

FOOD CONTACT

BYK Regulatory Information

CERACOL 615

Summary

CERACOL 615 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		
Europe	Regulation (EU) No. 10/2011	Yes – max 5% (See explanation)
	CoE ResAP (2004) 1	
	German BfR XIV. Polymer dispersions	
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
China	GB9685-2016, table A.2 'Coatings'	Yes
MERCOSUR	GMC Resolution n. 39/19	Adhesive use only

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

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 an additive and/or polymer production aid. No specific migration limit applies.

Polymer production aids used in this product, including solvents, fall under Article 6(1) and are subject to national legislation. 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) and/or any restrictions laid down in national legislation, specifically 21st Amendment to Consumer Goods Ordinance (GIO):

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
123	34590-94-8	Dipropylene glycol monomethyl ether (Group restriction No 37)	5	The mixture must not contain more than: – 0.3 % 2-methoxy-1-propanol (CAS No.: 1589-47-5) and 2-methoxy-1-propyl acetate (CAS No.: 70657-70-4), – 3 % 2-ethoxy-1-propanol (CAS No.: 19089-47-5) and 2-ethoxy-1-propyl acetate (CAS No.: 57350-24-0), – 5 % 2-Propoxy-1-propanol (CAS No.: 10215-30-2) calculated as the sum of the substances.

To the best of 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.

Therefore, this product can be considered suitable for use in food contact coatings. 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.

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.

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 components which are cleared under 21 CFR 178.3710 Petroleum wax, which may be cross-referenced for use in compliance with 21 CFR 175.300.

This product contains solvents which are not considered in the food contact evaluation, and are the responsibility of the downstream user to remove prior to use in food contact applications.

China

GB9685-2016, table A.2 'Coatings'

The active component of the product is listed in GB9685-2016 table A2 'Coatings'. Therefore, the product can be recommended for use in food contact coatings in China.

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

MERCOSUR

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

This product is authorized for use under MERCOSUR GMC Resolution n. 39/19 for use in adhesives, according to GMC 39/19.

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)

Ref.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
95858	-	Refined paraffin waxes derived from synthetic hydrocarbons or low-viscosity petroleum	0.05	Not allowed for use in objects in contact with fatty foods

Therefore, the product is not authorized for use in coatings. In addition, this product contains a component

General Remarks

These 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 is in effect for three years commencing the date of issue.

Food Contact Team
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This issue replaces all previous versions

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