Product Regulatory Overview (PRO)
Food Contact/ Drug Packaging
Marlex® HHM 5502LD Polyethylene

Company
Chevron Phillips Chemical (CPChem)

Food Contact

It is the responsibility of the packaging converter or food packager to verify that the finished article meets both the technical and regulatory requirements of the intended application.

U.S. FDA Food Contact
This product meets the requirements for polyolefin resins intended for food packaging applications as described in the FDA olefin polymer regulations 21 CFR 177.1520 including 21 CFR 177.1520(c) 3.1a and 21 CFR 177.1520(b). The resin may be used in contact with foods of > pH5, types I, IV-B, VI-B, VII-B, and VIII as defined in Table 1, 21 CFR 176.170(c), and at use conditions E through G as defined in Table 2, 21 CFR 176.170(c).

This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.

Canada Food Contact
A "Letter of No Objection" for this product has been approved by Health Canada. KS12011903

Mercosur Food Contact
The monomer(s) of this resin are listed in Mercosur /GMC/Res. N° 02/12 and its modification GMC/Res. N° 19/21.
The additive(s) in this product are listed in Mercosur/GMC/Res. N° 39/19.
GMC Res. No. 20/21, "Modification of GMC Resolution No. 56/92 General Provisions for plastic containers and equipment in contact with food," is applicable to a final article.

Brazil Food Contact
The monomer(s) of this resin are listed in Anvisa RDC 56/2012 and RDC No 589.
The additive(s) of this resin are listed in Anvisa RDC 326/2019.
RESOLUTION - RDC NO. 589, DE 20 DECEMBER 2021 Article 2 is applicable to a final article.

U.S. Pharmacopeia (USP)
This product meets the standards set by the United States Pharmacopoeia USP 39 <87> Biological Reactivity Tests, in Vitro.
This product meets the standards set by the United States Pharmacopoeia USP 39 <661.1> Plastic Materials of Construction – Identification, Physicochemical, and Extractable Metals tests.

European Pharmacopoeia (EUP)
This product contains an additive that is not listed on European Pharmacopoeia 3.1.13.

Drug Master File (DMF)
This product is listed in U.S. FDA Type III Drug Master File 1016.

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Animal-Derived Materials (ADM)/ BSE/TSE

This product is formulated with low levels of an animal/tallow-based component.

These tallow-based starting materials are produced in a manner that meets the U.S. Food and Drug Administration's (FDA's) definition of a tallow derivative. According to FDA, tallow derivatives present a negligible risk of transmission of bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE), and are not banned in food and food-contact material under 21 C.F.R. 189.5.

USDA

The USDA recognizes FDA statements provided by material suppliers for food packaging.

ICHs: Elemental Impurities and Residual Solvents

This product as shipped does not intentionally contain, except chromium (trivalent), the metals described in the ICH Harmonized Guideline for Elemental Impurities Q3D dated 26 April 2022 (including Cd, Pb, As, Hg, Co, V, Ni, Tl, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt, Li, Sb, Ba, Mo, Cu, Sn, Cr). These metals, except chromium, to the best of our knowledge are not intentionally added.

ICH/Q3C “Impurities: Guideline for Residual Solvents” is about the requirements for pharmaceuticals and as such is not applicable to polyethylene pellets.

Marlex® Polyethylene PRO Appendix

For additional information, please see the following link.

https://www.cpchem.com/who-we-are/environment-health-safety-security/regulatory-information
(SELECT “Appendix: MARLEX® Polyethylene”)

It is the responsibility of the customer to check compliance of the final articles with the relevant legislative and applicable regulatory requirements including their restrictions.

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Additional information on the health and safety aspects of our product is listed in the SDS of the product.

Address: Chevron Phillips Chemical Company LP, 9500 Lakeside Blvd., The Woodlands, TX 77381
Website: http://www.cpchem.com/en-us/ehs/pages/productregulatoryoverviews.aspx