FOOD CONTACT

BYK Regulatory Information

BYK-352

Summary

BYK-352 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 %
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
China	GB9685-2016, table A.2 'Coatings'	No
Japan	Japan Food Sanitation Act Positive List System	Yes
MERCOSUR	GMC Resolution n. 39/19	See explanation
	GMC Resolution n. 02/12	See explanation

Printing inks		
Europe	21st Amendment to Consumer Goods Ordinance (GIO)	Yes – max 1 %
	Swiss Ordinance 817.023.21	
Industry	Nestlé Standard "Printing Inks for Food Packaging"	Yes
	EuPIA Charter	Yes

This summary reflects only the regulations assessed to date and does not preclude permitted uses in other 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, as amended as of the date of this document

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 are subject to risk assessment in accordance with Article 19 of this Regulation.

This product contains the following substance(s) listed in national legislation with a Specific Migration Limit (SML) and/or restrictions:

- 1-Methoxy-2-propanol (CASRN 107-98-2)

Please note that it is the sole responsibility of downstream business operators to ensure that solvents are completely removed during downstream processing. For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS). Monitoring the complete removal of this substance is the sole responsibility of the end user.

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, residues of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out are not known or expected to be present in concentration exceeding the specific migration limits established by this regulation. Testing is not routinely performed for substances that are neither identified nor reasonably expected to be present.

In accordance with our role as a manufacturer of substances, 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, considering 40% solid content and the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, dry substrate weight of 12 g/m². The use level may be adjusted to reflect variations in coating thickness and solid content.

BfR Recommendations XIV. Polymer dispersions

This product may be used in accordance with BfR Recommendation XIV, as it is manufactured with substances authorized under Regulation (EU) No. 10/2011.

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.

This product contains solvents which are not considered in the food contact evaluation, and are the responsibility of the downstream user to remove prior to use in food contact applications.

China

GB9685-2016, table A.2 'Coatings'

The product does not comply with 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).

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. The restriction for the synthetic resin groups is "dose as needed" for Polymer Groups 1-5.

MERCOSUR

GMC Res No 02/12 and GMC Res. No. 39/19

The active components of this product are compositionally compliant with GMC Res No 02/12 MERCOSUR Technical Regulation on the positive list of monomers, other starting substances and polymers authorized for the manufacturing of plastic packaging and equipment in contact with food. However the product contains a solvent, 1-Methoxy-2-propanol, which is only allowed according to GMC Res. No. 39/19 for use in adhesives. As such, this product cannot be recommended for use as an additive in polymeric coatings.

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 Annex I of Regulation (EU) No 10/2011 without any restrictions indicated in columns 9 and/or 10.

The table below lists only the substances used or known to be present that are relevant for compliance with the specific migration limits (SML) and/or any restrictions laid down in the German Ink Ordinance and/or Regulation (EU) No 10/2011:

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
431	107-98-2	1-Methoxy-2-propanol (Group restriction No 37)	5	Please refer to the provisions laid down in the German Ink Ordinance

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.

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, 2026), subject to Article 35(b), or are not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR).

The table below lists only the substances used or known to be present that are relevant for compliance with the specific migration limits (SML) and/or any restrictions laid down in Annex 10 and/or Annex 2 of this Ordinance:

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
431	107-98-2	1-Methoxy-2-propanol (Group restriction No 37)	5	Please refer to the provisions laid down in the Swiss Ordiance Annex 10

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).

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).

EuPIA Exclusion Charter (March 2026)

The product intentionally does not contain any of the substances listed in Annexes 1 and 2 of the 'EuPIA Charter on Raw Material Selection and Exclusion for Printing Inks and Related Products' (March 2026). The product itself as raw material is not classified and labeled with any of the Hazard Statements for Group I or Group II substances as defined in the section 'Selection Criteria & Procedures'

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.

Food Contact Team
Regulatory Affairs
BYK-Chemie GmbH

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This issue replaces all previous versions

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