

## DECLARATION OF CONFORMITY

### Product Name

## Bavaris Purge Plus

### Technical Description

Cleaning Compound for extrusion lines, compounding lines and injection molding.

### Regulations

With regard to Regulation 1935/2004, we inform you that, according to the information provided by our raw material suppliers, the components of the aforementioned product comply with the legal requirements for materials and articles. This means that they meet the general requirements according to Article 3 and can be used in plastic materials and articles intended for food contact, provided that specific limits (such as SML, OML, etc.) are adhered to. (\*) Regulation 1935/2004, Article 3, General Requirements

1. Materials and articles, including active and intelligent materials and articles, must be manufactured in accordance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not release components into food in amounts that are likely to:
  - a) endanger human health, or
  - b) cause an unacceptable change in the composition of the food, or
  - c) cause a deterioration of the organoleptic properties of the food.
2. The labeling, advertising, and presentation of the materials and articles must not mislead the consumer.

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## **Traceability (Art. 17)**

Through the manufacturing control conducted, traceability of raw material batches is ensured, thereby fulfilling the requirements of Regulation 1935/2004 in this regard.

## **Regulation (EC) No. 2023/2006**

The above-mentioned product is produced in accordance with good manufacturing practice as per Regulation 1935/2004, Article 3.1, and Regulation 2023/2006, Articles 5, 6, and 7.

## **Specific Migration Limit substances (SMLs)**

According to our suppliers confirmations this product contains the following monomers and/or additives that can be found in Annex I of 10/2011/EC:

Here is the table with the specific migration limits for the specified substances:

Chemical Name / Nature	SML Limit (mg/kg)
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	1.8
Octene-1	4,5
Iron	14.4

## **Restrictions for Materials and Articles**

All other elements listed in table 1 of 10/2011/EC, "General List of Migration Limits for Substances Migrating from Plastic Materials and Articles," that are not included in the aforementioned table will not be introduced during the manufacture of the aforementioned product.

The presence or absence of the relevant elements has not been verified through chemical analysis. Therefore, traces cannot be excluded.

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### **Specific Migration Limit According to Article 11**

(1) Components of plastic materials and articles must not migrate into food in amounts that exceed the specific migration limits (SML) specified in Annex I. These specific migration limits (SML) are calculated as milligrams of the substance per kilogram of food (mg/kg).

### **Overall Migration Limit According to Article 12**

Plastic materials and articles must not transfer their components into food simulants in amounts exceeding 10 mg of the total released components per dm<sup>2</sup> of the surface area in contact with food (mg/dm<sup>2</sup>).

Since our products are only a component of the final product, testing/measurements on the final product must be conducted to confirm the safe use of the final article in contact with food. As manufacturers, we have no influence over the subsequent processing of the masterbatch. Therefore, the downstream processor or food packager, who brings the final material or product to market, is responsible for its suitability for intended or foreseeable conditions of use and for regular testing.

This declaration of conformity is available exclusively for our customers and the respective competent authorities. It is not intended for publication in printed or electronic form (e.g., via the Internet) by other parties. Therefore, neither partial nor complete publication is permitted without written approval. This statement is intended solely for your use. Unauthorized distribution to third parties is prohibited.

This document is provided electronically and does not require a legally binding signature. This document is valid for a maximum of 18 months from the date of issuance of the declaration, or until the next relevant legal and/or regulatory change. All previously issued declarations of conformity are replaced by this statement.

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### **REACH Authorisation List & Substances restricted under REACH**

Based on our current knowledge, we confirm that these products:

- do not contain substances subject to authorisation (Regulation (EC) No 1907/2006 (REACH) Annex XIV);
- do not contain any substances with conditions of restriction as described in Regulation (EC) No 1907/2006 (REACH) Annex XVII relevant to any known or listed use of the products.

No specific testing of these grades is performed for every listed Annex XIV and Annex XVII substances.

### **DECLARATION OF CONFORMITY - FDA**

#### **United States Food and Drug Administration – US-FDA**

The formulation components of the above-mentioned product comply, based on information from the raw material suppliers, with the following approvals from the United States Food and Drug Administration (US-FDA) as chemical substances.  
Percentage limitation: 26.5% in polyolefins

Carrier material:

21 CFR §177.1520(c) 2.1, 2.2

21 CFR §177.1520(c) 3.2a

Additives:

21 CFR §186.1256

21 CFR §184.1191

Food restrictions:

None

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## General

Temperature Restrictions: In LDPE: approved at temperatures according to §176.170(c), Table 2, E, F, G.

Since our products are only one component of the final product, testing/measuring of the final product must be conducted to confirm the safe usability of the final article in contact with food.

As manufacturers, we have no influence over the subsequent processing of the masterbatch; therefore, the processor or food packager bringing the final material or product to market is responsible for its suitability for intended or foreseeable conditions of use and for regular testing.

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