

Declaration of Compliance

for products made of plastic intended to come into contact with foodstuffs

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Product: Trovidur® EC white

We herewith confirm that the product mentioned above is in compliance with the requirements of the following regulations:

- (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, Gazette of the European Communities L 338/4 dated 13/11/2004, modified by Appendix nr. 5.17 of the regulation (EC) No 596/2009 dated 18th June 2009, Gazette of the European Communities L 188 dated 18/07/2009, article 3,
- Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code – LFBG) in the version of the notification of 22 August 2011 (BGBl. I p. 1770), §§ 30 and 31

Furthermore the product meets the requirements of

- (EU) No 10/2011 of the Commission of 14 January 2011 on plastic materials and articles intended to come into contact with food, Gazette of the European Communities L 21/1 dated 15/01/2011
- Decree on Consumer Goods in the version of the communication of 23 December 1997 (BGBl. 1998 I p.5), last modification by Article 5 of the Decree of 13 December 2011 (BGBl. I p. 2720).

with regard to the migration behaviour.

The manufacturing of the product mentioned above is carried out according to the method „Good Manufacturing Practice“ (GMP), corresponding to the regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. According to the regulation (EC) No 1935/2004, the traceability of our products is guaranteed at all levels and is carried out by means of the production number inscribed on the product label or the accompanying documents.

Testing conditions for migration tests based on the application

The product was tested according to the methods for “examination of utensils“ by means of several samples, according to the regulation B 80.30, 1 to 3 (EC) of the Official List of testing procedures according to § 64 LFBG (Germany), as well as the series of standards EN 1186, EN 13130 and CEN/TS 14234 “materials and goods in contact with foodstuffs – plastics“.

According to the general rules for migration tests, the total migration and the specific migrations of individual substances were determined by using food simulants and pre-defined testing conditions (time/temperature).

The overall migration as well as the specific migrations does not exceed the legal limits when used as specified in table 1.

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Table 1: Test conditions

Testing simulant	Testing conditions (time/temperature)	Intended contact with foodstuffs
3 weight % acetic acid	10 days at 40°C	Direct contact with foodstuffs of all kinds
10 vol.% ethanol	10 days at 40°C	
95 vol.% ethanol as substitute for fat	10 days at 40°C	
Isooctan as substitute for fat	2 days at 20°C	

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

$$\frac{S}{V} = 6$$

The following substances subject to restrictions and/or specifications are used in the product mentioned above:

Name of the substance	Restrictions
Additive 1	SML= < 0,01 mg/dm ²
Additive 2	SML= < 0,001 mg/dm ²
Additive 3	SML= < 0,01 mg/dm ²
Additive 4	SML= < 0,01 mg/dm ²
Additive 5	SML= < 0,01 mg/dm ²
Tin	SML= 0,013 mg/dm ²

SML = specific migration limit in food or in food simulant

QMA = max. permitted quantity in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs.

The following substances*, which are also approved as food additives („Dual use“), may be contained in the product mentioned above (EC directives 89/107/EEC, 95/2/EC):

Name of the substance	Restrictions
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* as far as information concerning this point is included in the conformity documents made available by the raw material producer

This declaration is valid for the product delivered by our company as described. The directives 82/711/EC and 85/572/EC define a guideline for the choice of testing conditions to be applied for the different foodstuffs. The product corresponds to the regulations of these directives, if the indicated food contact conditions are adhered to.

It is the user's own responsibility to insure the suitability of the product for the planned contact material, if this suitability exceeds the regulations of the directives.

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Product: Trovidur[®] EC white

The quality Trovidur[®] EC white can thus be used for the production of final products for the foodstuff industry without objection. Final products manufactured with this material can be in direct contact with foodstuffs of all kinds, as far as the quality Trovidur[®] EC white cited above is concerned and as far as the following restrictions are also respected:

- For aqueous and acerbic foodstuffs the proportion between contact surface of the PVC and weight of the treated foodstuff may not exceed 2 dm² per kilogram.
- For fatty foodstuffs this proportion is limited to 0,4 dm² PVC per kilogram foodstuff. For such foodstuffs, which are accorded a correction factor per kilogram foodstuff according to appendix III, table 2, directive (EU) No 10/2011, the contact surface per kilogram foodstuff may, however, be increased to 0.4 dm² multiplied with this correction factor. It is important that the contact time and temperature according to prescription (EU) No 10/2011 are not exceeded.

Röchling High-Performance Plastics

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General remark:

As our range of products is very large, measurements cannot be carried out for every form of delivery of a group of products. Random samples of different items of every group of products were tested and still are tested in a predefined procedure. Furthermore we make sure that generally only such raw materials are employed for the group of products the suitability of which has been proven. Our statements are based on the conformity documents made available by our suppliers, calculations carried out and migration tests carried out by us or a third party ("supporting documents"). It is the customer's own responsibility to test the suitability of plastic items manufactured from or with our products for the planned application in the foodstuff industry, that is to say:

- testing, if the physical characteristics of the plastic are suitable for the planned application,
- testing, if plastic parts manufactured by the customer fulfill the prescribed migration values,
- testing for possible influence of the plastic on the chemical composition and/or organoleptic characteristics of the foodstuffs,
- testing, if legal requirements are adhered to,
- necessity to remove the exterior extrusion bare layer of semi-finished products,
- necessity to clean the parts produced for application in contact with food in a suitable way before their first use.

The information above is based on the current state of our knowledge and does not constitute any guaranty. We are not liable for completeness and correctness of information contained herein. Existing laws and regulations must be respected by the receivers/users of our products in their own responsibility.

This declaration is reevaluated in case of modifications of directives and laws, raw materials compositions, manufacturing procedures or other. In case of modifications, new declarations are published on our website www.roechling.com, earlier declarations automatically become invalid in that case.