

August 05, 2019

minli  
hongrunplas  
In CHINA Guangdong Province Dongguan City Zhangmutou  
town



***Pro-fax 6323***

A product of Equistar Chemicals, LP

Dear minli:

The following is in response to your request for Product Stewardship Information (PSInfo) for the product listed above. The attached Product Stewardship Bulletin (PSB) details the regulatory status of this product.

LyondellBasell Industries responds to product stewardship requests with a standardized Product Stewardship Bulletin (PSB) which summarizes the global regulatory status of a product. LyondellBasell Industries will not complete customers' forms or questionnaires. Standardized responses provide each customer with consistent information in a timely fashion. Each request is reviewed to ensure our response documents provide relevant information.

Please note that compliance with these regulations should not be interpreted to guarantee that the product, will, in fact, perform in a particular application. Your Technical Service Representative can help you determine that the characteristics of the product are compatible with the desired conditions of use.

Should you have any further questions concerning a LyondellBasell product, or if we can assist in any other way, please do not hesitate to contact us.

Best regards,

A handwritten signature in black ink that reads "Tamara Greathouse". The signature is written in a cursive, flowing style.

Tamara Greathouse  
Sr. Product Steward  
713-309-7171  
tamara.greathouse@LyondellBasell.com

# Product Stewardship Bulletin



## *Pro-fax* 6323

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) and as amended, 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.

#### SML Components

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

SML = 1 mg/kg (expressed as Aluminium)

68320; Octadecyl 3(3,5-Di-tert-butyl-4-hydroxyphenyl) propionate; SML = 6 mg/kg

#### Dual Use Additives

This product contains one or more Dual Use Additives as defined in Regulation 10/2011/EC.

- ▶ E 470a Calcium salts of fatty acids

## **EU National Legislations**

The composition of this product complies with the following National Legislations, Recommendations or Communications for the production of food packaging. For other National Legislations, Recommendations or Communications not recognized below, please see compliance statement provided under EU Regulation 10/2011/EC (PIM).

Germany: BfR Recommendation VII - Polypropylene (as of 01.07.2016)

Warenwet: Verpakkingen en Gebruiksartikelen (Warenwet)- Last update, Chapter 1 - Kunststoffen.

## **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)(1)(i) and (c)1.1a.

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 meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

## **Canada**

A letter of "no objection" for food contact use of this product has been obtained from HPFB.

The HPFB publishes the polymer products which have "no objection" letters on their website at: [http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/polymers\\_tc-polymere\\_tm\\_e.html](http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/polymers_tc-polymere_tm_e.html).

Consult the HPFB list at the above website for information on this product and for any limitations of use that may have been assigned to this product by HPFB.

## **Allergen Statements**

### **Allergen - Food Allergen European Regulation 1169/2011**

The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, 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. However, this product has not been tested for these substances.

## **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(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: (1) U.S. FDA Class II, Health Canada Class II or Class III, and/or European Union Class II Medical Devices; (2) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned Medical Devices; (3) packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; (4) tobacco related products and applications; (5) electronic cigarettes and similar devices.

(iii) Additionally, the product(s) may not be used in: (1) U.S. FDA Class III, Health Canada Class IV, and/or European Class III Medical Devices; (2) applications involving permanent implantation into the body; (3) life-sustaining medical applications.

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

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

#### **Tallow**

Tallow derived additives may be used in the manufacture of this product.

#### **Europe - BSE/TSE - "Mad Cow"**

Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMA/410/01, and as amended.

#### **United States**

One or more additives in this product may be derived from animal sources. Our suppliers have stated that their additive is derived from bovine material. They have assured us that the animal material is sourced from the United States, Canada or Mexico. The bovine material can be any part of the animal. There were two sets of process conditions specified by our suppliers for processing the bovine material. These are: (1) Hydrogenation of tallow @200 deg. C, hydrolysis @260 deg. C, and 48 bar for 1.5-2 hours and vacuum distillation @232 deg. C; (2) Hydrolysis of tallow @260 deg. C and 700 psig for 3 hours, hydrogenation of stearic acid @232 deg. C and 300 psig for 2.5 hours, and distilled at 232 deg. C for 5 minutes.

