

## REGULATORY DATA SHEET

Product range concerned:

- **PLASTENE R2xx**

We confirm that in the manufacturing of the above mentioned product, the following substances or class of substances are either not intentionally used or the product complies with the applicable requirements of the regulatory reference cited:

SUBSTANCES	REGULATORY REFERENCE
Acrylamide	Reg. (EC) No 366/2011
Aromatic amines	Reg. (EC) No 1907/2006, Annex XVII
Asbestos fibres	Reg. (EC) No 1907/2006, Annex XVII
Azocolourants and Azodyes	Reg. (EC) No 1907/2006, Annex XVII
Benzophenone	Reg. (EC) No 1223/2009
Biocides	Reg. (EU) 528/2012
Bisphenol-A, Bisphenol-F, Bisphenol-S	Reg. (EC) No 321/2011
Butylhydroxytoluene(BHT); Butylhydroxyanisole (BHA)	---
Flame retardants (brominated, chlorinated, etc.)	---
Chlorinated aliphatic compounds; Alkanes, C <sub>10</sub> -C <sub>13</sub> , chloro (Short-Chain Chlorinated Paraffins - SCCPs)	Regulation (EC) 850/2004 (POP)
Colorants, pigments	Resolution AP 89(1)
Conflict Minerals: Tantalum, Tungsten, Tin, Gold, Cassiterite, Columbite-Tantalite (Colran), Wolframite and their derivatives	Dodd-Frank Wall Street Reform and Consumer Protection Act (2010)
Di(ethylhexyl) adipate (DEHA); di(ethylhexyl) maleate (DEHM)	---
Dimethylfumarate (DMF)	Commission Decision 2009/251/EC
Dioxins and difurans	---
Epoxy derivatives (BADGE, NOGE, BFDGE)	Regulation (EC) No 1895/2005
ESBO Epoxidized soy bean oil	Directive 2005/79/EC
Food allergens	Regulation (EC) 1169/2011 - annex II
Formaldehyde	EN 71-9
Genetically modified organisms (GMO)	Directive 2001/18/EC
Heavy metals: cadmium (Cd), hexavalent chromium (Cr VI), lead (Pb), mercury (Hg) and their compounds	Directive 94/62/EC "Packaging and packaging waste", Directive 2000/53/EC "End of Life Vehicles", Dir. 2011/65/EU "Restriction of Hazardous Substances - RoHS", US CONEG Legislation; GB/T 26572-2011 (China RoHS);

	GB/T 30512—2014 (China ELV)
Isopropyltioxantone (ITX)	Reg. (EC) No 2023/2006
Jatropha plant derivatives and extracts	---
Melamine	Reg. (EU) 284/2011
Nanomaterials	Commission Recommendation 2011/696
Natural Latex, natural rubber	---
Nitrosamines	Directive 1993/11/EEC
Nonylphenol, nonylphenol ethoxylates, TNPP, Alkylphenols etoxylated (APEO)	Reg. (EC) No 1907/2006, Annex XVII
Ozone depleting substances: chlorofluorohydrocarbons (CFC, HCFC)	Regulation (EC) No 1005/2009
Perfluorooctane sulfonates (PFOS), Perfluorooctanoic acid (PFOA)	Reg. (EC) No 1907/2006, Annex XVII
Persistent Organic Pollutants (POP)	Regulation (EC) 850/2004
Pesticides, Herbicides	Regulation (EC) No 1107/2009
Phthalates (e.g. DEHP, DBP, BBP, DINP, DIDP, DIBP, DNOP, etc.)	Reg. (EC) No 1907/2006, Annex XVII; Directive 2011/65/EU “Restriction of Hazardous Substances, RoHS”; Directive 2015/863/EU
Polychlorinated biphenyls, polychlorinated terphenyls (PCB, PCT)	Reg. (EC) No 1907/2006, Annex XVII
Polycyclic aromatic hydrocarbons (PAH)	Reg. (EC) No 1907/2006, Annex XVII
Polybrominated-diphenyl compounds (PBB, PBDE incl. penta- octa- and deca-BDE)	Reg. (EC) No 1907/2006, Annex XVII; Directive 2011/65/EU “Restriction of Hazardous Substances, RoHS”, GB/T 26572-2011 (China RoHS); GB/T 30512—2014 (China ELV).
PVC, PVDC, vinyl chloride monomer (VCM)	---
Radioactive substances	Council Directive 2013/59
Recycled materials	---
Tin organic compounds (MTB, DBT, TBT, etc.)	Reg. (EC) No 1907/2006, Annex XVII; Commission Decision 2009/425/EC
Thiuram mix	---
Sulphur	---
Antimony and its compounds	---
Halogen Free	---
Forbidden Mineral Oils (MOSH/MOAH)	---
Xylene	---

From the foregoing we can confirm that there is no reason that said substances may be found in the above mentioned material as supplied in original sealed packaging.

