



48N5 - High-Density Polyethylene Resin

Regulatory Data Sheet

Chemical Inventories

The components of this product comply with the following chemical inventories, as noted:

United States	Toxic Substances Control Act Inventory (TSCA), "Active"
Australia	Australian Inventory of Chemical Substances (AICS)
Canada	Domestic Substances List (DSL)
China	Inventory of Existing Chemical Substances Manufactured or Imported in China (IECSC)
Europe	This product complies with the registration requirements under REACH. The components of this product have been duly registered or are exempt from registration.
Japan	Existing and New Chemical Substances List (ENCS)
Korea	Korea Existing Chemicals Inventory (KECI). Shell has not registered this product or its components under K-REACH.
New Zealand	New Zealand Inventory of Chemicals (NZIoC)
Philippines	Philippines Inventory of Chemicals and Chemical Substances (PICCS)
Taiwan	Taiwan Chemical Substance Inventory (TCSI)
Vietnam	National Chemical Inventory (NCI)

Food Contact Regulations

Please find below the regulatory status of our polyethylene resin for use in food contact applications under various global jurisdictions. Please note it is the responsibility of the article or material manufacturer to understand and comply with the laws and regulations that govern the intended use of the article or material.

U.S. Food and Drug Administration Status

This product complies with the specifications for olefin polymers as described in 21 CFR 177.1520 paragraph (c) 3.1a or 3.2a, and thus may be safely used in articles or components of articles intended for use in contact with food. Finished articles may contact all food types identified in Table 1 of 21 CFR 176.170(c) under Conditions of Use A-H as described in Table 2 of 21 CFR 176.170 (c).

The above information is subject to good manufacturing practice, technical suitability, and any limitations set forth in the regulations.

Canada Health Products and Food Branch Status

We have obtained a letter of no-objection from Health Canada (file KS22051317) for this polyethylene resin for use in food packaging applications.

European Union Food Contact Status

This product complies with the relevant provisions of the European Union's Framework Regulation (EC) No. 1935/2004, Commission Regulation (EC) No. 2023/2006 on good manufacturing practice, and Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come in contact with food.

The monomers and additives used in this polymer are listed in Annex I of Regulation (EU) No. 10/2011, as amended, or are authorized in accordance with the provisions thereof.

Finished articles or materials intended to come in contact with food are subject to an overall migration limit (OML) of 10 mg/dm² or 60 mg/kg food.

Certain components of this product may be subject to specific migration limits (SML) and other restrictions, as follows:

- 1-Hexene (CAS# 592-41-6); SML of 3 mg/kg
- Zinc (CAS# 7440-66-6); SML of 5 mg/kg
- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (CAS# 2082-79-3); SML of 6 mg/kg, FRF is applicable

Dual-use Additives - this product does not contain dual-use additives.

Non-Intentionally Added Substances (NIAS) - Oligomers are considered NIAS in polyolefins as they are unavoidably formed during polymerization and cannot be removed. A recent joint study by polyolefin producers demonstrated that oligomers migrating from various types of commercial polyolefins consist of linear and branched alkanes (Polyolefin Oligomeric Saturated Hydrocarbons, POSH) and alkenes (Polyolefin Oligomeric Mono-unsaturated Hydrocarbons, POMH), no cyclic or aromatic compounds were found. The toxicological assessment concluded that the potential migration levels of the oligomers from plastic to food, and the corresponding potential for dietary exposure, are below any toxicological level of concern.

MERCOSUR Food Contact Status

This product complies with the relevant requirements of GMC Resolution No. 03/92 "General Criteria for packaging and articles to come into contact with foodstuffs".

The monomers used in this product are authorized under GMC Resolution No. 02/12 "Positive list of monomers, polymers, and other starting substances" and GMC Resolution No. 39/19 (replacing GMC Resolution No. 32/07) "Positive list of additives for the preparation of plastic materials and polymeric coatings".

