

Product Stewardship Bulletin



Lupolen 5261Z

A product of Basell Sales & Marketing, BV

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/dm² 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)

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

EU National Legislations

The composition of this product complies with the following National Legislations, Recommendations or Communications for the production of food packaging.

Austria: "K.V.O." N.476/2003 as amended at last by BGBl - Teil. II - N.140/2009

Belgium: "Arrete royal du 5 juillet 2006 (amending Arrete royal du 11 mai 1992 and modifying "Arrete royal du 3 juillet 2005").

Denmark: Bekendtgørelse N.579 (01/06/2011)

Finland: "KTM", Paatos 953/2002 of 12.11.2002 (amended by 107/2009 of 03/03/2009)

France: "Materiaux au contact des aliments et de denre destine a l'alimentation humaine" Brochure n.1227 edition Janvier 1994 as updated. Arrete du 02 Janvier 2003 (as modified at last by Arrete 03/09/2010).

Germany: Bedarfsgegenstaendeverordnung- 07 February 2011 (BGBl I S.226)

Greece: AXE Decision n.458/2003 modified by Decision n. 6/2011

Ireland: S.I. No. 587 of 2007, as amended by S.I. No.301 of 2010

Italy: "Decreto Ministeriale del 21/03/1973" amended on 26/4/1993 : D.M. N.220 and following updates (last update: D.M. of 16/02/2011).

Luxembourg: "Reglement Grand-Ducal" n. 163 du 05/11/2008.

Norway: Regulations 21 December 1993, No. 1381, on materials and articles intended to come into contact with foostuffs Chaper I General regulations, as amended.

Portugal: Decreto-Lei No. 62/2008 of 31/03/2008, and Amend. Decreto-Lei No. 29/2009, of 02/02/2009.

Spain: Real Decreto N.118 31/01/2003, modified by Real Decreto N.103/2009, of 06/02/2009.

Sweden: Ordinance of the National Food Administration on materials and articles intended to come into contact with foodstuffs LIVSFS 2011:7.

The Netherlands: Staatscourant n.6861 of 06.05.2010.

England: "The Plastic Materials and Articles in Contact with Food (England) Regulations 2009", Statutory Instrument 2009 n. 205.

Switzerland: BGVO 817.023.21 of 23 November 2005, as amended.

Czech Republic: Regulation of the Ministry of Health N.551/2006, modifying N.38/2001.

Dual use additives subject to restrictions in food as defined in Regulation 10/2011/EC are not intentionally used in the manufacture or formulation of this product.

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)(2)(i) and (c)2.2.

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.

Allergen Statements

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.

IMDS Information

The companies of LyondellBasell enter data into IMDS directly to assist automobile companies in the recycling effort, to confirm the compliance of products manufactured by LyondellBasell companies with the heavy metals article of the EU End of Life Vehicle (ELV) Directive, and to declare the presence of substances listed in the Global Automotive Declarable Substances List (GADSL) if required.

Note: LyondellBasell does not send MDS reports to customer recipient ID numbers. Our product MDSs are in a "Published" state accessible to every IMDS user through the IMDS website.

Please use the following IMDS ID-No. for your reference:

IMDS# 20190884

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.

Users should review the applicable Safety Data Sheet before handling the product.

Animal Based Raw-Materials (BSE/TSE)

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

Tallow

Tallow derived components 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.

Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act - September, 2010)

Please see link below for the position of LyondellBasell concerning this Act:

<http://www.lyondellbasell.com/InvestorRelations/FinancialReporting/SECFilings/>

The link to this document is located in the right margin of this website landing page titled "download our conflict minerals policy".

Halal Certification

This product is not certified as Halal.

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.

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.

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, as amended, and 2011/65/EU concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).

Nanomaterials

Nanomaterials (defined as natural, incidental or manufactured materials containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm) are not used in the manufacture of or the formulation of this grade. However, this product has not been tested for these chemical substances.

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.

