

UNIKA DANMARK A/S bekræfter hermed at nedenstående produkt POM er i overensstemmelse med de nævnte forordninger.



Declaration of Compliance

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

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Product: Sustarin C FG, natural and black coloured (POM-C)

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

- (EC) No 1935/2004 of the European Parliament and the Council dated 27th October 2004 applicable for materials and goods destined to come into contact with foodstuffs and for revocation of the 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 22nd of August 2011 (BGBl. I p. 1770), last amendment by article 1 of the Directive of 3 August 2012 (BGBl. P. 1708), §§ 30 and 31

Furthermore the product meets the requirements of

- (EC) No 10/2011 of the Commission dated 14th of January 2011 on plastic materials and articles to come into contact with food, Gazette of the European Communities L 21/1 dated 15/01/2011, last amendments by Commission Regulations (EU) No 1282/2011 dated 28 November 2011 and (EU) No 1183/2012 dated 30. November 2012.
- Decree on Consumer Goods in the version of the communication of 23rd of December 1997 (BGBl. 1998 I p.5), last modification by Article 5 of the Decree of 13th of December 2011 (BGBl. I p. 2720).

with regard to the composition and 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 December 2006 applicable for the good manufacturing practice for materials and goods destined to come into contact with foodstuffs.

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 migration do not exceed the legal limits set out in directive (EC) No 10/2011 when used as specified in table 1.

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Table 1 - Determination of migration behavior

Testing simulant	Testing conditions (time/temperature)	Intended contact with foodstuffs
Acetic acid 3%	10 days at 40°C	Long term contact at temperatures up to room temperature as well as the contact at 70°C for 2 hours and at 100°C over 15 minutes with all types of food except acidic foods with a pH value below 2,5 and the contact at 121°C for 1 hours and at 130°C for 30 minutes with fatty foodstuffs.
Ethanol 10 vol. %	10 days at 40°C	
Ethanol 95% instead of a migration test with fat	4 hours at 60°C (Substitute test for 1 hours at 121°C and 0,5 hours at 130°C)	

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

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

The following substances with restrictions and/or specification are used in the product mentioned above:

Name of the substance	FCM substance No	Restrictions
1,3,5,-trioxane	255	SML = 5,0 mg/Kg
1,3-dioxolane	363	SML = 5,0 mg/Kg
1,4-butanediol	254	SML = 5,0 mg/dm ²
1,4-butanediol formal	254	QMA = 0,05 mg/6 dm ²
melamine (2,4,6-Triamino-1,3,5-triazin)	239	SML = 2,5 mg/Kg
triethylenglykol-bis[3-(3-tert-butyl-4-hydroxy -5-methylphenyl)propionat]	680	SML = 9,0 mg/Kg
formaldehyde	98	SML = 15,0 mg/Kg
tetrahydrofuran	246	SML = 0.6 mg/Kg

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 :

Name of the substance	
salts of stearic acid	glycerol
silicon oil	

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

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The quality Sustarin C FG can be used safely for the manufacture of finished products for companies which are preparing and processing foodstuffs. The finished products may stand in direct contact with all types of food, except acidic foods with a pH value below 2,5, as far as the Sustarin C FG is concerned. The permitted surface to food mass ratio is about 6 dm²/Kg food. It is important that the above mentioned contact times and temperatures are not exceeded.

General remark:

The migration tests by an independent accredited institute according to the regulation 10/2011/EU on the formulation of the material mentioned in this declaration of conformity were performed by using different food simulants. The tests were carried out on samples that were machined out of our semi-finished plastics.

Furthermore, it is made sure that only raw materials with an existing verification of suitability (supporting documents) are being used.

It remains the customer's own responsibility to determine the suitability of the plastic components (made of our materials) for the projected application or application conditions (contact time, contact temperature for the respective type of food stuff).

Besides making sure that the material is suitable for the application in general (e.g. chemical resistance against the used cleaning agents), it remains the customer's own responsibility to make sure that the migration limits are kept, if the actual contact conditions exceed those conditions for "intended contact for foodstuffs" mentioned in this declaration of conformity.

Organoleptic testing:

The determination of color fastness was carried out on all colored material types (on all non-natural colored types) based on the method of testing for colored utensils made of plastics and other polymers of color fastness, 24th Communication on the testing of plastics, Bundesgesundheitsblatt 15 (1972) 285

Water, 3% acetic acid, 10% ethanol and olive oil were used as testing simulants. Result: the colorants do not migrate when coming into contact with the previous mentioned food simulants.

Odor- and taste tests were not carried out, because it is not possible to conduct a representative selection of suitable food stuffs and corresponding contact parameters (temperature/time) for our level of process chain, due to the fact that there are almost unlimited number of possible combinations of food stuffs and contact conditions.

The information above is based on the current state of our knowledge. The recipient / user of our products must pay attention to the existing laws and regulations. This declaration is a subject to reevaluation, if there are changes in laws, regulations and directives, raw materials, formulations, converting processes or similar.

*In case of any changes, new declarations of compliance are published on our website www.roechling.com and the previous declarations of compliance will automatically lose their validity.

Röchling High-Performance Plastics

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