FOOD CONTACT

BYK Regulatory Information

BYK-392

Summary

BYK-392 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	No
	German BfR XIV 'Polymer Dispersions'	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes - max 0.2%
China	GB9685-2016, table A.2 'Coatings'	No
Japan	Japan Food Sanitation Act Positive List System	Yes

This summary only reflects conducted evaluations on existing regulations. It does not exclude compliant use in additional 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

This product does not meet the compositional requirements laid down in Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

German BfR Recommendation XIV. Polymer Dispersions

This product is manufactured with substances permitted under BfR Recommendation XIV. Polymer Dispersions.

To enable downstream business operators to ensure compliance with Article 3 of Regulation (EC) No 1935/2004, this product contains the following substance(s) listed in national legislation with a Specific Migration Limit (SML) and/or restrictions:

- 1-Methoxy-2-propanol (CASRN 108-65-6)

Please note that it is the sole responsibility of downstream business operators to ensure that solvents are completely removed during downstream processing. For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS).

In accordance with our role as manufacturer of substances, and based on information provided to us by raw material suppliers, 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) allowing use in coatings on metal substrates in accordance with 21 CFR 175.300 under the following use conditions:

- Use level up to 0.2 weight % of this product in the wet coating formulation for formulations with a solid content of 40 %
- This anticipates a film thickness of 12 µm (0.5 mil).

- For coatings with other dry mass/ film thickness the use level may be adapted accordingly.

The solvent of this product is not included in this evaluation and must be completely removed by downstream users prior to use in food contact applications. 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.

MERCOSUR

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

The active components of this product are compositionally 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, and 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 which allow this product to be recommended for use as an additive in food contact coatings in MERCOSUR member states.

Please note that it is the responsibility of both the 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.

CHINA

GB9685-2016, table A.2 'Coatings'

This 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 for coatings application.

JAPAN

Japan Food Sanitation Act Positive List System

The ingredients in this product are listed in Japan's Food Sanitation Act Positive List (PL) system under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370. The restriction for the synthetic resin groups is "dose as needed" for Polymer Groups 1-5.

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.

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This issue replaces all previous versions

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