Regulatory Summary
Americas Styrenics Prime Grade General Purpose Polystyrene (GPPS)

A summary of the regulatory profile of our prime grade GPPS resins is provided below.
Please note the following:

1. The information presented in this document is not exhaustive. Additional Information may be found by consulting the relevant Safety Data Sheet (SDS), Technical Data Sheet or by contacting Customer Service.

Chemical Inventories

United States Toxic Substances Control Act (TSCA) Inventory	Listed (Active)
European Inventory of Existing Commercial Chemical Substances (EINECS)	Listed or exempt
EC Inventory	Listed or exempt
China Catalog of Hazardous chemicals 2015	Not Listed
New Zealand Inventory of Chemicals (NZIoC)	Listed
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	Listed
Vietnam National Chemical Inventory	Listed
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)	Listed

U.S. FDA Food Contact Status

When used unmodified and processed in accordance with good manufacturing practices for food contact applications, all prime grade GPPS resins will comply with the U.S. Food and Drug Administration's food additive regulation at 21 CFR § 177.1640, under the Federal Food, Drug, and Cosmetic Act. These products may be used to produce articles or components of articles used in contact with food for all food types described in Table 1 and Conditions of Use C-H described in Table 2 of U.S. FDA's regulation at 21 CFR § 176.170(c).

The preceding statement refers to regulatory requirements only, not to the physical utility of the product. The uses cited above are subject to good manufacturing practices and any limitations which are part of the regulations**.**

It is the responsibility of the article producer or food packager to determine that the article is suitable for its intended use. The regulations should be consulted for complete details.

Health Canada - Health Products and Food Branch (HPFB) No Objection Status

The resins listed below have been granted "No Objection" status for use in general food packaging applications by Health Canada's Food Packaging Materials Section of the Health Products and Food Branch (HPFB):

- STYRON™ 665
- STYRON™ 666D
- STYRON™ 668
- STYRON™ 675
- STYRON™ 678C
- STYRON™ 685D
- STYRON™ 685P
- MC3650
- MC3700
- EA3130
- EA3400
- STYRON™ 695
- STYRON™ 693
- PolyRenew® 1120 General PurposePolystyrene
- PolyRenew® 1625 Polystyrene
- PolyRenew® 5001 HE General Purpose Polystyrene
- PolyRenew® 5102 HE General Purpose Polystyrene

The Food Packaging Materials Section advises that each application is considered different even if the parameters are identical to another application for which they have previously offered an opinion.

Therefore, regardless of the above HPFB opinion, we recommend that you review the specifics of your application with HPFB and acquire the HPFB opinion regarding your specific application.

European Commission Food Contact Regulation (EU) No. 10/2011

The compositions of AmSty's resins as supplied from our factory comply with the food contact requirements of Commission Regulation (EU) No. 10/2011**.**

- No substances, which are subject to a restriction in food based on EU-Directive 95/2/EC (Feb. 20, 1995) incl. subsequent amendments like EU-Directive 2010/69/EU (Oct. 22, 2010), are present in these products.
- These resins are manufactured in accordance with good manufacturing practices as outlined in Commission Regulation (EC) No 2023/2006 of December 22, 2006.
- The raw materials used in the manufacture of these resins are of suitable purity for articles intended for use in contact with foodstuffs.

Drug Master File (DMF)

The following products currently have a Drug Master File on file at the FDA:

- STYRON™ 478
- STYRON™ 498
- STYRON™ 484
- STYRON™ 487R
- STYRON™ 421
- STYRON™ 685D
- STYRON™ 685DL
- STYRON™ 685P
- STYRON™ 665
- STYRON™ 675
- STYRON™ 695
- STYRON™ 693
- STYRON™ 610
- STYRON™ 666D
- STYRON™ 668
- EA6740
- EA3130
- EA3400
- MB3150
- MC3650
- MC3700
- EB6400
- EC6600
- EA6740
- EB6755
- EC6600

Animal Content/BSE/TSE

AmSty polystyrene resins are not intentionally formulated with raw materials of animal origin. These products are formulated with raw materials that are either synthetic or derived from plant sources.

Allergen Content

AmSty polystyrene resins are not intentionally formulated with raw materials that originate from peanuts, soybeans, milk, eggs, fish, shellfish, tree nuts and/or wheat or gluten.

Biocompatibility - USP Class VI Plastics Certification

The following products have been tested against the United States Pharmacopoeia <88> Biological Reactivity Tests *In Vivo* for Class VI Plastics and determined to be compliant with USP Class VI requirements.

- STYRON™ 685D
- STYRON™ 666D
- STYRON™ 478
- STYRON™ 484
- STYRON™ 414
- MC3650
- MC3700
- EB6755
- EA3130
- EA6740
- STYRON™ A-TECH™ 1115

California Prop 65

The compositions of the AmSty polystyrene products have been reviewed against the current Prop 65 list, and we confirm the following residual substances are listed on the current Prop 65 list: styrene and ethylbenzene. Please refer to the SDS, Section 15 for more information.

Conflict Minerals
In accordance with the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act, polystyrene resins manufactured by Americas Styrenics are not intentionally formulated with conflict minerals, such as tin, gold, tungsten, and tantalum.

CONEG(Coalition of Northeastern Governors)
Cadmium, hexavalent chromium, lead, or mercury is not intentionally introduced as an element during the manufacture or distribution of our polystyrene resins. The sum of the concentration levels of these elements incidentally present is not expected to exceed 100 ppm. Our GPPS resins are therefore CONEG compliant.

