



## Product Regulatory Overview (PRO) Marlex<sup>®</sup> 4517 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). Registration number(s) shown on the EU SDS are specific for CPChem entities

SWITZERLAND: Exemptions from the obligation to notify/register

JAPAN: Existing & New Chemical Substances (ENCS) Inventory

KOREA: Existing Chemicals List (ECL): A substance(s) in this product was not registered, notified to be registered, or exempted from registration by CPChem according to K-REACH regulations. Importation or manufacture of this product is still permitted provided the Korean Importer of Record has themselves notified the substance

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

NEW ZEALAND: Inventory of Chemical Substances (NZIoCS)

TAIWAN: Taiwan Chemical Substance Inventory (TCSI) On the inventory or in compliance with the inventory. Further registrations may apply.

UNITED STATES: On or in compliance with the active portion of the Toxic Substances Control Act (TSCA) Chemical Inventory

### **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 regulation 21 CFR 177.1520(c) 2.2. 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**

The monomer(s) and the additive(s) 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 meets the restriction(s) in Annex II amended by Commission Regulation (EU) 2020/1245.

This product was tested for the overall migration compliance. The tested sample thickness was 0.84 mm (33 mils). The single-side sample area of 2.34 dm<sup>2</sup> contacted with 100 ml food simulants of 3%



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acetic acid and 50% ethanol, and contacted with 90 g food simulant olive oil. This product was tested with 3% acetic acid and 50% ethanol after 2 hours contact at 70°C followed by 10 days at 40°C, and olive oil for 10 days at 40°C. This product complies with the overall migration limit.

This product does not carry any specific migration limit (SML).

This product does not contain any dual-use additive per Regulation (EC) No 1333/2008 and its Amendments.

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.

### Canada Food Contact

A “Letter of No Objection” for this product has been approved by Health Canada. This product may be used in the manufacture of bottles, food pails, caps, films, and casings intended to package all types of food under and at the temperature of 212 °F (100 °C). KS16050502

### China Food Contact

This product is an ethylene homopolymer, and is listed on GB 4806.6-2016 “Standard on food-contact use plastic resin” Appendix A Table A.1, as No 91.

This polyethylene resin was tested for GB 4806.6-2016 “see Note 5” compliance per

- GB 31604.3-2016 Test method of loss mass on drying
- GB 31604.6-2016 Test method of ignition residual of resin
- GB 31604.5-2016 Test method of (hexane) extractables from resin.

This resin meets the requirements of GB 4806.6-2016.

This product does not contain any additive. This product does not contain any specific migration limit (SML) in GB 9685-2016 “Standard on the uses of additives in food contact materials and articles”.

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 formal Positive List (PL) System for food-contact materials (FCM) used in the manufacture of food-contact utensils, containers, and packaging (UCP).



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- This product is an ethylene homopolymer (CAS number 9002-88-4). It is listed on Table 1(1) Base Polymers (Plastics) as 40 Polyethylene, Ref No 985, Serial No 4, Synthetic Resin Group 5, all types of food, and maximum temperature III.
- No additive is intentionally used as a component in the manufacture of this grade of polyethylene. Meets the requirements of Table 2 Additives.

### **Mercosur Food Contact**

The monomer of this resin is listed in Mercosur /GMC/Res. N° 02/12.

This product does not contain any additive. Meets the requirements of Mercosur/GMC/Res. N° 39/19.

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

This product meets the standards set by the United States Pharmacopoeia USP 39 <87> Biological Reactivity Tests, in Vitro.

This product meets the standards set by the United States Pharmacopoeia USP 22 <88> Biological Reactivity Tests, in Vivo - Class VI-70°C Plastic.

This product meets the standards set by the United States Pharmacopoeia USP 39 <661.1> Plastic Materials of Construction – *Identification, Physicochemical, and Extractable Metals tests*. This resin does not contain any additive.

