

## Declaration of compliance for semi-finished products intended to come into contact with food

Vink Plast ApS hereby declare that:

### FCM\*\* Ertalon® 6 PLA Natural, round rods, plates and tubes [PA6]

is intended to come into contact with food and is in compliance with:

- Comply with the requirements of the Regulation (EC) No. 1935/2004 of 27 October 2004
- Comply with the relevant requirements of the Regulation( EU) 10/2011 as amended up to and inclusive of the Commission Regulation (EU) No. 2019/37
- Are manufactured and handled according to good manufacturing practice (GMP) as set out in the Regulation (EC) 2023/2006 of 22. december 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- Declaration 681/2020/DK

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.

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 in  
10 % ethanol (v/v) and 3 % acetic acid (w/v):  
2 minutes at 80°C  
5 minutes at 40°C  
5 minutes at 80°C  
5 minutes at 100°C  
15 minutes at 5°C  
15 minutes at 10°C  
and  
vegetable oil: 1 hour t 121°C <sup>a</sup>
  - Specific migration tests run in  
10 % ethanol (v/v) and 3 % acetic acid (w/v)  
2 minutes at 80°C  
5 minutes at 40°C  
5 minutes at 80°C  
5 minutes at 100°C  
15 minutes at 5°C  
15 minutes at 10°C  
And vegetable oil: 1 hour at 121°C <sup>b</sup>

<sup>a</sup> Overall migration test in vegetable oil under standardized 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.

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

Tested in	Ratio of food contact surface area to volume (S/V) used to establish the compliance of the material
3 % acetic acid (w/v) (2 minutes at 80°C)	2.5 dm <sup>2</sup> /kg
3 % acetic acid (w/v) (5 minutes at 40°C)	6 dm <sup>2</sup> /kg
3 % acetic acid (w/v) (5 minutes at 80°C)	2 dm <sup>2</sup> /kg
3 % acetic acid (w/v) (5 minutes at 100°C)	0.7 dm <sup>2</sup> /kg
3 % acetic acid (w/v) (15 minutes at 5°C)	6 dm <sup>2</sup> /kg
3 % acetic acid (w/v) (15 minutes at 10°C)	6 dm <sup>2</sup> /kg
10 % ethanol (v/v) (2 minutes at 80°C)	2 dm <sup>2</sup> /kg
10 % ethanol (v/v) (5 minutes at 40°C)	6 dm <sup>2</sup> /kg
10 % ethanol (v/v) (5 minutes at 80°C)	1.6 dm <sup>2</sup> /kg
10 % ethanol (v/v) (5 minutes at 100°C)	0.6 dm <sup>2</sup> /kg
10 % ethanol (v/v) (15 minutes at 5°C)	6 dm <sup>2</sup> /kg
10 % ethanol (v/v) (15 minutes at 10°C)	6 dm <sup>2</sup> /kg
Vegetable oil (1 hour at 121°C, OM5) <sup>c</sup>	0.4 dm <sup>2</sup> /kg

b 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.

c Overall migration tests in vegetable oil under the standardized testing conditions OM 5 and 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.

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

Chemical name of substances:	Restrictions:
Caprolactam (CAS No 000105-60-2)	SML(T) = 15 mg/kg
Hexamethylene diisocyanate (CAS No 0000822-06-0)	SML (T) = ND (expressed as Isocyanate moiety) QMA = 1 mg/kg in final product expressed as isocyanate moiety
Caprolactam, sodium salt (CAS No 0002123-24-2)	SML(T) = 15 mg/kg

No substances, identified as dual use additives under Regulation (EU) 10/2011 as amended, are used in the products.


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.

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 compliance of the finished plastics 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.

- (1) 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.
- (2) This declaration expires 5 years after its date of issue or in case of regulatory or compositional changes which require re-evaluation. Please always contact Vink Plastic' customer service for latest version. For information about available dimensions, please contact Vink Plast' customer service.

\*\* FCM = Food Contact Material (In Danish FKM = Fødevare Kontakt Materiale)

Jan Busk

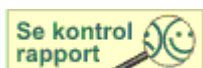


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Vink Plast ApS is officially authorized by the Danish Veterinary and Food Administration under the Danish Food Act § 281, cf. §15.