

# Product Regulatory Overview (PRO) Food Contact Marlex® 9503H 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, 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), except for use in contact with infant formula and human milk.

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

#### 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.

#### **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. <a href="https://www.cpchem.com/who-we-are/environment-health-safety-security/regulatory-information">https://www.cpchem.com/who-we-are/environment-health-safety-security/regulatory-information</a> (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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Disclaimer: Before using this product, the user is advised and cautioned to make its own determination and assessment of the safety and suitability of the product for the specific use in question and is further advised against relying on the information contained herein as it may relate to any specific use or application. It is the ultimate responsibility of the user to ensure that the product is suited and the information is applicable to the user's specific application. Chevron Phillips Chemical Company does not make, and expressly disclaims, all warranties, including warranties of merchantability or fitness for a particular purpose, regardless of whether oral or written, express or implied, or allegedly arising from any usage of any trade or from any course of dealing in connection with the use of the information contained herein or the product itself. The user expressly assumes all risk and liability, whether based in contract, tort or otherwise, in connection with the use of the information contained herein or the product itself. Further, information contained herein is given without reference to any intellectual property issues, as well as federal, state or local laws which may be encountered in the use thereof. Such questions should be investigated by the user. Any reference to registered trademarks for CPChem products generally refers to U.S. trademark registration of the same only, and trademark registrations in other jurisdictions may vary and should be confirmed by the user contacting its CPChem entity (or joint venture) representative.

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

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Website: http://www.cpchem.com/en-us/ehs/pages/productregulatoryoverviews.aspx