

FOOD CONTACT

BYK Regulatory Information

BYK-3755

Silicone-containing surface additive for solvent-borne coating systems with a medium reduction in surface tension and a medium increase in surface slip.

Technically recommended use level: 0.1 – 0.3%

Summary

BYK-3755 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
Europe	Suitable for food contact coatings	Yes
	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 (max. 2.2 %)
China	GB9685-2016, table A.2 'Coatings'	No
MERCOSUR	GMC Resolution n. 39/19	No
	GMC Resolution n. 02/12	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

Europe

Regulation (EU) No. 10/2011

The main active component is 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 (including all amendments).

German BfR XIV ‘Polymer Dispersions’

The active component of the product is conform with the compositional requirements of the German BfR-Recommendation XIV “Polymer Dispersions”

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 CoE ResAP (2004) 1, Version Feb. 2009.

Dual use additive

The product contains a ‘dual use additive’ (< 0.02 %) for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0).

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

Solvents and 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 the “no migration exemption”, we recommend following use conditions:

- Max. use level of 2.2 % in wet coating formulations
- For formulations with a solid content of 40% and a dry film thickness of 12 µm
- The use level can be adapted for deviating film thickness and solid content.

Solvents and 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).

MERCOSUR GMC Resolutions n. 39/19 & 02/12

The product does not comply with the compositional requirements of MERCOSUR GMC Resolution n. 39/19 and MERCOSUR GMC Resolution n. 02/12.

Therefore, the product is not authorized for use in coatings.

Solvents

The product contains a significant amount of solvents (see SDS). 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 CFR 21 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.

Food Contact Team
Regulatory Affairs
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This issue replaces all previous versions - Printed in Germany.

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