

FOOD CONTACT

BYK Regulatory Information

CERAFLOUR 961

Summary

CERAFLOUR 961 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
Europe	Regulation (EU) N° 10/2011	Yes
	BfR Recommendation XIV	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
China	GB9685-2016, table A.2 'Coatings'	Yes
Japan	Japan Food Sanitation Act Positive List System	Yes
MERCOSUR	GMC Resolution N° 39/19	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

Regulation (EU) No. 10/2011

The product may be used for the manufacturing of materials and articles within the scope of Regulation (EU) N° 10/2011 and its amendments , since the components are fully listed in Annex I, table 1. Specific migration limits (SML) or restrictions do not apply.

BfR Recommendations XIV 'Polymer dispersions'

This product may be used for polymer dispersions for coating commodities intended to come into contact with foods (e.g. adhesives or paper coatings), as its component(s) are listed by reference to Commission Regulation (EU) No 10/2011.

USA

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 for use as a release agent.

China

GB9685-2016, table A.2 'Coatings'

The active component of the product complies with 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 it is listed in table A.2 (additives for coatings).

Japan

Japan Food Sanitation Act Positive List System

The ingredients in this product are listed in Japan's Food Sanitation Act Positive List (PL) system under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370. The restriction for the synthetic resin groups is "dose as needed" for Polymer Groups 1-5.

MERCOSUR

GMC/Res. N° 39/19

The product may be used for the preparation of plastic materials and polymeric coatings intended to contact food according to MERCOSUR GMC/RES. N° 39/19, since the components are fully listed in the positive list of additives. Specific migration limits (SML) or restrictions do not apply.

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.

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This issue replaces all previous versions

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