

## Regulatory Status Mactac Medical Tape Products

### 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).

### SDS

Mactac products are considered non-hazardous and are not subject to the requirement of Safety Data Sheets (SDS – formerly MSDS) in accordance with OSHA Hazard Communication Standard (29 CFR 1910.1200), European Union Regulation (EC) No. 1272/2008, and other similar regulations worldwide.

### REACH

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 have substances of very high concern (SVHC) and Annex XIV as determined by European Chemical Agency that are subject to reporting, updated 1/15/2019. These articles comply with Annex XVII restrictions.

### 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 the reasonably anticipated uses.

## 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.

## 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).

## RoHS

Mactac Medical Tape Products meet the maximum concentration values (MCV) listed in European Commission Directive 2002/95/EC (RoHS) 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 abovementioned substances. Mactac Medical Tape products comply with the chemical requirements of China RoHS.

## 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.

## Substances of Interest

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

- Bisphenol A (CAS #80-05-7)
- Natural Rubber or Natural Rubber Latex
- Asbestos or Crystalline Silica
- Phthalate Plasticizers, including DEHP, DINP, DIDP, DnOP, DnHP, BBP, DBP, DIBP, DCHP
- Food Materials or Food Allergens

Mactac Medical Tape Products are not tested for the presence of these substances.