CMR Substances, Annex VI of CLP Regulation (EC) No. 1272/2008
AmSty polystyrene resins are not intentionally formulated with substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of Category 1A, 1B or 2 according to the criteria of Regulation (EC) No.1272/2008, above the concentration limits as defined in Sections 3.5.3.1 (Mutagen), 3.6.3.1 (Carcinogen) and 3.7.3.1 (Reproductive Toxicant).

Cosmetic Products Regulation (EC) No 1223/2009
Regulation (EC) No. 1223/2009 is applicable to the European Union and its Member States. AmSty products are not intentionally manufactured or formulated with the below substances mentioned in the referenced regulation:

- substances classified as Category 1A or 1B CMR (carcinogenic, mutagenic, or reprotoxic), present above 0.1%
- substances classified as endocrine-disrupting, present above 0.1%. Refer to Annex 15, List of 66 substances with classification high, medium or low exposure concern: https://ec.europa.eu/environment/archives/docum/pdf/bkh_annex_15.pdf

EU Regulation (EC) 2017/745
AmSty products are not intentionally manufactured or formulated with the below substances mentioned in Section 10.4.1 Design and manufacture of devices of Regulation (EU) 2017/745 on medical devices:

a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council
b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.

EU REACH SVHC, Annex XIV Authorization List, Annex XVII Restricted Substance List
AmSty polystyrene resins are not intentionally formulated with any substance classified as a REACH SVHC, Annex XIV Authorization List, or Annex XVII Restricted Substances List. The most recent update to the SVHC list occurred on July 08, 2021.

EU RoHS Directive 2011/65/EU (RoHS 3)
Polystyrene resins manufactured by Americas Styrenics are in compliance with the requirements of EU-Directive 2015/863/EU (RoHS 3). To the best of our knowledge, polystyrene resins manufactured by Americas Styrenics LLC (AmSty) are not intentionally manufactured or formulated with the following substances listed in Annex II of EU-Directive 2015/863/EU:

- Cadmium, hexavalent chromium, lead, and mercury
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

Nanomaterials
A commonly used industry definition for engineered nanomaterials (< 100 nm in size) is any material that exhibits novel properties and behaviors as a result of being engineered at nano (1 to 100 nanometers) level. Polystyrene resins manufactured by Americas Styrenics are not intentionally manufactured or formulated with these engineered nanomaterials.

Ozone Depleting Substances
Our Polystyrene resins are not manufactured with Class I or II substances as defined in Title VI of the Clean Air Act of 1990 under the final rule published in the Federal Register on February 11, 1993 (58 FR 8136) or with the EU 'Ozone Regulation' Regulation (EC) 1005/2009.

Phthalates
Polystyrene resins manufactured by Americas Styrenics are not intentionally manufactured or formulated with phthalate esters, including the below (not an exhaustive list):

- Benzyl butyl phthalate (BBP), CAS# 85-68-7
- Bis-(2-ethylhexyl) phthalate or di-(2-ethylhexyl) phthalate, (DEHP), CAS# 117-81-7
- Bis-(2-methoxyethyl) phthalate, CAS: 117-82-8
- Dibutyl phthalate (DBP), CAS# 84-74-2
- Diisobutyl phthalate (DIBP), CAS: 84-69-5
- Dimethyl phthalate (DMP), CAS: 131-11-3
- Diisononyl phthalate (DINP), CAS# 28553-12-0
- Di-n-octyl phthalate (DNOP), CAS: 117-84-0
- Di-iso-decyl phthalate (DIDP), CAS: 26761-40-0

However, we do not analyze for these specific substances or compounds.

Underwriters Laboratories (UL)
Many of our resins are UL listed. Click on the link for a list of resins: Americas Styrenics UL Listings

Substances
Polystyrene resins manufactured by Americas Styrenics are not intentionally formulated with the following regulated chemicals or substances of concern (not an exhaustive list):

- Antimony and Antimony Compounds
- Arsenic and Arsenic Compounds
- Asbestos
- Azocompounds
- Azo colorants/azo dyes
- Benzophenone
- Beryllium and Beryllium Compounds
- BHA/BHT
- Bismuth and Bismuth Compounds
- BPA A, BPA F, BPA S
- Brominated Organic Compounds
- Cadmium & Cadmium Compounds
- Cobalt
- Hexavalent Chromium Compounds
- Chlorinated Compounds
- Dimethyl fumarate (DMF)
- Epoxy derivatives
- Formaldehyde
- GMOs or derivatives
- Latex or Natural Rubber
- Lead and Lead Compounds
- Melamine
- Mercury and Mercury Compounds
- Medicinal substances
- Nickel and Nickel Compounds
- Nitrocellulose
- Nitrosamine
- Nonyl Phenols(NP), Nonyl Phenols Ethoxylates (NPE)
- Persistent Organic Pollutants (POPs)
- Pesticides
- Per- and polyfluoroalkyl substances (PFAS) including Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
- Phthalates
- Polyvinyl Chloride (PVC)/PVC blends
- Radioactive Substances
- Selenium and Selenium Compounds
- Tributyl Tin (TBT) & Triphenyl Tin (TPT)
- Tributyl Tin Oxide (TBTO)

Americas Styrenics Medical Application Policy

Americas Styrenics will not knowingly sell or sample any product or service ("Product") into any commercial or developmental application that is intended for

- permanent (long term) contact with internal body fluids or internal body tissues. "Long term" is defined as a use which exceeds 72 continuous hours.
- use in cardiac prosthetic devices regardless of the length of time involved (cardiac prosthetic devices include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems and ventricular bypass assisted devices).
- use as a critical component in medical devices that support or sustain human life.
- use in applications designed specifically to promote or interfere with human reproduction.

Contact Information

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