

## Declaration of Conformity

### Plastic Materials for Food Contact

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With respect to the Product: **TPU Filament – Shore D53 (Easy Flex)**

Declares that:

#### **ONE**

Presuming appropriate processing the products can be used in the countries of the European Community for food contact materials or articles according to article 3 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.

#### **TWO**

Compliance with the provisions of Regulation (EC) No 1935/2004 especially the suitability of the articles for the given application, the effect on smell and taste of the food, and observance of any given limitations, must be ensured by the person who introduces the articles into circulation.

#### **THREE**

The products are manufactured according to the requirements of Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

#### **FOUR**

The compositions of the products comply with the requirements of the Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food most recently amended by the Commission Regulation (EU) 2023/1627 of 10th August 2023.

## **FIVE**

Above mentioned products do contain dual use additives: FCM 315: SML= 3 mg/kg

The compositions of the products comply with "Bedarfsgegenständeverordnung" of 23.12.1997, last updated 15. February 2016.

Furthermore, the compositions of the products comply with Recommendation XXXIX of BfR, last updated 01. January 2012, which covers articles manufactured from polyurethane.

## **SIX**

### **The following restrictions have to be ensured:**

Generally, application simulating testing, in accordance with regulations in EU (e.g. Regulation (EU) 10/2011) has to demonstrate that global migration, specific migration and other restrictions for substances does not exceed allowed quantities. Among others it has to be proven that primary amines are not detectable (Regulation (EU) 10/2011, Annex II, Article 2). It is also a requirement that articles intended to come into contact with food shall not influence appearance, taste or odour of the foodstuff.

Based on exemplarily migration experiments performed on test samples we expect that articles made of the above-described materials will be suitable for repeated-use in food contact applications with all dry, aqueous, acidic foodstuffs and alcoholic foodstuffs with an alcohol content of < 20 % by volume. The migration experiments did not cover alcoholic foods having an alcohol content of > 20 %, fatty foodstuffs and milk products except milk powder. The migration tests have been exemplarily performed applying the standardized testing condition OM3 (2 h at 70°C) covering any contact conditions that include heating up to 70 °C for up to 2 hours or up to 100°C for up to 15 minutes, which are not followed by long-term room temperature or refrigerated temperature storage. Migration is amongst others dependent on food type, conditions of use, volume-to-surface ratio, film or part thickness and processing steps. Thus, it is the responsibility of the producer or seller of the final product to guarantee its compliance and to check it on a regular basis.

## **SEVEN**

### **Regulations in USA:**

The compositions of the products comply with the requirements of FDA Regulation 21 CFR 177.2600 "Rubber Articles Intended for Repeated Use".

## **EIGHT**

**Further general technical recommendations in Food Contact Applications to avoid material degradation: Material degradation might have possible impacts on the migration behaviour and might have an impact on the formation of primary amines.**

At the point of processing, it is necessary to ensure that the moisture content is < 0.02%. We also advise against steam sterilization as this might increase a generation of primary amines. Long-term operation of the final products under ambient high temperature conditions (as present in e.g. an oven) also might lead to material degradation. And finally, disinfectants containing active chlorine also can cause degradation of TPU.

## **NINE**

The scope of this declaration is limited to the composition and manufacture of the product mentioned above and not to any article or manufactured from it.

## **TEN**

This statement has been prepared in accordance with both the original version of the legal provisions and the successive amendments and corrections thereof published and in force on the date of signature of this document:

1. Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into
2. contact with food (OJ L 12, 15/01/2011, pp. 1-89)
3. Correction of errors in Regulation (EU) No. 10/2011 of January 14, 2011 (OJ L 278 of 25/10/2011, pp. 13-13)
4. Implementing Regulation (EU) No. 321/2011, of April 1, 2011 (OJ L 87, 02/04/2011, p.1-2)
5. Regulation (EU) No. 1282/2011, of November 28, 2011 (OJ L 328 of 10/12/2011, p.22-29)
6. Regulation (EU) No. 1183/2012, of November 30, 2012 (OJ L 338 of 12/12/2012, pp. 11-15)
7. Regulation (EU) No. 202/2014 of 3 March 2014 (OJ L 62 of 04/03/2014, pp. 13-15)
8. Regulation (EU) No. 865/2014 of August 8, 2014 (OJ L 238 of 09/08/2014, page 1-2)
9. Regulation (EU) No. 2015/174 of February 5, 2015 (OJ L 30 of 06/02/2015, pages 2-9)

10. Regulation (EU) No. 2016/1416, of August 24, 2016 (OJ L 230 of 08/25/2016, pp. 22-42)
11. Regulation (EU) No. 2017/752, of April 28, 2017 (OJ L 113 of 04/29/2017, pp. 18-23)
12. Regulation (EU) No. 2018/79 of 18 January 2018 (OJ L 4 of 19/01/2018, p.31-34)
13. Regulation (EU) No. 2018/213 of February 12, 2018 (OJ L 41 of 02/14/2018, pp. 6-12)

Important notice:

The properties stated above, cannot guarantee specific properties for specific applications. The user himself, has the responsibility to check the properties of our products, for his application with specific tests and test methods. The user is responsible for usage, storage, and handling of our products, following the general safety and environmental prescriptions for such products. Appropriate processing conditions for the articles must be applied. The information is provided in good faith and based upon the information and statements we received from our relevant up-stream suppliers. They correspond to the state-of-the-art and refer to the state of the laws at the date of issue. This declaration expires 12 months after the date of issue or in case of regulatory changes. No legal rights can be derived from it and Eolas prints disclaims any liability for any errors or omissions.

Reocín on April 24th, 2024  
Tanuj Goswami  
Eolas Prints S.L.  
Chief Technology Officer