Mactac
Regulatory Status

Medical Tape Product:

TM4130A - Single Coated 1/32 Medical Foam MP150 Acrylic Adhesive 96# Bleached Pck Release Liner

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Contents

Product Identification 3
Product Classification 3
SDS 3
US Regulation 4
FDA Status 4
Allergens 4
Toxics in Packaging Clearinghouse (TPCH) 4
Volatile Organic Compounds (VOC) 5
Toxic Substances Control Act (TSCA) Restricted Substance Declaration 5
Consumer Product Safety Improvement Act (CPSIA) 5
State of California Safe Drinking Water and Toxic Enforcement Act of 1986 - Prop 65 6
Dodd-Frank Wall Street Reform and Consumer Protection Act 6
Chemical Substances Undergoing Prioritization: High Priority 6
EU Regulations 7
REACH - Substances of Very High Concern (SVHC) 7
SCIP - **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts) 7
Restriction of Hazardous Substances in Electrical and Electronic Equipment - RoHS 7
Persistent organic pollutants (POPs) 7
EU Regulation on Packaging and Packaging Waste (PPWR - EU 2025/40) 8
Responsible Minerals Initiative (RMI) 8
TSE/BSE 8
Per- and polyfluoroalkyl (PFAS) and PFOS (Perfluorooctanesulfonic) substances 9
Nitrosamines 9
Substances of Concern 10

Product Identification

Product Classification

Mactac Medical tapes 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 tapes are exempt from the Safety Data Sheets (SDS) provisions of 29 C.F.R. 1910.1200(g)(6).

US Regulation

FDA Status

The adhesives used in the Mactac Medical tapes 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 tapes 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.

Toxics in Packaging Clearinghouse (TPCH)

The Toxics in Packaging Clearinghouse (TPCH) was established by the Coalition of Northeastern Governors (CONEG) to promote the Model Toxics in Packaging Legislation that CONEG developed. CONEG's Source Reduction Council created the model legislation in 1989 to reduce heavy metals in packaging. TPCH was formed in 1992 to support states to adopt it.
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 tapes, 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.

Volatile Organic Compounds (VOC)

Mactac Medical tapes 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.

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 tapes are not manufactured with the addition of the above listed chemicals.

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 tapes meet the safety requirements for lead and phthalates in Consumer Product Safety Improvement Act (CPSIA) of 2008 for children’s products.

State of California Safe Drinking Water and Toxic Enforcement Act of 1986 - Prop 65

Proposition 65 requires businesses to provide warnings to Californians about significant exposures to chemicals that cause cancer, birth defects or other reproductive harm.
The statements below cover regulatory status for the product as sold including face stock, adhesive and liner and it is provided to support downstream compliance under conditions of use where occupational or workplace exposure may occur.

Mactac products are intended, labeled and packaged for industrial conversion processes. It remains the responsibility of downstream users to assess their specific applications, processing conditions, and finished products to determine if a Proposition 65 warning is required for the final product or its packaging.

Mactac Regulatory has reviewed the recent California OEHHA update effective July 17, 2026, which added welding fumes and three specific pharmaceutical substances (hydrochlorothiazide, voriconazole, and tacrolimus) to the list. None of them are applicable to our products.
Because our products do not utilize, contain, or generate any of these newly listed substances, our chemical profile remains unchanged.

Mactac Medical tape identified in this document complies 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.

Dodd-Frank Wall Street Reform and Consumer Protection Act

The Public Law 111-203 Dodd-Frank Wall Street Reform and Consumer Protection Act, Section 1502 aims to prevent the use of Conflict Minerals that directly or indirectly finance or benefit armed groups in the Democratic Republic of the Congo or adjoining countries.
Mactac Roll Label 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).

Chemical Substances Undergoing Prioritization: High Priority

On December 20, 2019, EPA finalized the designation of 20 chemical substances as High-Priority Substances for TSCA risk evaluations. On December 18, 2024, EPA designated an additional five chemicals as High-Priority Substances, bringing the total of currently designated High-Priority substances to 25.
Of these 25 chemicals, 24 are not used in the manufacture of Mactac products that use Hotmelt rubber based adhesives. 1,3-Butadiene (commonly called “butadiene”), which is on EPA’s high-priority list, is used as a starting material for a rubber in rubber-based adhesives. After polymerization and downstream processing at the supplier and at Mactac, any residual monomeric 1,3-butadiene would be expected to be present at negligible concentrations in the finished adhesive and in finished Mactac products.
Acrylic Emulsion adhesives do not contain any of the twenty chemicals undergoing evaluation as High Priority under TSCA.

