

# Product Stewardship Bulletin



## Petrothene LR734001

A product of Equistar Chemicals, LP

### Global Food Contact Status:

#### European Union

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 10/2011/EC (PIM) as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments.

EU Regulation 10/2011/EC specifies 10 mg/dm<sup>2</sup> as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC and subsequent amendments. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

This product contains one or more components with Specific Migration Limit (SMLs)

68145; 2,2',2"-NITRILO[TRIETHYL-TRIS(3,3',5,5'-TETRA-tert-BUTYL-1,1'-BIPHENYL-2,2'-DIYL) PHOSPHITE]  
SML = 5 mg/kg (sum of phosphite and phosphate)

18820; 1-Hexene; SML = 3 mg/kg.

#### United States

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(3)(i) and (c)3.2a.

This product may also contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to our information, the substances used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b).

This product may only be used in conditions of use B-H and temperatures at or below 212 degrees F, as described in Table 2 or 176.170(c).

### **Allergen Statements**

The food ingredients listed in the Annex IIIa of European Directive 2007/68/EC, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

### **Allergen - Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)**

No major food allergens (e.g., Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Wheat, Peanuts, Soybeans, Sesame Seeds, Sulphites) nor protein derived from them are used in the formulation or manufacture of this product.

### **Food Allergens**

The following list of allergens are not used in the manufacture of or formulation of this product. However, we do not test our products for these substances.

The list includes:

Peanuts, peanut oil, any peanut products;  
tree nuts (almonds, Brazil nuts, chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts);  
refined or unrefined oils;  
Milk (casein) or milk products, dairy products, dairy derivatives, lactose with protein;  
Eggs or egg products;  
Soybeans, soy flour, any soy products;  
Fish (e.g. cod, salmon) or fish products;  
Shellfish, crustaceans (e.g. shrimp, crabs, lobsters, oysters, clams, scallops, crayfish);  
Molluscs (e.g. snails, clams, squid, octopi) or mollusc products;  
Sulfites;  
food colors;  
Carmine;  
Cochineal;  
Corn;  
Celery or celery products;  
wheat (gluten) or wheat products;  
Seeds (e.g. cotton, poppy, sesame, sunflower, mustard) or seed products;  
Aspartame;  
Monosodium glutamate (MSG);  
Caffeine;  
Hydrogenated vegetable protein (HVP);  
Hydrolyzed protein;  
Grains (e.g. rye, barley, oats);  
Lecithin;  
Lupine or lupine products;

### **Biomedical Policy**

This product may not be used in the manufacture of any of the following applications: U.S. FDA Class III medical devices; Health Canada Class IV medical devices; European Class III medical devices; applications involving permanent implantation into the body; life-sustaining medical applications; and lead, asbestos or MTBE related applications.

This product may not be used in any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I medical devices, without prior notification to Seller for each specific product and application.

This product may not be used in the manufacture of any of the following, without prior written approval by Seller for each specific product and application: U.S. FDA Class II medical devices; Health Canada Class II or III medical devices; European Union Class II medical devices; or any equivalent U.S. FDA, Health Canada, or European Union regulations pertaining to medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form; and tobacco-related products and applications.

All references to the U.S. FDA, Health Canada and European Union regulations include all other country's equivalent regulatory classifications.

## **Animal Based Raw-Materials (BSE/TSE)**

Components derived from animal sources are not used in the manufacture or formulation of this product.

## **Epoxy Derivatives**

The materials BADGE, BFDGE or NOGE are not intentionally added in this product as referenced in Commission Regulation 1895/2005/EC, on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs as plasticizers, additives or raw materials.

## **California Prop 65**

Please refer to the MSDS for communications regarding California Proposition 65.

## **CEPA Challenge Program**

Articles made from this product are not expected to contain any materials in the CEPA Challenge Program Lists 1 through 12 at levels that would trigger reporting when the items are imported into Canada.

## **CLP Regulation - Regulation (EC) No. 1272/2008**

CLP Regulation (for "Classification, Labeling and Packaging") Regulation (EC) No 1272/2008, aligns the European Union system of classification, labeling and packaging of chemical substances and mixtures to the Globally Harmonized System (GHS).

