

FOOD CONTACT

BYK Regulatory Information

BYK-054

Summary

BYK-054 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. 1% (see explanation)
	CoE ResAP (2004) 1	No
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes - 0.52% (see explanation)
MERCOSUR	GMC Resolution n. 39/19	No - See explanation
	GMC Resolution n. 02/12	No - See explanation

This summary reflects evaluations conducted based on existing regulations. It does not preclude the possibility of compliant use in other regions or applications. The explanations below provide details on the regulations and evaluations 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 authorized for use as an additive or polymer production aid. No specific migration limit applies.

Polymer production aids used in this product, including solvents, fall under Article 6(1) and are either subject to national legislation or to risk assessment in accordance with Article 19 of this Regulation. It is the responsibility of downstream business operators to ensure that any solvents present in this product are completely removed from intermediate or finished materials or articles. For further information, please refer to the Safety Data Sheet (SDS).

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, presence of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out is not known or expected. 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, 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 conducted 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 in formulations with a solid content of 40% w/w, and considering the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, dry film thickness of 12 µm.

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

Council of Europe Resolution AP (2004) 1

Neither the active components themselves nor the monomers/starting substances used for manufacturing are listed in the Council of Europe Resolution AP (2004) 1, Version February 2009.

USA

21 CFR 175.300 'Resinous and polymeric coatings'

This 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 as well as components which are cleared under 21 CFR 178.3530 Isoparaffinic petroleum hydrocarbons, synthetic, which may be cross-referenced for use in compliance with 21 CFR 175.300.

This product also includes a component that is cleared under a US Food Contact Notification (FCN). Subject to this FCN, coatings containing this product may be used for single-use applications in contact with all food types under Conditions of Use A through H as described in 21 CFR 176.170(c), Table 2. This product is not for use in contact with infant formula and human milk. This product is for use at a level not to exceed 0.52 weight percent in finished food contact coatings.

MERCOSUR

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

The active components of this product are compositionally compliant with GMC Res. No. 39/19. The solvent used in this product is not compliant with MERCOSUR GMC Resolution n. 02/12 and GMC Resolution 39/19 and has a Boiling Point above 150°C. As such, this product cannot be recommended for use as an additive in polymeric coatings as delivered unless the solvent is completely removed by the downstream user.

CHINA

GB9685-2016, table A.2 'Coatings'

The product complies with the compositional requirements of 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).

Solvents and other formulation aids are not covered by the food contact status.

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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