Product Regulatory Overview (PRO)
Food Contact
Marlex® HHM TR-144 Polyethylene

Company
Chevron Phillips Chemical (CPChem)[1]

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).

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, 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)

This product was tested for overall and specific migration compliance per Commission Regulation (EU) No 10/2011. The tested sample thickness was 3.175 mm (125 mils). The surface-to-volume ratio was 1 dm^2 sample totally immersed in 1dl simulant. For measuring the overall migration levels, this product was tested with 3% acetic acid for 10 days at 40°C, with 50% ethanol for 10 days at 40°C, and with olive oil for 10 days at 40°C. For measuring specific migration levels, this product was tested with 3% acetic acid for 10 days at 60°C, with 50% ethanol for 10 days at 60°C, and with olive oil for 10 days at 60°C. This product complies with the overall migration limit (OML) and specific migration limits (SML).

This product is an ethylene hexene copolymer. With regard to chemical substances carrying SMLs, based on the levels in this resin 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, the SMLs

[1]Note: Marlex® HHM TR-144 Polyethylene as sold by CPChem and produced by CPChem and one or more its affiliates including Saudi Polymers Company (SPCo).

compliance without testing would be up to 0.14 cm (= 56 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. 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) 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.

Germany BfR Recommendations

This product meets the requirements on catalyst residues and residual decomposition products in German BfR Recommendations on Food Contact Materials III Polyethylene.

Swiss Food Contact

The monomer(s) and the additive(s) of this resin are listed in SR 817.023.21 Regulation on materials and articles intended to come into contact with food Annex 2.

This product was tested for overall and specific migration compliance per Commission Regulation (EU) No 10/2011. The tested sample thickness was 3.175 mm (125 mils). The surface-to-volume ratio was 1 dm^2 sample totally immersed in 1dl simulant. For measuring the overall migration levels, this product was tested with 3% acetic acid for 10 days at 40°C, with 50% ethanol for 10 days at 40°C, and with olive oil for 10 days at 40°C. For measuring specific migration levels, this product was tested with 3% acetic acid for 10 days at 60°C, with 50% ethanol for 10 days at 60°C, and with olive oil for 10 days at 60°C. This product complies with the overall migration limit (OML) and specific migration limits (SML).

This product is an ethylene hexene copolymer. With regard to chemical substances carrying SMLs, based on the levels in this resin 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, the SMLs compliance without testing would be up to 0.14 cm (= 56 mils) thickness of an article fully made of this resin only.

China Food Contact

This polyethylene resin is an ethylene and hexene copolymer, and is listed on GB 4806.7-2023 “Standard on food-contact use plastic materials and articles” Appendix A Table A.1, as No 152, CAS 25213-02-9. The monomer 1-hexene has SML 3 mg/kg.

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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.

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

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

- This resin was tested overall migration level for overall migration limit (OML) compliance. The tested sample thickness was 3.175 mm (125 mils). The surface-to-volume ratio was 6 dm^2/1L (kg). 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, and with olive oil for 10 days at 40°C.
- This resin was tested for the $KMnO_4$ consumption in water (60°C, 2h).
- This resin was tested for 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.

This product family was tested for specific migration compliance. The tested sample thickness was 3.175 mm (125 mils). The surface-to-volume ratio was 0.6 dm^2 sample immersed in 1dl simulant. For measuring the specific migration levels, this product was tested with 4 % acetic acid for 10 days at 60°C, with 10 % ethanol for 10 days at 60°C, with 50 % ethanol for 10 days at 60°C, with olive oil for 10 days at 60°C. This product met the specific migration limit(s) (SML).

With regard to chemical substances carrying SMLs, based on the levels in this resin 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, the SMLs compliance without testing would be up to 0.26 cm (= 104 mils) thickness of an article fully made of this resin only.

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 took 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. Additive(s) in this product meet the maximum use level limit(s). There are no restrictions on food types or temperature.

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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 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 contain, except chromium (trivalent), 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). These metals, except chromium, to the best of our knowledge are not intentionally added.

ICH/Q3C "Impurities: Guideline for Residual Solvents" is about the requirements for pharmaceuticals and as such is not applicable to polyethylene pellets, but this product, as shipped, does not intentionally contain Class I, Class II or Class III solvents.

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*

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Additional information on the health and safety aspects of our product is listed in the SDS of the product.

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