Regarding other substances not listed in this statement, we confirm that our mentioned product complies with all the applicable restrictions set by the REACH Regulation (EC) No 1907/2006, annex XVII “Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles” and following amendments: these laws and their amendments represent our applicable regulatory reference in case of claims.

## OTHER REGULATIONS / NORMS / INFORMATION

The product is in compliance with the applicable requirements of the following regulations / norms / information:

**BSE/TSE:** The product does not contain specified risk materials as defined by Regulation (EC) 999/2001/EC and by the EMEA guideline 410/01 rev. 3; additives manufactured by raw materials from animal origin are certified as BSE/TSE-free by their suppliers.

**Toy safety standards:** The product complies with the applicable requirements of Directive 2009/48/EC on the safety of toys and in compliance with the compositional requirements of EN 71-3 "Safety of toys - Migration of certain elements". This product may contain zinc compounds, in a quantity below the migration limit set by the Directive.

The product complies with the compositional requirements of the Consumer Product Safety Improvement Act of 2008 (CPSIA - USA); no lead and lead-based compounds (section 101 of the Act) and phthalates (section 108 of the Act) are used in the production.

**Proposition 65:** we do not intentionally use chemicals listed in Proposition 65 (latest list issued of 25 May 2018) in the production of our mentioned material.

**GADSL:** the product is in compliance with the requirements of the Global Automotive Declarable Substance List (GADSL), 2018 version.

**Switzerland VOC ordinance:** the product is exempted by the Ordinance 814.018 (OCOV) as the residual volatile compounds are below the regulation's 3% limit.

**CMR substances:** no substances classified in Category 1A, 1B and 2 by Regulation (EC) 1272/2008 is used in the production of this material.

**Reused/Recycled materials:** No reused or recycled materials are used in the production of the mentioned Poliplast S.p.A. product, Reg. (EC) No 282/2008 is not applicable to our product.

### National chemical inventories

The product and the ingredients used in their formulation are listed in the following national chemical inventories:

USA: Toxic Substances Control Act (TSCA)

Canada: Domestic Substances List (DSL)

Europe: EINECS/ELINCS; REACH pre-registration and Registration procedure (where applicable)

Australia: Inventory of chemical substances (AICS)

New Zealand: Inventory of chemical substances (NZIoC)

Korea: Existing Chemical List (ECL)

Japan: Inventory of Existing and new chemical substances (ENCS)

Philippines: Inventory of Chemicals and Chemical Substances (PICCS)

China: Inventory of Exist. Chem. Substances Manufactured or Imported in China (IECSC)



Taiwan: Taiwan Chemical Substances Inventory (TCSI)

### **Food Contact Status**

The product complies with the rules in force in Europe for plastic materials intended for food contact applications (Regulation (EC) n.10/2011 and following amendments) as well as in other Countries.

### **MERCOSUR**

Our material complies with the applicable requirements of MERCOSUR Technical Regulation N°32/07 "Positive List of Materials for Equipment and Containers for Food contact". The polymer types mentioned are listed in the Technical Regulation N°24/04 and by Technical Regulation N°02/12.

Pls. note that is a responsibility of the end user to carry out the necessary migration test according to the MERCOSUR Technical Regulation N°32/10 and N°36/92.

### **Content of not intentionally added substances (NIAS):**

As mentioned in its Atotoxicity Declaration, the product in ref. contains monomers and additives approved for food packaging application according to several regulations including the EU Regulations 10/2011.

Regarding the content of not intentionally added substances (NIAS), these are mainly made of the oligomeric fraction, which are regarded for this family of polymers as safe.

The above is based on a migration study jointly made with our industry association at a third party laboratory. The other impurities and degradation products present, by the way at a very tiny level, are not going to migrate at all or migrate below toxicologically relevant amounts from our products in the expected use conditions.

We confirm that these substances, for their chemical structure are not expected to have CMR properties nor they are in nanoform.

To the best of our knowledge, based on the above, we can declare that with our products, converted applying the good manufacturing practices, can be obtained materials and articles in compliance with the requirement of article 3 of Regulation 1935/2004 on "materials and articles intended to come into contact with food".

As Poliplast is not a producer of final product, but is a transformer, it is not obliged to carry out any analytical tests on the products that it produces and markets.

We therefore suggest that you carry out all the necessary laboratory tests directly on the finished article, validating it of our assumptions.

### **This document is issued by the Product Compliance Department of Poliplast S.p.A.**

The product complies with the regulations shown in this document.

It is not excluded that the material may be compliant with other regulations and subsequent updates of what is reported.

*Disclaimer: the information and data presented herein are to the best of our knowledge true and accurate; but no warranty or guarantee, expressed or implied, is made nor is any liability accepted with respect to the use of such information and data. The reference are the applicable regulatory requirements.*