PolyMirae

PolyMirae Company Ltd.

Regulatory Affairs

Regulatory Affairs Product Information Data Sheet (RAPIDS)

Moplen HP602N

- **PRODUCT MANUFACTURER**

This product is manufactured by PolyMirae Company Ltd.

FOOD APPROVALS

EU:

The monomers used to produce the resin are listed in EU Directive 2002/72/EC and amendments up to Commission Regulation (EC) No 975/2009.
The additives used to produce the resin are listed in EU Directive 2002/72/EC and amendments up to Commission Regulation (EC) No 975/2009 or in the relevant national legislations.
The additives/monomers for which a QM was imposed by Regulations (if any) are under our own responsibility.

No dual use additives subject to a restriction in food are used to produce this resin.

There are NO restrictions (SML;QMA) specified by the regulations for the components (monomers/additives) of this resin.

A substance present as impurity of a "technical support agent" used in this product has a SML.
Substance PM/REF: 74880.
The concentration of the substance in the polymer is <0,05%.
For further details see below under "phthalates".

EU Directive 2002/72/EC and amendments up to Directive 2008/39/EC, which applies to all EU Member States, specifies 10 mg/dm2 as the maximum overall migration from finished plastic food contact articles. This is the responsibility of the converter.

And, there is a process aid used in this product which has a SML.

To fully comply with food regulations in Europe, the overall migration as specified in 2002/72/EC and amendments from the final article to food can be no greater than 10 mg/dm2. The overall migration is determined using the procedures in Directives 97/48/EC (amending 82/711/EC) and 85/572/EC for the intended uses. In addition, the migration of the component(s) mentioned above must be checked to ensure compliance to the SML(s). This is the responsibility of the manufacturer of the final article. In order to obtain the identity of the component(s) with SML(s), a secrecy agreement will need to be established between PMC and the manufacturer of the final article. In addition, we remind you that the manufacturers of the final article must verify that the final article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

United States of America:
The base resin in *Moplen* HP602N meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 (a) (1) (i) and (c) (1.1a). According to information received from all of our suppliers, all other ingredients used in *Moplen* HP602N meet the requirements of their respective FDA regulations and 21 CFR 177.1520 (b). *Moplen* HP602N meets the FDA criteria in 21 CFR 177.1520 for food contact applications listed under conditions of use A through H in 21 CFR 176.170 (c), Table 2. *Moplen* HP602N can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table 1.

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Chemical Inventories

All ingredients in *Moplen* HP602N are in compliance with the following chemical inventories:

United States:	Toxic Substances Control Act Inventory (TSCA)
Canada:	Domestic Substances List (DSL) – Non Domestic Substances List (NSDL)
Europe:	European Inventory of Existing Commercial Chemical Substances (EINECS)
Australia:	Australian Inventory of Chemical Substances (AICS)
Korea:	Korean Existing Chemicals List (ECL)
China:	Inventory of Existing Chemical Substances (SEPA)
Japan:	Japanese Existing and New Chemical Substances (ENCS)
Philippines:	Philippine Inventory of Chemicals and Chemical Substances (PICCS)

Moplen HP602N has no special requirements under US TSCA (e.g. consent orders, test rules, 12 (b) requirements, etc.).

- **European Pharmacopoeia (EP)**

Moplen HP602N cannot be certified for E.P

- **US Pharmacopeia (USP)**

Moplen HP602N cannot be certified for USP

- **TOYS**

EN71.3

We do not intentionally use the heavy metals listed in EN 71-3 in the production and formulation of these products. Testing of resins similar to these products has shown the following metals are not present at the sensitivities listed in parenthesis: antimony(2 ppm), arsenic(2 ppm), barium(1 ppm), cadmium(1 ppm), chromium(1 ppm), cobalt(1 ppm), copper(1 ppm), lead(2 ppm), mercury(2 ppm), selenium(2 ppm), vanadium(1 ppm).

EN71.9

We do not intentionally use the chemical substances listed in Tables 2D, 2E and 2I "EN71-9 Organic Chemical Compounds in Toys" in the production and formulation of this product. However we do not test our product for the presences of these chemical substances.

PHTHALATES IN TOYS

The phthalates ex art.1 of Decision 1999/815/EC are not used in the manufacture of or the formulation of *Moplen* HP602N. We do not intentionally use the following Phthalates in the manufacturing and formulation of our product : di-iso-nonyl phthalate(DINP), di-(2-ethylhexyl)phthalate(DEHP), di-n-butyl phthalate(DBP), di-iso-decyl phthalate(DIDP), butylbenzyl phthalate(BBP), di-iso-octyl phthalate(DIOP), di-ethyl phthalate(DEP), di-cyclo-hexyl phthalate(DCHP), di-methyl-cyclo-hexyl phthalate(DMCHP) and di-methoxy-ethyl phthalate(DMEP). However, we do not test our resins for the above mentioned substances.

The phthalates ex art.1 of Decision 1999/815/EC are not used in the manufacture of or the formulation of *Moplen* HP602N.

- **Ozone Depleting Substances**

Ozone Depleting Substances are not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of these substances in our product.

- **EU Directive 2002/95/EC on Restriction of certain Hazardous Substances (RoHS) in Electrical & Electronic Equipments**

We do not intentionally use Lead, Cadmium, Mercury, Chromium (VI), PolyBrominated Biphenyl and PolyBrominated Diphenyl Ether in the production and formulation of *Moplen* HP602N. However we do not test for presence of these substances in our product.

- **PHTHALATES**

The phthalates as for Decree of Italian Ministry of Health n°538 of 17/12/1999 are not used in the manufacture of or the formulation of *Moplen* HP602N.