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

This product meets the requirements of European Pharmacopoeia 3.1.3. the 6<sup>th</sup> edition “Polyolefines” materials used for the manufacture of containers.

This product meets the requirements of European Pharmacopoeia 3.1.4 the 6<sup>th</sup> edition “Polyethylene without 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 1572.

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

Regulation 1223/2009 is not applicable to this product when it is used as a raw material for manufacturing cosmetic containers.

### **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.

### **Animal-Derived Materials (ADM)/ BSE/TSE**

No animal-derived materials are used in the manufacture or formulation of this product. This product can be considered free from bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSE).

### **Kosher**

No animal-derived materials are used in the manufacture or formulation of this product and as such no materials of porcine/pigs, fish, shellfish, rabbits, reptiles, blood, or derived from blood are used. No grape, grape derived, ethanol, or ethanol derived materials are used. CPChem has established



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manufacturing practices to assure that the quality of the product is maintained during manufacture and distribution. Chevron Phillips Chemical Company has not made any efforts to certify its Polyethylene resins as Kosher or in compliance with Kosher guidelines.

### **Halal**

No animal-derived materials are used in the manufacture or formulation of this product and as such no materials of ruminant animals (bovinæ/cattle, caprine/goat, ovine/sheep), non-ruminant animals (humans, insects, fish, porcine, poultry), blood, or derived from blood are used. No ethanol, ethanol derived materials or fermented materials are used in the manufacture of this product. Chevron Phillips Chemical Company has not made any efforts to certify its Polyethylene resins as Halal or in compliance with Halal guidelines.

### **Plant/ Vegetal Materials**

This product does not utilize substances derived from plants or plant-based material.

### **USDA**

The USDA recognizes FDA statements provided by material suppliers for food packaging.

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

This product, as shipped, does not 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. See following link for latest review date per most recent Prop 65 update.

<https://www.cpchem.com/who-we-are/environment-health-safety-security/regulatory-information>  
(SELECT Prop 65 Update)

### **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**

This product does not contain any ozone depleting substances, including those listed in Regulation (EC) No 1005/2009.

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)

### **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:



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- Directive (EU) 2017/2102, 2015/863, 2011/65/EU and 2002/95/EC (RoHS)
- China RoHS directive SJ/T 11363-2006
- 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 / Model Toxics in Packaging Legislation
- California Toxics in Packaging Prevention Act

### **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 22 March 2019 (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).

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

### **Toys**

This product complies with the requirements of ASTM F963, EN 71-3, EN71-9, EU Directives 2005/84/EC and 2009/48EC.

### **Phthalates**

No phthalates, including di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP), diisobutyl phthalate (DIBP), dimethyl phthalate (DMP), and diethyl phthalate (DEP) are intentionally added to this product. This product therefore meets the requirements of the Consumer Product Safety Improvement Act of 2008 and EU Directive 2005/84/EC.

### **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 *dated in the link below*. This product does not contain substances restricted under REACH Annex XVII (Restricted Substances List) or subject to authorization under REACH Annex XIV (Authorization List).

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

### **Canadian Environmental Protection Act (CEPA) “Challenge” Substances**

This product, as shipped, does not intentionally contain high priority chemical substances listed on the “Challenge” Substance Batches as issued by CEPA.

### **Nanomaterial**

This product is not a nanomaterial and does not contain any intentionally added functional nanoparticles.



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### **Conflict Minerals**

Neither tantalum, tin, gold, and tungsten, nor the minerals associated with these metals (Columbite-Tantalite, Cassiterite, Gold, or Wolframite) are intentionally added to this product. These substances are not necessary to the production of this product.

