



## Product Regulatory Overview (PRO) Marlex® 4517 Polyethylene

### Product Manufacturer

Chevron Phillips Chemical Company LP

### Chemical Inventories

All the components of this product are listed on

AUSTRALIA: Australian Inventory of Industrial Chemicals (AIIC)

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

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 (NZIoC)

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 regulations 21 CFR 177.1520 including 21 CFR 177.1520(c)2.2. 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**

The monomer(s) and the additive(s) of this resin are listed in Annex I, 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.



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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% 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 specific migration limit (SML).

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 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.

### 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 additive. This product does not contain 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.



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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).

- 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 and its modification GMC/Res. N° 19/21.

This product does not contain additive. Meets the requirements of 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 of this resin is listed in Anvisa RDC 56/2012 and RDC No 589.

This product does not contain additive. Meets the requirements of 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 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 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.



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### **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 (ADM) are intentionally used in the formulation this product. However, we note that the manufacture of this Marlex® Polyethylene grade does involve the use of one process chemical that may contain low (ppm levels) of an ADM. This ADM ingredient, based on vendor-supplied information, can be considered free from risk of bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSE) as rigorous regulatory guidelines such as FDA 21 CFR 189 and 700 and EU 98/16/EC are used by the vendor, such as control of the origin of the raw materials as well as using rigorous hydrolysis processing with high temperature and pressure. In addition, the manufacturing process of the Marlex® grade itself involves the use of high temperatures and extremely high pressures.

### **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)



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### **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:

- 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, Tl, 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 in a concentration above 0.1% w/w 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, as shipped, does not contain substances with applicable restrictions (but there are conditions per entry listed below) under REACH Annex XVII (Restricted Substances List) or subject to authorization under REACH Annex XIV (Authorization List). The product supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

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



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### **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.

### **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.

### **PFAS**

Poly- and perfluoroalkyl substances (PFAS) or Perfluorinated Chemicals or Compounds (PFC) are not used in the formulation of this product. See Appendix for additional information.

### **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 as well as EU 649/2012 Annex I substances not contained above classification limits: <http://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals/tabid/1132/language/en-US/Default.aspx>
- 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
- Global Automotive Declarable Substances List (GADSL), does not contain substances at or above the restricted limits
- 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, acrylonitrile co-polymers, or Polyacrylonitrile (PAN)
- Aflatoxin and Mycotoxin; or derivatives of these substances



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- 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, and US FDA Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) such as: peanuts, tree nuts, milk, eggs, wheat gluten, soybeans, sesame, fish and shellfish
- Aromatic amines
- Asbestos
- Azo and azoxyalkyl compounds (e.g. Azodicarbonamide)
- Benzophenone
- 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 (e.g. as defined by Biocidal Products Regulation (BPR) 528/2012 and 334/2014).
- Bisphenol compounds, including but not limited to: BPA, BPAF, BPB, BPC, BPE, BPF, BPH, BPS, and BPZ
- Brominated or halogenated flame retardants
- Butylated Hydroxyanisole (BHA), and Tertiary butylhydroquinone (TBHQ)
- Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
- Chlorinated paraffins, Chlorinated hydrocarbons
- Cobalt (CAS RN® 7440-48-4)
- Colophony (also known as wood rosin, gum rosin, tree rosin or yellow rosin CAS No.® 8050-09-7)
- Colorants, dyes or pigments e.g. Green 7 CAS No.® 1328-53-6, Green 36, Pigment Red 104 CAS No.® 12656-85-8, Yellow #5, CI Pigment Yellow 34 CAS No.® 1344-37-2, Yellow 138 CAS No.® 14302-13-7, Violet 23 CAS No.® 215247-95-3; EU resolution AP(89) not applicable, colorants not contained
- Cyanuric acid
- Di(ethylhexyl) adipate (DEHA), diethyl hydroxyl amine (DEHA), or di(ethylhexyl)maleate (DEHM)
- Dimethylfumarate (DMF)
- 1,4-Dioxane (CAS RN® 123-91-1)
- Dioxins or furans; or derivatives of these substances
- Dyes (also see Colorants) and dye intermediates and precursors such as 2,4-Xylidine (CAS RN® 95-68-1); 4-aminoazobenzene (CAS RN® 60-09-3); 2-aminotoluene (CAS RN® 95-53-4); 4,4'-thiodianiline (CAS RN® 139-65-1); 4-cresidine (CAS RN® 120-71-8), 3,3'-dimethoxybenzidine (CAS RN® 119-90-4); 3,3'-dimethylbenzidine (CAS RN® 119-93-7); Benzidine (CAS RN® 92-87-5); 4-aminodiphenyl (CAS RN® 92-67-1); 4-chloro-o-toluidine (CAS RN® p-Phenylenediamine (CAS RN® 106-50-3); 2-naphthylamine (CAS RN® 91-59-8); 2-amino-4-nitrotoluene (CAS® RN 99-57-0); (CAS RN® 4-chloro-o-toluidine 95-69-2)
- Endocrine disruptors e.g. Alkylphenol ethoxylate (APE), Nonylphenol ethoxylate (NPE), Octylphenol ethoxylate (OPE)
- Epoxy derivatives listed in EU Directives 2002/16/EC and 1895/2005
- Epoxidized Soybean Oil
- Ethylene Oxide (CAS RN® 75-21-8)



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- FDA Banned Food Additives: benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, pyridine, styrene
- Formaldehyde (for additional information related to aldehydes and processing see the SDS)
- Fungicides, preservatives (for the purpose of preserving food in packaging), or fumigants
- Genetically-modified organisms (GMO)
- Halogens
- Human materials, derivatives of human materials, blood, blood plasma, or blood products
- Iron (Fe)
- Isocyanates
- Melamine
- Methyl bromide
- Mica, natural (CAS RN® 12001-26-2)
- Microorganisms, yeast, or bacteria not intentionally contained
- 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 NaNO<sub>2</sub>.
- Nitrocellulose
- Nonyl phenol (NP)
- Optical brighteners
- Organotin compounds
- Ozone-depleting chemicals
- Palm oil or derivatives of palm oil
- Parabens (e.g. ethyl paraben, propyl paraben, butyl paraben)
- Perchlorates
- Pesticides, fungicides, and rodenticides
- 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)
- Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- Radioactive Substances: No radiation sources are used to alter the product characteristics.
- Recycled materials (i.e. No post-consumer recycled materials utilized.)
- Silicone a.k.a. Polydimethylsiloxane (PDMS) or Silicone Oil CAS No.® 63148-62-9 not intentionally contained
- Siloxanes not intentionally contained
- Sulfonamide
- Titanium dioxide; TiO<sub>2</sub> (CAS RN® 13463-67-7)
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether), Triclocarban
- Tris-Nonylphenol Phosphite (TNPP)





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- Vinylidene chloride (Dichloroethene), Vinyl Chloride Monomer (VCM), Polyvinyl Chloride (PVC), Polyvinylidene Dichloride (PVDC) or copolymers

### **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 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>