Product Regulatory Overview (PRO)
Food Contact / Drug Packaging
Marlex® 5104 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)2.2. 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).

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 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 Amendmentsincluding 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)

This product does not carry specific migration limit (SML) in Annex I of Commission Regulation (EU) No 10/2011. For full compliance, an overall migration limit of 10 mg/dm^2 applies to the final article intended to come into contact with food.

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.

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This product does not contain food additive(s) or flavoring(s) 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.

China Food Contact

This product is an ethylene homopolymer, and is listed on GB 4806.7-2023 “Standard on food-contact use plastic materials and articles” Appendix A Table A.1, as No 139, CAS 9002-88-4.

No additive is intentionally used as a component in the manufacture of this grade of polyethylene. This product meets the requirement of GB 9685-2016 “Standard on the uses of additives in food contact materials and articles”. This product does not have an associated specific migration limit (SML).

This polyethylene resin family meets the sensory requirements (as resin and in food simulants).

This polyethylene resin family was tested per GB 4806.7-2023 for the following items, and meets the corresponding requirements.

- This resin family was tested overall migration levels for overall migration limit (OML) compliance. The tested sample thickness was 3.175 mm (125 mils). The surface-to-volume ratio was 6 dm^2 sample immersed in 1 L simulant. This product was tested with 4% acetic acid for 10 days at 40°C, with 10 % ethanol for 10 days at 40°C, with 50 % ethanol for 10 days at 40°C, with 95 % ethanol for 10 days at 40°C, and with isooctane for 2 days at 20°C.
- This resin family was tested for the $KMnO_4$ consumption in water (60ºC, 2h).
- This resin family was tested for heavy metal as Pb in 4 % acetic acid (60ºC, 2h).

Primary aromatic amines and colorant are not intentionally used as additives or raw materials in the manufacture of this product.

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 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 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.
- No additive is intentionally used as a component in the manufacture of this grade of polyethylene. This product meets the requirements of Table 2 Additives.

Mercosur Food Contact

The monomer of this resin is listed in Mercosur /GMC/Res. N° 02/12 and its modification GMC/Res. N° 19/21.

This product does not contain additives. This product meets the requirements of 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 of this resin is listed in Anvisa RDC 56/2012 and RDC No 589.

This product does not contain additives. This product meets the requirements of 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 22 <88> Biological Reactivity Tests, in Vivo - Class VI-70ºC Plastic.

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. This product does not contain plastic additives.

European Pharmacopoeia (EUP)

This product meets the requirements of European Pharmacopoeia 3.1.4 "Polyethylene without 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 1572.

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.

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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.

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