

Mactac

Regulatory Status

Medical Tape Products

Contents

Product Identification	3
Product Classification.....	3
SDS	3
US Regulation.....	4
FDA Status.....	4
Prop 65.....	4
Chemical Substances Undergoing Prioritization: High Priority.....	4
Persistent, Bio-accumulative, and Toxic (PBT) Chemicals under Toxic Substances Control Act – TSCA ..	5
Toxics in Packaging (Formerly CONEG)	5
Volatile Organic Compounds (VOC’s)	5
CPSIA	5
Uyghur Forced Labor Prevention Act.....	6
EU Regulations	6
REACH - Substances of Very High Concern (SVHC)	6
Restriction of Hazardous Substances in Electrical and Electronic Equipment - RoHS (1, 2 & 3)	6
Persistent organic pollutants (POPs)	7
Conflict Minerals	7
TSE/BSE	7
Substances of Interest	8

Product Identification

Product Classification

Mactac Medical Tape Products are considered **Articles** as defined by the Federal Occupational Safety and Health Administration (OSHA).

According to the OSHA's Hazard Communication Standard (29 CFR 1910.1200 (c):

Article means a manufactured item other than a fluid or particle:

- (i) which is formed to a specific shape or design during manufacture;*
- (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and*
- (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical and does not pose a physical hazard or health risk to employees.*

SDS

According to 29 C.F.R. 1910.1200 (b)(6)(V), the section *1910.1200 - Hazard Communication* does not apply to articles. Consequently, as articles, Mactac Medical Tape products are exempt from the Safety Data Sheets (SDS) provisions of 29 C.F.R. 1910.1200(g)(6).

US Regulation

FDA Status

The adhesives of Mactac Medical Tape products comply with 21 CFR 175.105 – Adhesives. Compliance with this section requires the adhesive is either separated from food by a functional barrier or used subject to the following limitations:

- In dry food. The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.
- In fatty and aqueous food. The quantity of adhesive that contacts packaged fatty and aqueous food shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.

The end-user is responsible for determining the applicability of FDA requirements for the intended use(s).

Prop 65

Mactac Medical Tape products comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65. A warning label is not required on the basis that there is no exposure to any Proposition 65 substances in known applications.

Chemical Substances Undergoing Prioritization: High Priority

On December 20, 2019, EPA finalized the designation of 20 chemical substances as a high priority for upcoming risk evaluations. Of the twenty chemicals undergoing evaluation as High Priority under TSCA, nineteen are not used in the manufacture of Mactac Medical Tape products. One chemical, butadiene, is used as a starting material for a rubber in rubber-based adhesives. After processing from the supplier and Mactac, it is anticipated that butadiene is present in negligible concentrations in Mactac Medical Tape products.

UV Acrylic adhesives do not contain any of the twenty chemicals undergoing evaluation as High Priority under TSCA.

Persistent, Bio-accumulative, and Toxic (PBT) Chemicals under Toxic Substances Control Act – TSCA

On January 6, 2021, the U.S. Environmental Protection Agency (EPA) published final rules under Toxic Substances Control Act (TSCA) Section 6(h) to restrict the importation and use of five Persistent, Bio-accumulative, and Toxic (PBT) chemicals listed below:

- 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP, CAS 732-26-3)
- Decabromodiphenyl ether (DecaBDE, CAS 1163-19-5)
- Phenol, isopropylated phosphate (3:1) (PIP 3:1, CAS 68937-41-7)
- Pentachlorothiophenol (PCTP, CAS 133-49-3)
- Hexachlorobutadiene (HCBd, CAS 87-68-3)

Based on supplier information, formulation, and manufacturing practices, Mactac Medical Tape Products are not manufactured with the addition of the above listed chemicals.

Toxics in Packaging (Formerly CONEG)

Mactac does not intentionally add the following heavy metals (or their compounds): cadmium, hexavalent chromium, lead, mercury in Medical Tape Products. We have not specifically analyzed this product for the presence of these substances. Based on our knowledge of the raw materials and the manufacturing process, we expect that the sum of any trace quantities of lead, mercury, cadmium, and hexavalent chromium is below legislation limit of 100 ppm.

Volatile Organic Compounds (VOC's)

Mactac Medical Tape products are coated from 100% solids or from water-based emulsion. No solvents are used. Any residual monomers are expected to be substantially removed during the coating and drying processes.

Mactac does not routinely test for VOC's.

