

FOOD CONTACT

BYK Regulatory Information

BYK-094

Summary

BYK-094 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 – max. 0.6% (see explanation)
	German BfR XIV ‘Polymer Dispersions’	See explanation
USA	21 CFR 175.105 ‘Adhesives’	Yes – max 0.07%
China	GB9685-2016, table A.5 ‘Adhesives’	No
Coatings		
Europe	Regulation (EU) No. 10/2011	Yes – max. 0.6% (see explanation)
	CoE ResAP (2004) 1	No
USA	21 CFR 175.300 ‘Resinous and polymeric coatings’	Yes – max 0.07%
China	GB9685-2016, table A.2 ‘Coatings’	No
Paper and Board		
Europe	German BfR XXXVI ‘Paper and board for food contact’	See explanation
Printing inks		
Europe	21 st Amendment to Consumer Goods Ordinance (GIO)	Yes – max. 0.6% (see explanation)
	Swiss Ordinance 817.023.21	
Industry	Nestlé Standard “Printing Inks for Food Packaging”	See explanation
	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 authorized for use as a polymer production aid.

The substances used in its manufacture are either listed in Annex I, authorized in national legislation, and/or have been risk assessed in accordance with Article 19 of this Regulation.

One substance is regulated by a specific migration limit (SML) under national legislation. However, assuming the worst-case scenario outlined below, the calculated migration level does not exceed this limitation when BYK's recommended conditions of use for food contact applications are observed. No additional restrictions and/or specifications apply.

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 adhesives. 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.

German BfR XIV 'Polymer Dispersions'

The product is covered by the compositional requirements of BfR XIV 'Polymer Dispersions', except for one component with defoaming activity.

USA

Adhesives 21 CFR 175.105

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 and substances which are Generally Recognized As Safe (GRAS) allowing use in adhesives in accordance with 21 CFR 175.105 under the following use conditions:

- Max. use level of 0.07% 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.

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”.

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 application.

China

GB9685-2016, table A.5 ‘Adhesives’

The product does not comply with table A.5 ‘Adhesives’ 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.

Coatings**EUROPE**

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

This product can be considered suitable for use in food contact coatings. For further information, please refer to the Adhesives section.

CoE ResAP (2004) 1 on coatings intended to come into contact with foodstuffs

The product does not meet the compositional criteria set out in Council of Europe Resolution AP (2004) 1, version dated February 2009.

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 0.07% 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.

Paper and Board**EUROPE**

German BfR XXXVI 'Paper and board for food contact'

The product is covered by the compositional requirements of BfR XXXVI 'Paper and board for food contact', except for one component with defoaming activity.

Printing Inks**EUROPE**

21st Amendment to Consumer Goods Ordinance (GIO)

All intentionally added substances are either listed in Annex 14, Table 1 of the GIO, subject to derogation under §4, Abs. 5, Sentence 5 ("salt rule"), included in Regulation (EU) No 10/2011 without restriction in column 9 and/or 10 ("cross-reference to GIO"), carcinogenic, mutagenic, or toxic to reproduction (CMR) according to the criteria defined in Regulation (EC) No 1272/2008 (CLP).

One substance is regulated by a specific migration limit (SML) under German Ink Ordinance. However, assuming the worst-case scenario outlined below, the calculated migration level does not exceed this limitation when BYK's recommended conditions of use for food contact applications are observed. No additional restrictions and/or specifications apply.

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

This product is manufactured with substances that are either directly listed in Annex 2 and/or Annex 10 of Swiss Ordinance 817.023.21 (version January 1, 2025), subject to Article 35(b), or not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR).

One substance is regulated by a specific migration limit (SML) under Swiss Ordinance Annex 10. However, assuming the worst-case scenario, the calculated migration level does not exceed this limitation when BYK's recommended conditions of use for food contact applications are observed. No additional restrictions and/or specifications apply.

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 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) (CASRN 556-67-2), Decamethylcyclopentasiloxane (D5) (CASRN 541-02-6) and Dodecamethylcyclohexasiloxane (D6) (CASRN 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.

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 deems to be actual for three years commencing from the date of issue.

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This issue replaces all previous versions

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