Restricted Substance List (RSL)

Medical Devices

Table of Contents

General

H&M has established H&M Chemical Restrictions for all products due to concern for the health of customers as well as for the environment and working conditions. H&M Chemical Restrictions consist of several parts with regard to product types. This document concerns Chemical Restrictions for Medical Devices. Each limit in H&M Chemical Restrictions is valid for homogeneous parts of the concerned product if not otherwise stated. Test methods are specified for all restricted chemicals, in case of undated test method, the latest version is valid.

In addition to this part of the H&M Chemical Restrictions, production of Medical Devices must also fulfill H&M Chemical Restrictions regarding the Manufacturing Restricted Substance List (MRSL). Furthermore, if a product is sold in a packaging it must comply with H&M Chemical Restrictions Packages. These documents are to be found on the Supplier Portal as well as on www.**hm**.com/**chemical**-restrictions.

The official and valid version of this document is in English. Any translation of the document is prepared for reference only. H&M accepts no liability for any mistakes done in the translation.

Commitment

By accepting H&M Standard Purchase Conditions, the Supplier commits to comply with H&M Chemical Restrictions. It is the Supplier's responsibility to assure compliance with H&M Chemical Restrictions and to inform all their downstream suppliers and subcontractors about the content of H&M Chemical Restrictions.

By accepting H&M Standard Purchase Conditions, each Supplier acknowledges that H&M reserves the right to:

- *Inspect and test any product, any part of production and/or packaging, by any listed or appropriate method, at any time or at any stage of production.*
- *Cancel the Order, or, if the products are already delivered, return the products to the Supplier if the product, production and/or packaging do not correspond to the H&M Chemical Restrictions.*
- *Hold the Supplier responsible for any damage caused by the ordered product if the product, production and/or packaging do not correspond to the H&M Chemical Restrictions.*
- *Receive the Safety Data Sheets (SDS) for all substances and preparations (dyes, colorants, solvents, chemicals etc.) used in the production of a specific Order.*

In the case of contradictory test results, H&M test result will prevail.

Definitions

Concentration Limit	The substance must not be present in the product at concentrations above this limit.
Not Detected	The substance must not be present in the finished product at concentrations above the analytical reporting limit.
Usage ban	The substance must not be used in production and it must not be added to the product[1].
Homogeneous	Uniform composition throughout, i.e. a material that cannot be mechanically disjointed into different materials.
Reporting limit	Describes the level of detection times a safety factor selected by the laboratory that ensures repeatability and reproducibility.
Self-declaration	All chemicals used should have Safety Data Sheets, SDS, showing that no restricted substance is included. Upon request supplier must be able to present the SDS for the chemicals used in the production of the requested product. Other supporting documents such as certificates from subcontractors etc. can also be considered as a part of the SD.
Substances defined as hazardous due to intrinsic properties.	Persistent, bio accumulative and toxic (PBT), very persistent and very bio accumulative (vPvB), carcinogenic, mutagenic and toxic for reproduction (CMR), endocrine disruptors (ED) or equivalent concern

Abbreviations

CAS no	Chemical Abstracts Service number, an identification number for chemicals in this database.
MRSL	Manufacturing Restricted Substances List
ppm	Parts per million, which is the same as mg/kg.
Percentage	Percentage is weight by weight, % w/w
REACH	Registration, Evaluation, Authorization and restriction of Chemicals
SVHC	Substances of Very High Concern

[1] Impurities at low concentrations of these substances may be accepted only if technically unavoidable due to e.g. raw materials, formation in the manufacturing process, storage or packaging.

Requirements – All Medical Devices

Requirement	Limit/Requirement
H&M Chemical Restrictions Apparel / Accessories / Footwear / Home Interior Textile Products	All Medical Devices must comply with, and be tested for risky chemicals in H&M Chemical Restrictions Apparel / Accessories / Footwear / Home Interior Textile Products
H&M Chemical Restrictions Chemical products	The chemical composition (e.g. glue for skin contact application) must be formulated as to avoid any classification according to the CLP regulation as defined in H&M Chemical Restrictions for Chemical products.
H&M Chemical Restrictions Cosmetic Products	Chemical content (e.g. glue for skin contact application) must comply with H&M Chemical Restrictions for Cosmetic Products
H&M Chemical Restrictions Toys	Medical Devices intended for children (e.g. plasters) must comply with H&M Chemical Restrictions for Toys
H&M Chemical restrictions Packaging	All Packaging of Medical Devices must comply with, and be tested for risky chemicals in H&M Chemical Restrictions Packaging
Medical Devices Directive (MDD)	All Medical Devices must comply with the Essential Requirements that are listed in Annex I of MDD 93/42/EEC
Classification	All Medical Devices are classified as Class I (non-sterile) products in accordance with Rule 4 of Annex IX of MDD 93/42/EEC
Conformity Assessment	All Medical Devices must have a Conformity Assessment which demonstrates that the Medical Device complies with the requirements of MDD 93/42/EEC
Clinical evaluation	Compliance with the Essential Requirements in Annex I of MDD 93/42/EEC must be demonstrated by a clinical evaluation in accordance with Annex X of MDD 93/42/EEC
Declaration of Conformity (DoC)	All Medical Devices must have a Declaration of Conformity (DoC) which demonstrates that the Medical Device complies with the requirements of MDD 93/42/EEC
CE-Marking	Compliance with the MDD 93/42/EEC must be demonstrated by a CE Mark in accordance with Annex XII of MDD 93/42/EEC
Quality management systems	Production must demonstrate its ability to provide Medical Devices which meets regulatory requirements according to Quality Management System ISO 13485
SVHC Check the ECHA website for the updated Candidate List of Substances of Very High Concern for Authorisation[2]	1000 mg/kg in each homogenous part of the product, except if lower limit applies as per other part of this document
Substances defined as hazardous due to intrinsic properties Criteria for hazardous as defined in REACH Article 57[3]	1000 ppm, except if lower limit applies as per other parts of this document

