

**DECLARATION OF COMPLIANCE FOR MATERIALS AND ARTICLES INTENDED  
TO COME INTO CONTACT WITH FOOD (1)**

**Date of issue:** 9 July 2019 (2)

**Mitsubishi Chemical Advanced Materials N.V.**  
**Industriepark Noord**  
**Galgenveldstraat 12**  
**B-8700 Tielt**

The issuer of this declaration and manufacturer of the products concerned hereby confirms that the products:

**“TIVAR® CleanStat UHMW-PE Food Grade black” [PE-UHMW]**

**Semi-finished products: round rods, plates and profiles(3) and  
Finished parts machined from these semi-finished products by Mitsubishi Chemical  
Advanced Materials**

- **comply with the requirements of the articles 3, 11(5), 15 and 17 of the Regulation (EC) No 1935/2004,**
- **comply with the relevant requirements of the Regulation (EU) No 10/2011 as amended up to and inclusive of the Commission Regulation (EU) 2019/37,**
- **are manufactured according to Good Manufacturing Practice (GMP) as set out in Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.**

Based on migration tests performed on the products according to Regulation (EU) 10/2011 as amended, the overall migration as well as the specific migration does not exceed the legal limits set out in Regulation (EU) 10/2011, **when used as specified below.**

Specifications on the intended use of the products:

- Type(s) of food intended to come into repeated contact with the material:  
**All types of food**
- Type(s) of food NOT intended to come into repeated contact with the material:  
**Not applicable**
- Time and temperature of treatment and storage when in contact with the food:
  - **Overall migration tests run under the standardised testing conditions**  
**OM2 in 10 % ethanol (v/v) and 3 % acetic acid (w/v) and**  
**OM5 in vegetable oil <sup>1</sup>**
  - **Specific migration tests run in**  
**3 % acetic acid (10 days, 40 °C),**  
**10 % ethanol (10 days, 40 °C) and**  
**Vegetable oil (1 h at 121 °C) <sup>2</sup>**

<sup>1</sup> Overall migration tests in vegetable oil under the standardised testing conditions OM5 being replaced by tests in isooctane (2 h, 60 °C) and 95 % ethanol (4 h, 60 °C) in accordance with Directive 82/711/EEC as vegetable oil is technically not feasible with the used methods of analyses.

<sup>2</sup> Specific migration tests in vegetable oil (1 h at 121 °C) being replaced by tests in isooctane (2 h, 60 °C) and 95 % ethanol (4 h, 60 °C) in accordance with Directive 82/711/EEC as vegetable oil is technically not feasible with the used methods of analyses.

- **Visible migration tests run according to the analytical method described in the Appendix of European Resolution AP (89)1, "On the use of colorants in plastic materials coming into contact with food", dated September 13, 1989, under III.1.**

- Ratio of food contact surface area to volume (S/V) used to establish the compliance of the products:

$$S/V = 6 \text{ dm}^2/\text{kg}$$

The following substance, subject to restrictions under Regulation (EU) 10/2011 as amended, is used in the products:

Chemical name of the substances	Restrictions
Zinc stearate	Group SML = 5 mg/kg (expressed as zinc)

The following substances, identified as dual use additives under Regulation (EU) 10/2011 as amended, are used in the products:

Chemical name of the substances
Calcium stearate (CAS No 1592-23-0)

A risk assessment of Non-Listed Substances (NLS), such as catalysts and Non-Intentionally Added Substances (NIAS), such as reaction and degradation products has been performed in accordance with Article 3 of the Framework Regulation ((EU) 1935/2004) and Article 19 of the Plastic Regulation ((EU) 10/2011), based on the conditions mentioned above.

It remains the responsibility of the customer putting the plastic articles manufactured from the products into the intended use, to assess the final suitability of the plastic material for the intended food contact application; i.e. checking if the physical properties of the plastic material make it suitable for the intended application, checking compliance of the finished plastic articles with the relevant migration limits, checking for possible influence of the plastic material on the composition and/or organoleptic properties of the contacting foodstuff, etc..

- (1) Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC – Article 16.
- (2) This declaration expires 5 years after its date of issue or in case of compositional changes which require its re-evaluation.
- (3) For information about the available dimensions, please contact your Mitsubishi Chemical Advanced Materials sales office.

**NOTES:**

- Finished food contact articles shall be manufactured such that the surface skin(s) of the semi-finished products is (are) taken away.
- It remains the responsibility of the customer putting the plastic articles manufactured from the products into the intended use that in accordance with good manufacturing practice, finished food contact articles are thoroughly cleansed prior to their first use in contact with food.
- This declaration of compliance is only valid for products that are carrying the Mitsubishi Chemical Advanced Materials "for food contact label" (sticker), the relevant Mitsubishi Chemical Advanced Materials "trade name label" (sticker) and the label (sticker) carrying the unique 'production order

number' that allows traceability. For finished parts these stickers can be on the product itself or on their packing.

- It is the responsibility of the buyer to assure the traceability of the material during any further downstream use up to and including the finish machined part as well as the equipment in which it is assembled.
- Other language versions of this declaration of compliance can be downloaded from the Mitsubishi Chemical Advanced Materials website [mcam.com](http://mcam.com).

**TIVAR®** is a registered trademark of the **Mitsubishi Chemical Advanced Materials Group**.

This document and any data and specifications presented on our website shall provide promotional and general information about the Engineering Plastic Products (the "Products") manufactured and offered by Mitsubishi Chemical Advanced Materials and shall serve as a preliminary guide. All data and descriptions relating to the Products are of an indicative nature only. Neither this document nor any data and specifications presented on our website shall create or be implied to create any legal or contractual obligation.

Any illustration of the possible fields of application of the Products shall merely demonstrate the potential of these Products, but any such description does not constitute any kind of covenant whatsoever. Irrespective of any tests that Mitsubishi Chemical Advanced Materials may have carried out with respect to any Product, Mitsubishi Chemical Advanced Materials does not possess expertise in evaluating the suitability of its materials or Products for use in specific applications or products manufactured or offered by the customer respectively. The choice of the most suitable plastics material depends on available chemical resistance data and practical experience, but often preliminary testing of the finished plastics part under actual service conditions (right chemical, concentration, temperature and contact time, as well as other conditions) is required to assess its final suitability for the given application. It thus remains the customer's sole responsibility to test and assess the suitability and compatibility of Mitsubishi Chemical Advanced Materials' Products for its intended applications, processes and uses, and to choose those Products which according to its assessment meet the requirements applicable to the specific use of the finished product. The customer undertakes all liability in respect of the application, processing or use of the aforementioned information or product, or any consequence thereof, and shall verify its quality and other properties.