FOOD CONTACT

BYK Regulatory Information

CERACOL 610

Summary

CERACOL 610 is suitable according to the following compositional provisions for food contact applications, as indicated:

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

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.

German BfR XIV 'Polymer Dispersions'

This product complies with the compositional requirements of the German BfR-Recommendation XIV "Polymer Dispersions".

CoE ResAP (2004) 1

The components are listed in the CEPE 'Code of practice for food contact coatings', Edition 4, Version Feb. 2009.

Solvents and other formulation aids are not covered by the food contact status.

USA

21 CFR 175.300 'Resinous and polymeric coatings'

The product complies with the compositional requirements of 21 CFR 175.300. This product includes components that are listed in 21 CFR 178.3710 Petroleum wax, which may be cross-referenced for use under 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 product does not comply with table A.2 "Coatings" 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).

MERCOSUR

GMC Resolutions 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. However this product contains an unlisted solvent with a Boiling Point above 150°C. As such, this product cannot be recommended for use as an additive in polymeric coatings as delivered unless the solvent is completely removed by the downstream user.

The product contains a significant amount of solvent [Solvent naphtha (petroleum), heavy aromatic, with a boiling range from 160 °C – 220°C]. Solvents are currently not regulated by food contact positive lists as it is assumed that solvents evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 should be fulfilled.

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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