CPSIA

Mactac Medical Tape products meet the safety requirements for lead and phthalates in Consumer Product Safety Improvement Act (CPSIA) of 2008 for children's products. A General Conformity Certificate is not required.

Uyghur Forced Labor Prevention Act

Raw material sourced by Mactac are not sourced from companies or persons located in the Xinjiang Uyghur Autonomous Region (XUAR) pursuant to the Uyghur Forced Labor Prevention Act of 2021.

EU Regulations

REACH - Substances of Very High Concern (SVHC)

Mactac Medical Tape products are classified as “articles” per European Union Regulation (EC) No. 1907/2006 and are not articles with an intended release of a chemical substance. They are exempt from the registration requirements.

These articles do not contain intentionally added Substance of Very High Concerned (SVHC) as published by the European Chemicals Agency (ECHA) on June 10th, 2022, under the provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in concentration exceeding 0.1% w/w.

Restriction of Hazardous Substances in Electrical and Electronic Equipment - RoHS (1, 2 & 3)

Mactac Medical Tape Products are in compliance with concentration values listed in European Commission Directive 2002/95/EC and Annex II of Directive 2011/65/EU (RoHS 2) and (EU) 2015/863 restricting the use of certain hazardous substances in each of the homogeneous material in electrical and electronic equipment (EEE) as follows:

- Less than 0.1% by weight for lead, mercury and hexavalent chromium
- Less than 0.1% by weight for polybromo biphenyls (PBB) and polybrominated biphenyl ethers (PBDE)
- Less than 0.01% by weight for cadmium
- Less than 0.1% by weight for bis (2-ethylhexyl phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP)

Mactac Medical Tape products are not tested for the above mentioned substances. Mactac Medical Tape products also comply with the chemical requirements of China RoHS.

Persistent organic pollutants (POPs)

Mactac products do not contain intentionally added Persistent organic pollutants (POPs) according to the **Regulation (EU) No 2019/1021 of the European Parliament** on persistent organic pollutants (POPs Regulation).

Conflict Minerals

Mactac Medical Tape products do not contain Conflict Minerals (columbite-tantalite, cassiterite, wolframite, and gold as identified in Public Law 111-203) and their derivatives (tantalum, tin, and tungsten), as enumerated in 77 Federal Register 56273 and 56285).

TSE/BSE

Mactac Medical Tape Products utilizing rubber-based adhesive contain an animal sourced rubber that is present on the adhesive at 25% or less.

The fatty acids substances are not a BSE/TSE (Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy) agent. The conditions of manufacturing are hydrolysis at 220°C for six hours under pressure. Tallow derivatives manufactured under these conditions are unlikely to present any TSE risk and can be considered in compliance.

Animal by-products on Mactac rubber-based adhesives are considered processing aid.

Mactac products manufactured using UV acrylic adhesives do not contain Animal Derived Materials.

Substances of Interest

Mactac Medical Tape products are not intentionally formulated with the following substances:

- Aromatic amines
- Asbestos or Crystalline Silica
- Azo Dyes
- Benzophenone
- BHT and BHA
- Bisphenol A (BPA)
- Brominated Flame Retardants
- Chlorinated compounds
- Dimethyl Fumarate
- Dioxins
- Epoxy Derivatives
- Food Materials or Food Allergens
- Formaldehyde
- Natural Rubber or Natural Rubber Latex
- Ozone Depleting Substances
- Per - and polyfluoroalkyl substances (PFASs)
- Perfluorooctanoic acids (PFOAs) and Perfluoro octane Sulfonates (PFOSs)
- Persistent Organic Pollutants
- Phthalate Plasticizers, including DEHP, DINP, DIDP, DnOP, DnHP, BBP, DBP, DIBP, DCHP
- Polychlorinated Biphenyls (PCBs)
- Short-chained Chlorinated Paraffins (SCCP)
- Tri Nonyl Phenyl Phosphite (TNPP)

DISCLAIMER:

This Regulatory Bulletin has been prepared by Mactac NA for general information only. It is meant to answer the most common regulatory questions. Regulations, status, and standards will evolve and Mactac will update this document on a regular basis. The determination of the suitability of the final use of the products is the sole responsibility of the customer. Mactac does not perform tests, nor does it require its suppliers to carry out testing. Information on this Regulatory Bulletin is based on supplier information, formulation, and manufacturing practices. For more Regulatory information, please contact your Mactac sales representative or our regulatory team at res-377-regulatoryrequests@mactac.com