
Subject: Declaration of Compliance for Food Contact

Issue Date: 07.08.2020
Revision Date: 20.03.2025
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STATEMENT

Declaration of Compliance for Food Contact for Europe:

Sasa PET BG-76, Sasa PET BG-80 and Sasa PET BG-84 polymer chips products can be used in articles intended to come into contact with food.

Regulation (EC) No 1935/2004: Sasa PET BG-76, Sasa PET BG-80 and Sasa PET BG-84 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 PET BG-76, Sasa PET BG-80 and Sasa PET BG-84 polymer chips products are in compliance with Regulation (EU) No 10/2011 comply with European Regulation 10/2011/EC and all its amendments up to the Reg. (EU) 351/2025.

Specific migration limits of PET polymer ingredients are specified in the list of authorized monomers and other starting substances in Annex 1 of the Directive.

<u>Polymer Ingredient</u>	<u>Ref No</u>
Ethylene glycol	16990/53650
Diethylene glycol	13326/15760/4760
Terephthalic acid	24910
Isophthalic acid	19150
Antimony trioxide	35760
Phosphoric acid	23170/72640

Dual Use Additives: Sasa PET BG-76, Sasa PET BG-80 and Sasa PET BG-84 polymer chips products contain phosphoric acid (PM Ref No: 23170/ 72640, Cas No: 7664-38-2) as dual use additive.

Colorants: We use colorant pigment in production of the product. The colorant pigment we use in our production is listed in "List of Substances" under item (e) of section 178.3297 "Colorants for Polymers" of 21 CFR. There is no restrictions.

Listed in 21 CFR 178.3297 Colorants for polymers for use at toning levels. (4ppm in polymer)

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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.

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Also our supplier stated that shows no detectable migration at a use level of 0.2%, Aqueous, acidic and low alcohol foods, condition of use C-G. Therefore is not considered a food additive and does not require premarket approval from the FDA.

As a result, Sasa PET BG-76, Sasa PET BG-80 and Sasa PET BG-84 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 Sasa PET BG-76, Sasa PET BG-80 and Sasa PET BG-84 polymer chips products above the maximum thresholds given in the same sections.

Good Manufacturing Practice: Sasa PET BG-76, Sasa PET BG-80 and Sasa PET BG-84 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.

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 PET BG-76, Sasa PET BG-80 and Sasa PET BG-84 polymer chips products 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, terephthalic acid and ethylene glycol are listed in the "List of Substances and Limitations" under item (e)(4)(ii) of the same section of 21 CFR.

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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 ÇELİK
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Product Safety Lead