Certain components of this product may be subject to specific migration limits (SML) and other restrictions, as follows:

- 1-Hexene (CAS# 592-41-6); SML of 3 mg/kg
- Zinc (CAS# 7440-66-6); SML of 5 mg/kg
- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (CAS# 2082-79-3); SML of 6 mg/kg, FRF is applicable

China Food Contact Status

This product meets the requirements of GB4806.1-2016: National Food Safety Standard on General Safety Requirements of Food Contact Materials and Articles.

The basic polymer is listed in Table A.1 of GB 4806.7-2023: National Food Safety Standard on Food Contact Use Plastic Materials and Articles.

The additives used in this product are authorized according to GB 9685-2016: National Standard for the use of Additives in Food-Contact Materials and Articles.

Certain components of this product may be subject to specific migration limits (SML) and other restrictions, as follows:

- 1-Hexene (CAS# 592-41-6); SML of 3 mg/kg
- Zinc (CAS# 7440-66-6); SML of 25 mg/kg
- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (CAS# 2082-79-3); SML of 6 mg/kg

Japan Food Contact Status

This product complies with Japan's Draft Positive List system for Food Utensils, Containers and Packaging materials. The basic monomers and additives used in this product are listed in the new draft of Table 1 (base materials) and new draft of Table 2 (additives), respectively, or are exempt from the Positive List system.

U.S. Pharmacopeia (USP)

This product has not been tested under U.S. Pharmacopeia standards.

Shell Chemical does not recommend or endorse the use of this product in any Class II or Class III medical devices as defined by the Food and Drug Administration.

European Pharmacopeia (EUP)

This product has not been tested under EU Pharmacopeia standards.

Drug Master File (DMF)

This product has not been registered in a Drug Master File (DMF).

EU REACH Substances of Very High Concern (SVHC's)

This product does not contain any of the substances on the Candidate List of Substances of Very High Concern (SVHC's), as of the June 27, 2024 update, above the threshold of 0.1 % by weight.

EU Classification and Labelling

This product is not classified as a dangerous substance according to Regulation (EC) No 1272/2008 on the Classification, Labelling, and Packaging of substances and mixtures.

EU Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS 2)

This product complies with the applicable requirements of the RoHS 2 or RoHS recast Directive 2011/65/EC as amended up to Directive (EU) 2015/863 and the original RoHS Directive 2002/95/EC.

Shell Chemical does not intentionally use or add lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB's), polybrominated diphenyl ethers (PBDE's), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP).

EU Waste Electrical and Electronic Equipment (WEEE)

This product does not contain substances that would require selective treatment in accordance with Annex VII of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

EU End of Life Vehicles (ELV)

This product does not contain intentionally introduced lead, mercury or hexavalent chromium at concentrations exceeding 0.1% wt or cadmium at concentrations exceeding 0.01% wt and would therefore comply with the applicable provisions of the End-of-Life Vehicles Directive 2000/53/EC, as amended.

Toxics in Packaging and Packaging Waste

This product does not contain intentionally introduced metals such as antimony, arsenic, barium, cadmium, chromium (VI), lead, mercury, selenium, silver; per- and polyfluoroalkyl substances (PFAS) and ortho-phthalates; therefore, the product complies with the applicable requirements of the following regulations:

- Model Toxics in Packaging Legislation (formerly CONEG) - last update February 2021
- Packaging and Packaging Waste Directive 94/92/EC as amended up to Directive (EU) 2018/852
- California Toxics in Packaging Prevention Act

PFAS

Per- and Polyfluoroalkyl substances (PFAS) are not intentionally added or used in the manufacture of this product. Although this product is not tested for their presence, based on knowledge of product composition these substances are not expected to be present in the finished product as supplied by Shell. However, this product may come into contact with containers, packaging, seals, gaskets, etc. and this contact could lead to extremely low, but detectable, levels of PFAS entering the product after manufacture.

