



## **Regulatory Summary (EU) General Purpose Polystyrene (GPPS)**

A summary of the European Regulations compliance status 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](#).

**Framework Regulation (EC) No 1935/2004 - Materials and articles intended to come into contact with Food.** AmSty resins are suitable to come into contact with food as provided in our statement regarding Commission Regulation (EU) 10/2011.

**Elements below demonstrate that the AmSty resins are safe for use in contact with food, in compliance with the provisions of the Regulation (EC) No 1935/2004 of October 2004 on food contact materials.**

### **Commission Regulation (EC) No 2023/2006 – European Good Manufacturing Practices**

In reference to Article 3 of Regulation (EC) No 1935/2004 concerning the generic product safety requirements of materials and articles intended to come into contact with foodstuffs: The above resins are manufactured in accordance with good manufacturing practices (GMP) as outlined in Commission Regulation (EC) No 2023/2006 of December 22, 2006, applicable as of 1 August 2008. The raw materials used in the manufacture are of suitable purity for articles intended for use in contact with foodstuffs.

In extenso, AmSty applies GMP guidelines issue by Plastics Europe available on their website ("Guidelines for good manufacturing practice for plastic materials and articles intended for food contact applications" at [www.plasticseurope.org](http://www.plasticseurope.org)).

### **Commission Regulation (EU) No 10/2011 (PIM) – Plastic Materials and articles intended to come into contact with food.**

The composition of the above resins as supplied complies with the food contact requirements of Commission Regulation (EU) No. 10/2011, including amendments. This Regulation is applicable to the European Union and its Member States:

All the monomers used in the resin are listed as authorized monomers.

All the additives are listed as approved additives with no conditions or levels of use.

Some of the components are subject to specific migration limits that must be met by the finished food contact products.

Substances which are subject to a restriction in food (so called "Dual Use Additives") will not migrate in quantities having a technical effect in the final foods.

All the solvents and catalysts used have suitable national listings demonstrating their suitability for use as intended.

**CONEG (Coalition of Northeastern Governors)/ EU Directive 94/62/EC**

The heavy metals cadmium, hexavalent chromium, lead, or mercury are not intentionally added during the manufacture of our polystyrene resins. The sum of the concentration levels of these elements incidentally present is not expected to exceed 100 ppm. Therefore, our resins are compliant with CONEG and with the concentration levels of heavy metals specified in EU-Directive 94/62/EC.

**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)

**Annex VI of CLP Regulation - CMR Substances****Regulation (EC) No. 1272/2008**

AmSty polystyrene resins are not intentionally formulated with substances classified as sensitizers (Category 1) or carcinogenic, mutagenic or toxic for reproduction (CMR) (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).

**Regulation (EU) 2022/692**

AmSty polystyrene resins are not intentionally formulated with substances listed in Regulation (EU) 2022/692 on May 3, 2022 to amend Regulation (EC) 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation, consolidated version to March 2022). changes to the list of chemicals falling under Annex VI to the CLP Regulation.

**Regulation (EU) 2023/1434 & (EU) 2023/1435**

AmSty polystyrene resins are not intentionally formulated with substances listed in Regulation (EU) 2023/1434 or (EU) 2023/1435 of 25 April 2023 amending, for the purposes of its adaptation to technical and scientific progress (ATPs), Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards the addition of notes to Part 1, section 1.1.3, of Annex VI of CLP.

**Regulation (EC) 2017/745 ANNEX I**

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 (1), or

**b)** substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health 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.

*(1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing*

*Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ( OJ L 353, 31.12.2008, p. 1).*

*(2) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).*

*(3) Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products (OJ L 167, 27.6.2012, p. 1).*

#### **Annex XVII - Conditions of restriction**

**a )** substances included in Annex XV dossier restricting the use of lead in articles produced from PVC if the concentration of lead is equal to or greater than 0,1 % by weight of the PVC material set on Regulation (EU) 2023/923 of 3 May 2023 amending entry 63 to Annex XVII of Regulation (EC) No. 1907/2006 as regards lead and its compounds in PVC.

**b)** Commission Regulation (EU) 2023/1132 of 8 June 2023 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards carcinogenic, mutagenic or reproductive toxicant substances subject to restrictions.

#### **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](https://ec.europa.eu/environment/archives/docum/pdf/bkh_annex_15.pdf)

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