

**Subject:** Declaration of Compliance for Food Contact

**Issue Date:** 12.01.2021

**Revision Date:** 17.09.2021

**Revision No:** 1

**Pages:** 1 of 2

**Valid until replaced**

### STATEMENT

#### **Declaration of Compliance for Food Contact for Europe:**

Sasa Advanite 19013 polymer chips products can be used in articles intended to come into contact with food.

**Regulation (EC) No 1935/2004:** Sasa Advanite 19013 polymer chips products are in compliance with Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, referring to Article 3(1) on General Requirements, Article 16 on Declaration of Compliance and Article 17 on Traceability.

**Specific Migration Limits:** Sasa Advanite 19013 polymer chips products are in compliance with Regulation (EU) No 10/2011, on plastic materials and articles intended to come into contact with food and its all amendments including Regulation (EU) No 2021/382. Regulation (EU) No 10/2011 is the consolidated version of 2002/72/EC and its all amendments and updates including Regulation (EU) No 1183/2012 relating to plastic materials and articles intended to come into contact with foodstuffs. Specific migration limits of PET polymer ingredients are specified in the list of authorized monomers and other starting substances in Annex 2 of the Directive. Sasa Advanite 19013 polymer chips products are in compliance with Regulation (EU) No 321/2011, amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles.

<u>Polymer Ingredient</u>	<u>Ref No</u>
Ethylene glycol	16990/53650
Diethylene glycol	13326/15760/47680
Terephthalic acid	24910
Antimony trioxide	35760
Phosphoric acid	23170/72640

**Dual Use Additives:** Sasa Advanite 19013 polymer chips product contains phosphoric acid (PM Ref No: 23170/ 72640, Cas No: 7664-38-2) as dual use additive.

**Colorants:** There is no colorant used in Sasa Advanite 19013 polymer chips products. As a result, Advanite 19013 polymer chips products are in compliance with Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food and Recommendation IX of the BfR on Colorants for Plastics and other Polymers Used in Commodities.

In sections from 2.1 to 2.6 of Appendix of Resolution AP (89) 1, the metals and other substances which should not be present in or as colorants used in the production of plastic materials are explained with the maximum thresholds not to be exceeded under certain conditions. All metals and other substances referred in these sections are not intentionally added in or as colorants and/or are not present as impurities in the composition of Advanite 19013 polymer chips products above the maximum thresholds given in the same sections.

**Good Manufacturing Practice:** Sasa Advanite 19013 polymer chips products are in compliance with Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, referring to article 5 on quality assurance system, article 6 on quality control system and article 7 on documentation.

**SASA Polyester Sanayi A.S.**  
**Turhan Cemal Beriker Blv. No:559**  
**01355 Adana/Turkey**  
**Phone: +90 322 4410053**  
**Fax: +90 322 4410114**

**LIABILITY NOTE:** This information is correct to the best of our knowledge as of the date above; but, users remains responsible to make their own assessment to confirm that the material meets the requirements for its intended use(s) and compliant with all laws and regulations applicable. The information should not be used as a substitute for Customer's own tests. To the extent permitted by the applicable law, Sasa Polyester A.S. accepts no liability for any damage, loss or injury resulting from the use of this information.

**Subject:** Declaration of Compliance for Food Contact

**Issue Date:** 12.01.2021

**Revision Date:** 17.09.2021

**Revision No:** 1

**Pages:** 2 of 2

**Valid until replaced**

There are several applications in our production philosophy which are in correlation with GMP mentality. We take samples from the production rather frequently to ensure the quality consistency of the whole bulk, produced. Each step of the process is documented and recorded according to ISO standards and all documents and data records are stored in hard copies, hard discs and databases to enable intensive traceability of the products.

In correlation with GMP mentality, Sasa has always been giving trainings to its employees of all levels, reinforcing the knowledge and auditing the applications by internal or external sources. This understanding of continuous improvement and sustainable quality is a commitment of company management.

### **Declaration of Compliance for Food Contact for US FDA 21CFR:**

The chemistry of Sasa Advanite 19013 polymer chips product is polyethylene terephthalate. Ethylene terephthalate polymers are mentioned in section 177.1630 "Polyethylene Phthalate Polymers" of 21 CFR. It is indicated that ethylene terephthalate polymers may be safely used as, or components of plastics (films, articles or fabric) intended for use in contact with food.

Our raw materials, dimethyl terephthalate and ethylene glycol are listed in the "List of Substances and Limitations" under item (e)(4)(ii) of the same section of 21 CFR.

The catalytic system we use (content in the ppm range) complies with the FDA requirements for PET polymer.

Chemical migration studies for the raw PET chips do not exist. However we underline that migration studies have to be carried out on the final product according to the FDA requirements. During the downstream processes, chips will be remelt and recrystallized. Due to the change in the crystallinity of the polymer, migration behaviour of the final product will be different from raw PET. Therefore, migration measurements on the raw PET have very limited meaning. According to best of our knowledge, we expect that the final product should pass the migration tests.

According to the explanations above, the verification of compliance regarding the specifications as laid down in section 177.1630, items (f) to (j) is within the responsibility of the manufacturer of the final plastic material. The examination has to be done in accordance with the specifications as laid down for the intended conditions of use.

In case of further questions, please do not hesitate to contact us.

Yours sincerely,



Gamze GÜNER  
SASA Polyester San. A.S.  
Product Safety Steward

**SASA Polyester Sanayi A.S.**  
**Turhan Cemal Beriker Blv. No:559**  
**01355 Adana/Turkey**  
**Phone: +90 322 4410053**  
**Fax: +90 322 4410114**

**LIABILITY NOTE:** This information is correct to the best of our knowledge as of the date above; but, users remains responsible to make their own assessment to confirm that the material meets the requirements for its intended use(s) and compliant with all laws and regulations applicable. The information should not be used as a substitute for Customer's own tests. To the extent permitted by the applicable law, Sasa Polyester A.S. accepts no liability for any damage, loss or injury resulting from the use of this information.