

FOOD CONTACT

BYK Regulatory Information

BYK-325 N

Silicone-containing surface additive for solvent-borne coatings to improve leveling, with a slight reduction in surface tension and minor increase in surface slip.

Technically recommended use level: 0.05 - 0.6%

Summary

BYK-325 N is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings based on national regulations	
EU	Regulation (EU) No. 10/2011	No
	BfR XV. 'Silicones'	Yes
USA	21 CFR 175.300	No
China	GB9685-2016	No

Solvents and other formulation aids are not covered by above statement.

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. The monomers/starting substances used for the manufacturing of the product are listed in EU/10/2011, or considered 'out of scope' with Regulation EU/10/201, or are listed in national regulations.

BfR XV. 'Silicones'

The siloxane starting substance used for the manufacturing of the active ingredient is listed within BfR XV. 'Silicones'.

Therefore, BYK-325 N can be recommended for use in coatings in the EU.

Solvents and other formulation aids are not covered by above statement.

USA**21 CFR 175.300 Resinous and polymeric coatings**

The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives.

The components are not fully listed under sections 175.300 or 175.320.

China**GB9685-2016 “National Food Safety Standard of the People’s Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles”**

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).

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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