

FOOD CONTACT

BYK Regulatory Information

BYK-A 535

Summary

BYK-A 535 is suitable according to the following compositional provisions for food contact applications, provided that its use does not exceed the maximum concentration as indicated below:

Adhesives		
EU	Regulation (EU) No. 10/2011	Yes – max 1.5% (see explanation)
	German BfR XIV ‘Polymer Dispersions’	Yes
USA	21 CFR 175.105 ‘Adhesives’	Yes – max 0.52%
China	GB9685-2016, table A.5 ‘Adhesives’	No
Printing inks		
Europe	21 st Amendment to Consumer Goods Ordinance (GIO)	Yes – max 1.5% (see explanation)
	Swiss Ordinance 817.023.21	
Industry	Nestlé Standard “Printing Inks for Food Packaging”	Yes
	EuPIA Exclusion Policy	Yes

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

Adhesives

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 as a polymer production aid.

Substances used in its manufacture are either listed in Annex I, and/or authorized in national legislation, and/or have been risk assessed in accordance with Article 19 of this Regulation. No Specific Migration Limits (SML) apply.

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 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 considering the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, substrate weight of 15 g/m²

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

Adhesives 21 CFR 175.105

This product complies with the compositional requirements of 21 CFR 175.105. 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 dry food contact coatings. Therefore, the product can be

recommended for use in food contact adhesives in compliance with 21 CFR 175.105 Adhesives.

China

GB9685-2016, table A.5 'Adhesives'

Not all active components of BYK-A 535 are listed in GB9685-2016. Therefore, this product cannot be recommended for use in adhesives in China.

Printing Inks

EUROPE

21st Amendment to Consumer Goods Ordinance (GIO)

Intentionally added substances in this product are either listed in Annex 14, Table 1 of the GIO, subject to derogation under §4, Abs. 5, Sentence 5 ("salt rule"), or are included in Regulation (EU) No 10/2011 without any restrictions indicated in columns 9 and/or 10. No Specific Migration Limits (SML) apply.

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, and considering the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, substrate weight of 15 g/m².

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

Swiss Ordinance 817.023.21

Intentionally added substances in this product are either listed in Annex 2 and/or Annex 10 of Swiss Ordinance 817.023.21 (version January 1, 2025), subject to Article 35(b), or are not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR). No Specific Migration Limits (SML) apply.

Therefore, this product can be considered suitable for use in food contact packaging inks that are not in contact with food (non-direct food contact inks). Additional information regarding limitations, restrictions and/or specifications is available in the German Ink Ordinance section.

Industry

Nestlé Standard “Printing Inks for Food Packaging” (02/04/2024)

None of the intentionally added substances in the product are listed in the exclusion and/or minimisation lists of the Nestlé Standard “Printing Inks for Food Packaging” (version St-80.001-01 of 02/04/2024). Therefore, the use of this product does not prevent downstream business operators from fulfilling the relevant requirements set forth in the aforementioned Nestlé Standard.

EuPIA Exclusion Policy for printing inks and related products (April 2025)

The classification and composition of this product allows the formulation of printing inks in accordance with the EuPIA Exclusion Policy.

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

Food Contact Team
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This issue replaces all previous versions

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