### **Regulatory or Industry Lists**

To the best of our knowledge this product, as shipped, meets the following requirements as being within stipulated limits as listed as of this date:

- Stockholm Convention Persistent Organic Pollutants (POPs): Directive 850/2004/EC, EU 2019/1021 and 2020/78 substances not used.
- Rotterdam Convention Prior Informed Consent (PIC) substances Annex III substances not used: <http://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals/tabid/1132/language/en-US/Default.aspx>
- Substances in the Japan Class I Specified Chemical list not used.
- Substances defined as Persistent, Bioaccumulating, Toxic (PBT) or very Persistent very Bioaccumulating (vPvB) per EU not used.
- Chemicals of High Concern to Children in Children's Products (CHCC): does not contain reportable substances as specified in the CHCC regulations of the states of Oregon, Washington, Vermont and Maine
- US Lacey Act, EU Timber Regulation 995/2010; FLEGT or CITES licenses: This requirement is not applicable to polyethylene pellets, this product does not utilize timber or timber products.

### **Substances and Chemicals**

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

- Abietic acid
- Acrylamide
- Acrylonitrile or acrylonitrile co-polymers
- Aflatoxin and Mycotoxin; or derivatives of these substances
- Alkylphenols
- 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
- 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE), Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether (BFDGE), and/or Novolac glycidyl ethers (NOGE)
- Biocides
- Bisphenol compounds, including but not limited to: BPA, BPAF, BPB, BPC, BPE, BPF, BPH, BPS, and BPZ
- Brominated or halogenated flame retardants



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- Butylated Hydroxytoluene (BHT), Butylated Hydroxyanisole (BHA), and Tertiary butylhydroquinone (TBHQ)
- Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
- Chlorinated paraffins, Chlorinated hydrocarbons
- Colorants or pigments
- Cyanuric acid
- Di(ethylhexyl) adipate (DEHA), diethyl hydroxyl amine (DEHA), or di(ethylhexyl)maleate (DEHM)
- Dimethylfumarate (DMF)
- Dioxins or furans; or derivatives of these substances
- Endocrine disruptors
- Epoxy derivatives listed in EU Directives 2002/16/EC and 1895/2005
- Epoxidized Soybean Oil
- FDA Banned Food Additives: benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, pyridine, styrene
- Formaldehyde
- Fungicides, preservatives or fumigants
- Genetically-modified organisms (GMO)
- Halogens
- Human materials or derivatives of human materials
- Iron
- Materials derived from plants
- Melamine
- Methyl bromide
- Natural rubber latex, dry natural rubber, or synthetic latex
- Nitrites, Nitrates, Nitrosamines, Nitrosamines impurities: N-nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), N-diisopropylnitrosoamine (NDIPA), N-ethyl-N-isopropylnitrosoamine (NEIPA); or nitrosating reagent  $\text{NaNO}_2$ .
- Nitrocellulose
- Nonyl phenol (NP)
- Optical brighteners
- Organotin compounds
- Ozone-depleting chemicals
- Parabens
- Poly- and perfluoroalkyl substances (PFAS), as perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS)
- Pesticides and fungicides
- Photoinitiators, including: benzophenone, hydroxybenzophenone, and 4-methylbenzophenone, and Isopropylthioxanthone (ITX)
- Plasticizers
- Polycyclic aromatic hydrocarbons (PAH), also called polyaromatic hydrocarbons
- Polybrominated Diphenyl Ethers (PBDEs) included: decaBDE, octaBDE, and pentaBDE
- Polycarbonates
- Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)



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- Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- Polydimethylsiloxane (PDMS)
- Radioactive Substances
- Recycled materials
- Silicone
- Sulfonamides
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether), Triclocarban
- Tris-Nonylphenol Phosphite (TNPP)
- Vinylidene chloride (Dichloroethene), Vinyl Chloride Monomer (VCM), Polyvinyl Chloride (PVC), Polyvinylidene Dichloride (PVDC) or copolymers

### **Marlex<sup>®</sup> 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<sup>®</sup> 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 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 SDS of the product.**

Address: Chevron Phillips Chemical Company LP, 10001 Six Pines Drive, The Woodlands, TX 77380

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