

FOOD CONTACT

BYK Regulatory Information

BYK-333

Summary

BYK-333 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		
Europe	Regulation (EU) No. 10/2011	Yes – max. 0.3% (see explanation)
USA	21 CFR 175.105 'Adhesives	Yes – max. 0.1%
China	GB9685-2016, table A.5 'Adhesives'	No
MERCOSUR	GMC Resolution n. 39/19	No
	GMC Resolution n. 02/12	No
	GMC Resolution n. 40/15	No
	GMC Resolution n. 54/97	No
	GMC Resolution n. 28/99	No
	GMC Resolution n. 32/99	No
Coatings		
Europe	Regulation (EU) No. 10/2011	Yes – max 0.3% (see explanation)
	CoE ResAP (2004) 1	
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes – max. 0.1%
China	GB9685-2016, table A.2 'Coatings'	No
MERCOSUR	GMC Resolution n. 39/19	No
	GMC Resolution n. 02/12	No
Paper and paperboard		
USA	21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'	No
	21 CFR 176.180 'Components of paper and paperboard in contact with dry food'	No
China	GB9685-2016, table A.6 'Paper'	No

Printing inks		
Europe	21st Amendment to Consumer Goods Ordinance (GIO)	Yes – max. 0.3% (see explanation)
	Swiss Ordinance 817.023.21	
Industry	Nestlé Printing Inks for Food Packaging (April 2024)	See explanation
	EuPIA Exclusion Policy (April 2025)	Yes – max. 0.3% (see explanation)

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 an additive. No specific migration limit applies.

Polymer production aids used in this product, including solvents, fall under Article 6(1) and are subject to national legislation.

Aids to polymerization used in this product are subject to Art. 6(4) and listed in national legislation and/or self-risk assessed in accordance with Art. 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 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.

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 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 0.1% in wet coating formulations

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- 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 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. n. 39/19, n. 02/12, n. 40/15, n. 54/97, n. 28/99, & n. 32/99

The product does not comply with the compositional requirements of MERCOSUR GMC Resolution n. 39/19, MERCOSUR GMC Resolution n. 02/12, MERCOSUR GMC Resolution n. 40/15, and MERCOSUR GMC Resolutions n. 54/97, 28/99 and 32/99.

Therefore, the product is not authorized for use in adhesives.

CHINA

GB9685-2016, table A.5 ‘Adhesives’

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

Therefore, the product cannot be recommended for use in food contact adhesives in China.

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. Additional information is available in the adhesive section.

Please note that the assessments for coatings are based on a maximum use level of 0.3% in wet coating formulations, assuming a dry coating thickness of 12 µm and a solid content of 40% w/w. The use level may be adjusted to reflect variations in coating thickness and solid content.

It remains 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.

CoE ResAP (2004) 1

Either the components themselves or the monomers and starting substances used for manufacturing are covered by the CoE ResAP (2004) 1, Version Feb. 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 0.1% 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 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. n. 39/19 & n. 02/12

The product does not comply with the compositional requirements of MERCOSUR GMC Resolution n. 39/19 or MERCOSUR GMC Resolution n. 02/12.

Therefore, the product is not authorized for use in coatings.

CHINA

GB9685-2016, table A.2 'Coatings'

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

Therefore, the product cannot be recommended for use in food contact coatings in China.

Paper and paperboard

USA

21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'

The product does not comply with the compositional requirements of 21 CFR 176.170.

21 CFR 176.180 'Components of paper and paperboard in contact with dry food'

The product does not comply with the compositional requirements of 21 CFR 176.180.

Therefore, the product cannot be recommended for paper and paperboard in contact with food.

China

GB9685-2016, table A.6 'Paper'

The product does not comply with table A.6 'Paper' 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)

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. No specific migration limit applies.

For any non-intentionally added substances (NIAS) subject to the provisions of Article 3(1) of Regulation (EC) No 1935/2004 which have become known to us, we perform risk assessments in accordance with internationally recognized scientific principles on risk assessment. 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, ink 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 January 2025, or are subject to derogation as per Art. 35(b) or are not classified as CMR according to CLP (Art. 35(c)).

Please note that it is the responsibility of both the 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.

Industry

Nestlé Printing Inks for Food Packaging (April 2024)

None of the intentionally used substances in the product are listed in the exclusion lists and/or minimisation lists of the Nestlé Guidance Note on Packaging Inks (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' and with the exception of residual trace amounts of ethylbenzene (CAS 100-41-4) which is listed on Nestlé Minimisation list for Solvents (Table 8.2) and residual trace amounts of toluene (CAS 108-88-3) which is listed on Nestlé Exclusion list for Solvents (Table 8.1). Therefore, the use of the above mentioned product is not an obstacle for the compliance to the Nestlé Guidance Note.

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

These 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.

Food Contact Team
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This issue replaces all previous versions

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