Mitsubishi Chemical Advanced Materials NV
Compliance Department
I.P. Noord – Galgenveldstraat 12 B-8700 Tielt
T: +32 (0)51/ 42.35.45
regulatorysupport.mcam@mcgc.com
mcam.com

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

**Date of issue:** 14 September 2026 ([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™ Ceram P FG UHMW-PE yellow-green" [PE-UHMW]

**Semi-finished products: plates ([3]) and**
**Finished parts machined from these semi-finished products by Mitsubishi Chemical Advanced Materials**

**European Union**

The above mentioned products

- **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) 2026/1380,**
- **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 [1]***

[1] Overall migration tests in vegetable oil under the standardised testing conditions OM5 being replaced by tests in isooctane (2 h, 60 °C), 95 % ethanol (4 h, 60 °C) and MPPO (1 h, 121 °C) in accordance with Directive 82/711/EEC as vegetable oil is technically not feasible with the used methods of analyses.

TEMPLATE FOR INFORMATION ONLY
MCAM.COM

Copyright © 2026 The Mitsubishi Chemical Advanced Materials group of companies. All rights reserved. - Date of issue: 14 September 2026

Mitsubishi Chemical Advanced Materials NV
Compliance Department
I.P. Noord – Galgenveldstraat 12 B-8700 Tielt
T: +32 (0)51/ 42.35.45
regulatorysupport.mcam@mcgc.com
mcam.com

- ***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)***
- ***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 dm²/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 |
|---|---|
| Copper | SML = 5 mg/kg |
| Zinc stearate | Group SML = 5 mg/kg (expressed as zinc) |
| Aluminium | SML = 1 mg/kg |
| 1,1,1-Trimethylolpropan (CAS No 77-99-6) | SML = 6 mg/kg |
| Proprietary substances ([4]) | |
| | |

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) |
| Calcium carbonate (E170) |
| Magnesium stearate (E470b) |
| Silicium dioxide (E551) |
| Titanium dioxide |
| Proprietary substances ([4]) |
| |

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.

**United States**

We hereby provide the following information on the compliance status of the Mitsubishi Chemical Advanced Materials stock shapes mentioned above, as set out in the regulations that apply in the United States of America (FDA) for plastic materials and articles intended to come into contact with foodstuffs:

- **TIVAR Ceram P FG UHMW-PE yellow-green** complies with the requirements of the FDA regulations 21 CFR § 177.1520 and 21 CFR § 178.3297, as well as with those of other applicable FDA regulations.

TEMPLATE FOR INFORMATION ONLY
MCAM.COM

Copyright © 2026 The Mitsubishi Chemical Advanced Materials group of companies. All rights reserved. - Date of issue: 14 September 2026

Mitsubishi Chemical Advanced Materials NV
Compliance Department
I.P. Noord – Galgenveldstraat 12 B-8700 Tielt
T: +32 (0)51/ 42.35.45
regulatorysupport.mcam@mcgc.com
mcam.com

**TIVAR Ceram P FG UHMW-PE yellow-green stock shapes** may basically be used for the manufacture of articles or components of articles intended for repeated food-contact use with all food types I to IX under conditions of use A to H as defined in tables 1 and 2 in 21 CFR 176.170(c), respectively.

This product has not been evaluated for use in contact with infant formula and/or human (breast) milk.

## Japan

Based on the compliance status of **the raw materials** used at present by Mitsubishi Chemical Advanced Materials for the manufacture of the stock shapes mentioned above, **with respect to their composition**, as set out by the Japan's Ministry of Health, Labour & Welfare (MHLW) in the Official Notification (Notification No. 324 of 2023) of 30 November 2023 for utensils, containers and packaging intended to come into contact with foodstuffs:

- **TIVAR Ceram P FG UHMW-PE yellow-green** complies with the compositional requirements of the 'Base materials' and 'Additives' Japan food contact positive lists, as published by Japan's Consumer Affairs Agency on 27 September 2024.
  Based on their composition, **TIVAR Ceram P FG UHMW-PE yellow-green stock shapes** may basically be used for the manufacture of articles or components of articles intended for food-contact use with all food types, under maximum temperature conditions III.

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.
(4) Substances subject to restrictions under Regulation (EU) No 10/2011 as amended are used in the products. Upon request, the identity of these substances can be disclosed to third parties (e.g. test laboratories) under the terms of a Non-Disclosure Agreement.

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.

TEMPLATE FOR INFORMATION ONLY

Copyright © 2026 The Mitsubishi Chemical Advanced Materials group of companies. All rights reserved. - Date of issue: 14 September 2026

Mitsubishi Chemical Advanced Materials NV
Compliance Department
I.P. Noord – Galgenveldstraat 12 B-8700 Tielt
T: +32 (0)51/ 42.35.45
regulatorysupport.mcam@mcgc.com
mcam.com

- 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.

TEMPLATE FOR INFORMATION ONLY
MCAM.COM

**TIVAR**™ is a protected trademark of Mitsubishi Chemical Advanced Materials.

All statements, technical information, recommendations, and advice are for informational purposes only and do not constitute any express or implied warranties or representations whatsoever. This includes, but is not limited to, all warranties provided for by any applicable law, any implied warranty of merchantability, of fitness for a particular purpose, or any warranty against hidden defects or redhibitory defects or vices, or that the products are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in invasive or implantable medical devices or medical devices essential to the restoration of or continuation of a body function or structure important to the continuation of human life. The customer, however, is cautioned that nothing herein shall be construed as guarantee of the accuracy or completeness and it is the customer’s sole responsibility to test and assess the suitability of our products in any given or intended application, process or for use in a finished or non-finished device.

**Copyright © 2026 The Mitsubishi Chemical Advanced Materials group of companies. All rights reserved.** - Date of issue: 14 September 2026