[2]https://echa.europa.eu/candidate-list-table
[3] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02006R1907-20150601&from=EN

Product Standards

Requirement	Standard
Risk assessment	
Risk management for medical devices	EN 14971
Biocompatibility	
Cytotoxicity	ISO 10993-5
Chemical characterization of materials	ISO 10993-18
Packaging & Labelling	
Packaging for terminally sterilized medical devices	ISO 11607
Requirements on package of medical devices	EN 868
Symbols, Medical Device labels, labelling and information to be supplied	ISO 15223-1
Related glossary, symbols and information of medical devices	EN 1041
Sterility	
Hygienic standard of disinfection for single use medical products	GB 15980
Validation and routine control requirements of ethylene oxide sterilization	ISO 11135
Biological indicators for ethylene oxide sterilization processes	ISO 11138-2
Tests for genotoxicity, carcinogenicity and reproductive toxicity	ISO 10993-3
Determination of a population of microorganisms on products	11737-1
Tests of sterility performed in the definition, validation and maintenance of a sterilization process	11737-2
Ethylene oxide sterilization residuals	ISO 10993-7
Sterility	European Pharmacopoeia (EuP) Ch 2.6.1 USP 71
Performance requirements	
Aspects of absorbency	EN 13726-1
Moisture vapor transmission rate	EN 13726-2
Waterproofness	EN 13726-3
Conformability	EN 13726-4
Odor control	EN 13726-6
Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze	EN 14079
Adhesion strength	ASTM D1000-10 (section 46-53)

Additional Requirements/ Restricted substances – All Materials

Requirement/ Restricted substance	CAS	Limit	Test Method	Reporting Limit
Glue on Medical Devices for skin contact application	-	Chemical content must comply with H&M Chemical Restrictions for Cosmetic Products, and the chemical composition must be formulated as to avoid any classification according to the CLP regulation as defined in H&M Chemical Restrictions for Chemical products.		
Cyanoacrylate-based adhesives (Including, but not limited to: Ethyl cyanoacrylate; Methyl cyanoacrylate; Isopropyl cyanoacrylate)	Various	Usage ban in products for skin contact		
N-nitrosamines, Total amount				
N-nitrosodimethylamine	62-75-9	Sum < 0.1 mg/kg	DIN EN ISO 71-12 GC-MS analysis	50 µg/kg
N-nitrosodiethylamine	55-18-5			
N-nitrosodipropylamine	621-64-7			
N-nitrosodibutylamine	924-16-3			
N-nitrosopiperidine	100-75-4			
N-nitrosopyrrolidine	930-55-2			
N-nitrosomorpholine	59-89-2			
N-nitroso-N-methylaniline	614-00-6			
N-nitroso-N-ethylaniline	612-64-6			
Polyaromatic Hydrocarbons (PAH)				
Benzo(a)anthracene	56-55-3	0.5 mg/kg	AfPS GS 2014:01 Extraction with toluene followed by GC-MS analysis	0.2 mg/kg
Benzo(a)pyrene	50-32-8	0.5 mg/kg		
Benzo(b)fluoranthene	205-99-2	0.5 mg/kg		
Benzo(e)pyrene	192-97-2	0.5 mg/kg		
Benzo(g,h,i)perylene	191-24-2	0.5 mg/kg		
Benzo(j)fluoranthene	205-82-3	0.5 mg/kg		
Benzo(k)fluoranthene	207-08-9	0.5 mg/kg		
Chrysene	218-01-9	0.5 mg/kg		
Dibenzo(a,h)anthracene	53-70-3	0.5 mg/kg		
Indeno(1,2,3-c,d)pyrene	193-39-5	0.5 mg/kg		

Requirement/ Restricted substance	CAS	Limit	Test Method	Reporting Limit
Acenaphthene	83-32-9	Sum <10 mg/kg	AfPS GS 2014:01 Extraction with toluene followed by GC-MS analysis	0.2 mg/kg
Acenaphthylene	208-96-8			
Anthracene	120-12-7			
Fluoranthene	206-44-0			
Fluorene	86-73-7			
Phenanthrene	85-01-8			
Pyrene	129-00-0			
Naphthalene	91-20-3	<2 mg/kg		
Sum of 18 PAH	-	<10 mg/kg		