

Material Data Sheet | 10mil Clear Polyurethane Film

Polymer: thermoplastic polyurethane, aromatic polyether – blown film

Key Attributes: Very tough, abrasion resistant

Excellent chemical resistance

Good low-temperature-flex properties

Physical Properties	Test Method	Units	Typical Properties
Hardness	D-224	Shore A	85
Tensile Strength @ 100% Modulus	D-412	psi	990
Tensile Strength @ 300% Modulus	D-412	psi	1750
Tensile Strength Ultimate	D-412	psi	7000
Elongation at Break	D-412	%	570
Tear Resistance	D-624 Die C	pli	475

This product "may be used in food-contact applications in compliance with 21 CFR 177.1680 (Polyurethane resins) and 177.2600 (Rubber articles intended for repeated use), for repeated-use applications in contact with dry solids (i.e., food types VIII and IX).

This product may be used up to "a maximum temperature of 82°C (180°F) as described in Tables 1 and 2 of 21 CFR 176.170."

This product "is a synthetic organic material that does contain substances derived from tallow sources. Our suppliers have assured us that processing conditions used in the production of this tallow derivative product are in compliance with the minimum conditions described below for the processing of rendered fats listed in Annex XIII, Chapter XI of the EU Regulation 142/2011/EC, Commission Regulation 722/2012 and the Notes for Guidance EMA/410/01 Rev 3.

Process Conditions: Regulation 142/2011/EC Annex XIII Chapter XI

- a) Transesterification or hydrolysis at at least: 200°C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); or
- b) Saponification with NaOH 12 M (glycerol and soap) in a batch process at 95°C for 3 hours, or in a continuous process at 140°C, 2 bars (2,000 hPa) for 8 minutes; or
- c) Hydrogenation at 160° C at 12 bars (12,000 hPa) for 20 minutes.

These conditions are considered to be sufficient to inactivate BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) transmitters. The conditions also meet the requirements of ISO 22442-1:2007 Annex C.5 regarding the processing of tallow derivatives used in medical devices. Additionally, this tallow derivative product is compliant with the U.S. Food and Drug Administration regulations regarding the use of prohibited cattle materials in food (21 CFR § 189.5) and cosmetics (21 CFR § 700.27), as prohibited cattle materials do not include tallow derivatives."

This product "is subject to the limitations of these regulations and any other applicable regulation."

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