

# FOOD CONTACT

BYK Regulatory Information

## CERAFLOUR 994

### Summary

CERAFLOUR 994 is suitable for food contact applications under the following compositional provisions, provided that its use does not exceed the maximum concentration as indicated below:

Coatings		
EU	Regulation (EU) No. 10/2011	Yes – See explanation
	CoE ResAP (2004) 1	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
China	GB9685-2016, table A.2 'Coatings'	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes

This summary reflects evaluations conducted based on existing regulations. It does not preclude the possibility of compliant use in other regions or applications. The explanations below provide details on the regulations and evaluations considered.

## Explanation

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### Coatings

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#### EUROPE

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

This product is authorized to be used as an additive or a polymer production aid. No specific migration limit applies.

To our knowledge and understanding, additives authorized for use in both food contact plastics and as direct food additives according to Regulations (EC) No 1333/2008 are not present in this product.

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, presence of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out is not known or expected. 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, 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.

Therefore, this product can be considered suitable for use in food contact coatings. Please note that it is the responsibility of both the 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.

#### **CoE ResAP (2004) 1**

Either the product itself, or the monomers and starting substances used in its manufacture, are listed in the Council of Europe Resolution AP (2004) 1, Version February 2009.

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

This product is manufactured with substances permitted by reference to Regulation (EU) No. 10/2011.

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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' for use as an additive to food contact coatings. This product includes components that are listed 21 CFR 178.3860 Release agents, which may be cross-referenced for use in compliance with 21 CFR 175.300.

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**MERCOSUR**

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**GMC Res. No. 39/19 MERCOSUR Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coatings that come into contact with food**

The active components of this product are compositionally compliant with GMC Res. No. 39/19 which allow this product to be recommended for use as an additive in food contact coatings in MERCOSUR member states.

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**CHINA**

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

The product complies with the compositional requirements of table A.2 '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), since its components are listed in table A.2 (Additives for coatings).

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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. 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 deems to be actual 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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