

FOOD CONTACT

BYK Regulatory Information

BYK-1790

Summary

BYK-1790 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:

Coatings		
Europe	Regulation (EU) No. 10/2011	Yes – max 0.7% (see explanation)
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes – max 1%
China	GB9685-2016, table A.2 'Coatings'	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes
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 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 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

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:

- Max. use level of 1 % in wet coating formulations

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- For formulations with a solid content of 40% and a dry thickness of 12 µm
 - The use level can be adapted for deviating thickness and solid content

This product has been evaluated for use in food contact formulations for the general population and is not recommended for sensitive applications, such as infant formula and human milk.

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).

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. Therefore this product can be recommended for use in food contact coatings in MERCOSUR member states.

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 used substances in the product are listed in the exclusion lists 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 the above-mentioned product is not an obstacle for the compliance to the Nestlé Standard “Printing Inks for Food Packaging”.

EuPIA Exclusion Policy (April 2025)

The classification and composition of the above-mentioned product allows the formulation of printing inks in compliance 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. 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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