VINK PLAST

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

Date of issue: 20. June 2024 [1)]

Vink Plast ApS hereby declare that:

Ertacetal C POM-C FCM natural (POM-C) round rods and 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)
    - OM3 in 3 % acetic acid (w/v)
    - OM5 in Vegetable oil [3)]
  - Specific migration tests run in
    - 3 % acetic acid (2 h, 70 °C)
    - 10 % ethanol (10 days, 40 °C)
    - Vegetable oil (1 h at 121 °C) [3)]
- Ratio of food contact surface area to volume (S/V) used to establish the compliance of the Products:
  - S/V = 6 dm^2/kg

The following substances, subject to restrictions under Regulation EU 10/2011 as amended, are used in the products:

Chemical name of the substances	**Restriction**
Trioxane (CAS no. 110-88-3)	SML = 5 mg/kg
Formaldehyde (CAS no. 50-00-0)	SML(T) = 15 mg/kg
1.3-Dioxolane (CAS no. 646-06-0)	SML = 5 mg/kg
Triethyeneglycol bis (3-(3-terbutyl-4hydroxy-5-methylphenyl) propionate) (CAS no. 36443-68-2)	SML = 9 mg/kg
2,4,6-triamino-1,3,5-triazine (CAS no. 108-78-1)	SML = 2,5 mg/kg
2,5-bis (5-tert-butyl-2-benzoaxzolyl)thiophene (CAS no. 7128-64-5)	SML = 0,6 mg/kg
Proprietary substances [4)]	

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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
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 based on the compliance status of the raw materials used at present by the producer for the manufacture of the stock shapes mentioned above, with respect to their composition as set out the compliance status of the stock shapes mentioned above, with respect to their composition, 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:

- Ertacetal C POM-C natural FCM complies with the compositional requirements of the FDA regulations 21 CFR § 177.2470 “Polyoxymethylene copolymer,” as well as with those of other applicable FDA regulations.
  Ertacetal C POM-C FCM natural rods and plates may basically be used for the manufacture of articles or components of articles intended for repeated food-contact use with all types of food types I to IX, excluding alcoholic beverages that exceed 15 percent alcohol by volume and infant formula and breast milk, under conditions of use A to H where use temperature does not exceed 121 °C (250 °F) as defined in tables 1 and 2 in 21 CFR 176.170(c), respectively.

Japan

Based on the compliance status of the raw material 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 Notificaton (Notification no. 196 of 2020) of 28 April 2020 for utensils, contaiers and packaging intended to come into contact with foodstuffs:

- Ertacetal C POM-C FCM natural complies with the compositional requirements of the ‘Base polymers(Plastics)’ and ‘Additives’ Japan food contact positive lists.
  Based on their composition, Ertacetal C POM-C FCM natural 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 II.

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.

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Notes:

[1)] This declaration expires 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)] Reguation (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)] Specific migration tests in vegetable oil under the standardized testing conditions OM5 being replaced by tests in isooctane (2h, 60 °C) and 95 % ethanol (4h, 60 °C) and MPPO (1 h, 121 °C) being replaced by tests in isooctane (2 h, 60 °C), 95 % ethanol (4h, 60 °C) and MPPO (1 h, 121 °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.

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