

FOOD CONTACT

BYK Regulatory Information

BYK-4510

Summary

BYK-4510 is suitable for food contact applications under the following compositional provisions as indicated below:

Coatings		
Europe	Regulation (EU) No 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
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
	Swiss Ordinance 817.023.21	
Industry	Nestlé Standard "Printing Inks for Food Packaging"	Yes
	EuPIA Charter	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 manufactured with monomers and other starting substances listed in Annex I - Table I of Regulation (EU) No 10/2011 and/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 108-65-6)

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).

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, other 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 assuming 40% solid content and the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, dry film thickness 12 µm. The use level may be adjusted to reflect variations in coating thickness and solid content.

German BfR Recommendation XIV. Polymer Dispersions

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

USA

21 CFR 175.300 ‘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.

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.

MERCOSUR

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

The active components of this product are compositionally compliant with 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 with the polymeric components complying 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.

CHINA

GB9685-2016, table A.2 ‘Coatings’

The active components of BYK-4510 are listed in GB9685-2016 table A2 for coating applications.

Therefore, the product can be recommended for use in food contact coatings 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.

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 the 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 Ordinance 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.

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This issue replaces all previous versions

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