

FOOD CONTACT

BYK Regulatory Information

BYK-310

Summary

BYK-310 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%
	German BfR XIV ‘Polymer Dispersions’	No
USA	21 CFR 175.300 ‘Resinous and polymeric coatings’	Yes - max 0.32%
China	GB9685-2016, table A.2 ‘Coatings’	Yes - max. 0.1% on dry coating film
Japan	Japan Food Sanitation Act Positive List System	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes – max. 0.3% (see explanation)
	GMC Resolution n. 02/12	Yes – max. 0.3% (see explanation)

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 is manufactured with monomers and other starting substances listed in Annex I - Table I of Regulation (EU) No 10/2011 or subject to derogation as per Article 6(3).

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.

The table below lists only substances that are used or known to be present and that are relevant for compliance with the specific migration limits (SML) and/or any restrictions set out in Annex I of this Regulation or in national legislation. For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS).

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
381	1330-20-7	Xylene	1	n.a.
139	100-41-4	Ethylbenzene	0,6	n.a.

n.a.: not applicable

To the best of our knowledge and understanding, additives authorized for use in both food contact plastics and as direct food additives according to Regulations (EC) No 1333/2008 are not present in this product.

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, the presence of substances listed in Annex II with restrictions is not known or expected. Substances for which genotoxicity has not been ruled out, and which could migrate from the final material under foreseeable conditions of use at levels exceeding 0.00015 mg/kg of food or food simulant, cannot be definitively excluded.

To enable downstream business operators to ensure compliance with Article 3 of Regulation (EC) No 1935/2004, this product contains up to 61 ppm of dibutyltin dilaurate (CAS-No 77-58-7), which is not intended to remain in the final polymer. Any residue in the intermediate materials or final articles shall be assessed by downstream business operators in accordance with internationally recognized scientific principles on risk assessment. The products are not regularly tested for substances that are neither identified nor reasonably foreseen to be present.

In accordance with our role as manufacturer of substances, and based on information provided to us by raw material suppliers, other 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, and assuming 40% solid content and the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, dry film thickness 12 µm. The use level may be adjusted to reflect variations in coating thickness and solid content.

Therefore, this product can be considered suitable for use in food contact coatings. 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.

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 a legal opinion supporting the safe use of this product in food contact coatings as follows:

- Use level up to 0.32 weight % BYK-310 in the wet coating formulation (for a solid content of 40 %; corresponding to a concentration of 0.8 % BYK-310 in the dried coating).
- The film thickness may not exceed 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.

CHINA

GB9685-2016, table A.2 'Coatings'

The active component of the product is listed in table A.2 (additives for 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), with restrictive use.

Therefore, the product can be recommended for use in food contact coatings in China, with a maximum use level of 0.1% solid on dry coating film.

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. Please contact separately for use Limit by Synthetic Resin Group (%).

MERCOSUR

GMC Res. No. 39/19 and 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 Positive List of Monomers, Polymers, and Starting Substances which allow this product to be recommended for use as an additive in food contact coatings in MERCOSUR member states.

The table below lists only the substances used or known to be present which are relevant to be considered for compliance with the specific migration limits (SML) laid down in GMC Res. No. 39/19 and GMC Res No 02/12:

Ref. No.	CAS-No.	Name	SML
M35	1330-20-7	Xylene	SML = 1.2 mg/kg Only for use in: a) Adhesives; b) Polymeric and resinous coatings
53255	100-41-4	Ethylbenzene	SML = 0.6 mg/kg, only for use in polymeric and resinous coatings

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.

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, and assuming 40% solid content and the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, dry film thickness 12 µm. The use level may be adjusted to reflect variations in coating thickness and solid content.

Therefore, this product can be considered suitable for use in food contact coatings. 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.

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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