EU Regulations

REACH - Substances of Very High Concern (SVHC)

Mactac Medical tapes 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 February 4th, 2026, 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 - **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts)

SCIP is the database for information on **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts) 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

Mactac Medical tapes comply with the substance concentration limits established under European Commission Directive 2002/95/EC (RoHS), Directive 2011/65/EU and its subsequent amendments (RoHS 2), including Directive (EU) 2015/863 (commonly referred to as RoHS 3), which restrict the use of certain hazardous substances in each homogeneous material of 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 polybrominatedbiphenyl 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 tapes also comply with the chemical requirements of China RoHS. No analytical testing or laboratory verification has been performed

Persistent organic pollutants (POPs)

Mactac products using rubber-based adhesives do not contain any intentionally added Persistent organic pollutants (POPs) according to the requirements of **POPs Regulation: Regulation (EU) No 2019/1021, (EU) No 2023/1006 of the European Parliament** and the **12th Conference of the Parties (COP)**.

EU Regulation on Packaging and Packaging Waste (PPWR - EU 2025/40)

Regulation (EU) 2025/40 entered into force on 11 February 2025 and replaces Directive 94/62/EC. It introduces harmonized, directly applicable requirements across the EU, including rules on substances of concern, recyclability, and material restrictions. Mactac Roll Label products comply with the PPWR - EU 2025/40 on the following:

Recyclability: At this time, Mactac has not conducted recyclability testing on our Medical Tapes. However, all Mactac products using paper or PET liner are considered fully recyclable through established liner recycling solutions, such as those offered by CELAB Europe and TLMI in the United States.

Per- and Polyfluoroalkyl Substances: based on supplier information, Mactac Medical Tapes do not contain intentionally added PFAS and meet the applicable PFAS restrictions under the PPWR.

Restriction of Hazardous Substances in Electrical and Electronic Equipment - RoHS: Mactac Medical Tapes are also RoHS compliant; because RoHS restricts lead, cadmium, mercury, and hexavalent chromium, this compliance supports conformity with the heavy metal requirements of PPWR Article 5(4).

Responsible Minerals Initiative (RMI)

Mactac does not directly source or intentionally add any of the Conflict Minerals listed below.

Conflict Minerals Template (CMRT v. 6.5):

Tantalum
Tin
Gold
Tungsten

Extended Mineral Reporting Template (EMRT v. 2.0):

Cobalt	Lithium
Copper	Mica
Graphite	Nickel

In addition, Mactac conducts supply chain survey to ensure that our suppliers are in compliance with the Responsible Minerals Initiative (RMI) requirements.

TSE/BSE

Mactac Medical tapes utilizing cross-linked polyethylene foam or rubber-based hotmelt adhesives may contain bovine tallow derivatives. Mactac keeps supplier documentation that the conditions of manufacturing process of our suppliers are the recommended by World Health Organization and in compliance with EMEA 410 Rev. 3, Section 6.4.

Tallow derivatives manufactured according to these conditions are unlikely to present any TSE risk and can be considered in compliance.

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

Several U.S. states have adopted laws restricting or prohibiting the manufacture, distribution, sale, or offering for sale of certain products containing intentionally added per- and polyfluoroalkyl substances (PFAS).

Based on supplier declarations, raw material composition information, formulation data, and manufacturing knowledge, Mactac Industrial tapes are not intentionally formulated with PFAS, including perfluoroalkyl and polyfluoroalkyl substances and perfluorooctane sulfonate (PFOS).

This statement is based on information provided by suppliers and internal product knowledge. No analytical testing for PFAS has been performed.

Nitrosamines

Nitrosamines are a class of chemical compounds that are formed when amines react with nitrates and nitrites.

Based on supplier information, formulation, and manufacturing practices Nitrates and Nitrites are not used as components, nor intentionally added to the manufacturing process or incorporated into Mactac products. Therefore, the formation of nitrosamines is not expected in Mactac products.

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 tapes:

- 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
- EPS – Expanded Polystyrene
- Food Materials or Food Allergens
- Melamine
- Nanomaterial
- Natural Rubber or Natural Rubber Latex
- Ozone Depleting Substances
- Parabens
- 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