



Product Regulatory Overview (PRO) Lotrène® Q 5502BN Polyethylene

Product Manufacturer

Qatar Chemical Company Ltd (Q-Chem)
Qatar Chemical Company II Ltd (Q-Chem II)

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: 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.

This product was tested per Commission Regulation (EU) No 10/2011. The tested sample thickness was 3.175 mm (125 mils). For measuring the overall migration limit (OML), this product was tested with 3% acetic acid for 10 days at 40°C, with 50% ethanol for 10 days at 40°C, and with olive oil for 10 days at 40°C. For measuring specific migration limits (SML), this product was tested with 3% acetic acid for 10 days at 60°C, with 50% ethanol for 10 days at 60°C, and with olive oil for 10 days at 60°C. This product complies with the OML and SMLs. This product is suitable to be used in contact with aqueous, acidic, alcoholic, dairy and oily or fatty foodstuffs.

This product does not contain any dual-use additive per EU Directive No 95/2/EC and its Amendments.

This product meets the requirements of Framework Regulation (EC) No. 1935/2004 of The European Parliament and of The Council of 27 October 2004, on materials and articles intended to come in contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

This product is produced in accordance with good manufacturing practice (GMP) as outlined in EU GMP Regulation (EC) No 2023/2006.

Germany BfR Recommendations

This product meets the requirements on catalyst residues and residual decomposition products in German BfR Recommendations on Food Contact Materials III Polyethylene.



Product Regulatory Overview (PRO) Lotrène® Q 5502BN Polyethylene

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).

This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.

Brazil Food Contact

All constituents of this product are listed in Brazilian Legislation ANVISA Resolution No. 105 (May 19th, 1999) Annex II and Annex III.

For full compliance, a total migration limit applies to the final article intended to come in contact with food. This product has not been tested for the purpose of complying with Brazilian food contact regulations.

China Food Contact

All additives of this resin are listed in GB 9685-2008 "Hygienic standards for uses of additives in food containers and packaging materials", and meet the relevant specific migration limits. There are no regulatory food type restrictions on this resin.

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. Pharmacopoeia (USP)

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

This product also meets the standards set by the United States Pharmacopoeia (USP 26), <661> Containers Physicochemical Tests and Polyethylene Containers.

European Pharmacopoeia (EUP)

This product meets the requirements of European Pharmacopoeia 3.1.3. the 8th edition "Polyolefines" materials used for the manufacture of containers.

This product meets the requirements of European Pharmacopoeia 3.1.5 the 8th 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 30064.

This product is listed in Health Canada Drug Master File 2015-227.

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.



Product Regulatory Overview (PRO) Lotrène® Q 5502BN Polyethylene

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.

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.

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 and all amendments:

- 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

Product Regulatory Overview (PRO) Lotrène® Q 5502BN Polyethylene

(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.

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

Product Regulatory Overview (PRO) Lotrène® Q 5502BN Polyethylene

- Fungicides, preservatives or fumigants
- Genetically-modified organisms (GMO)
- Materials derived from plants
- 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)
- 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 LP, Qatar Chemical Company Ltd (Q-Chem), and Qatar Chemical Company II Ltd (Q-Chem II), do not make, and expressly disclaim, 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.*



Product Regulatory Overview (PRO) Lotrène® Q 5502BN Polyethylene

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

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