Regulatory Affairs Product Stewardship Information / Certification Data Sheet (RAPIDS)

Moplen EP546T

Product Manufacturer and/or Supplier

This product is manufactured by HMC Polymers Company, Ltd.

REACH (Regulation (EC) No. 1907/2006)

This product is manufactured by HMC Polymers Company, Ltd.

Under the EC Regulation REACH this product is classified as a preparation. The importer into the European Economic Area (EEA) is responsible for compliance with the registration requirements of the REACH Regulation. Please contact us if you need to discuss the potential compliance with REACH before importing this product into the EEA.

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 10, 2022) 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 the following link to the ECHA website:
http://echa.europa.eu/web/guest/candidate-list-table.

Chemical Inventories

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)

Taiwan: Taiwan Chemical Substance Inventory (TCSI)

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

For status of other country inventories, please contact HMC Polymers.

Food Contact

European Union (EU) Food Contact

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation), 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.

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.

Dual Use Additives

This product contains one or more components identified as Dual Use Additive as defined in Commission Regulation (EU) 10/2011.

Specific Migration Limit (SML)

This product contains one or more components with Specific Migration Limit (SML).

In order to obtain the identity of the component(s) that are dual additives or that have a SML, please contact HMC Polymers.

US Food and Drug Administration (FDA)

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. According to our information, all other ingredients 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, 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.

China Food Contact Regulations

China Food Contact Regulations

GB4806.1-2016 - Food Contact Material & Articles General Safety Requirement

This product complies with relevant requirements of GB4806.1-2016 - Food Contact Material & Articles General Safety Requirement, as applicable to Plastic Resins.

GB4806.6-2016 “National Food Safety Standard : Food Contact Resins”

The base resin in this product complies with the specifications established in GB4806.6-2016 “National Food Safety Standard : Food Contact Resins” Appendix A.1, Serial Number 29, type PP.

Monomers with SML /SMT(T) specifications : None

GB9685-2016 “National Food Safety Standard : Additives for use in Food Contact Materials and Articles”

The additives used in this product comply with the requirement of “GB9685-2016 National Food Safety Standard : Additives for use in Food Contact Materials and Articles” and relevant approval announcements.

One or more additives with SML and/or SML (t) specifications may be used in this product.

Additives with Max Residual (QM) are not intentionally used in this product.

Following additives with Specific Migration Limit (SML) and Total Specific Migration Limit (SML (t)) specifications are used in this product :

FCA0145 Sodium 2,2'-methylenebis(4,6-di-tert-butylphenyl)phosphate ; SML 5mg/kg

FCA0151 2,2'-Methylenebis(4,6-di-tert-butylphenyl)lithium phosphate ; SML 5mg/Kg; Lithium SML 0.6mg/Kg according to Appendix C

FCA1126 Tetradecanoic acid, lithium salt ; Lithium SML 0.6mg/Kg according to Appendix C

This product may contain other components that warrant QM or SML restrictions, however, these substances with QMs or SMLs are non-detectable in our product.

General Reminder

GB4806.1-2016 "Food Contact Materials & Articles -General Safety Requirement" Clause 8.4, requires only the manufacturer of the finished plastic food contact article to declare compliance with OML specification.

Final plastic food contact articles may have additional compliance requirements, and are the responsibility of the manufacturer of the finished plastic food article.

Japan – Positive Lists for Food Contact

With reference to announcement by Japan Ministry of Health, Labour and Welfare, dated 24 December 2021 about Positive List for Food Utensils, Containers and Packaging, we can confirm as follows;

Base Resins in this product are listed under Item 67 of the Positive List of Base Polymers.

Additives intentionally used in this product are listed in the Positive List of Additive authorized for use in the Base Resins.

Tallow

Tallow derived additives are not intentionally used in the formulation of this product.

Kosher

We do not certify our resins to be Kosher or in compliance with Kosher requirements.

Halal

We do not certify our resins to be Halal or in compliance with Halal requirements. However, animal derived additives are not intentionally used in the formulation of this product.

Food Allergens

The following lists of allergens are not used in the manufacture of or formulation of this product. The list includes:

Peanuts, peanut oil, any peanut products;
tree nuts (almonds, Brazil nuts, chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts);
refined or unrefined oils;
Milk (casein) or milk products, dairy products, dairy derivatives, lactose with protein;
Eggs or egg products;
Soybeans, soy flour, any soy products;
Fish (e.g. cod, salmon) or fish products;
Shellfish, crustaceans (e.g. shrimp, crabs, lobsters, oysters, clams, scallops, crayfish);
Molluscs (e.g. snails, clams, squid, octopi) or mollusc products;
Sulphur dioxide and Sulphites;
food colors;
Carmine;
Cochineal;
Corn;
Celery or celery products;
wheat (gluten) or wheat products;
Seeds (e.g. cotton, poppy, sesame, sunflower, mustard) or seed products;
Aspartame;
Monosodium glutamate (MSG);
Caffeine;
Hydrogenated vegetable protein (HVP);
Hydrolized protein;
Grains (e.g. rye, barley, oats);
Lecithin;
Lupine or lupine products.

However, we do not test our products for these substances.

Genetically Modified Organisms (GMO)

Based on the available documentation from raw materials suppliers, GMO are not used in their raw material.

European Pharmacopeia (EP)

This product cannot be certified for compliance to EP requirements.

Drug Master File (DMF)

Information on this product is not listed in a DMF.

US Pharmacopeia (USP)

This product has not been tested for USP.

Latex

"Natural rubber latex", "dry natural rubber", "synthetic latex" or "rubber that contains natural rubber" are not used in the formulation of this product.

Heavy metals (ELV Directive 2000/53/EC and its following amendments)

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.

Coalition of Northeastern Governors (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).

Packaging and Packaging Waste - EU Directive 94/62/EC (as amended)

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.

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)

This material does not contain listed substances known to the State of California to cause cancer, birth defects, or other reproductive harm that would require a warning under the statute.

Ozone Depleting Chemicals (ODCs)

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 formulation of this product.

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.

Phthalates

Phthalates are not used in the manufacture of or the formulation of this product. However, this product has not been tested for phthalates.

Regulation (EC) N.1895/2005

BADGE, NOGE and BFDGE are not used in the formulation of this product according to requirement of Regulation N.1895/2005.

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 1nm-100nm) are not used in the formulation of this grade. However, this product has not been tested for these chemical substances.

Dimethyl Fumarate (DMF) - EU Commission Decision 2009/251/EC

Dimethyl fumarate [2-butenedioic acid (2E)-, dimethyl ester] (DMF) (CAS#: 624-49-7) is not used in the formulation of this product. However, we do not test this product for DMF.

Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act - September, 2010)

Conflict minerals, which include columbite-tantalite (also known as coltan) [source for tantalum], cassiterite [source for tin], gold, wolframite [source for tungsten] or their derivatives are not intentionally used in the formulation of this product. However, we do not test this product for these substances.

Thailand Hazardous Substances Act

The chemical substances in List #4 (Prohibitive Substances) of the Thailand Hazardous Substances Act B.E.2562 are not used in the manufacture of or formulation of this product. However, this product is not tested for these substances.

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 intentionally used in the formulation of this product and are not expected to be present. However, we do not test this product for these substances.

2,4,4'-trichloro-2'-hydroxydiphenyl ether (Triclosan) (CAS number 3380-34-5)

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol [also called 2-(2'-Hydroxy-3',5'-di-t-butylphenyl)benzotriazole] (CAS number 3846-71-7)

2-Mercaptobenzothiazole [also called 2(3H)-Benzothiazolethione or Benzothiazole-2-thiol or MBT] (CAS No. 149-30-4)

Acrylamide (CAS number 79-06-1)

Aromatic Amines

Asbestos
Azo Dyes and Pigments

Bisphenol A (BPA) (CAS number 80-05-7)

Bisphenol B (CAS No. 77-40-7)

Bisphenol F (CAS No. 620-92-8)

Bisphenol S (CAS No. 80-09-1)

Bisphenol A diglycidyl ether (BADGE) (CAS number 1675-54-3)

Bisphenol F diglycidyl ether (BFDGE) (CAS number 2095-03-6)

Butylated hydroxytoluene (BHT) (CAS number 128-37-0)

Butylated hydroxyanisole (BHA) (CAS numbers 121-00-6 and 25013-16-5)

Chlorinated flame retardants

Chlorinated paraffins

Cyanuric acid (Isocyanuric Acid or CYA) (CAS No. 108-80-5)

Dioxin

Epichlorohydrin (ECH) (CAS number 106-89-8)

Fluorocarbons; Fluorotelemers, Zonyl fluoroadditives (DuPont trade name), perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), perfluorochemicals (PFC) or other fluorocarbon substances

Formaldehyde (CAS No. 50-00-0)

Halogenated Flame Retardants

Melamine (1,3,5-triazine-2,4,6-triamine) (CAS number 108-78-1)

Nonylphenol (CAS number 25154-52-3)

Nonylphenol ethoxylates

Organo-tin Compounds; Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds

Polycyclic Aromatic 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)

Polychlorinated Biphenyls (PCBs)

Polychlorinated Terphenyls (PCTs)

Polychlorinated Naphthalenes (PCNs)

Polybrominated Biphenyls (PBBs)

Polybrominated Diphenyl Ethers (PBDEs)

Polybrominated Terphenyls (PBTs)

Polyvinyl Chloride (PVC)

Radioactive substances

Tris-nonylphenol phosphite (TNPP) (CAS No. 26523-78-4)

Vinyl Chloride (CAS number 75-01-4)

Styrene (CAS number 100-42-5) and Polystyrene

Per- and Polyfluoroalkyl Substances (PFAS)

Decabromodiphenyl ether (DecaBDE) (CAS No. 1163-19-5)

Phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CAS No. 68937-41-7)

2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP) (CAS No. 732-26-3)

Pentachlorothiophenol (PCTP) (CAS No. 133-49-3)

Hexachlorobutadiene (HCBD) (CAS No. 87-68-3)

Composting - CEN Standard prEN 13432

This product is not suitable for composting.

Energy Recovery - CEN Standard EN 13431:2004

The calorific gain from polypropylene in an energy recovery process is 24 MJ/kg.

Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications. Because of possible changes in the law and in regulations, HMC recommends that customers continuing to use our product verify status every year from the issue date of the RAPIDS.

Certified by:

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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 HMC Website to obtain the most current information on this product. Regulatory Affairs Product Stewardship Information / Certification Data Sheets not directly received from the HMC system are uncontrolled documents.

Before using a HMC Polymers product, 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;
(iv) tobacco related products and applications, electronic cigarettes and similar devices.
(v) safety components in automotive applications, for example: air bags, air bag unit housings and covers, seat belt mechanisms, brake systems, pedals and pedal supports, steering systems.

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.