One or more additives in this product may be derived from either animal or vegetable sources.

#### **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 US SDS for communications regarding California Proposition 65.

### **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 SDS at <http://www.lyondellbasell.com> for classification and labeling of chemicals which are legally binding within the EU.

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

Components derived from vegetable sources are used in the manufacture of this product. These vegetable sources are not believed to be sourced from Genetically Modified Organisms (GMO's).

### **Kosher Certification**

This product is not certified Kosher.

### **Latex**

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

### **Medical**

### **US FDA Drug Master File (DMF)**

Information on this product is listed in DMF# 1698. Contact LyondellBasell for a DMF letter of authorization (LOA) to be sent to FDA.

### **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 as amended concerning the defined limit(s) of heavy metals.

### Heavy Metals Testing

Testing of resins similar to this product has shown the following metals are not present at the sensitivities listed in parenthesis: antimony(3 ppm), arsenic(2 ppm), barium(2 ppm), cadmium(1 ppm), chromium(1 ppm), lead(2 ppm), mercury(0.01 ppm), selenium(3 ppm), silver(1 ppm).

### Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC and 2011/65/EU, as amended, concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

### Other Chemicals

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

- ▶ 2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol; (Benzotriazole); CAS# 3846-71-7;
- ▶ 2,4,4'-trichloro-2'-hydroxydiphenyl ether; (Triclosan); CAS# 3380-34-5;
- ▶ 2-mercaptobenzothiazole; MBT; CAS# 149-30-4;
- ▶ Acrolein; (propenal); (CAS# 107-02-8);
- ▶ Acrylamide; CAS# 79-06-1;
- ▶ Alkylphenols
- ▶ Aromatic amines;
- ▶ Asbestos;
- ▶ Azo Dyes and Pigments;
- ▶ 1,2-dihydro-acenaphthene; (PAH); CAS# 83-32-9;
- ▶ 9H-fluorene; (PAH); CAS# 86-73-7;
- ▶ Acenaphthylene; (PAH); CAS# 208-96-8;
- ▶ Anthracene; (PAH); CAS# 120-12-7;
- ▶ Benz(a)anthracene; (PAH); CAS# 56-55-3;
- ▶ Benzo(a)pyrene; (PAH); CAS# 50-32-8;
- ▶ Benzo(b)fluoranthene; (PAH); CAS# 205-99-2;
- ▶ Benzo(e)pyrene; (PAH); CAS# 192-97-2;
- ▶ Benzo(ghi)perylene; (PAH); CAS# 191-24-2;

- ▶ Benzo(j)fluoranthene; (PAH); CAS# 205-82-3;
- ▶ Benzo(k)fluoranthene; (PAH); CAS# 207-08-9;
- ▶ Chrysene; (PAH); 218-01-9;
- ▶ Dibenz(a,h)anthracene; (PAH); CAS# 53-70-3;
- ▶ Fluoranthene; (PAH); CAS# 206-44-0;
- ▶ Fluorene; (PAH); CAS# 86-73-7;
- ▶ Indeno(1,2,3-cd)pyrene; (PAH); CAS# 193-39-5;
- ▶ Phenanthrene; (PAH); CAS# 85-01-8;
- ▶ Naphthalene; (PAH); CAS# 91-20-3;
- ▶ Polycyclic aromatic hydrocarbons;
- ▶ Pyrene; (PAH); CAS# 129-00-0
- ▶ Bisphenol A; (BPA); CAS# 80-05-7;
- ▶ Butylated hydroxyanisole; (BHA); CAS# 121-00-6 & 25013-16-5;
- ▶ Chlorinated paraffins;
- ▶ Dimethyl fumarate; (DMF); CAS# 624-49-7;
- ▶ Dioxins;
- ▶ Epichlorohydrin; (ECH); CAS# 106-89-8;
- ▶ Flame Retardants;
- ▶ Fluorocarbons;
- ▶ Fluorotelomers
- ▶ Formaldehyde; CAS# 50-00-0;
- ▶ Melamine; (1,3,5-Triazine-2,4,6-triamine); CAS# 108-78-1;
- ▶ Nonylphenol; CAS# 25154-52-3;
- ▶ Nonylphenol ethoxylates;
- ▶ Organotin compounds;
- ▶ Perfluorochemicals; (PFCs);
- ▶ Perfluorooctane sulfonate; (PFOS); CAS# 1763-23-1;
- ▶ Perfluorooctanoic acid; (PFOA); CAS# 335-67-1;



