Docusign Envelope ID: 5DF4B229-4624-4E09-80A3-4C343FCB11DE

Declaration

for plastic materials that come into contact with food

1. **Company:**
   EOS GmbH Electro Optical Systems
   Robert-Stirling-Ring 1
   82152 Krailling/München, Deutschland

2. **Material: PA 2200 polyamide (PA12)**

3. **Date of declaration:** 19.12.2024

It is based on the declarations of compliance provided by our suppliers for the raw materials, additional information, further basic knowledge of the material as well as tests and assessments carried out by us.

We hereby declare that the above mentioned product is manufactured exclusively using monomers and additives that are approved for the respective intended use in accordance with Regulation (EU) No. 10/2011 for food contact plastics in the version valid at the time of issuance.

The colorants used in the manufacture of this product meet the requirements of the Council of Europe Resolution AP (89) 1 on the use of colorants in plastic materials intended to come into contact with food.

The product complies with the general legal requirements of Regulation (EU) No. 1935/2004 for food contact materials applicable at our stage of the supply chain and is manufactured in accordance with the requirements of Commission Regulation (EC) 2023/2006 of December 22, 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

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4. Information on ingredients with restrictions:

According to the information provided by our suppliers, the material supplied by us contains monomers and/or additives that are subject to restrictions according to Regulation (EU) No. 10/2011 for food contact plastics Annex I and/or II.

In addition, the product contains additives that are also approved as food additives by Regulation (EC) No. 1333/2008 or as flavoring substances by Regulation (EC) no. 1334/2008. (Dual-use additives).

Regulation (EU) No 10/2011 requires suppliers to disclose comprehensive information within the supply chain on substances that are included in the Union list and whose use in food is restricted. This requires the disclosure of confidential information.

On request, the identity of these substances will be disclosed to an independent testing institute for the purpose of carrying out the compliance work required for articles manufactured with them.

5. Information on Not Intentionally Added Substances (NIAS):

Polyamides are produced from their monomers by a polycondensation reaction. This polymerization reaction ends with an equilibrium in which the polymer, together with a small residual portion of the monomer and other short-chain side reaction products so called oligomers are present.

In addition to the residual content in our material, their content and migration capability is mainly dependent on the further processing. We therefore strongly recommend that to take the technical information on processing provided by us into account.

As far as the information available to us on the composition of the above mentioned product is concerned, it does not contain any substances classified as genotoxic.

Compliance with the limit value for the overall migration and with the legal restrictions for monomers and additives as well as for not intentionally added substances (NIAS) have to be tested on the end product, taking into account the intended use.

Krailling, 19.12.2024

Signiert von:
Moritz Kügler
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Moritz Kügler, VP Business Unit Polymer Material

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Aktuelle Version: 1.0.0, issued 19.12.2024, GES

Ersetzte Version: -

EOS GmbH Electro Optical Systems • Robert-Stirling-Ring 1 • D-82152 Krailling

Declaration of Compliance

for materials made from plastic intended to come into contact with non-alcoholic foods based on FDA 21 CFR §175.300 (b)(3)xxxii (resinous and polymeric coatings) and FDA 21 CFR §177.1500 (a)(9) (nylon resins) with restriction as mentioned in §177.1500 (b)(9) and (b)

Manufacturer	EOS GmbH Electro Optical Systems Robert-Stirling-Ring 1 D-82152 Krailling/München
Date of issue	17 February 2021
Product name	PA 2200, PA 2201
Product number	9012-0014 / 200000061, 9012-0019 / 200000332
Compliance to regulations	Hereby we declare that the products PA 2200 and PA 2201 complies with its polymeric compositions with the following section of FDA 21 CFR §175.300 (b)(3)(xxxii)(resinous and polymeric coatings) and FDA 21 CFR §177.1500 (a)(9) (nylon resins) with restrictions as mentioned in §177.1500 (b)(9)(a) and (b).
Restrictions	There are restrictions in each of the regulations that must be taken into account by using PA 2200 and PA 2201. Users must review all applicable regulations and restrictions to assure compliance.

Keep in mind that it is the responsibility of the user and / or medical / foodstuff manufacturer to determine that the product is safe, lawful, and technically suitable for the intended use.

Fabrication conditions, part design, additives, process aids, finishing steps, and end use conditions all affect the performance and regulatory status of the end application. Due to variation in methods, conditions and equipment, no warranties or guarantees are made as to the suitability or accuracy of this information for use in any end application.

T. Tayarani

Thomas Tayarani
Regulatory Affairs Specialist

Version 2.0 issued on February 17, 2021