

Product Stewardship Bulletin



Purell GA7760

A product of Basell Sales & Marketing Company B.V.

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.

Specific Migration Limits

This product does not contain monomers, additives or other components which have SMLs or QMAs as specified by Regulation 10/2011/EC.

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

- ▶ E 470a Calcium salts of fatty acids

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 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.

China

All additives used in this product comply with the requirements of GB9685-2008 and Ministry Of Health Announcement 2012 No.5, with no restrictions in specific migration limit (SML) or maximum quantity per area (QMA).

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.

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 EMEA/410/01, rev. 3".

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:

<https://www.lyondellbasell.com/en/investors/corporate-governance/?id=52>

The link to this document is located in the right margin under the heading "Corporate Governance Documents" titled "Conflict Minerals Policy".

Genetically Modified Organisms (GMO)

Additives derived from Genetically Modified Organisms (GMO's) are not intentionally used in the formulation of this product.

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.

Medical

European Pharmacopeia (EP)

This product meets the EP requirements for 3.1.3, Polyolefins - 8th Edition of European Pharmacopeia.

ISO 10993

Biological reactivity evaluations have been performed on representative samples of this product, specifically the Chapter 88 USP Biological Reactivity Tests, In Vivo for a Class VI plastic (Systemic Injection Test, Intracutaneous Test, Implantation Test). These USP tests may fit the requirements of certain sections of 10993-10 (tests for irritation and skin sensitization) and 10993-11 (tests for systemic toxicity). Despite this, the manufacturer of a medical device made with this product must still evaluate the medical device to show that it fully meets the requirements of the applicable sections of ISO 10993.

Results provided by Seller are intended to be representative in nature only and are not to be construed as a guarantee of future product performance. Seller makes no express or implied warranty by virtue of disclosing pass/fail status.

US Pharmacopeia (USP)

Representative samples of this product have passed the Chapter 88; USP Biological Reactivity Tests, In Vivo for a Class VI plastic (Systemic Injection Test, Intracutaneous Test, Implantation Test). In addition, the Physico-chemical testing of this product met the USP limits defined in Chapter 661.

Results provided by Seller are intended to be representative in nature only and are not to be construed as a guarantee of future product performance. Seller makes no express or implied warranty by virtue of disclosing pass/fail status.

US FDA Drug Master File (DMF)

Information on this product is listed in DMF N. 5654. Contact LyondellBasell for a DMF authorization letter to be sent to FDA.

ICH Harmonized Guideline Q3D (Elemental Impurities)

The elemental impurities of Class 1, 2, 3 listed in the ICH Harmonized Guideline Q3D of 16 December 2014 are not intentionally used in the manufacture or formulation of this product. However this product has not been tested for these substances.

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 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).

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;

Antimony;

Aromatic amines;

Arsenic;

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);

Barium;

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

Cadmium;

Chlorinated paraffins;

Chromium;

Cobalt;

Copper;

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

Iridium;

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

Lead

Lithium;

Mercury;

Molybdenum;

Nickel; CAS# 7440-02-0;

Nonylphenol; CAS# 25154-52-3;

Nonylphenol ethoxylates;

Novolac glycidyl ether;

Organotin compounds;

Osmium;

Palladium;

Perfluorochemicals; (PFCs);

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

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

Platinum;

Plasticizers (e.g. DEHA, DINCH, BTHC, TOTM, etc.):

DEHA bis(2-ethylhexyl) adipate; CASRN: 103-23-1

DINCH 1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester, CASRN: 166412-78-8

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;

Rhodium;

Ruthenium;

Selenium;

Silver;

Styrene monomer; CAS# 100-42-5;

Sulphur dioxide; CAS# 7446-09-5;

Tallium;

Tin;

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

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

Vanadium;

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. However, this product has not been tested for phthalates.

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, 2016) 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:

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

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. Product Stewardship Bulletins not directly received from the PSInfo system are uncontrolled documents.

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.

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

This product(s) may not be used in the manufacture of any of the following, without prior written approval by Seller for each specific product and application:

- (i) U.S. FDA Class I or II Medical Devices; Health Canada Class I, II or III Medical Devices; European Union Class I or II Medical Devices;
- (ii) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned medical devices;
- (iii) 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; tobacco related products and applications, electronic cigarettes and similar devices.

The product(s) may not be used in:

- (i) U.S. FDA Class III Medical Devices; Health Canada Class IV Medical Devices; European Class III Medical Devices;
- (ii) applications involving permanent implantation into the body;
- (iii) life-sustaining medical applications.

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

In addition to the above, LyondellBasell may further prohibit or restrict the use of its products in certain applications. For further information, please contact a LyondellBasell representative.

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