California Proposition 65

This product does not contain any of the substances on the California Proposition 65 list, as of the December 29, 2023 update, which are known to the State of California to cause cancer or reproductive toxicity.

Ozone-Depleting Substances

This product does not contain ozone-depleting substances that are identified in the following regulations:

- Class I or Class II substances as listed in 40 CFR Part 82 Subpart A
- Montreal Protocol of 1987 and amendments - Annexes A, B, C, & E
- Regulation (EC) No 1005/2009, last amended by Regulation (EU) 2017/605 amending Annex VI

Conflict Minerals (Dodd-Frank)

This product does not contain any of the conflict minerals (tantalum, tin, gold, or tungsten) that are identified in section 1502 of the Dodd-Frank Act.

Persistent Organic Pollutants (POPs)

This product does not contain Persistent Organic Pollutants as listed in the Stockholm convention.

Phthalates

This product does not contain phthalates and therefore complies with the relevant provisions of the Consumer Product Safety Information Act of 2008 and Commission Regulation (EU) 2018/2005.

Global Automotive Declarable Substance List (GADSL)

This product does not contain substances that are declarable under the GADSL.

Toy Safety

This product complies with the requirements for materials for use in toys as set forth in ASTM F963, EN 71-3, EN 71-9, EU Directives 2005/84/EC and 2009/48EC. Please note zinc compounds may be present.

Nanomaterials

This product is not a nanomaterial, nor it is produced from nanomaterials.

Food Allergens

This product does not contain food allergens as identified by the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 or Annex II of Regulation (EU) 1169/2011, as amended. Food allergens include but are not limited to milk, eggs, fish (e.g., bass, flounder, cod), crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans. None of these foods are intentionally added or used in the manufacture of the product.

Animal Derived Ingredients

This product does not contain substances of animal origin including bovine or tallow derived substances, kosher/halal-offending substances, or any animal substances that may carry the risk of transmitting Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE), nor are such substances present in the raw materials used in the manufacture of this product. Shell Chemical has not pursued kosher/halal certification; however, you should anticipate no difficulty in obtaining these certifications if desired.

Absence Declarations

The following chemical substances are not intentionally added or used in the manufacture of this product. Although this product is not tested for their presence, based on knowledge of product composition these substances are not expected to be present in the finished product as supplied by Shell.

- Acrylamide
- Acrylonitrile or acrylonitrile co-polymers
- Alkylphenols
- Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Aromatic amines
- Asbestos
- Azo compounds
- BADGE: 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether, BFDGE: Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether, and/or NOGE: Novolac glycidyl ethers

- Biocides
- Bisphenol compounds, including but not limited to BPA, BPB, BPC, BPE, BPF, BPH, BPS, and BPZ
- Brominated or halogenated flame retardants
- Butylated Hydroxytoluene (BHT), Butylated Hydroxyanisole (BHA), and Tertiary butylhydroquinone (TBHQ)
- Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
- Chlorinated paraffins, Chlorinated hydrocarbons
- Colorants, dyes, pigments
- Colophony/Rosin
- 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 (ESBO)
- Formaldehyde
- Genetically modified organisms (GMO)
- Halogens
- Materials derived from plants
- Melamine
- Methyl bromide
- Natural rubber latex, dry natural rubber, or synthetic latex
- Octyl- and nonylphenol
- Organotin compounds
- Parabens
- Pesticides and fungicides
- Photoinitiators, including benzophenone, hydroxybenzophenone, and 4-methylbenzophenone, and Isopropylthioxanthone (ITX)
- Plasticizers (adipates, phthalates such as BBP, DBP, DEHP, DnHP, DIDP, DINP, DNOP)
- 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)

- Polydimethylsiloxane (PDMS)
- Radioactive substances
- Recycled materials
- Silicone
- Styrene
- Sulfonamides
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether), Triclocarban
- Tris-Nonylphenol Phosphite (TNPP)
- Vinyl Chloride Monomer (VCM) and Polyvinyl Chloride (PVC) or copolymers

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