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;

Aromatic amines;

Asbestos;

Azo Dyes and Pigments;

Polyaromatic Hydrocarbons - PAHs:

1,2-dihydro-acenaphthene; (CAS# 83-32-9);

9H-Fluorene; (CAS# 86-73-7);

Acenaphthylene; (CAS# 208-96-8);

Anthracene; (CAS# 120-12-7);

Benz(a)anthracene; (CAS# 56-55-3);

Benzo(a)pyrene; (CAS# 50-32-8);

Benzo(b)fluoranthene; (CAS# 205-99-2);

Benzo(e)pyrene; (CAS# 192-97-2);

Benzo(ghi)perylene; (CAS# 191-24-2);

Benzo(j)fluoranthene; (CAS# 205-82-3);

Benzo(k)fluoranthene; (CAS# 207-08-9);

Chrysene; (CAS# 218-01-9);

Dibenz(a,h)anthracene; (CAS# 53-70-3);

Fluoranthene; (CAS# 206-44-0);

Indeno(1,2,3-cd)pyrene; (CAS# 193-39-5);

Naphthalene; (CAS# 91-20-3);

Phenanthrene; (CAS# 85-01-8);

Pyrene; (CAS# 129-00-0);

Benzophenone; CAS RN 119-61-9;

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

Bisphenol A diglycidyl ether; (BADGE); CAS# 1675-54-3;

Bisphenol F diglycidyl ether; BFDGE; CAS# 2095-03-6;

Butylated hydroxyanisole; (BHA); CAS# 121-00-6 & 25013-16-5;

Butylated hydroxytoluene; (BHT); CAS# 128-37-0

Chlorinated paraffins;

Cyanuric acid; (Isocyanuric Acid or CYA); CAS# 108-80-5;

Dimethyl fumarate; (DMF); CAS# 624-49-7;

Dioxins;

Epichlorohydrin; (ECH); CAS# 106-89-8;

Fluorocarbons;

Fluorotelomers

Formaldehyde; CAS# 50-00-0;

- ▶ Formaldehyde in specific conditions could be formed during the resin processing (see MSDS)

Gold(Au); CAS# 7440-57-5;

Halogenated Flame Retardants

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

Nonylphenol; CAS# 25154-52-3;

Nonylphenol ethoxylates;

Novolac glycidyl ether;

Organotin compounds;

Perfluorochemicals; (PFCs);

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

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

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;

Sulphur dioxide; CAS# 7446-09-5;

Tin oxide (SnO₂); (Cassiterite); CAS# 8062-08-6;

Tris-nonylphenol phosphite; (TNPP); CAS# 26523-78-4;

Vinyl chloride; CAS# 75-01-4;

Wolframite; Tungsten (W); CAS# 1332-08-7;

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.

Phthalates

Phthalates are not used in the manufacture of or the formulation of 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 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 16, 2014) 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 Chemical Control Regulations

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

United States: Toxics Substances Control Act Inventory (TSCA)

Canada: Domestic Substances List (DSL)

Europe: EINECS/ELINCS replaced by REACH

Australia: Australian Inventory of Chemical Substances (AICS)

Korea: Korean Existing Chemicals List (KECL)

Japan: Japanese Inventory of Existing and New Chemical Substances (ENCS)

The Philippines: Philippines Inventory of Chemicals and Chemical Substances (PICCS)

China: Inventory of Existing Chemical Substances Manufactured or Imported in China (IECS)

New Zealand: New Zealand Inventory of Chemicals (NZIoC)

This product has no special requirements under US TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.).

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.

VOC Content

Switzerland VOC Declaration

This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland Regulations "VOC-LENKUNGSABGABE."

CEN Standard prEN 13432

This product is not suitable for composting.

Energy Recovery - CEN Standard prEN 13431

The calorific gain from polyethylene in an energy recovery process is 22 MJ/Kg.

Disclaimer

The information in this document is, to our knowledge, true and accurate at the time and date of issue. However, information in this document may be updated periodically due to changes in the laws and regulations, or for other reasons, therefore we cannot guarantee that the status of this product will remain unchanged. Users are expected to regularly visit the PSInfo Website to obtain the most current information on this product.

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: (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; and (6) pressure pipe or fittings that are considered a part or component of a nuclear reactor.

(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; and (4) lead, asbestos or MTBE related applications.

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

Users should review the applicable Material Safety Data Sheet before handling the product.

Addhere, Adflex, Adstif, Adsyl, Akoafloor, Akoalit, Alathon, Amazing Chemistry, Aquamarine, Aquathene, Avant, Catalloy, Clyrell, CRP, Crystex, Dexflex, Explore & Experiment, Flexathene, Glacido, Hifax, Histif, Hostacom, Hostalen, Ideal, Integrate, Koattro, LIPP, Lucalen, Luflexen, Lupolen, Lupolex, Luposim, Lupostress, Lupotech, Metocene, Microthene, Moplen, Nerolex, Nexprene, Petrothene, Plexar, Pristene, Prodflex, Pro-Fax, Purell, Sequel, Softell, Spherilene, Spheripol, Spherizone, Starflex, Stretchene, Superflex, Toppyl, Trans4m, Ultrathene, Vacido and Valtec are trademarks owned or used by the LyondellBasell family of companies.

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