



Product Regulatory Overview (PRO)
Food Contact
Marlex® 5563 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) and 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 this 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 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.

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/dm² and a specific migration limit (SML) apply to the final article intended to come into contact with food.

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 0.0144 cm (=5.7 mils) thickness of an article fully made of this 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



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up to 5.7 mils. 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 EU 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 for food contact applications such as bottles, food pails, caps, films, and casings under and at temperature of 212°F (100°C), provided the films do not exceed 2.5 mils in thickness and will be in direct contact with non-alcoholic foods only. KS09032717

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.

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" or on an official approved announcement, and meet the corresponding allowed maximum use levels.

This polyethylene resin meets the sensory requirements as resin.

This product has not been tested per following requirements of GB 4806.7-2023. A final article may be tested.

- Sensory requirements in food simulants
- Overall migration level for overall migration limit (OML) compliance.
- KMnO₄ consumption in water (60°C, 2h).
- Heavy metal as Pb in 4 % acetic acid (60°C, 2h).

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

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 0.0144 cm (=5.7 mils) thickness of an article fully made of this resin only.



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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.
- 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. 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 - RDC NO. 589, DE 20 DECEMBER 2021 Article 2 is applicable to a final article.

U.S. Pharmacopeia (USP)

This product has not been tested according to any US 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.

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, Ti, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt, Li, Sb, Ba, Mo, Cu, Sn, Cr).



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ICH/Q3C "Impurities: Guideline for Residual Solvents" is about the requirements for pharmaceuticals and as such is not applicable to polyethylene pellets.

Appendix

For additional regulatory information and list of absence of substances, please see the Appendix for Marlex® Polyethylene.

<https://www.cpchem.com/who-we-are/environment-health-safety-security/regulatory-information>
(SELECT Appendix MARLEX® PE)

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>