

FOOD CONTACT

BYK Regulatory Information

BYK-300

Summary

BYK-300 is suitable for food contact applications under the following compositional provisions, provided that its use does not exceed the maximum concentration as indicated below:

Coatings		
Europe	Regulation (EU) No. 10/2011	Yes – max. 0.3%
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes – max. 0.08%
China	GB9685-2016, table A.2 'Coatings'	No
Japan	Japan Food Sanitation Act Positive List System	No
MERCOSUR	GMC Resolution n. 39/19	No
	GMC Resolution n. 02/12	No

This summary reflects only the regulations assessed to date and does not preclude permitted uses in other regions or applications. Please refer to the explanation section below for detailed information on the regulations and assessment criteria considered.

Explanation

Coatings

EUROPE

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as amended as of the date of this document

This product may be used as an additive or as a polymer production aid. No specific migration limit (SML) applies.

Polymer production aids, including solvents, and aids to polymerization used in this product are either listed in national legislation or subject to risk assessment in accordance with Article 19 of this Regulation. This product contains the following substances, which must be removed during downstream processing:

- Xylene, mixture of isomers (CAS No. 1330-20-7)
- Ethylbenzene (CAS No. 100-41-4)
- Iso-butanol (CAS No. 78-83-1)

For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS). Monitoring the complete removal of this substance is the sole responsibility of the end user.

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, residues of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out are not known or expected to be present in concentration exceeding the specific migration limits established by this regulation. Testing is not routinely performed for substances that are neither identified nor reasonably expected to be present.

In accordance with our role as a manufacturer of substances, non-intentionally added substances (NIAS) which have become known to us are assessed in accordance with internationally recognized scientific principles of risk assessment to ensure compliance with the requirements of Article 3(1)(a) of Regulation (EC) No 1935/2004.

The assessments are carried out under the assumption that this product is used in accordance with BYK's recommendations for food contact applications and/or under normal or foreseeable conditions of use, considering 40% solid content and the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, dry substrate weight of 12 g/m². The use level may be adjusted to reflect variations in coating thickness and solid content.

USA

21 CFR 175.300 'Resinous and polymeric coatings'

The product complies with the compositional requirements of 21 CFR 175.300 Resinous and polymeric coatings. This product includes components that are listed in 21 CFR 175.300 and substances which are Generally Recognized As Safe (GRAS) subject to a

legal opinion allowing use in coatings on metal substrates in accordance with 21 CFR 175.300 under the 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
- As a component of can coatings that will contact aqueous, acidic, alcoholic (up to 50% ethanol content), and dry foods under temperatures corresponding to FDA's Conditions of Use B ("boiling water sterilized").
- The use level can be adapted for deviating thickness and solid content

This product has been evaluated for use in food contact formulations for the general population and may not be appropriate for sensitive applications, such as infant formula and human milk or medical devices.

This product contains solvents which are not considered in the food contact evaluation and are the responsibility of the downstream user to remove prior to use in food contact applications.

China

GB9685-2016, table A.2 'Coatings'

The product does not comply with table A.2 'Coatings' of 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).

Japan

Japan Food Sanitation Act Positive List System

The ingredients in this product does not comply with Japan's Food Sanitation Act Positive List (PL) system under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370.

MERCOSUR

GMC Res No 02/12 and GMC Res. No. 39/19

The active components of this product are not compliant with GMC Res. No. 39/19 MERCOSUR Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coatings that come into contact with food with the polymer components complying with GMC Res No 02/12 MERCOSUR Technical Regulation on the positive list of monomers, other starting substances and polymers authorized for the manufacturing of plastic packaging and equipment in contact with food.

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. Please note that it is the responsibility of both manufacturers of finished food contact articles and downstream business operators to ensure compliance with the applicable migration limits and restrictions of the finished materials or articles under specific real and/or foreseeable conditions of use.

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 is in effect for three years commencing the date of issue.

Food Contact Team
Regulatory Affairs
BYK-Chemie GmbH

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This issue replaces all previous versions

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