Product Stewardship Bulletin

Moplen HP500N

A product of Basell Sales & Marketing Company B.V.; 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 Specific Migration Limits (SMLs).

39815; 9,9-bis(methoxymethyl)-9H-fluorene; SML = 0.05mg/kg

Reference No: 39090; N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine; SML(T) = 1,2 mg/kg

Reference No: 39120; N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides; SML(T) = 1.2 mg/kg (Expressed as tertiary amine excluding HCl)

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.

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: Bekendtgorelse 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 in der Fassung vom 23 Dezember 1997 (BGBI. I 1998 S.5), zuletzt geandert durch Art. 1 der Verordnung vom 24 Juni 2013 (BGBI I S. 1682)

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.

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 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, these substances used in this product meet the requirements of their respective FDA regulations, FCNs, 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

The base resin in this product complies with requirements of China GB9693-1988 “Hygienic Standards for Polypropylene Resins for food packaging”.

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

All additives in this product comply with the requirements of GB9685-2008 and Ministry of Health Announcement 2012 No.5. However there is one or more substances used in this product for which a Specific Migration Limit (SML) has been established in GB9685-2008. Please be reminded that this specification applies to the final articles as defined in GB9685-2008 section 2.5.

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.

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)

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 fullfill 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.

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;

Aromatic amines;

Asbestos;

Azo Dyes and Pigments;

Polyaromatic Hydrocarbons - PAHs:

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

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;

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

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.

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 polypropylene in an energy recovery process is 24 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.
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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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