

FOOD CONTACT

BYK Regulatory Information

OPTIGEL-WM

Rheology additive based on an activated phyllosilicate for aqueous systems to generate thixotropic flow behavior.

Summary

OPTIGEL-WM is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	Yes
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
Adhesives		
	Suitable for food contact adhesives	Yes
Europe	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
	German BfR XXXVI 'Paper and board for food contact'	Yes
	USA 21 CFR 175.105 'Adhesives'	Yes
China	GB9685-2016, table A.5 'Adhesives'	Yes

This summary only reflects conducted evaluations on existing regulations. It does not exclude compliant use in additional regions or applications. Explanations below show details on considered regulations and evaluations.

Explanation

Coatings

Europe **Regulation (EU) No. 10/2011**

This product is covered by the compositional requirements of Regulation (EU) No. 10/2011.

German BfR XIV 'Polymer Dispersions'

The product is covered by the compositional requirements of BfR XIV 'Polymer Dispersions'.

CoE ResAP (2004) 1

Either the components themselves or the monomers and starting substances used for manufacturing are covered by the CoE ResAP (2004) 1, Version Feb. 2009.

Therefore, the product can be recommended for use in food contact coatings in Europe.

USA **21 CFR 175.300 'Resinous and polymeric coatings'**

The product is covered by the compositional requirements of Sec. 175.300 'Resinous and polymeric coatings'.

Therefore, the product can be recommended for use in food contact coatings, in regards to Sec. 175.300 of 21 CFR FDA.

China **GB9685-2016, table A.2 'Coatings'**

The active components of OPTIGEL-WM are listed in GB9685-2016 table A2 for coating applications.

Adhesives

Europe **Regulation (EU) No. 10/2011**

This product is covered by the compositional requirements of Regulation (EU) No. 10/2011.

German BfR XIV 'Polymer Dispersions'

The product is covered by the compositional requirements of BfR XIV 'Polymer Dispersions'.

German BfR XXXVI 'Paper and board for food contact'

The product is covered by the compositional requirements of BfR-Recommendation XXXVI 'Paper and board for food contact'.

Therefore, the product can be recommended for use in food contact adhesives in Europe.

USA **21 CFR 175.105 'Adhesives'**

The product is covered by the compositional requirements of Sec. 175.105 'Adhesives'.

Therefore, the product can be recommended for use in food contact adhesives, in regards to Sec. 175.105 of 21 CFR FDA.

China **GB9685-2016, table A.5 'Adhesives'**

The active components of OPTIGEL-WM are listed in GB9685-2016 table A5 for adhesive 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. 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 deems to be actual for three years commencing the date of issue.

Food Contact Team
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