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC (for dangerous substances) and 1999/45/EC (for dangerous preparations), and amending Regulation (EC) No 1907/2006.

See Product's European MSDS at <http://www.lyondellbasell.com> for classification and labeling of chemicals which are legally binding within the EU - including carcinogen, mutagenic and reproductive toxins (CMR).

## **CONEG - Coalition of Northeastern Governors**

The chemical materials listed below are not used in the manufacture or the formulation of this product. However, this product has not been tested for these chemical materials:

Lead, mercury, cadmium and hexavalent chromium, as identified in the CONEG Model Legislation.

## **Genetically Modified Organisms (GMO)**

This product is manufactured by a synthetic process and no materials of plant or animal origin are incorporated as raw materials, processing aids or additives.

## **Kosher Certification**

This product is not certified Kosher. The additives and ingredients used to manufacture this resin are derived from non-animal sources. The use of this resin should have no adverse impact on the Kosher status of your customer's food product and you should anticipate no difficulty in obtaining Kosher certification with use of the above listed product.

### **Latex**

No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.

### **Metals Content**

### **US CONEG**

Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

### **EU Packaging and Packaging Waste**

Based on the available documentation from raw materials suppliers, this product complies with the directive 94/62/EC and its following amendments concerning the defined limit(s) of heavy metals.

### **Other Chemicals**

The chemical materials listed below are not used in the manufacture or the formulation of this product and are not expected to be present. However, this product has not been tested for these chemical materials.

Acrolein; (propenal); (CAS# 107-02-8);

Asbestos;

Azo Dyes and Pigments;

Bisphenol A; (BPA); CAS# 80-05-7;

Formaldehyde; CAS# 50-00-0;

Halogenated Flame Retardants

Melamine; (1,3,5-Triazine-2,4,6-triamine); CAS# 108-78-1;

Organotin compounds;

Perfluorooctane sulfonate; (PFOS); CAS# 1763-23-1;

Perfluorooctanoic acid; (PFOA); CAS# 335-67-1;

Phthalates;

Styrene monomer; CAS# 100-42-5;

Vinyl chloride; CAS# 75-01-4;

## **Ozone Depleting Substances**

### **European Union**

The ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation ( EC ) No 1005/2009 of 16 September 2009, are not intentionally used in the manufacture of or formulation of this product.

### **United States**

Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFC's and Class II, HCFC's, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not intentionally used in the production of this product.

### **Penta- and Octa- BDE**

Please note that as of June 1, 2009 REACH Annex XVII replaces Directive 76/769/EEC – The "Limitation Directive" for Dangerous Substances and Preparations which places restrictions on the marketing and use of certain dangerous substances and preparations namely pentabromodiphenyl ether, and octabromodiphenyl ether.

Neither pentabromodiphenyl ether nor octabromodiphenyl ether are used in the formulation of this product and will not be found in concentrations higher than 0.1 % by mass in this product.

### **REACH Information**

This product is manufactured by affiliates and subsidiaries of the LyondellBasell group of companies around the world.

Under the EC Regulation REACH this product is classified as a preparation. If the product has been purchased from Basell Sales & Marketing Company B.V. BSM), we confirm that all substances in this preparation have been pre-registered or, where required under REACH, registered, and that we have the intention either to proceed with their registration in accordance with the deadlines set forth in REACH, or to procure substances only from suppliers from which confirmation has been received that the suppliers are aware of their REACH requirements, that they have met their pre-registration and applicable registration obligations of their substances, and that they will supply the relevant Safety Data Sheets (SDS) with REACH registration numbers as soon as the registrations occur. In no event shall any LyondellBasell group be liable for any non-compliance deriving from false or incorrect statements of its suppliers.

We remind you, if this product is purchased from any supplier, including other companies of the LyondellBasell group, which is not established in the European Union, the importer into the European Economic Area (EEA) is responsible for compliance with the requirements of REACH.

Please contact REACH@LyondellBasell.com if you need to discuss the potential compliance with REACH before importing this product into the EEA.

