

FOOD CONTACT

BYK Regulatory Information

BYK-3740

Summary

BYK-3740 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	See explanation
	German BfR XIV 'Polymer Dispersions'	Yes
	CoE ResAP (2004) 1	No
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes (0.35%)
China	GB9685-2016, table A.2 'Coatings'	No
Solvents and other formulation aids are not covered by the food contact status		

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 active polymeric silicone component as such is not listed as a “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive.

However, this product is used as a polymer production aid (PPA) in accordance with the definitions of Regulation (EU) No 10/2011, even though it is not listed as such, if a technical effect is achieved only in the application process, and the product may be present, but is neither intended to be present in the finished materials or articles nor does it have a physical or chemical effect in the final material or article. PPAs other than those listed in the Union list may be used to manufacture plastics, subject to national legislation. The final decision regarding the concerned use (“polymeric additive” or PPA) is depending on the use application and falls into the responsibility of the manufacturer of the final product.

German BfR XIV ‘Polymer Dispersions’

The product complies with the compositional requirements of BfR XIV ‘Polymer Dispersions’.

CoE ResAP (2004) 1

The active silicon component of this product is not fully covered by the CoE ResAP (2004) 1, 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 can be used in compliance with the requirements of FDA 21 CFR 175.300, if used as recommended below. Based on studies and external consultation, we recommend following use conditions:

- Max. use level of 0.35% in wet coating formulations;
- For formulations with a solid content of 40% and a dry thickness of 12 µm;
- The use level can be adapted for deviating thickness and solid content.

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

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

The active components of the product are not listed in GB9685-2016.

Therefore, the product cannot be recommended for use in food contact coatings in China.

Solvents The product contains a significant amount of solvent with an initial boiling point of > 160°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 and 174.5 of 21 CFR FDA 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.

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