# Product Regulatory Overview (PRO)
# Food Contact / Drug Packaging
# Marlex® 9005 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 foods as defined in Table 1, 21 CFR 176.170(c) at use conditions B-H as defined in Table 2, 21 CFR 176.17(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
The monomer(s) and the additive(s) of this resin are listed in Table 1, Annex I, 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 two 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.

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.

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This product meets the restriction(s) on 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 in contact with food.

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

**China Food Contact**

This polyethylene resin is an ethylene and hexene copolymer, and is listed on GB 4806.6-2016 “Standard on food-contact use plastic resin” Appendix A Table A.1, as No 101, CAS 25213-02-9. The monomer 1-hexene has SML 3 mg/kg. The typical residual levels of free 1-hexene in this resin would be less than 1 ppm.

The additive(s) of this resin are all listed on GB 9685-2016 “Standard on the uses of additives in food contact materials and articles”, and meet the corresponding allowed maximum use levels.

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 resin meets the requirements of GB 4806.6-2016.

This resin meets the requirements of GB 4806.1-2016 General safety requirements for food contact materials and articles.

This resin is produced in accordance with good manufacturing practice (GMP) as outlined in GB 31603-2015 General hygiene standard on manufacturing food contact materials and articles.

**Japan Food Contact**

Japanese Ministry of Health, Labor and Welfare (MHLW) published a formal Positive List (PL) System for food-contact materials (FCM) used in the manufacture of food-contact utensils, containers, and packaging (UCP).

- This product is polyethylene 1-hexene/ethylene copolymer (CAS Number 25213-02-9). It is listed on Table 1(1) Base Polymers (Plastics) as 40 Polyethylene, Ref No 982, Serial No 1, Synthetic Resin Group 5, all types of food, and maximum temperature III.

- Additive(s) in this product are all listed on Table 2 Additives. Meet the maximum use limit(s) and restriction(s).

**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 - DRC 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 42 <661.1> Plastic Materials of Construction – *Identification and Physicochemical tests.*

**European Pharmacopoeia (EUP)**

This product has not been tested under any European Pharmacopoeia guidelines.

**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")

*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 LP 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