



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

### **Product Manufacturer**

Chevron Phillips Chemical Company LP

### **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: In compliance with EU Seventh Amendment Directive 92/32/EEC

JAPAN: Existing & New Chemical Substances (ENCS) Inventory

KOREA: Existing Chemicals List (ECL)

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 product are listed in EU Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs, and comply with its later Amendments 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, and 2008/39/EC. This product complies with the global and relevant specific migration limits. It is suitable for contact with aqueous, acidic, ethanolic (up to 15%) and fatty foodstuff for any time at room temperature.

This product is produced in accordance with good manufacturing practice (GMP) as outlined in 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).

#### **Canada Food Contact**

A "No Objection" letter for this product has been approved by Health Canada.

*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 requirements of USP 26 <661> Containers Physicochemical Tests and Polyethylene Containers.

This product also meets the requirements set by the United States Pharmacopoeia (USP 26), National Formulary 21 (NF 21), 2003, for the Class VI Biological Test for Plastics.

### **European Pharmacopoeia (EUP)**

This product meets the requirements of European Pharmacopoeia 3.1.3. the 5<sup>th</sup> edition "Polyolefines" materials used for the manufacture of containers.



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This product meets the requirements of European Pharmacopoeia 3.1.5 the 5<sup>th</sup> edition “Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations.”

This product meets with the requirements of European Pharmacopoeia Monograph 3.2.2, “Plastic Containers and Closures for Pharmaceutical Use”.

### **Drug Master File (DMF)**

This product is listed in U.S. FDA Type III DMF 1016.

This product is listed in Health Canada DMF 9389.

### **California’s Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**

This product, as shipped by Chevron Phillips Chemical Company LP, is not known to 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.

### **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:

- 2002/95/EC (RoHS)
- 2002/96/EC (WEEE)
- 2000/53/EC (ELV)
- 94/62/EC (Packaging Waste Directive)
- USA CONEG Regulation

### **Toys**

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

### **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, such as peanuts, tree nuts, milk, eggs, wheat gluten, soy, fish, and shellfish
- Aromatic amines
- Asbestos
- Azo compounds
- Bisphenol A
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)



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- Dioxins
- Epoxy derivatives listed in EU Directive 2002/16/EC
- Genetically-modified Organisms (GMOs)
- Melamine
- Methyl bromide
- Natural rubber latex and dry natural rubber
- Nonyl phenol
- Ozone-depleting chemicals
- Phthalates
- Polyaromatic Hydrocarbons
- 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 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.*

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