



## **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**

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 up to and including Commission Regulation (EU) 2016/1416.

This product was tested for the overall and specific migration compliance per Commission Regulation (EU) No 10/2011. The tested sample thickness was 3.175 mm (125 mils). The surface-to-volume ratio was 1 dm<sup>2</sup> sample immersed in 1dl simulant. For measuring the overall migration level, 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 the specific migration level, 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 overall migration limit (OML) and specific migration limit (SML).

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 on materials and articles intended to come in contact with food.



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

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.

### **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. 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 26 <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, Extractable Metals, and Plastic Additives tests.



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

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

This product meets the requirements of European Pharmacopoeia 3.1.3. the 8<sup>th</sup> edition “Polyolefines” materials used for the manufacture of containers.

This product meets the requirements of European Pharmacopoeia 3.1.5 the 8<sup>th</sup> 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.

### **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 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**

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)
- Hazardous Air Pollutants (CAA Section 112)
- Accidental Release Prevention Substances (CAA Section 112(r))
- Volatile Organic Chemicals (CAA Section 111)



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

### **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 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 20 June 2016. 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.

### **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.



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

### 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
- 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)
- 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



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

- 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.*

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

Address: Qatar Chemical Company Ltd, 18th Floor, Amwal Tower, Omar Al Muhktar Street, Al Dafna (Zone 61), Doha, Qatar