FOOD CONTACT

BYK Regulatory Information

BYK-306

Summary

BYK-306 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 0.5%
	German BfR XIV ‘Polymer Dispersions’	
USA	21 CFR 175.300 ‘Resinous and polymeric coatings’	Yes – max 0.26%
China	GB9685-2016, table A.2 ‘Coatings’	No

Printing inks		
Europe	21st Amendment to Consumer Goods Ordinance (GIO)	Yes – max 0.5%
	Swiss Ordinance 817.023.21	
Industry	Nestlé Standard “Printing Inks for Food Packaging”	See explanation
	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 may be used as an additive or a polymer production aid. The table below lists only substances that are used or known to be present and that are relevant for compliance with the specific migration limits (SML) and/or any restrictions set out in Annex I of Regulation (EU) No 10/2011:

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
315	128-37-0	2,6-di-tert-butyl-p-cresol	3	/

Polymer production aids, including solvents, in this product are either listed in national legislation or subject to risk assessment in accordance with Article 19 of this Regulation. This product contains the following substances, which should be removed or appropriately monitored during downstream processing:

- Xylene (CAS-No. 1330-20-7)

- 2-Phenoxyethanol (CAS-No. 122-99-6)

For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS). Please note that ensuring compliance with applicable regulatory requirements remains the sole responsibility of downstream operators.

This product contains the following substance, which is also authorized for use as a food additive under Regulation (EC) No 1333/2008:

- 2,6-di-tert-butyl-p-cresol, E 321

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 by reference to substances already permitted under 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 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 0.26% in wet coating formulations.
- 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 may not be appropriate for sensitive applications, such as infant formula and human milk or medical devices.

This product contains a solvent, xylene, which is not considered in the food contact evaluation, and is 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.

Printing Inks

EUROPE

21st Amendment to Consumer Goods Ordinance (GIO)

This product may be used in printing inks for packaging materials not intended for direct food contact in accordance with the requirements laid down in the German Consumer Goods Ordinance (Bedarfsgegenständeverordnung). The components of this product are either listed, covered by applicable derogations under this Ordinance, or are not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR) according to the criteria defined in Regulation (EC) No 1272/2008 (CLP).

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

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
315	128-37-0	2,6-di-tert-butyl-p-cresol	3	/
381	1330-20-7	Xylene	1	/

To enable downstream business operators to ensure compliance with the requirements laid down in this Ordinance, the migration of the following substance from printing inks into food or food simulant shall not exceed 10 µg/kg of food:

- 2-Phenoxyethanol (CAS-No. 122-99-6)

For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS). Please note that ensuring compliance with applicable regulatory requirements remains the sole responsibility of downstream operators.

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

This product may be used in the manufacture of printing inks for packaging that are not intended to come into direct contact with food according to Swiss Ordinance 817.023.21 (as of 1 January 2026) since intentionally added substances in this product are either listed in Annex 2 and/or Annex 10 of this Ordinance, subject to Article 35(b), or are not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR).

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

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
721	128-37-0	2,6-di-tert-butyl-p-cresol	3	/
1179	1330-20-7	Xylene	1	

To enable downstream business operators to ensure compliance with the requirements laid down in this Ordinance, the migration of the following substance from printing inks into food or food simulant shall not exceed 10 µg/kg of food:

- 2-Phenoxyethanol (CAS-No. 122-99-6)

For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS). Please note that ensuring compliance with applicable regulatory requirements remains the sole responsibility of downstream operators.

Industry

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

Based on the current knowledge of the product composition and manufacturing process, this product does not intentionally contain any substances listed in Section 4 ("General Nestlé Exclusions and Minimisations") or Tables 5–8 of the Nestlé document Printing Inks for Food Packaging.

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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