

FOOD CONTACT

BYK Regulatory Information

OPTIGEL-CK

Summary

OPTIGEL-CK 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 n. 39/19	Yes
Adhesives		
Europe	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 175.105 'Adhesives'	Yes
China	GB9685-2016, A.5 'Adhesives'	Yes
Plastics		
Europe	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 177.1520 'Olefin polymers'	Yes
China	GB9685-2016, A.1 'Plastics'	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.

German BfR XIV 'Polymer Dispersions'

All components of this product are covered by 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.

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 which are cleared under 21 CFR 184, which may be cross-referenced for use in compliance with 21 CFR 175.300.

China

GB9685-2016, table A.2 'Coatings'

The active components are listed in GB9685-2016 A.2 for coating applications.

MERCOSUR

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 which allow this product to be recommended for use as an additive in food contact plastic material in MERCOSUR member states

Adhesives

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.

USA

21 CFR 175.105 'Adhesives'

The product complies with the compositional requirements of 21 CFR 175.105. This product includes components that are listed in 21 CFR 175.105.

China

GB9685-2016, table A.2 'Coatings'

The active components are listed in GB9685-2016 A.5 for adhesive applications.

Plastics

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.

USA

21 CFR 177.1520 'Olefin polymers'

The product complies with the compositional requirements of 21 CFR 177.1520. This product includes components which are cleared under 21 CFR 184, which may be cross-referenced for use in compliance with 21 CFR 177.1520.

China

GB9685-2016, table A.1 'Plastics'

The active components are listed in GB9685-2016 A.2 for coating applications.

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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