

# Mactac

# Regulatory Status

## Medical Tape Products

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## 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).

### Allergens

Mactac Medical Tape products are not intentionally formulated to contain the following foods that are known to be allergens, as defined in the US Food Allergen Labeling and Consumer Protection Act of 2004:

- Milk
- Eggs
- Fish
- Crustacean shellfish
- Tree nuts
- Peanuts
- Wheat
- Soybeans
- Sesame

This information is based on supplier information, formulation, and manufacturing practices. Mactac does not routinely test for these substances, nor does it require its suppliers to carry out testing.

### 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.

## Toxic Substances Control Act (TSCA) Restricted Substance Declaration

The United States Toxic Substances Control Act (TSCA) is a federal chemicals management regulation. Under TSCA Section 6, certain substances, and substance families (including treated articles containing these substances) are restricted from distribution in U.S. commerce, including:

- Asbestos
- Lead, when used in paint\*
- Polychlorinated biphenyls (PCBs)
- Dioxins
- Chlorofluorocarbons (CFCs, ozone depleting substances)
- Metallic mercury, when used in consumer products
- Formaldehyde, when used in composite wood products\*
- Nitrites, when used in certain cutting fluids\*
- Hexavalent chromium compounds, when used in water treatment\*
- Five Persistent, Bioaccumulative, and Toxic substances restricted in 2021:
  - PIP 3:1 (CAS 68937-41-7)
  - DecaBDE (CAS 1163-19-5)
  - 2,4,6 TTBP (CAS 732-26-3)
  - HCBd (CAS 87-68-3)
  - PCTP (CAS 133-49-3)

\*Not applicable to Mactac products

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

## 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.

### Toxics in Packaging Clearinghouse (TPCH)

Mactac does not intentionally add the following heavy metals (or their compounds): cadmium, hexavalent chromium, lead, mercury, as well as phthalates and perfluoroalkyl and polyfluoroalkyl substances (PFAS) to any of the Medical Tape products, as defined on the 2021 Toxic in Packaging Clearinghouse (TPCH) update. Mactac does not specifically analyze the products for the presence of these substances. Based on our knowledge of the raw materials and the manufacturing process, the sum of any trace quantities of lead, mercury, cadmium, and hexavalent chromium is below legislation limit of 100 ppm.

### Consumer Product Safety Improvement Act (CPSIA)

Under the chemical substance requirements set forth in the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), the presence of heavy metals in substrates are restricted in all children’s products. In addition, the phthalates denominated as DEHP, DBP, BBP, DINP, DIDP, and DNOP are restricted in toys for children and childcare articles.

Based on supplier information, formulation and manufacturing process, 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.

### 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 January 23<sup>rd</sup>, 2024, 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.

### SCIP - Substances of Concern In articles as such or in complex objects (Products)

SCIP is the database for information on Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (WFD).

To ensure compliance with SCIP, Companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% weight by weight (w/w) on the EU market have to submit information on these articles to ECHA.

Refer to REACH-SVHC statement above for SCIP compliance.

### 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).

### Extended Mineral Reporting – Mica and Cobalt

Based on supplier information, formulation, and manufacturing practices Mica and Cobalt are not used as components, nor are added to the manufacturing process or to Mactac Medical Tape products.

### 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.

### Per- and polyfluoroalkyl (PFAS) and PFOS (Perfluorooctanesulfonic) substances

Several U.S. states have adopted varying laws prohibiting the manufacture, known distribution, or sale of products containing intentionally added perfluoroalkyl and polyfluoroalkyl substances (PFAS). Based on supplier information, formulation, and manufacturing practices, Mactac Medical Tape Products do not contain intentionally added Organic Fluorine Compounds including PFAS (Per- and polyfluoroalkyl) and PFOS (Perfluorooctanesulfonic) substances.



## Substances of Concern

Based on supplier information, formulation and manufacturing process, the Substances of Concern listed below are not used as components, nor are added to the manufacturing process or to 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)
- Bisphenol S (BPS)
- Brominated Flame Retardants
- Chlorinated compounds
- Dimethyl Fumarate
- Dioxins
- Epoxy Derivatives
- Food Materials or Food Allergens
- Formaldehyde
- Microplastics
- Nanomaterial
- Natural Rubber or Natural Rubber Latex
- Ozone Depleting Substances
- 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 [Mactac-Regulatory Mailbox](#).