



## Product Regulatory Overview (PRO) Marlex® 9006 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

EUROPEAN UNION: All necessary components have been registered according to Regulation (EU) No. 1907/2006 (REACH)

SWITZERLAND: Exemptions from the obligation to notify/register

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.

Appropriate representatives of this series polyethylene resins were tested for the overall and specific migration compliance. The tested sample thickness was 0.43 mm (16.9 mils). The surface-to-volume ratio was 2.34 dm<sup>2</sup> sample single-side contact with 1dl simulant. The samples were tested with 3% acetic acid, 50% ethanol, and olive oil for 2 hours at 70°C followed by 10 days at 40°C. Typical migration results are below the overall and relevant specific migration limits.

Based on the use amount and assuming 100% migration from a packaging article into food, SML compliance without testing would be up to 0.07 cm (= 27 mils) thickness of an article fully made of this resin only.

This product does not contain dual use additives that would be a concern in food.

This product meets the requirements of Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come in contact with food.

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. This 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).

*It is the responsibility of the converter to verify that the finished article meets both the technical and regulatory requirements of the intended application.*

### **U.S. Pharmacopeia (USP)**

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

It also meets the requirements of United States Pharmacopoeia (USP 26), <661> Containers Physico-Chemical tests.

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

This product meets the requirements of European Pharmacopoeia 3.1.3. 6th edition "Polyolefines" materials used for the manufacture of containers.

It also meets the requirements of European Pharmacopoeia 3.1.5 6th edition "Polyethylene with 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 1646.

This product is listed on the Canadian Drug Master File 9389.

### **Regulation 1223/2009 of 2009-11-30 on Cosmetic Products**

Regulation 1223/2009 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 Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. It is also not a hazardous substance or mixture according to EC directives 67/548/EEC or 1999/45/EC.

### **Animal-Derived Materials / Kosher**

No animal-derived materials are used in the manufacture or formulation of this product. Chevron Phillips Chemical Company LP does not certify the resin to be Kosher or in compliance with Kosher requirements.

### **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.



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### **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 does not contain any of the following substances regulated by the Clean Air Act:

- Class I or Class II Ozone-Depleting Substances (CAA Section 602)
- Hazardous Air Pollutants (CAA Section 112)
- Accidental Release Prevention Substances (CAA Section 112(r))
- Volatile Organic Chemicals (CAA Section 111)

### **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), Deca Brominated Diphenyl Ethers (Deca BDE), or phthalates are intentionally added to this product. This product therefore meets the relevant requirements of the following Directives or Regulations:

- 2015/863/EU, 2011/65/EU and 2002/95/EC (RoHS)
- 2002/96/EC and 2012/19/EU (WEEE)
- 2000/53/EC (ELV)
- 94/62/EC, 2005/20/EC, and 2013/2/EU (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 17 December 2015. 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.

### **Nanomaterial**

This product is not a nanomaterial.

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### **Absence of Substances and Chemicals**

None of the following substances are used as additives or raw materials in the manufacture of this product:

- Acrylamide
- Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Allergens, including but not limited to those listed in EU Regulation 1169/2011, Directives 2000/13/EC, 2003/89/EC, and Section B.01.010.1 (1) of Canadian Regulation C.R.C., c. 870 such as: peanuts, tree nuts, milk, eggs, wheat gluten, soybeans, fish and shellfish
- Aromatic amines
- Asbestos
- Azo compounds
- Biocides
- Bisphenol compounds, including but not limited to: BPA, BPB, BPC, BPE, BPF, BPS, and BPZ
- Brominated or halogenated flame retardants
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
- Chlorinated paraffins
- Colorants or pigments
- Conflict minerals, including Columbite-Tantalite, Cassiterite, Gold, or Wolframite
- Cyanuric acid
- Di(ethylhexyl) adipate (DEHA), diethyl hydroxyl amine (DEHA), or di(ethylhexyl)maleate (DEHM)
- Dimethylfumarate (DMF)
- Dioxins or furans
- Endocrine disruptors
- Epoxy derivatives listed in EU Directives 2002/16/EC and 1895/2005
- Epoxidised Soybean Oil
- Formaldehyde
- Fungicides, preservatives or fumigants
- Genetically-modified organisms (GMO)
- Melamine
- Methyl bromide
- Natural rubber latex, dry natural rubber, or synthetic latex
- Nonyl phenol
- Organotin compounds
- Ozone-depleting chemicals
- Perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS)
- Pesticides and fungicides
- Photoinitiators, including: benzophenone, hydroxybenzophenone, and 4-methylbenzophenone, and Isopropylthioxanthone (ITX)
- Plasticizers
- Polyaromatic Hydrocarbons (PAHs)



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- Polybrominated Diphenyl Ethers (PBDEs) included: decaBDE, octaBDE, and pentaBDE
- Polycarbonates
- Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)
- Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- Radioactive Substances
- Recycled materials
- Silicone
- Sulfonamides
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether)
- Tris-Nonylphenol Phosphite
- Vinyl Chloride Monomer (VCM) and Polyvinyl Chloride (PVC) or copolymers

*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 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.**

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Website: <http://www.cpchem.com/en-us/ehs/pages/productregulatoryoverviews.aspx>