FOOD CONTACT

BYK Regulatory Information

BYK-3754

Silicone surface additive for solvent-borne, solvent-free and aqueous coating systems with a strong reduction in the surface tension. Excellent substrate wetting, prevents cratering and increases surface slip.

Summary

BYK-3754 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. 0.08 %)
China	GB9685-2016, table A.2 ‘Coatings’	No

Solvents and 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 component of this product (Polyether modified polydimethylsiloxane) is evaluated as SCF-list 0-4 and directly 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.

German BfR XIV 'Polymer Dispersions'

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

CoE ResAP (2004) 1

The product complies with the compositional requirements of CoE ResAP (2004) 1.

Dual use additive

The product contains a 'dual use additive' (< 0.1 %) for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0).

Therefore, the product can be recommended for 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 studies and external consultation, we recommend following use conditions:

- Max. use level of 0.08 % 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 formulation aids are not covered by the food contact status.

China

GB9685-2016, table A.2 'Coatings'

Not all components of the product are listed in GB9685-2016.

Solvents
The product contains a significant amount of solvent [see SDS for more info]. 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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This issue replaces all previous versions

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