



Product Regulatory Overview (PRO) Marlex® HHM 5502BN Polyethylene

Product Manufacturer

Chevron Phillips Chemical Company LP
Qatar Chemical Company Ltd (Q-Chem)

Chemical Inventories

All the components of this product are listed on

AUSTRALIA: Australian Inventory of Chemical Substances (AICS)

CANADA: Domestic Substances List (DSL)

PEOPLE'S REPUBLIC OF CHINA: Inventory of Existing Chemical Substances (IECSC)

EUROPEAN UNION: On the inventory, or in compliance with the inventory

JAPAN: Existing & New Chemical Substances (ENCS) Inventory

KOREA: Existing Chemicals List (ECL)

NEW ZEALAND: Inventory of Chemical Substances (NZIoC)

PHILIPPINES: Philippine Inventory of Chemicals and Chemical Substances (PICCS)

UNITED STATES: Toxic Substances Control Act (TSCA) Chemical Inventory

Food Contact

European Union (EU) Food Contact

All constituents of this resin are listed in Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and all its Amendments.

This product was tested per EU Directive 82/711/EEC. The tested sample thickness was 0.4 mm (16 mils). This product was tested with 3% acetic acid, 50% ethanol, and olive oil for 2 hours contact at 70°C followed by 10 days at 40°C. This product complies with the overall and specific migration limits. It is suitable for contact with dry, aqueous, acidic, ethanolic (up to 50%) and fatty foodstuff, including milk products, for 2 hours at 70°C followed by a storage period longer than 24 hours at room temperature.

This product does not contain any dual-use additive per EU Directive No 95/2/EC and its Amendments.

This product meets the requirements of Framework Regulation (EC) No. 1935/2004 of The European Parliament and of The Council of 27 October 2004, on materials and articles intended to come in contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

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

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(c) 3.2a. 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).



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This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.

Canada Food Contact

A “Letter of No Objection” for this product has been approved by Health Canada. This product may be used as a food-contact article such as bottle, food pail, cap, and casing under and at the temperature of 212 °F (100 °C).

China Food Contact

All additives of this resin are listed in GB 9685-2008 “Hygienic standards for uses of additives in food containers and packaging materials”, and meet the relevant specific migration limits. There are no regulatory food type restrictions on this resin.

It is the responsibility of the converter to verify that the finished article meets both the technical and regulatory requirements of the intended application, and in particular does not modify the organoleptic properties of the food.

U.S. Pharmacopeia (USP)

This product meets the standards set by the United States Pharmacopoeia (USP 26), <88> Class VI Biological Test for Plastics.

This product also meets the standards set by the United States Pharmacopoeia (USP 26), <661> Containers Physicochemical Tests and Polyethylene Containers.

European Pharmacopoeia (EUP)

This product meets the requirements of European Pharmacopoeia 3.1.3. the 7th edition “Polyolefines” materials used for the manufacture of containers.

This product meets the requirements of European Pharmacopoeia 3.1.5 the 7th edition “Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations.”

Drug Master File (DMF)

This product is listed in U.S. FDA Type III Drug Master File 1016.

This product is listed in Health Canada Drug Master File 9389.

Directive 76/768/EEC of 1976-07-27 on the approximation of the laws of the Member States relating to cosmetic products

Directive 76/768/EEC is not applicable to this product. This product is not defined in the regulation as a cosmetic product, and it does not contain any substances listed as prohibited in cosmetic products.

EU Classification and Labeling

This product is not a dangerous substance according to Globally Harmonized System of Classification and Labeling of Chemicals (GHS) 1272/2008. It is also not a hazardous substance or mixture according to EC directives 67/548/EEC or 1999/45/EC.



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California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)

This product, as shipped, does not intentionally contain any carcinogens or reproductive toxins presently known by the State of California to cause cancer or reproductive toxicity at a level of exposure subject to the requirements of California Proposition 65.

Consumer Product Safety Improvement Act of 2008 (H.R. 4040)

This product does not contain lead and phthalates. It therefore complies with the relevant sections of the Consumer Product Safety Improvement Act of 2008 (H.R. 4040).

Clean Air Act

This product is in compliance with the federal Clean Air Act, as amended in 1990.

Heavy metals, RoHS, WEEE, Waste packaging, CONEG

No heavy metals (i.e., antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, or silver) are purposely added to this product in quantities that would violate governmental guidelines. The summation of lead, cadmium, mercury, and hexavalent chromium in this product is less than 20 ppm. No polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), and Deca Brominated Diphenyl Ethers (Deca BDE) are intentionally added to this product. This product therefore meets the relevant requirements of the following Directives or Regulations:

- 2011/65/EU and 2002/95/EC (RoHS)
- 2002/96/EC (WEEE)
- 2000/53/EC (ELV)
- 94/62/EC (Packaging Waste Directive)
- USA CONEG Regulation
- California Toxics in Packaging Prevention Act

Toys

This product complies with the requirements of ASTM F963 and EN 71-3 and EN71-9.

Phthalates

No phthalates, including di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP), are intentionally added to this product. This product therefore meets the requirements of the Consumer Product Safety Improvement Act of 2008.

European Chemicals Agency (ECHA) Substances of Concern

This product does not contain any Substances of Very High Concern (SVHC) as listed on the candidate list published by ECHA as of 19 December 2012. It also does not contain any substances on the REACH Annex XVII Restriction Substance list.

Canadian Environmental Protection Act (CEPA) "Challenge" Substances

This product does not contain any high priority chemical substances listed on the "Challenge" Substance Batches as issued by CEPA.



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Absence of Substances and Chemicals

None of the following substances are used in the process nor are they expected to be part of the raw materials used to manufacture this product:

- Acrylamide
- Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Allergens, including but not limited to those listed in EU Directives 2000/13/EC and 2003/89/EC
- Aromatic amines
- Asbestos
- Azo compounds
- Bisphenol A
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- Colorants or pigments
- Conflict minerals, including Columbite-Tantalite, Cassiterite, Gold, or Wolframite
- Dioxins
- Epoxy derivatives listed in EU Directives 2002/16/EC and 1895/2005
- Fungicides, preservatives or fumigants
- Genetically-modified Organisms (GMOs)
- Materials derived from plants
- Melamine
- Methyl bromide
- Natural rubber latex and dry natural rubber
- Nonyl phenol
- Ozone-depleting chemicals
- Photoinitiators, including: 4-Methylbenzophenone, Benzophenone, and Isopropylthioxanthone
- Polyaromatic Hydrocarbons (PAHs)
- Polybrominated Diphenyl Ethers (PBDEs)
- Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)
- Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonates (PFOS)
- Radioactive Substances
- Organo-Tin Compounds
- Tris-Nonylphenol Phosphite
- Vinyl Chloride Monomer (VCM) and Polyvinyl Chloride (PVC)

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 and Qatar Chemical Company Ltd (Q-Chem) do not make, and expressly disclaims, all warranties, including warranties of merchantability or fitness*



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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.

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