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The phthalates for which opinions have been given by EFSA (European Food Safety Authority) and TDI's (Tolerable Daily Intake) established for use in plastics for containers in food applications, are not intentionally added in the manufacture of or the formulation of this product. The phthalates are di-iso-nonyl phthalate (DINP), di-(2-ethylhexyl) phthalate (DEHP), di-n-butyl phthalate (DBP), di-iso-decyl phthalate (DIDP), butylbenzyl phthalate (BBP).

PolyMirae is aware of the publicity about phthalate plasticizers. 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. PolyMirae does not use any plasticizers in the resins it supplies. Polyolefins do not require the use of plasticizers to make them soft and flexible. Those phthalate plasticizers that have been associated with potential health issues, specifically di(2-ethylhexyl) phthalate (DEHP), di-iso-nonyl phthalate (DINP), di-iso-decyl phthalate (DIDP), di-n-butyl phthalate (DBP) and butyl benzyl phthalate (BBP), are not intentionally used by PolyMirae in the manufacture of or formulation of its resins.

All PolyMirae operations are guided by our commitment to be a responsible supplier, always respecting the health and safety of our employees, our contractors, our customers and the community, as well as the quality of the environment in which we live and operate. PolyMirae is a firm supporter of the chemical industry's Responsible Care® program and the Product Stewardship code. PolyMirae supplies polyolefin resins that are safe when used properly for their intended applications.

As for this product, a phthalate compound, diisobutyl phthalate (DIBP), is a minor component of the catalyst system used to manufacture some of the base polyolefin resins. This is typical of polypropylene resins produced with high mileage catalysts. An impurity in the DIBP is di-n-butyl phthalate (DNBP), sometimes referred to as dibutyl phthalate (DBP). During processing, DIBP reacts and converts to two related phthalate compounds diethyl phthalate (DEP) and ethyl isobutyl phthalate. The phthalates are "technical support agents" as defined by European Union Directive 2007/19/EC. None of the four phthalates has been determined to be human carcinogens or endocrine disrupters at the low levels as suggested by environmentalists. Testing of several resins has resulted in the identification of residual phthalates content no more than 10-15 parts per million. Further testing with food simulants, per general conditions of use as established in European Union Directives 2002/72/EC and 82/711/EC and their amendments, has resulted in phthalates not detected at a sensitivity of 20 parts per billion (0,02 parts per million or 0,02 mg/kg).

A SML (Specific Migration Limit) equal to 0,3 mg/kg (300 ppb) has been established in Directive 2007/19/EC for DNBP. The SML will enter into force when Directive 2007/19/EC is implemented by each member State in their local legislation.

- **Latex**

"Natural rubber latex", "synthetic latex" or "natural rubber" are not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of these substances in our product.

- **Heavy metals (Directive 94/62 EEC)**

CADMIUM, CHROMIUM (VI), MERCURY, LEAD are not intentionally added to our grade *Moplen* HP602N and the incidental sum of the concentration in this product does not exceed 100 parts per million by weight. *Moplen* HP602N can be recycled according to Directive 94/62 requirements.

- **Coalition of Northeastern Governors (CONEG)**

Cadmium, chromium, lead and mercury are not used in the manufacture of or the formulation of *Moplen* HP602N. Therefore, it meets the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

- **SWITZERLAND "VOC-LENKUNGSABGABE"**

Moplen HP602N contains less than 3% VOC's of the Substances in the positive lists of the above Regulations.

- **ASBESTOS**

ASBESTOS is not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of this substance in our product.

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- **PCB's/ PCT's**

"PCB's" / "PCT's" are not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of these substances in our product.

- **BISPHENOL A**

Bisphenol A is not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of this substance in our product.

- **Tin compounds**

"Tin compounds" are not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of these substances in our product.

- **Melamine**

Melamine is not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of this substance in our product.

- **Benzotriazoles**

Benzotriazoles are not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of these substances in our product.

- **Perfluoro Octanoic Sulfonate (PFOS), Perfluoro Octanoic Acid (PFOA)**

Perfluro Octanoic Sulfonate (PFOS) and Perfluoro Octanoic Acid (PFOA) are not used in the manufacture of or the formulation of *Moplen* HP602N. However, we do not test for presence of these substances in our product.

- **EU REACH – SVHC**

Moplen HP602N does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (fifteen(15) in the list dated October 28, 2008; fourteen(14) in the list dated January 13, 2010; one(1) in the list dated March 30, 2010; and eight(8) in the list dated June 18, 2010) 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 combined lists can be found at the following link to the ECHA website:
http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

- **Animal Derived Ingredients**

Animal derived ingredients are not used in the manufacture of or the formulation of *Moplen* HP602N according to our additives supplier's information. But, we do not test our resins for the substances whether it is derived animal ingredients.

- **Energy Recovery** (Ref: CEN Standard prEN 13431)

The calorific gain from this raw material in an energy recovery process is 24MJ/Kg.

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All information ("Information") contained herein is provided without compensation and is intended to be general in nature. You should not rely on it in making any decision. PolyMirae accepts no responsibility for results obtained by the application of this Information, and disclaims liability for all damages, including without limitation, direct, indirect, incidental, consequential, special, exemplary or punitive damages, alleged to have been caused by or in connection with the use of this Information. PolyMirae disclaims all warranties, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose, that might arise in connection with this information.

Certified for PolyMirae by:

KS Park

KS Park
Director – ADTS / Innovation

Product Stewardship & regulation affairs: Tel: +82-61-689-4252, e-mail: **chj.kim@polymirae.com**
This certificate shall continue in effect for 1 year from its effective date

(Effective Date: June 25th, 2010)