

# FOOD CONTACT

BYK Regulatory Information

## CERACOL 609 N

### Summary

CERACOL 609 N is suitable for food contact applications under the following compositional provisions as indicated below:

Coatings		
Europe	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	No
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
China	GB9685-2016, table A.2 'Coatings'	Yes

This summary only reflects conducted evaluations on existing regulations. It does not exclude compliant use in additional regions or applications.

Please refer to the explanation section below for detailed information on the regulations and assessment criteria considered.

## Explanation

### Coatings

### EUROPE

#### **Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food**

This product is authorized for use as a polymer production aid. Substances used in its manufacture are either listed in Annex I, authorized under national legislation or have been risk-assessed in accordance with Article 19 of this Regulation.

Polymer production aids used in this product, including solvents, fall under Article 6(1) and are subject to national legislation. This product contains the following substances, which must be removed during downstream processing.:

- Solvent naphtha (petroleum), heavy aromatic, CAS No 64742-94-5

For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS). Monitoring the complete removal of this substance is the sole responsibility of the end user.

This product contains the following substance, which is also authorized for use as a food additive under Regulation (EC) No 1333/2008:

- Carnauba wax, E 903

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, the presence of substances listed in Annex II with restrictions is not known or expected. However, substances for which genotoxicity has not been ruled out and which could, under foreseeable conditions of use, migrate from the final material at levels exceeding 0.00015 mg/kg food or food simulant, cannot be definitively excluded. The products are not regularly tested for substances that are neither identified nor reasonably foreseen to be present.

In accordance with our role as manufacturer of substances, and based on information provided to us by raw material suppliers, other non-intentionally added substances (NIAS) which have become known to us are assessed in accordance with internationally recognized scientific principles of risk assessment to ensure compliance with the requirements of Article 3(1)(a) of Regulation (EC) No 1935/2004.

The assessments are carried out under the assumption that this product is used in accordance with BYK's recommendations for food contact applications and/or under normal or foreseeable conditions of use, and assuming 40% solid content and the following parameters: 100% migration, 1 kg of food in contact with 6 dm<sup>2</sup> of packaging material, dry film thickness 12 µm. The use level may be adjusted to reflect variations in coating thickness and solid content.

#### **German BfR Recommendation XIV. Polymer Dispersions**

This product does not meet the compositional requirements of the German BfR Recommendation XIV. Polymer Dispersions

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**USA**

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**21 CFR 175.300 'Resinous and polymeric coatings'**

This product complies with the compositional requirements of 21 CFR 175.300 Resinous and polymeric coatings. This product includes components that are listed in 21 CFR 175.300 as well as components which are cleared under 21 CFR GRAS regulations which may be cross-referenced for use in compliance with 21 CFR 175.300.

The product contains a significant amount of solvent naphtha (petroleum), heavy aromatic. The solvent of this product is not included in this evaluation and must be completely removed by downstream users prior to use in food contact applications.

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**CHINA**

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**GB9685-2016, table A.2 'Coatings'**

The active components of the product is listed in table A.2 (additives for coatings) of the National Food Safety Standard of the People's Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles (GB9685-2016). Therefore, this product can be recommended for use in food contact coatings in China.

Solvents and other formulation aids are not covered by the above statement.

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**General Remarks**

Regulations apply within the context of respective regional framework regulations, e.g. Regulation (EU) No. 1935/2004 and FDA 21 CFR 174.5. Please note that it is the responsibility of both manufacturers of finished food contact articles and downstream business operators to ensure compliance with the applicable migration limits and restrictions of the finished materials or articles under specific real and/or foreseeable conditions of use.

Since traces of unknown processing aids cannot be fully excluded, compliance with general requirements is the responsibility of the end user.

BYK reserves the right to change or update the information without notice. At most, this letter is in effect for three years commencing the date of issue.

**Food Contact Team**  
Regulatory Affairs  
BYK-Chemie GmbH

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*This issue replaces all previous versions*

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