

FOOD CONTACT

BYK Regulatory Information

BYK-077

Silicone-containing leveling additive with good defoaming properties for solvent-borne coating systems.

Technically recommended use level: 0.05 – 0.6%

Summary

BYK-077 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	Suitable for food contact coatings	Yes (max: 0.08%)
	Regulation (EU) No. 10/2011	Yes (max: 0.08%)
	German BfR XIV 'Polymer Dispersions	Yes (max: 0.08%)
	CoE ResAP (2004) 1	Yes (max: 0.08%)
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes (max: 0.1%)
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 product complies with the compositional requirements of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food, when a maximum use level of 0.08% is maintained.

German BfR XIV 'Polymer Dispersions'

The product complies with the compositional requirements of the German BfR-Recommendations XIV 'Polymer Dispersions', when a maximum use level of 0.08% is maintained.

CoE ResAP (2004) 1

The product is conform with the compositional requirements of the Council of Europe Framework Resolution ResAP (2004) 1 on coatings intended to come into contact with foodstuffs.

Therefore, the product can be recommended for food contact coatings in the EU, with a maximum use level of 0.08%.

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 the "no migration exemption", we recommend following use conditions:

- Max. use level of 0.1% 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 other formulation aids are not covered by the food contact status.

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

The active components of BYK-077 are not listed in GB9685-2016 table A2.

Solvents

The product contains a significant amount of solvents. For more information about the solvents, please refer to the Safety Data Sheet. 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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