Product Regulatory Overview (PRO)
Food Contact
Marlex® 5735 Polyethylene

Company
Chevron Phillips Chemical (CPChem)

Food Contact

It is the responsibility of the converter 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)2.2. and 21 CFR 177.1520(b). This resin may be used in the manufacture of articles or components of articles intended for use in contact with nonalcoholic foods at use conditions B-H as defined in Table 2,21 CFR 176.170(c). A further requirement is that the food contact surface comprising the resin may not exceed a thickness of 4.4 mils.

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, 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.

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.

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

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

Based on the use amount and assuming 100% migration from a packaging 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 0.0144 cm (=5.7 mils) thickness of an article fully made of above resin only.

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 when an article thickness is up to 5.7 mils. Primary aromatic amines are not intentionally used as additives or raw materials in the manufacture of this product.

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Food Contact
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This product does not contain intentionally added 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.

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 took effect on June 1, 2025.

- This product is an ethylene homopolymer (CAS number 9002-88-4). 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 limit(s). There are no restrictions on temperature. This product is not to be used in the articles coming into contact with alcoholic beverage.

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 has not been tested under any United States Pharmacopoeia guidelines.

European Pharmacopoeia (EUP)

This product contains an additive that is not listed in European Pharmacopoeia 3.1.3. Polyolefins.

Animal-Derived Materials (ADM)/ BSE/TSE

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

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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.

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.

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