- ▶ Plasticizers:
  - DINCH; 1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester; CASRN: 166412-78-8;
  - DEHA; Bis(2-ethylhexyl) adipate; CASRN: 103-23-1;
  - BTHC; Butyryl tri-n-hexyl citrate; CASRN: 82469-79-2;
  - TOTM; Tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate; CASRN: 3319-31-1;
  - DINP; Diisononyl Phthalate; CASRN: 28553-12-0;
  - DEHP; di(2-ethylhexyl) phthalate
  - DOP; di-octyl phthalate; CASRN: 117-81-7;
  - DIDP; di-iso-decyl phthalate; CASRN: 26761-40-0;
  - DBP; di-butyl phthalate; or DNBP; di-n-butyl phthalate; CASRN 84-74-2;
  - BBP; butyl benzyl phthalate; CASRN 85-68-7;
  - DNOP; di-n-octyl phthalate; CASRN: 117-84-0;
  - Glycerides, castor-oil mono-, hydrogenated, acetates; CASRN: 736150-63-3;
- ▶ Polybrominated biphenyls; (PBBs);
- ▶ Polybrominated diphenyl ethers; (PDBEs);
- ▶ Polybrominated terphenyls; (PBTs);
- ▶ Polychlorinated biphenyls; (PCBs);
- ▶ Polychlorinated naphthalenes; (PCNs);
- ▶ Polychlorinated terphenyls; (PCTs);
- ▶ Polystyrene;
- ▶ Polyvinyl chloride; (PVC); CAS# 9002-86-2;
- ▶ Radioactive substances;
- ▶ Radon; CAS# 10043-92-2;
- ▶ Styrene monomer; CAS# 100-42-5;
- ▶ Tris-nonylphenol phosphite; (TNPP); CAS# 26523-78-4;
- ▶ 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, CFCs 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.

### Montreal Protocol

ODCs listed in the Montreal Protocol are not used in the manufacture of or formulation of this product.

## **Phthalates**

Polyolefins do not require the use of plasticizers (such as phthalates) to make them soft and flexible. LyondellBasell does not add phthalates to its polyolefin products as plasticizers. However, traces of phthalates may be present in some products as impurities from the catalytic system.

## **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 any company of the LyondellBasell group of companies registered in the European Union, we confirm that all substances in this preparation have been registered under REACH, in accordance with the deadlines set forth in REACH (Regulation (EU) No. 1907/2006)

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@LYB.COM if you need to discuss the potential Only Representative functionality before importing this product into the EEA.

This product does not contain any of the Annex XIV substances on the Authorisation list or Annex XIV candidate chemicals proposed to be Substances of Very High Concern for Authorisation (List as of July 16, 2019) 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:

<https://www.echa.europa.eu/candidate-list-table>

## **Global Chemical Control Regulations**

All ingredients in this product are in compliance with the following chemical inventories:

See Section 15, of the SDS (Safety Data Sheet) for Global Chemical Inventories.

## **CEN Standard EN 13432:2004**

This product is not suitable for composting.

## **Energy Recovery - CEN Standard EN 13431:2004**

The calorific gain from polypropylene in an energy recovery process is 24 MJ/kg.

## **Disclaimer**

Information in this document is accurate to the best of our knowledge at the date of publication. The document is designed to provide users general information for safe handling, use, processing, storage, transportation, disposal and release and does not constitute any warranty or quality specification, either express or implied, including any warranty of merchantability or fitness for any particular purpose. Users shall determine whether the product is suitable for their use and can be used safely and legally.

In addition to any prohibitions of use specifically noted in this document, LyondellBasell may further prohibit or restrict the sale of its products into certain applications. For further information, please contact a LyondellBasell representative.

## **Trademarks**

The Trademark referenced within the product name is owned or used by the LyondellBasell family of companies.