

FOOD CONTACT

BYK Regulatory Information

DISPERBYK-190

Summary

DISPERBYK-190 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:

Adhesives				
EU	Regulation (EU) No. 10/2011	Yes	-	See explanation
USA	21 CFR 175.105 'Adhesives'			No
China	GB9685-2016, table A.5 'Adhesives'			No
Coatings				
Europe	Regulation (EU) No. 10/2011	Yes	-	See explanation
USA	21 CFR 175.300 'Resinous and polymeric coatings'			No
China	GB9685-2016, table A.2 'Coatings'			No
Printing inks				
Europe	21 st Amendment to Consumer Goods Ordinance (GIO)	Yes	-	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 manufactured with monomers/other starting substances and additives listed in Annex I - Table I of Regulation (EU) No 10/2011 or subject to derogation as per Article 6(3).

Polymer production aids and aids to polymerization used in this product fall within the scope of Articles 6(1) and 6(4) of this Regulation. These substances 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

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 175.105 'Adhesives'

The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives. The components are not fully listed under section 175.105.

China**GB9685-2016, table A.5 'Adhesives'**

The product does not comply with 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).

Coatings**EUROPE****Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food**

For further information, please refer to the 'Adhesives' section.

USA**21 CFR 175.300 'Resinous and polymeric coatings'**

The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives. The components are not fully listed under section 175.300.

China**GB9685-2016, table A.2 'Coatings'**

The product does not comply with 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)**

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. Substances used beyond the scope of paragraphs 5 and 6 of this Regulation and/or listed in Annex I of Regulation (EU) No 10/2011 are not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR) according to the criteria established in Regulation (EC) No 1272/2008 (CLP).

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 that are not in contact with food (non-direct 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).

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 (April 2025)

The classification and composition of this product allow the formulation of printing inks in accordance 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. 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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