

FOOD CONTACT

BYK Regulatory Information

BYK-011

Process Silicone-free, polymer-based defoamer for aqueous coating systems (also radiation curable systems). Particularly recommended for two pack polyurethane systems. Very good re-coatability.

Technically recommended use level: 0.1 – 2.5%

Summary

BYK-011 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	Yes (0.2%)
EU	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	Yes (0.2%)
	CoE ResAP (2004) 1	Yes (0.2%)
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes (0.2%)
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 main active 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 in compliance with this regulation.

German BfR XIV ‘Polymer Dispersions’

For this product, either the components themselves or the monomers and starting substances used for manufacturing, with the exception of the defoamer, are covered by the German BfR-Recommendation XIV. ‘Plastic Dispersions’.

For the defoamer, an EFSA opinion is available, describing a restricted use in coating formulations.

CoE ResAP (2004) 1

For this product (excluding the active defoamer component), either the 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.

For the defoamer, an EFSA opinion is available, describing a restricted use in coating formulations.

The product can be used in compliance with the requirements of coating-use in the EU, if used as recommended below. Based on the “no migration exemption”, we recommend following use conditions:

- Max. use level of 0.2% 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 other formulation aids are not covered by above statement.

US 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 0.2% 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 other formulation aids are not covered by above statement.

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), table A.2 'Coatings'.

Solvents The product contains a significant amount of solvents [see SDS for more information about the solvents]. 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
BYK-Chemie GmbH

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