

June 12, 2013



**Moplen RP340N**

A product of Basell Sales & Marketing, BV

Dear Roto srl

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, appearing to read 'Paolo Pozzati'.

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**Product  
Stewardship  
Bulletin**



**Moplen RP340N**

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), 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.

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.

This product contains one or more process aids that have a Specific Migration Limit (SML).

DNBP and DEHP (see phthalate section below for more information) are impurities of a "technical support agent" used in this product.

Substance Reference No.: 74880 DNBP has a SML equal to 0.3 mg/kg (300 ppb).

Substance Reference No.: 74640 DEHP has SML equal to 1.5 mg/kg (1500 ppb)

Phthalates are subject to a SML(T) of 60 mg/kg.

This product may contain a component used in the catalyst system for which a SML is established.

## **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 foodstuffs Chapter 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)(3)(i) and (c)3.1a.

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.

## **Allergen Statements**

The food ingredients listed in the Annex IIIa of European Directive 2007/68/EC, 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 may not be used in the manufacture of any of the following applications: U.S. FDA Class III medical devices; Health Canada Class IV medical devices; European Class III medical devices; applications involving permanent implantation into the body; life-sustaining medical applications; and lead, asbestos or MTBE related applications.

This product may not be used in 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.

This product may not be used in the manufacture of any of the following, without prior written approval by Seller for each specific product and application: U.S. FDA Class II medical devices; Health Canada Class II or III medical devices; European Union Class II medical devices; or any equivalent U.S. FDA, Health Canada, or European Union regulations pertaining to medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form; and tobacco-related products and applications.

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

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

### **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".

## **Tallow**

Tallow derived additives may be used in the manufacture 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.

## California Prop 65

This product may contain two chemical substances at very low levels (less than 1 ppm) which are known to the State of California to cause cancer and/or reproductive toxicity under California Proposition 65. These substances are:

Di-n-butyl phthalate (DnBP) or simply dibutyl phthalate (DBP) (CAS# 84-74-2) – reproductive toxin

Di(2-ethylhexyl) phthalate (DEHP) or di-octyl phthalate (DOP) [CAS# 117-81-7] – carcinogen and reproductive toxin

DBP and DEHP are not intentionally added or used in the production of this product (see Phthalate section of the RAPIDS). However, there is potential for trace level DBP and DEHP contamination, because both are impurities in diisobutyl phthalate (DIBP), which is a minor component of the catalyst system used to make the base resin in this product. Calculated estimates confirmed by testing of several resins indicate a potential total residual phthalate (all phthalates) content of less than 10-15 ppm (parts per million). Further testing with food simulants, per general conditions of use as established in European Union Regulation 10/2011/EC did not detect any phthalate migration at a detection sensitivity of 20 ppb (parts per billion) (0.02 parts per million or 0.02 mg/kg). A worst case estimate of the amount of DBP or DEHP that could potentially migrate from the resin is calculated to be less than 10 ppb (parts per billion) each. Under Proposition 65, DBP has a maximum allowable dose level (MADL) of 8.7 micrograms per day. The DEHP MADL for intravenous exposure is 4200 (adults), 600 (infant boys, age 29 days- 24 mos.) and 210 (neonatal infant boys, age 0-28 days) and for oral exposure is 410 (adults), 58 (infant boys, age 29 days- 24 mos.) and 20 (neonatal infant boys, age 0-28 days), all values in micrograms per day. DEHP has a no significant risk level (NSRL) of 310 micrograms per day.

It is the responsibility of the California business owner to develop his or her own regulatory compliance plan.

This product may contain two chemical substances at very low levels (less than 10 ppm), due to impurities in a manufacturing process aid, which are known to the State of California to cause cancer and/or reproductive toxicity under California Proposition 65. These substances are:

Ethylene oxide (CAS# 75-21-8) - carcinogen and reproductive toxin

1,4-Dioxane (CAS# 123-91-1) – carcinogen

Under Proposition 65, for carcinogenicity, ethylene oxide has a no significant risk level (NSRL) of 2 micrograms per day, and for reproductive toxicity, ethylene oxide has a maximum allowable dose level (MADL) of 20 micrograms per day. For carcinogenicity of 1,4-dioxane, the NSRL is 30 micrograms/day.

It is the responsibility of the California business owner to develop his or her own regulatory compliance plan.

## 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 (insoluble or biopersistent and intentionally manufactured materials with one or more external dimensions, or an internal structure, on the scale from 1 to 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; 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 (SnO<sub>2</sub>); (Cassiterite); CAS# 8062-08-6; Tris-

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

chloride; CAS# 75-01-4;

Wolframite; 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.

#### **Phthlates**

Phthalate plasticizers are in general used in specific non-olefinic resin systems to soften these resins and make them flexible. When phthalate plasticizers are added, they can constitute up to 50% of the resultant plastic material. Polyolefins do not require the use of plasticizers to make them soft and flexible. No phthalates plasticizers, such as di(2-ethylhexyl) phthalate (DEHP) or di-octyl phthalate (DOP) [CAS# 117-81-7], di-iso-nonyl phthalate (DINP) [CAS# 28553-12-0], di-iso-decyl phthalate (DIDP) [CAS# 26761-40-0], di-butyl phthalate (DBP) or di-n-butyl phthalate (DNBP) [CAS# 84-74-2], butyl benzyl phthalate (BBP) [CAS# 85-68-7] and di-n-octyl phthalate (DNOP) [CAS# 117-84-0], are intentionally used in the formulation of this product. However, a phthalate compound, diisobutyl phthalate (DIBP) [CAS# 84-69-5], could be used in the manufacturing process as a "technical support agent" (as defined by the European Union), i.e. a minor component of the catalyst system. This is typical of polypropylene and polybutene resins produced with high mileage catalysts. Impurities in the "technical support agent" and catalyst system include DBP (or DNBP), DEHP (or DOP), diethyl phthalate (DEP) [CAS# 84-66-2] and isobutyl ethyl phthalate (IBEP) [CAS# 94491-96-0]. Testing of several resins has resulted in the identification of the overall residual phthalate content no more than 10-15 parts per million. Further testing with food simulants (per EU Regulation 10/2011/EC) has resulted in phthalates not detected at a sensitivity of 20 parts per billion (0.02 parts per million). To put these results in perspective, plastic materials that require phthalate plasticizers, referred to above, can have up to 500,000 parts per million (50%) of the phthalate plasticizer in them.

### **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 of this preparation are compliant with the pre-registration requirements of REACH, and that we have the intentions to proceed with the registration of these substances, 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 pre-registered and/or will timely register their substances, and that they will supply the relevant Safety Data Sheets (SDS) with REACH registration numbers as soon as the registrations occur. BSM shall in no event 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 other than BSM, including other companies of the LyondellBasell group, the importer into the European Economic Area (EEA) is responsible for compliance with the requirements of the REACH Regulation. Please contact our helpdesk 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 19, 2012) 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(IECSC)

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.).

#### **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.

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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: U.S. FDA Class II medical devices; Health Canada Class II or III medical devices; European Union Class II medical devices; or any equivalent U.S. FDA, Health Canada, or European Union regulations pertaining to medical devices; packaging in direct contact with a pharmaceutical active ingredient and/or dosage form; and tobacco-related products and applications. This product(s) may not be used in the manufacture of any of the following applications: U.S. FDA Class III medical devices; Health Canada Class IV medical devices; European Class III medical devices; applications involving permanent implantation into the body; life-sustaining medical applications; and lead, asbestos or MTBE related applications. All references to the U.S. FDA, Health Canada and European Union regulations include another country's equivalent regulatory classification.

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