Regulatory Compliance Requirements

Purpose of Regulatory Compliance Requirements

As manufacturer of hygiene products, Ontex sees quality and product safety as its key-priorities. All raw materials are selected carefully in accordance with all applicable regulations on product safety. Furthermore, we want our products to be compliant with various other legal obligations, official recommendations and safety standards. Purpose of this document is to list all applicable regulations and safety standards we want our product to be compliant with.

List of regulations and safety standards - product focus

Our product offer is belonging, depending on the region, to the following categories:
- Consumer Goods
- Medical Devices Class I and Class IIa (EU) / Class I and Class II (US)
- Cosmetic Products

Safety assessments are based on legislations and standards relevant to the type of material and the intended market. Therefore, our suppliers need to ensure that raw materials supplied to Ontex will not be an obstacle to finished goods compliance to the following standards :

- Directive (EC) 2001/95 on general product safety and as of 13 December 2024 the General Product Safety Regulation (EU) 2023/988
- US Consumer Product Safety Act (CPSA) and US Consumer Product Safety Improvement Act (CPSIA)
- German guidelines for the evaluation of personal sanitary products ("Hinweise zur Beurteilung von Intimhygieneerzeugnissen") Federal Health Gazette („Bundesgesundheitsblatt") 39, 124 (1996);
- TGA AS 2869-2008 on Tampons
- Regulation on medical devices (EU) 2017/745
- US Federal Food, Drug and Cosmetic Act and FDA 21 CFR
- Regulation on cosmetic products (EC) N°1223/2009 for cosmetic product and preparation
- Directive 94/62/EC on Packaging and Packaging Waste and amendments when applicable
- Regulation on Biocidal Products (EC) N°528/2012 when biocidal substances present

List of regulation and standards applicable to substances and preparations

As a downstream user of substances, preparations and semi-finish goods, Ontex ask it's supplier to to ensure their compliance with standards directly or indirectly applicable for their technology as follow:

- Regulation (EC) No 1907/2006 concerning the registration, evaluation and authorization of chemical substances, as well as the restrictions applicable to these substances (REACH)
- Regulation 2019/1021/EU on persistent organic pollutants (POPs)

- Regulation (EC) No. 1272/2008 (CLP regulation)
- Toxic Substances Control Act and California Proposition 65 regarding the list of restricted or unauthorized substances and the resulting obligations
- CFR: Code of Federal Regulations: (in particular 21 CFR §§ 176.210, 176.170, 177.2800, 177.1850,177.1520, 175.105) for all materials supply to Ontex.
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food for all materials supply to Ontex.
- German Recommendations for materials in contact with foodstuff (in particular recommendations: III, VII, IX, XV, XXXVI and LIII) for all materials supply to Ontex.
- European Council of Paint, Printing Ink and Artists` Colours Industry (CEPE): Exclusion list for printing inks and related products, 3rd Edition for all inks and colorants (EUPIA) for all printing materials supply to Ontex.
- Code of Practice of the International Fragrance Association (IFRA) for all perfumes supply to Ontex.

Disclaimer: Depending on the item purchased & related risks, we may divert from the general requirements listed in this document.