

FOOD CONTACT

BYK Regulatory Information

BYK-307

Summary

BYK-307 is suitable for food contact applications under the following compositional provisions, provided that its use does not exceed the maximum concentration as indicated below:

Adhesives		
EU	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions' BfR XXXVI 'Paper and board for food contact'	
USA	21 CFR 175.105 'Adhesives'	Yes
China	GB9685-2016, table A.5 'Adhesives'	No
Coatings		
EU	Regulation (EU) No. 10/2011	Yes
	CoE ResAP (2004) 1	
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
China	GB9685-2016, table A.2 'Coatings'	No
Printing inks		
EU	21st Amendment to Consumer Goods Ordinance (GIO)	Yes
	Swiss Ordinance 817.023.21	
Industry	Nestlé Standard "Printing Inks for Food Packaging"	See explanation
	EuPIA Exclusion Policy	Yes
China	GB9685-2016, table A.4 "Inks"	No

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

Adhesives

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 polymer production aid. No specific migration limit applies.

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, 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, we are committed to supporting downstream users with their compliance work. Accordingly, the following non-intentionally added substances (NIAS), which may originate from raw material impurities, the manufacturing process, or adventitious contamination, are known to be present in this product. For additional information regarding concentrations, please refer to the Safety Data Sheet (SDS) of this product.

FCM No.	CAS-No.	Name
n.a.	556-67-2	Octamethylcyclotetrasiloxane (D4)
n.a.	541-02-6	Decamethylcyclopentasiloxane (D5)
n.a.	540-97-6	Dodecamethylcyclohexasiloxane (D6)

n.a.: not applicable

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 considering the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, substrate weight of 15 g/m².

German BfR Recommendation XIV. Polymer Dispersions

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

German BfR Recommendation XXXVI. Paper and board for food contact

This product is authorized for use as a sizing agent under Section B. Production Aids, by cross-reference to compliance with BfR Recommendation XIV. Polymer Dispersion.

USA**21 CFR 175.105 'Adhesives.'**

The product complies with the compositional requirements of 21 CFR 175.105 Adhesives. This product includes components that are listed in 21 CFR 175.105 as well as components which are cleared under 21 CFR 176.210(d), which may be cross-referenced for use in compliance with 21 CFR 175.105.

Therefore, the product can be recommended for use in food contact adhesives in compliance with 21 CFR 175.105 Adhesives. As per the limitations outlined in that regulation, the final adhesive must either be separated from the food by a functional barrier or used subject to the following additional limitations:

- In dry foods: The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.
- In fatty and aqueous foods:
 - The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.
 - Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement "food-packaging adhesive".

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

This 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 table A.5 for adhesives application.

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.

CoE ResAP (2004) 1

Either the product itself, or the monomers and starting substances used in its manufacture, are listed in the Council of Europe Resolution AP (2004) 1, Version February 2009.

USA

21 CFR 175.300 'Resinous and polymeric coatings'

The product can be used in compliance with the requirements of FDA 21 CFR 175.300, if used as recommended below based on a legal opinion supporting the safe use of this product as follows:

- Permitted for use at a maximum of 0.5% as a component of can coatings
- Food type restriction-coatings that use this product may be used in contact with aqueous, acidic, alcoholic (up to 50% ethanol content), and dry foods under temperatures corresponding to FDA's Conditions of Use B ("boiling water sterilized") and below.

CHINA

GB9685-2016, table A.2 'Coatings'

This 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 table A.2 for coatings application.

Printing Inks

EUROPE

21st Amendment to Consumer Goods Ordinance (GIO)

All intentionally used substances are either listed in Annex 14, Table 1 of the GIO or are subject to derogation as per §4, Abs.5, S.5 (“salt rule”) or are listed in Regulation (EU) No 10/2011 without restriction in column 9 and/or 10 (“gliding reference to GIO”) or are not classified as CMR according to CLP Regulation.

In accordance with our role as manufacturer of substances, and based on information provided to us by raw material suppliers, we are committed to supporting downstream users with their compliance work. Accordingly, the following non-intentionally added substances (NIAS), which may originate from raw material impurities, the manufacturing process, or adventitious contamination, are known to be present in this product. For additional information regarding concentrations, please refer to the Safety Data Sheet (SDS) of this product.

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n.a.: not applicable

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 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

All substances used or known to be present are either directly listed in Annex 2 and/or 10 of Swiss Ordinance 817.023.21, version applicable from 1 July 2025, or are subject to derogation as per Art. 35(b) or are not classified as CMR according to CLP (Art. 35(c)).

To enable downstream users to conduct their compliance work, please refer to the ‘21st Amendment to Consumer Goods Ordinance (GIO)’ section for further details on restricted substances and/or non-intentionally added substances (NIAS).

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), with the exception of residual trace amounts of

the SVHC substances Octamethylcyclotetrasiloxane (D4) [CAS 556-67-2], Decamethylcyclopentasiloxane (D5) [CAS 541-02-6] and Dodecamethylcyclohexasiloxane (D6) [CAS 540-97-6] which are mentioned under 4. 'General Nestlé Exclusions and Minimisations'. 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.

CHINA

GB9685-2016, table A.4 "Inks"

Not all components of the product are listed in GB9685-2016.

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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