



Overensstemmelseserklæring

Dato 13. maj 2026

KB Metal erklærer hermed at:

FKM PEHD 1000, er egnet og godkendt til kontakt med fødevarer i henhold til gældende direktiver,

- Forordning 1935/2004 angående FKM-materialer.
- Bekendtgørelse 681/2020/DK angående FKM-materialer.
- Forordning 2023/2006 angående GMP-procedurer.
- Forordning 10/2011 angående overensstemmelseserklæringer.

Ovenstående suppleret med informationer i vedhæftede erklæringer fra vores leverandører.

Vi erklærer samtidigt at emnerne vi bearbejder ud fra de indkøbte FKM-materialer, bliver håndteret og produceret uden materialet bliver forurenset med ikke fødevaregodkendte stoffer.

Det er KB Metals ansvar, at sikre sporbarheden på de emner vi leverer til kunden.

Dette dokument er gyldig så længe vedhæftede leverandør erklæringer er gyldige.

Kennet Bager Nielsen

Administrerende Direktør

DECLARATION OF COMPLIANCE FOR SEMI-FINISHED PRODUCTS INTENDED TO COME INTO CONTACT WITH FOOD

Date of issue: 10. June 2024 ¹⁾

Vink Plast ApS hereby declare that:

Tivar 1000 FCM blue (PE UHMW) round rods, plates and finished parts machined from these products by Vink Plast ApS ²⁾:

European Union

- 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 in Regulation (EU) 10/2011 as amended up to and inclusive the commission Regulation (EU) no. 2023/1627
- Are manufactured and handled according to good manufacturing practice (GMP) as set out in the (EC) 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- Comply with declaration 681/2020/DK

Based on the 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.

Specification 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 standardized testing conditions in
 - OM2 in 10 % ethanol (v/v) and 3 % acetic acid (w/v)
 - OM5 in vegetable oil ³⁾
 - Specific migration tests run in
 - 3 % acetic acid (10 days, 40 °C)
 - 10 % ethanol (10 days, 40 °C)
 - Vegetable oil (1 hour 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 substances, subject to restrictions under Regulation EU 10/2011 as amended, is used in the products:

Chemical name of the substances	Restriction
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
Butanedioic acid, sulfo-, 1,4-bis(2-ethylhexyl) ester, sodium salt (CAS no. 577-11-7)	SML = 5 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 substance
Calcium stearate (CAS no. 1592-23-0)
Calcium carbonate (CAS no. 471-31-1)
Magnesium stearate (CAS no. 557-04-0)
Silicium dioxide (CAS no. 14808-60-7)
Stearic acid (CAS no. 57-11-7)
Proprietary substances ⁴⁾

A risk assessment of the 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 producers 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 1000 FCM blue (PE-UHMW) complies with the requirements of FDA regulations 21 CFR § 177.1520 "Olefin polymers" and 21 CFR § 178.3297 "Colorants for polymers," as well as with those other applicable FDA regulations. Tivar 1000 FCM blue stock shapes may basically be for the manufacture of articles or components for 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.

Japan

Based on the compliance status of the raw materials used at present by the producer for the manufacture of 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. 196 of 2020) of 28 April 2020 for utensils, containers and packaging intended to come into contact with foodstuffs:

- Tivar 1000 FCM blue (PE UHMW) complies with the compositional requirements of the 'Base polymers (Plastics)' and 'Additives' Japan food contact list. Based on their composition, Tivar 1000 FCM blue (PE UHMW) stock shapes may basically be used for the manufacture of articles or components for 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 article manufactured from the products into the intended use, to assess the final suitability of the plastics material for the intended food contact application; i.e. checking if the physical properties of the plastics material make it suitable for the intended application, checking compliances of the finished plastic article with the relevant migration limits, checking for possible influence of the plastics material on the composition and/or organoleptic properties of the contacting foodstuff, etc.

Notes:


- ¹⁾ This declaration expires 5 years after its date of issue or in case of regulatory or compositional changes which require reevaluation. Please always contact Vink Plast' customer service for latest version. For information about available dimensions, please contact Vink Plast' customer service.
- ²⁾ Regulation (EC) no. 1935/2004 of the European Parliament and 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.
- ³⁾ Overall migration tests in vegetable oil under the standardized testing conditions OM3 being replaced by tests in isoctane (0,5h, 40 °C) and 95 % ethanol (2h, 60 °C) in accordance with Directive 82/711EEC as vegetable oil is technically not feasible with the used methods of analysis.
- ⁴⁾ Substances subject to restrictions under Regulation EU 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.

Jan Busk



QHSE- & CSR-Manager
Vink Plast ApS.

Morten Grue Jakobsen



Business Unit Director
Vink Plast ApS.

Overensstemmelseserklæring

Nordisk Plast bekræfter hermed at nedenstående produkt PE HD 1000 Blå presset, er i overensstemmelse med de nævnte forordninger.

ORBILAN[®]
GmbH Kunststoffwerk

Product Information

relating to plastic materials and articles intended to come into contact with foodstuffs

Product

ORBILAN PE 1000, pressed, ultramarine blue (similar to RAL 5002), sheet

Hereby we confirm that the product listed above meets the requirements of the following guidelines and regulations:

- 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
- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
- 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

Migration limits

The testing regarding the suitability of the plastic article, which is intended to come into contact with foodstuff and adherence of the migration limits of Commission Regulation (EU) No 10/2011 is up to the user.

Information on substances used from Annexes I and II of Regulation (EU) No. 10/2011

The following substances, from Annexes I and II of Regulation (EU) No. 10/2011, may be contained in the product listed above.

Annex I

Name of the substance	FCM substance No	CAS No	Limits
1,1,1-trimethylolpropane	141	0000077-99-6	SML = 6 mg/kg

As far as information about this is available in the raw material manufacturers conformity documents.

