Restricted	Case by case
CMR and EDC substances, according to CLP (5)	Declarable or restricted	1000 ppm

(1) The first requirement relates to authorisation and information obligation under the REACH regulation if a substance is listed on the REACH authorisation or candidate list. The REACH candidate list is a list of Substances of Very High Concern and candidates for REACH authorisation. The candidate list is published in accordance with article 59 (10) for the REACH regulation. The REACH authorisation list is the List of substances included in Annex XIV of the REACH regulation. If a REACH authorization listed substance is present in Coloplast devices or production, and the reason for the listing is due to environmental effects, then medical devices are exempted from the authorization requirement. However, Coloplast' position is that these substances should be removed from the devices, unless it can be demonstrated that this will compromise product safety or clinical performance. If a REACH candidate- or authorisation listed substance is present in a component of a device in a concentration higher than 0.1% w/w, information must be shared with customers if asked, in tenders and in product safety data sheets. The concentration of the substance is a total concentration, either determined in an exhaustive extraction of the substance from the device component or determined based on information by raw material supplier.

(2) The second requirement relates to the substances restricted under REACH for certain usages and certain articles. Restrictions are an instrument to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions are normally used to limit or ban manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures or specific labels. A restriction may apply to any substance on its own, in a mixture or in an article, including those that do not require registration.

(3) The third requirement relates to the exposure of any Cal prop 65 listed substance to the customer during device use. Cal prop 65 is an abbreviation of "The Safe Drinking Water and Toxic Enforcement Act of 1986, in the state of California, USA". The Cal prop 65 regulation is dealing with human health concern only (not environment) and only for the toxicological endpoint's cancer and reproduction toxicity. If the exposure to a substance in a device exceeds the established No Significant Risk Limit (NSRL) or Maximum Allowable Dose Limit (MADL) in Cal prop 65 for the substance, then a warning label on the device is required. This is what should be avoided. In case Cal prop 65 does not have any established limit for the substance, the exposure of the substance should be evaluated to biocompatible and associated with a low and acceptable risk. Practically this is done in the Biological Evaluation Report where the evaluation demonstrates a Margin of Safety (MOS) value >>1.

(4) The fourth requirement relates to all Persistent Organic Pollutants (POPs) listed in the Stockholm Convention. The POPs are therefore dealing directly with substances of environmental concern, and only indirectly with human health concern. Substances listed here are not necessarily included in REACH. Parties of the Stockholm Convention, such as Denmark, must take measures to eliminate the production and use of the chemicals listed. In the Stockholm convention is listed allowable limits for medical devices, meaning that this requirement is for Coloplast products to contain POP listed substances below this limit.

(5) The fifth requirement relates to the CLP Regulation and the requirement in EU MDR. Carcinogenic, Mutagenic, Reprotoxic (CMR) substances category 1A/1B and Endocrine disrupting substances (EDC) harmonized classified under CLP, must be labelled for and their presence justified, if present in concentration above 0.1% w/w and used in:

- Components of devices that are invasive and come into direct contact with the human body
- Devices that "(re)administer medicines, body liquids or other substances, including gases, to/from the body."
- Devices that "transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

Coloplast position is to avoid the use of CMR and EDC substances leading to the requirement for labelling and justification under MDR. Also to eliminate the use of these substances in Coloplast devices, even though it is demonstrated that the devices are biocompatible.

(6) Use of thresholds:

- Maximum concentration limit for restricted substances.
  Coloplast acknowledges that some materials contain a certain number of restricted substances being naturally present. However, when a substance is present above the listed maximum threshold limit value, whether it be in product or the primary packaging material of the product, the substance is restricted to the maximum concentration limit as indicated in the CRSL. Thresholds can either be legal limits set by authorities or refer to analytical thresholds being temporarily accepted. Restricted substances are measured at homogeneous material level (unless otherwise specified, meaning these thresholds must be declared on the homogeneous material level. Substances, for which the use is exempt in medical devices products or specifics applications as defined by legislation, are allowed for use.
- Maximum concentration limit for declarable substances:
  Declarable substances (e.g. REACH candidate listed substances) are substances, of which the use needs to be monitored due to a regulatory requirement or because Coloplast wants to monitor the uses from a precautionary point of view. The use of these substances must be reported when above the maximum concentration limit as defined in the CRSL.

2. Appendix 2. SCIP notifications

SCIP is the database for information on Substances of Concern in articles as such or in complex objects (Products). The database was established under the Waste Framework Directive (WFD) requiring that companies supplying articles containing REACH candidate listed substances in a concentration above 0.1% weight/weight on the EU market, must submit information on these articles to the European Chemical Agency (ECHA).
The SCIP database is part of a global trend towards increased transparency in the supply chain. The database ensures that the information on articles containing REACH Candidate List substances is available throughout the whole lifecycle of products and materials, including the waste stage. The information in the database is made available to waste operators and consumers. Coloplast completed their relevant 17 SCIP submissions in January 2021. The list will be updated as substitution projects will be finalised.
As part of our sustainability strategy, we are looking into reducing the Coloplast SCIP notifications in the SCIP database.

3. Appendix 3. List of abbreviations

Cal prop 65	California Proposition 65 list. The Safe Drinking Water and Toxic Enforcement Act of 1986, in the state of California, USA.
CLP	Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic, Reprotoxic substances
CSRL	Coloplast Substance Requirement List
EDC	Endocrine disrupting substances
EU MDR	European Union (EU) Medical Device Regulation (MDR) 2017/745
MADL	Maximum Allowable Dose Limit
NSRL	No Significant Risk Limit
FDA	U.S. Food and Drug Administration
POP	The Stockholm Convention on Persistent Organic Pollutants
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals
RoHS	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SCIP	Substances of Concern in articles as such or in complex objects (Products)
WEEE	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment