



## Product Regulatory Overview (PRO) Asterene® HHM 5502 Polyethylene

### **Product Manufacturer**

Aster Polymer Solutions Pte. Ltd.

### **Chemical Inventories**

All the components of this product are listed on

AUSTRALIA: Australian Inventory of Industrial Chemicals (AIIC)

CANADA: Domestic Substances List (DSL)

PEOPLE'S REPUBLIC OF CHINA: Inventory of Existing Chemical Substances

EUROPEAN UNION: This product produced by Aster Polymer Solutions Pte. Ltd. can only be imported into the European Union (EU) by Aster Polymer Solutions Pte. Ltd.

JAPAN: Existing & New Chemical Substances (ENCS) Inventory

KOREA: Existing Chemicals List (ECL): A substance(s) in this product was not registered, notified to be registered, or exempted from registration by CPChem according to K-REACH regulations. Importation or manufacture of this product is still permitted provided the Korean Importer of Record has themselves notified the substance

NEW ZEALAND: Inventory of Chemical Substances (NZIoC)

PHILIPPINES: Philippine Inventory of Chemicals and Chemical Substances (PICCS)

TAIWAN: Taiwan Chemical Substance Inventory (TCSI): On the inventory or in compliance with the inventory. Further registrations may apply.

UNITED STATES: On or in compliance with the active portion of the Toxic Substances Control Act (TSCA) Chemical Inventory

### **Food Contact**

*It is the responsibility of the packaging converter or food packager to verify that the finished article meets both the technical and regulatory requirements of the intended application.*

#### **U.S. FDA Food Contact**

This product meets the requirements for polyolefin resins intended for food packaging applications as described in the FDA olefin polymer regulations 21 CFR 177.1520 including 21 CFR 177.1520(c) 3.1a, 3.2a, and 21 CFR 177.1520(b). The resin may be used in contact with all types of food as defined in Table 1, 21 CFR 176.170(c) and at use conditions B-H as defined in Table 2, 21 CFR 176.170(c).

This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.

#### **European Union (EU) Food Contact**

As plastic intermediate material, the monomer(s) and the additive(s) of this resin are listed in Annex I Table 1, Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and all its Amendments including Commission Regulation (EU) 2023/1442 and 2023/1627. The monomer(s) and the additive(s) do not have any restriction(s) and specification(s) in Column 10 of Table 1, Annex I of Commission Regulation (EU) No 10/2011.



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This resin was tested overall migration levels for overall migration limit (OML) compliance. The tested sample thickness was 3.175 mm (125 mils). This product was tested with 4% acetic acid for 10 days at 40°C, with 10 % ethanol for 10 days at 40°C, with 50 % ethanol for 10 days at 40°C, and with olive oil for 10 days at 40°C. This product complies with the overall migration limit (OML).

This product contains the following SMLs listed in Table 1, Annex I of Commission Regulation (EU) No 10/2011:

- 1-hexene, CAS 592-41-6, FCM substance No 356, Ref No 18820, SML 3 mg/kg
- 2,6-di-tert-butyl-p-cresol, CAS 128-37-0, FCM substance No 315, Ref No 46640, SML 3 mg/kg
- thiodipropionic acid, didodecyl ester, CAS 123-28-4, FCM substance No 294, Ref No 93120, SML(T) 5 mg/kg

Based on the use amount and assuming 100% migration from a packaging article into food, and default plastics packaging factor of 6 decimeters squared of package area holding 1 kg food, SML compliance without testing would be up to 0.0175 cm (= 7 mils) thickness of an article fully made of this resin only.

This product meets the restriction(s) on the substances in Table 1, Annex II of Commission Regulation (EU) No 10/2011 amended by Commission Regulation (EU) 2020/1245. Primary aromatic amines are not intentionally used as additives or raw materials in the manufacture of this product.

This product does not contain intentionally added genotoxic substance that would be expected to migrate from resin exceeding 0.00015 mg/kg in food or food simulant to cause genotoxic effect.

This product does not contain food additive(s) or flavoring(s) that would be a concern in food per Regulation (EC) No 1333/2008 or Regulation (EC) No 1334/2008.

This product meets the requirements of Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.

This product is produced in accordance with good manufacturing practice (GMP) as outlined in GMP Regulation (EC) No 2023/2006.

### China Food Contact

This polyethylene resin is an ethylene and hexene copolymer, and is listed on GB 4806.7-2023 "Standard on food-contact use plastic materials and articles" Appendix A Table A.1, as No 152, CAS 25213-02-9. The monomer 1-hexene has SML 3 mg/kg.

The additive(s) of this resin are all listed on GB 9685-2016 "Standard on the uses of additives in food contact materials and articles", and meet the corresponding allowed maximum use levels.

This polyethylene resin meets the sensory requirements (as resin and in food simulants).

This polyethylene resin was tested per GB 4806.7-2023, and meets the corresponding requirements.



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- This resin was tested overall migration level for overall migration limit (OML) compliance. The tested sample thickness was 3.175 mm (125 mils). The surface-to-volume ratio was 0.6 dm<sup>2</sup> sample immersed in 1dl simulant. This product was tested with 4% acetic acid for 10 days at 40°C, with 10 % ethanol for 10 days at 40°C, with 50 % ethanol for 10 days at 40°C, and with olive oil for 10 days at 40°C.
- This resin was tested for the KMnO<sub>4</sub> consumption in water (60°C, 2h).
- This resin was tested for heavy metal as Pb in 4 % acetic acid (60°C, 2h).
- Primary aromatic amines and colorant are not intentionally used as additives or raw materials in the manufacture of this product.

This product contains the following SMLs:

- 1-hexene, CAS 592-41-6, FCA0105, SML 3 mg/kg
- 2,6-di-tert-butyl-p-cresol, CAS 128-37-0, FCA1135, SML 3 mg/kg
- thiodipropionic acid, didodecyl ester, CAS 123-28-4, FCA0318, SML(T) 5 mg/kg

This resin meets the requirements of GB 4806.1-2016 General safety requirements for food contact materials and articles.

This resin is produced in accordance with good manufacturing practice (GMP) as outlined in GB 31603-2015 General hygiene standard on manufacturing food contact materials and articles.

### **Japan Food Contact**

Japanese Ministry of Health, Labor and Welfare (MHLW) published a formal Positive List (PL) System for food-contact materials (FCM) used in the manufacture of food-contact utensils, containers, and packaging (UCP).

- This product is polyethylene 1-hexene/ethylene copolymer (CAS Number 25213-02-9). It is listed on Table 1(1) Base Polymers (Plastics) as 40 Polyethylene, Ref No 982, Serial No 1, Synthetic Resin Group 5, all types of food, and maximum temperature III.
- Additive(s) in this product are all listed on Table 2 Additives, meet the maximum use limit(s), and have no other restriction.

### **U.S. Pharmacopeia (USP)**

This product meets the requirements of USP 25 <661> Containers Physicochemical Tests and Polyethylene Containers.

However, this product has not been tested per the standards set by the United States Pharmacopoeia USP 39 <661.1> Plastic Materials of Construction – *Identification, Physicochemical, Extractable Metals, and Plastic Additives tests.*

### **European Pharmacopoeia (EUP)**

This product has not been tested under any European Pharmacopoeia guidelines.

### **Regulation 1223/2009 of 2009-11-30 on Cosmetic Products**

Regulation 1223/2009 is not applicable to this product when it is used as a raw material for manufacturing cosmetic containers.



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### **EU Classification and Labeling**

This product is not a dangerous substance according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

### **Animal-Derived Materials (ADM)/ BSE/TSE**

No animal-derived materials are used in the manufacture or formulation of this product. This product can be considered free from bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSE).

### **Kosher**

No animal-derived materials are used in the manufacture or formulation of this product and as such no materials of porcine/pigs, fish, shellfish, rabbits, reptiles, blood, or derived from blood are used. No grape, grape derived, ethanol, or ethanol derived materials are used. Aster Polymer Solutions Pte. Ltd. has established manufacturing practices to assure that the quality of the product is maintained during manufacture and distribution. Aster Polymer Solutions Pte. Ltd. has not made any efforts to certify its polyethylene resins as kosher or in compliance with kosher guidelines.

### **Halal**

No animal-derived materials are used in the manufacture or formulation of this product and as such no materials of ruminant animals (bovine/cattle, caprine/goat, ovine/sheep), non-ruminant animals (humans, insects, fish, porcine, poultry), blood, or derived from blood are used. No ethanol, ethanol derived materials or fermented materials are used in the manufacture of this product.

This product has been certified as in compliance with halal requirements.

### **Plant/ Vegetal Materials**

This product utilizes a substance potentially derived from palm oil. The sourcing is not currently confirmed as Roundtable on Sustainable Palm Oil (RSPO) certified.

### **USDA**

The USDA recognizes FDA statements provided by material suppliers for food packaging.

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

This product, as shipped, does not contain any carcinogens or reproductive toxins presently known by the State of California to cause cancer or reproductive toxicity at a level of exposure subject to the requirements of California Proposition 65.

### **Consumer Product Safety Improvement Act of 2008 (H.R. 4040)**

This product does not contain lead or phthalates. It therefore complies with the relevant sections of the Consumer Product Safety Improvement Act of 2008 (H.R. 4040).



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### **Clean Air**

This product does not contain any ozone depleting substances, including those listed in Regulation (EC) No 1005/2009.

This product does not contain any of the following substances regulated by the Clean Air Act:

- Class I or Class II Ozone-Depleting Substances (CAA Section 602)

### **Heavy metals, RoHS, WEEE, Waste packaging, CONEG**

No heavy metals (i.e., antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, or silver) are purposely added to this product in quantities that would violate governmental guidelines. The summation of lead, cadmium, mercury, and hexavalent chromium in this product is less than 20 ppm. No polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Deca Brominated Diphenyl Ethers (Deca BDE), or phthalates are intentionally added to this product. This product therefore meets the relevant requirements of the following Directives or Regulations:

- Directive (EU) 2017/2102, 2015/863, 2011/65/EU and 2002/95/EC (RoHS)
- China RoHS directive SJ/T 11363-2006
- 2002/96/EC and 2012/19/EU (WEEE)
- 2000/53/EC (ELV)
- 94/62/EC, 2005/20/EC, and 2013/2/EU (Packaging Waste Directive)
- USA CONEG Regulation / Model Toxics in Packaging Legislation
- California Toxics in Packaging Prevention Act

### **ICHs: Elemental Impurities and Residual Solvents**

This product as shipped does not intentionally contain, except chromium (trivalent), the metals described in the ICH Harmonized Guideline for Elemental Impurities Q3D dated 22 March 2019 (including Cd, Pb, As, Hg, Co, V, Ni, Tl, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt, Li, Sb, Ba, Mo, Cu, Sn, Cr). These metals, except chromium, to the best of our knowledge are not intentionally added.

ICH/Q3C "Impurities: Guideline for Residual Solvents" is about the requirements for pharmaceuticals and as such is not applicable to polyethylene pellets, but this product, as shipped, does not intentionally contain Class I, Class II or Class III solvents. The process utilizes a diluent which is not, by definition, a solvent. The diluent used is not a substance listed as a Class I, Class II, or Class III solvent in ICH/Q3C.

### **Toys**

This product complies with the requirements of ASTM F963, EN 71-3, EN71-9, EU Directives 2005/84/EC and 2009/48EC.

### **Phthalates**

No phthalates, including di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP), diisobutyl phthalate (DIBP), dimethyl phthalate (DMP), and diethyl phthalate (DEP) are



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intentionally added to this product. This product therefore meets the requirements of the Consumer Product Safety Improvement Act of 2008 and EU Directive 2005/84/EC.

### **European Chemicals Agency (ECHA) Substances of Concern**

This product does not contain in a concentration above 0.1% w/w any Substances of Very High Concern (SVHC) as listed on the candidate list published by ECHA. This product, as shipped, does not contain substances with applicable restrictions (but there are conditions per entry listed below) under REACH Annex XVII (Restricted Substances List) or subject to authorization under REACH Annex XIV (Authorization List). The product supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

### **Canadian Environmental Protection Act (CEPA) “Challenge” Substances**

This product does not intentionally contain high priority chemical substances listed on the “Challenge” Substance Batches as issued by CEPA.

### **Nanomaterial**

This product is not a nanomaterial and does not contain any intentionally added functional nanoparticles.

### **Conflict Minerals**

Neither tantalum, tin, gold, and tungsten, nor the minerals associated with these metals (Columbite-Tantalite, Cassiterite, Gold, or Wolframite) are intentionally added to this product. These substances are not necessary to the production of this product.

### **PFAS**

Poly- and perfluoroalkyl substances (PFAS) or Perfluorinated Chemicals or Compounds (PFC) are not used in the formulation of this product. See Appendix for additional information.

### **Regulatory or Industry Lists**

To the best of our knowledge, this product as shipped meets the following requirements as being within stipulated limits as listed as of this date:

- Stockholm Convention Persistent Organic Pollutants (POPs): Directive 850/2004/EC, EU 2019/1021 substances not used.
- Rotterdam Convention Prior Informed Consent (PIC) substances Annex III substances as well as EU 649/2012 Annex I substances not contained above classification limits:  
<http://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals/tabid/1132/language/en-US/Default.aspx>
- Substances defined as Persistent, Bioaccumulating, Toxic (PBT) or very Persistent very Bioaccumulating (vPvB) per EU not used.



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- Chemicals of High Concern to Children in Children's Products (CHCC): does not contain reportable substances as specified in the CHCC regulations of the states of Oregon, Washington, Vermont and Maine
- US Lacey Act, EU Timber Regulation 995/2010; [FLEGT](#) or [CITES](#) licenses: This requirement is not applicable to polyethylene pellets, this product does not utilize timber or timber products.

### **Substances and Chemicals**

None of the following substances are intentionally used as additives or raw materials in the manufacture of this product.

- Abietic acid
- Acrylamide
- Acrylonitrile, acrylonitrile co-polymers, or Polyacrylonitrile (PAN)
- Aflatoxin and Mycotoxin; or derivatives of these substances
- Alkylphenols
- Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Allergens, including but not limited to those listed in EU Regulation 1169/2011, Directives 2000/13/EC, 2003/89/EC, and Section B.01.010.1 (1) of Canadian Regulation C.R.C., c. 870, and US FDA Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) such as: peanuts, tree nuts, milk, eggs, wheat gluten, soybeans, sesame, fish and shellfish
- Aromatic amines
- Asbestos
- Azo and azoxyalkyl compounds (e.g. Azodicarbonamide)
- Benzophenone
- 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE), Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether (BFDGE), and/or Novolac glycidyl ethers (NOGE)
- Biocides (e.g. as defined by Biocidal Products Regulation (BPR) 528/2012 and 334/2014).
- Bisphenol compounds, including but not limited to: BPA, BPAF, BPB, BPC, BPE, BPF, BPH, BPS, and BPZ
- Brominated or halogenated flame retardants
- Butylated Hydroxyanisole (BHA), and Tertiary butylhydroquinone (TBHQ)
- Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
- Chlorinated paraffins, Chlorinated hydrocarbons
- Cobalt (CAS RN® 7440-48-4)
- Colophony (also known as wood rosin, gum rosin, tree rosin or yellow rosin CAS No.® 8050-09-7)
- Colorants, dyes or pigments e.g. Green 7 CAS No.® 1328-53-6, Green 36, Pigment Red 104 CAS No.® 12656-85-8, Yellow #5, CI Pigment Yellow 34 CAS No.® 1344-37-2, Yellow 138 CAS No.® 14302-13-7, Violet 23 CAS No.® 215247-95-3; EU resolution AP(89) not applicable, colorants not contained
- Cyanuric acid
- Di(ethylhexyl) adipate (DEHA), diethyl hydroxyl amine (DEHA), or di(ethylhexyl)maleate (DEHM)

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- Dimethylfumarate (DMF)
- Dioxins or furans; or derivatives of these substances
- Dyes: See Colorants
- Endocrine disruptors e.g. Alkylphenol ethoxylate (APE), Nonylphenol ethoxylate (NPE), Octylphenol ethoxylate (OPE)
- Epoxy derivatives listed in EU Directives 2002/16/EC and 1895/2005
- Epoxidized Soybean Oil
- FDA Banned Food Additives: benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, pyridine, styrene
- Formaldehyde (for additional information related to aldehydes and processing see the SDS)
- Fungicides, preservatives (for the purpose of preserving food in packaging), or fumigants
- Genetically modified organisms (GMO)
- Halogens
- Human materials or derivatives of human materials, blood or blood products
- Isocyanates
- Melamine
- Mica, natural (CAS RN® 12001-26-2)
- Microorganisms, yeast, or bacteria not intentionally contained
- Mineral Oil Saturated Hydrocarbons (MOSH) or Mineral Oil Aromatic Hydrocarbons (MOAH)
- Natural rubber latex, dry natural rubber, or synthetic latex
- Nitrites, Nitrates, Nitrosamines, Nitrosamines impurities: N-nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), N-diisopropylnitrosoamine (NDIPA), N-ethyl-N-isopropylnitrosoamine (NEIPA); or nitrosating reagent NaNO<sub>2</sub>.
- Nitrocellulose
- Nonyl phenol (NP)
- Optical brighteners
- Organotin compounds
- Ozone-depleting chemicals
- Parabens
- Pesticides and fungicides
- Photoinitiators, including: benzophenone, hydroxybenzophenone, and 4-methylbenzophenone, and Isopropylthioxanthone (ITX)
- Plasticizers
- Polycyclic aromatic hydrocarbons (PAH), also called polyaromatic hydrocarbons
- Polybrominated Diphenyl Ethers (PBDEs) included: decaBDE, octaBDE, and pentaBDE
- Polycarbonates
- Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)
- Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- Radioactive Substances: No radiation sources are used to alter the product characteristics.
- Recycled materials (i.e. No post-consumer recycled materials utilized.)
- Silicone a.k.a. Polydimethylsiloxane (PDMS) or Silicone Oil CAS No.® 63148-62-9 not intentionally contained
- Siloxanes not intentionally contained



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- Sulfonamides
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether), Triclocarban
- Tris-Nonylphenol Phosphite (TNPP)
- Vinylidene chloride (Dichloroethene), Vinyl Chloride Monomer (VCM), Polyvinyl Chloride (PVC), Polyvinylidene Dichloride (PVDC) or copolymers.

*It is the responsibility of the customer to check compliance of the final articles with the relevant legislative and applicable regulatory requirements including their restrictions.*

**Disclaimer:** *Before using this product, the user is advised and cautioned to make its own determination and assessment of the safety and suitability of the product for the specific use in question and is further advised against relying on the information contained herein as it may relate to any specific use or application. It is the ultimate responsibility of the user to ensure that the product is suited and the information is applicable to the user's specific application. Aster Polymer Solutions Pte. Ltd. do not make, and expressly disclaim, all warranties, including warranties of merchantability or fitness for a particular purpose, regardless of whether oral or written, express or implied, or allegedly arising from any usage of any trade or from any course of dealing in connection with the use of the information contained herein or the product itself. The user expressly assumes all risk and liability, whether based in contract, tort or otherwise, in connection with the use of the information contained herein or the product itself. Further, information contained herein is given without reference to any intellectual property issues, as well as federal, state or local laws which may be encountered in the use thereof. Such questions should be investigated by the user.*

**Additional information on the health and safety aspects of our product is listed in the SDS of the product.**

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