Product Regulatory Overview (PRO)
Food Contact / Drug Packaging
Marlex® 9006 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) 3.2a and 21 CFR 177.1520(b). The resin may be used in contact with all types of food as defined in Table 1, 21 CFR 176.170(c) and at use conditions B-H 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.

European Union (EU) Food Contact
As plastic intermediate material, the monomer(s) and the additive(s) of this resin are listed in Annex I Table 1 of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and all its Amendments including Commission Regulation (EU) 2023/1442 and 2023/1627. The monomer(s) and the additive(s) do not have restriction(s) and specification(s) in Column 10 of Table 1, Annex I of Commission Regulation (EU) No 10/2011.

See following link for latest amendment review:
https://www.cpchem.com/who-we-are/environment-health-safety-security/regulatory-information
(SELECT Food Contact Amendment)

Bisphenol A (BPA), other bisphenols and bisphenol derivatives are not intentionally used as additives or raw materials in the manufacture of this product. This product complies with Commission Regulation (EU) 2024/3190.

For full compliance, an overall migration limit of 10 mg/dm^2 and specific migration limits (SML) apply to the final article intended to come into contact with food.

This product is ethylene hexene copolymer. The co-monomer 1-hexene (CAS# 000592-41-6) is listed as FCM No 356, Ref No 18820, SML = 3 mg/kg. The typical residual levels of free 1-hexene in this resin would be less than 1 ppm.

Injection molding polyethylene resins were tested for the overall and specific migration compliance. The tested sample thickness was 0.43 mm (16.9 mils). The surface-to-volume ratio was 2.34 dm^2 sample single-side contact with 1dl simulant. The samples were tested with 3% acetic acid and with 50% ethanol, for 2 hours at 70°C followed by 10 days at 40°C, and with olive oil for 10 days at 40°C.

Typical migration results are below the overall migration limit (OML) and relevant specific migration limits (SML).

Based on the use amount and assuming 100% migration from a packaging article into food, and default plastics packaging factor of 6 decimeters squared of package area holding 1 kg food, SML compliance without testing would be up to 0.07 cm (= 27 mils) thickness of an article fully made of this resin only.

This product meets the restriction(s) of the substances in Table 1, Annex II of Commission Regulation (EU) No 10/2011 amended by Commission Regulation (EU) 2020/1245. Primary aromatic amines are not intentionally used as additives or raw materials in the manufacture of this product.

This product does not contain intentionally added genotoxic substance that would be expected to migrate from resin exceeding 0.00015 mg/kg in food or food simulant to cause genotoxic effect.

This product does not contain food additive(s) or flavoring(s) that would be a concern in food per Regulation (EC) No 1333/2008 or Regulation (EC) No 1334/2008.

This product meets the requirements of Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.

This product is produced in accordance with good manufacturing practice (GMP) as outlined in GMP Regulation (EC) No 2023/2006.

Canada Food Contact

A “Letter of No Objection” for this product has been approved by Health Canada. This product may be used as a food-contact article such as bottle, food pail, cap, and casing under and at the temperature of 212 °F (100°C). KS09022605

Japan Food Contact

Japanese Ministry of Health, Labor and Welfare (MHLW) published a revised version of Positive List (PL) System for food-contact materials (FCM) used in the manufacture of food-contact utensils, containers, and packaging (UCP) in late 2023. The requirements will take effect on June 1, 2025.

- This product is polyethylene 1-hexene/ethylene copolymer (CAS Number 25213-02-9). It is listed on APPENDED TABLE 1, Table 1 Base Materials as “polymer composed of alkenes as the main monomer” Polymer Group 2.
- Additive(s) in this product are all listed on APPENDED TABLE 1, Table 2 Additives or are exempted. Additive(s) in this product meet the maximum use level limit(s). There are no restrictions on food types or temperature.

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.

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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 Pharmacopeia USP 26 <88> Biological Reactivity Tests, in Vivo - Class VI Plastics - 70ºC.
This product meets the standards set by the United States Pharmacopoeia USP 39 <661.1> Plastic Materials of Construction – Identification, Physicochemical, Extractable Metals, and Plastic Additives tests.

European Pharmacopoeia (EUP)

This product meets the requirements of European Pharmacopoeia 3.1.3. 10th edition "Polyolefins" materials used for the manufacture of containers.
It also meets the requirements of European Pharmacopoeia 3.1.5 10th edition "Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations."

Drug Master File (DMF)

This product is listed on the U.S. FDA Type III Drug Master File 1646.
This product is listed on the Canadian Drug Master File 1990-147.

Animal-Derived Materials (ADM)/ BSE/TSE

Animal-derived materials are not intentionally used in the manufacture or formulation of this product.

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 use 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).

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")

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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.

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.

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