

FOOD CONTACT

BYK Regulatory Information

CERAFLOUR 925 N

Summary

CERAFLOUR 925 N is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
Europe	Regulation (EU) No. 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 No. 39/19	Yes
	GMC Resolution No. 02/12	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 apply.

BfR Recommendations XIV 'Polymer dispersions'

This product may be used 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 as well as 21 CFR 177.1520 Olefin polymers, which may be cross-referenced for use in compliance with 21 CFR 175.300.

China

GB9685-2016, table A.2 'Coatings'

All the components of this product are listed in the National Standard of the People's Republic of China, Standards for Uses of Additives in Food Contact Materials and Articles (GB9685-2016), Table A.2 – 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 No. 02/12 and GMC Res. No. 39/19

The active components of this product are compositionally compliant with 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 with the polymer components complying with GMC Res No 02/12 MERCOSUR Technical Regulation on the positive list of monomers, other starting substances and polymers authorized for the manufacturing of plastic packaging and equipment in contact with food which allow this product to be recommended for use as an additive in food contact coatings in MERCOSUR member states.

The table below lists only the substances used or known to be present which are relevant to be considered for compliance with the specific migration limits (SML) laid down in GMC Res. No. 39/19 and GMC Res No 02/12:

Ref. No.	CAS-No.	Name	SML
80077	68441-17-8	Polyethylene waxes, oxidised	60 mg/kg
		Barium	1 mg/kg

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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