Annex II

Name of the substance	Limits
Aluminum	SML = 1 mg/kg
Calcium	
Copper	SML = 5 mg/kg
Magnesium	
Sodium	

As far as information about this is available in the raw material manufacturers conformity documents.

02.2025

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Information on "dual-use substances"

The following substances, which are also authorised as food additives, may be present in the product listed above:

E-Nummer	Bezeichnung des Stoffes
E 170	Calcium carbonate
E 171	Titanium dioxide
E 470b	Magnesium Stearate
E 551	Silicon dioxide

As far as information about this is available in the raw material manufacturers conformity documents.

Information about "functional barrier"

No functional barrier is used in accordance with Regulation (EU) No. 10/2011.

Please note that the user is responsible for the objects produced from or with our material as well as their compliance to the requirements of applicable legal provisions.

The present declaration is valid for a period of two years starting from its publication.

Yours faithfully
ORBILAN GmbH Kunststoffwerk

This product information is for informational purpose only. It cannot be seen as a warranty. The information is based on our present knowledge and experience. We strongly recommend doing application tests because of the different influences of processing. Substances are not included in this product information which are e.g. present due to a spread of minimum quantities and which can be defined due to the refined analytical methods. Furthermore, we would like to point out that an analytical control of possible contamination of our products is not a point of our quality control.

02.2025

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Declaration of Conformity



acc. to Regulation (EG) No. 1935/2004
as well as to Regulation (EU) No. 10/2011

Product: **PROIen 6000 VIRGIN Ultramarin-Blue – semi finished products**

PROFILAN herewith declares that the above product meets the following provisions:

1. Plastic products that are intended to come in contact with food are subject to the requirements and test conditions from Regulation (EU) No. 10/2011 and its subsequent enlargements by the commission Regulation (EU) no. 2024/3190 of 19 December 2024, up to and including commission Regulation (EU) no. 2025/351 of 21 February 2025.
2. With respect to the applied test conditions the tested material samples meet the requirements of § 31 (1) of the German Food and Feed Code (LFGB) as well as article 3 of the Regulation (EG) No. 1935/2004 in conjunction with the Regulation No. (EU) 10/2011. The results of all test runs were far below the stated critical value for the global migration of 10 mg/dm².

3. Specification of the intended use:

- Foods that are intended to come in contact with the material:

All types of food

- Conditions of use:

Any long-term storage at room temperature or below, including packaging by hot filling and / or heating to a temperature up to 121° C.

Declaration of Conformity



acc. to Regulation (EG) No. 1935/2004
as well as to Regulation (EU) No. 10/2011

Product: **PROIen 6000 VIRGIN Ultramarine-Blue – semi finished products**

4. The migration test was carried out according to Regulation (EU) No. 10/2011 Appendix V under the following conditions:

Test simulant	Testing condition I	Testing condition II
3 % Acetic acid	2 h 100°C	10 d 40°C
Sunflower oil	2 h 100°C	10 d 40°C
10 % Ethanol	2 h 100°C	10 d 40°C
50 % Ethanol	2 h 100°C	10 d 40°C

Ratio of the surface in contact with the foodstuff to volume (S/V), used to determine the conformity of the material.

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

5. All substances / monomers and additives according to Regulation (EU) No. 10/2011 are listed. The following substances have legal restriction and / or specification:

Name of the substance	Restriction
Aluminium	SML = 1 mg/kg
Barium	SML = 1 mg/kg
Copper	SML = 5 mg/kg
Iron	SML = 48 mg/kg
Nickel	SML = 0,02 mg/kg
Zinc	SML = 5 mg/kg
Cobalt	SML = 0,05 mg/kg

The limit values for the metals listed in Appendix II of the Regulation (EU) No. 10/2011 are respected.

Declaration of Conformity



acc. to Regulation (EG) No. 1935/2004
as well as to Regulation (EU) No. 10/2011

Product: **PROIen 6000 VIRGIN Ultramarin-Blue – semi finished products**

The limit values for the above mentioned raw materials according Appendix I of the Regulation (EU) No. 10/2011 well as the subsequent additions thereto, are fulfilled under the applied test conditions.

The following food additives* or flavoring agents* with „Dual Use“ may be included:

Name of the substance
Calcium stearate

* as far as these could be taken from the documents of the raw material supplier

- The above-mentioned product is manufactured on the basis of the „Good Manufacturing Practice“ (GMP) method, according to Regulation (EG) No. 2023/2006.
- In case a batch-related traceability is required, the production of material and respective documentation will be done separately. These products are additionally marked „**FoodClass**“.
- All non-intentionally introduced substances (**NIAS**) have been tested for non-intentionally introduced substances by means of GS-MS screening on representatively selected test samples as part of the conformity assessment.

No impurities or side reaction or degradation products (NIAS) could be identified.

Name of the substance	Restriction
-	-

The above information are based on our current state of information and knowledge and relate to the product we deliver. Under the specified food contact conditions, the product meets the legal requirements, the conformity test was carried out under the conditions mentioned above. PROFILAN has no control and assumes no responsibility / liability for finished articles or their manufacture, processing and conditions of use and therefore assumes no responsibility for their conformity. The end product manufacturer is responsible for the compliance with the requirements of the applicable legal provisions. Rather, the end product manufacturer is in turn obliged to check the conformity for the intended purpose. The declaration is no guarantee declaration. Subject to change. Previous declarations are hereby invalid.

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Date: 07/2025

Declaration of Conformity



acc. to Regulation (EG) No. 1935/2004
as well as to Regulation (EU) No. 10/2011

Product: **PROlen 6000 VIRGIN Ultramarin-Blue – semi finished products**