

**Product
Stewardship
Bulletin**



Moplen EP332K

A product of Basell International Trading FZE

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.

SML Components

This product contains one or more components with SMLs. Some of these components may not be disclosed in this document. To obtain the identity of all the component(s) that have SML(s) please use the following email address to submit your request. Please include your contact information and product name.

SML@lyb.com

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

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)3.1a.

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).

In summary, this product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, excluding cooking, listed under conditions of use C 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.

Asia

China

The base resin in this product complies with the requirement of China Ministry of Health Announcement 2011 No.23 – “107 Types of Resins that can be used for Use in Food Packaging”. Please refer to website provided below for the types of polypropylene resins listed. See Item 71 for Polypropylene Copolymers.

<http://www.nhfpc.gov.cn/sps/s7891/201111/0ee62a149d474cef96debb86f1f8b105.shtml>

All additives used in this product comply with the requirements of GB9685-2008 and Ministry Of Health Announcement 2012 No.5. However, this product contains one additive for which a Specific Migration Limit (SML) and/or Maximum Permitted Quantity (QM) in the final article has been established in GB9685-2008 or Ministry Of Health Announcement 2012 No.5. Please be reminded that these specifications apply to the final articles as defined in GB9685-2008, section 2.4 and 2.5.

Allergen Statements

Allergen - General

This product contains no identified allergenic materials including:

Cereals containing gluten or products of these, wheat or wheat products
Dairy or dairy products, egg or egg products
Peanut or peanut products, soybean or soybean products
Tree nut or tree nut products, seed or seed products
Fish or fish products, shellfish or shellfish products
Phenylalanine, tartrazine
Sugar, monosaccharides or disaccharides, modified cornstarch, yeast
Preservatives, artificial color, artificial flavor, sulfur dioxide or sulfites

No identified allergenic materials are present in the manufacturing facility and the product is manufactured in dedicated equipment.

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.

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.

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 - 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.

Halogenated Compounds

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

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 does not meet the EP requirements for 3.1.3, Polyolefins - 7th Edition of European Pharmacopeia.

USP Class VI

This product has not been tested for USP Class VI.

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.

End of Life Vehicle

To the best of our knowledge, based on the available documentation from raw materials suppliers, we deem that this product complies with the directive 2000/53/EC and its following amendments as concerns 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).

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);

Benzo(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);

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 flame retardants;

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;

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

Halogenated Flame Retardants

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

Nickel; CAS# 7440-02-0;

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;

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;

Styrene monomer; CAS# 100-42-5;

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

Vinyl chloride; CAS# 75-01-4;

Ozone Depleting Substances

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.

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 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 December 17, 2015) 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.

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.

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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