

FOOD CONTACT

BYK Regulatory Information

BYK-P 105

Controlled flocculating wetting and dispersing additive for solvent-borne and solvent-free adhesives as well as ambient-curing resin systems to stabilize fillers.

Technically recommended use level: 0,5 – 1,5%

Summary

BYK-P 105 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	Yes
EU	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'	No
Adhesives		
	Suitable for food contact adhesives	Yes
EU	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'	No

Solvents and other formulation aids are not covered by the food contact status. For further details, please refer to the 'Explanation'.

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

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

The monomers and starting substances used for manufacturing of the product are listed in Annex I – Table I of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food. However, the main active component is not listed as “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in plastics in compliance with this regulation.

German BfR XIV ‘Polymer Dispersions’

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

CoE ResAP (2004) 1

The product is covered by the compositional requirements of CoE ResAP (2004) 1. For this product, either the active components themselves or the monomers and starting substances used for manufacturing are listed in the CEPE ‘Code of practice for food contact coatings’, Edition 4, Version Feb. 2009.

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

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 Title 21 CFR (FDA) Regulations for indirect food additives. The components are fully listed under section 175.300, but restrictions apply.

Therefore, the product can be recommended for use in food contact coatings in regards to Sec. 175.300, as described above.

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

China **GB9685-2016, table A.2 ‘Coatings’**

The product does not comply with 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).

Adhesives

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

The monomers and starting substances used for manufacturing of the product are listed in Annex I – Table I of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food. However, the main active component is not listed as “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in plastics in compliance with this regulation.

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 XXXVI ‘Paper and board for food contact’.

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

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

USA **21 CFR 175.105 ‘Adhesives’**

The product can be used in compliance with the requirements of FDA 21 CFR 175.105. The components are fully listed under section 175.105, but restrictions apply.

Therefore, the product can be recommended for use in food contact adhesives in regards to Sec. 175.105, as described above.

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

China **GB9685-2016, table A.5 ‘Adhesives’**

The product does not comply with 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).

Solvents

The product contains ca. 2% of a volatile organic compound (boiling point ca. 146°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. 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
Regulatory Affairs
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