

FOOD CONTACT

BYK Regulatory Information

BYK-1719

Summary

BYK-1719 is suitable for food contact applications under the following compositional provisions, provided that its use does not exceed the maximum concentration as indicated below:

Adhesives		
Europe	Regulation (EU) No. 10/2011	Yes – max. 1 % (see explanation)
	German BfR XIV ‘Polymer Dispersions’	
USA	21 CFR 175.105 ‘Adhesives’	Yes
China	GB9685-2016, table A.5 ‘Adhesives’	No
Paper and paperboard		
Europe	German BfR XXXVI ‘Paper and paperboard in contact with food’	Yes – max. 1 % (see explanation)
Printing inks		
Europe	21 st Amendment to Consumer Goods Ordinance (GIO)	Yes – max. 1 % (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. No specific migration limit applies.

Polymer production aids used in this product are either listed in Annex I, authorized under national legislation, or have been risk assessed in accordance with Article 19 of this Regulation.

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.

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.

German BfR Recommendation XIV. Polymer Dispersions

This product is manufactured with substances permitted by reference to Regulation (EU) No. 10/2011.

USA

21 CFR 175.105 'Adhesives.'

The product complies with the compositional requirements of 21 CFR 175.105 Adhesives. This product includes components that are listed in 21 CFR 175.105.

Therefore, the product can be recommended for use in food contact adhesives in compliance with 21 CFR 175.105 Adhesives. As per the limitations outlined in that regulation, the final adhesive must either be separated from the food by a functional barrier or used subject to the following additional limitations:

- In dry foods: The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.
- In fatty and aqueous foods:
 - The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.
 - Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement “food-packaging adhesive”.

China

GB9685-2016, table A.5 ‘Adhesives’

Not all active components of BYK-1719 are listed in GB9685-2016.

Paper and Paperboard

EUROPE

German BfR XXXVI ‘Paper and board for food contact’

This product is permitted for use as a sizing agent in accordance with BfR Recommendation XIV. Polymer Dispersions, and as a surface refining and coating agent, as it is manufactured using substances authorized under Regulation (EU) No. 10/2011.

Printing inks

EUROPE

21st Amendment to Consumer Goods Ordinance (GIO)

This product is authorized for use in the manufacture of printing inks intended for food contact applications, as its components are either listed 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 limit (SML) applies.

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 packaging 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

This product is authorized for use in the manufacture of printing inks intended for food contact applications, as its components 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).

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

These 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.

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This issue replaces all previous versions

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