### **REACH Annex XVII**

REACH Annex XVII – Restriction on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Preparations and Articles.

The chemical materials listed are not used in the manufacture or the formulation of this product. However, this product has not been tested for these chemical materials.

See Product's European MSDS at <http://www.lyondellbasell.com> for classification and labeling of chemicals which are legally binding within the EU - including carcinogen, mutagenic and reproductive toxins (CMR).

### **REACH Only Representative (OR) Services**

Companies of LyondellBasell in North America will evaluate enquiries for OR services.

Please forward your request for OR services to [reach@lyondellbasell.com](mailto:reach@lyondellbasell.com).

### **REACH Substances of Very High Concern (SVHC)**

This product does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (List as of June 20, 2013) above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing.

The current list of all SVHCs can be found at ECHA website link listed below:

<http://echa.europa.eu/web/guest/candidate-list-table>

### **Global Toy Regulations:**

CEN EN Standards refer to safety of toys and not specifically to plastic raw materials. According to the information provided by our raw material suppliers, we deem this product should comply with the requirements of CEN standards EN71-3 / EN71-9 (as amended) as applicable to plastic raw materials (pellets, powder, flakes). However, this product has not been tested according to these CEN Standards.

H.R. 4040 establishes consumer product safety standards and other safety requirements for children's products and reauthorizes and modernizes the Consumer Product Safety Commission. The product listed above is a commercial product not a consumer product although some manufacturers may choose to use this material in consumer products. We have reviewed the act and believe that this material will not impair the ability of our customers to comply with the act however it is the responsibility of our customers to insure compliance and provide any required testing.

We have reviewed Standard Consumer Safety Specification of Toy Safety: ASTM F-963-96. It appears that Section 4.3.5 applies to paints or similar coatings and section 8.3 describes testing protocol for these coatings. Our conclusion is that the standard is to be applied to paint or coatings on a finished toy (8.3.3), therefore the standard is not applicable to the resin supplied by the companies of LyondellBasell. Analyses of representative polyolefin resin samples have shown metal content to be less than 2 ppm.

#### **USDA**

It is our understanding that it is not necessary to obtain a letter of chemical acceptance from USDA prior to using a packaging material for meat or poultry products provided that the packer has on file a letter from the materials supplier assuring that its products are in compliance with the Federal Food, Drug and Cosmetic Act.

#### **WEEE - European Union (EU) Directives 2011/65/EU**

The chemical materials listed below are not used in the manufacture or the formulation of this product. However, this product has not been tested for these chemical materials.

Lead, mercury, cadmium, hexavalent chromium, Polybrominated biphenyl (PBB) and Polybrominated diphenyl ethers (PBDE) as identified in 2011/65/EU: Commission Decision of 8 June 2011 repealing Directive 2002/95/EC and its successive amendments.

The RoHS Directive complements the WEEE Directive.

EU legislation restricting the use of hazardous substances in electrical and electronic equipment (Directive 2002/95/EC) and promoting the collection and recycling of such equipment (Directive 2002/96/EC).

#### **Disclaimer**



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Before using a product sold by a company of the LyondellBasell family of companies, users should make their own independent determination that the product is suitable for the intended use and can be used safely and legally.

SELLER MAKES NO WARRANTY, EXPRESS OR IMPLIED (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY) OTHER THAN AS SEPARATELY AGREED TO BY THE PARTIES IN A CONTRACT.

This product(s) may not be used in:

(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I medical devices, without prior notification to Seller for each specific product and application; or  
(ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: U.S. FDA Class II medical devices; Health Canada Class II or III medical devices; European Union Class II medical devices; or any equivalent U.S. FDA, Health Canada, or European Union regulations pertaining to medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form; and tobacco-related products and applications. This product(s) may not be used in the manufacture of any of the following applications: U.S. FDA Class III medical devices; Health Canada Class IV medical devices; European Class III medical devices; applications involving permanent implantation into the body; life-sustaining medical applications; and lead, asbestos or MTBE related applications. All references to the U.S. FDA, Health Canada and European Union regulations include another country's equivalent regulatory classification.

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