

FOOD CONTACT

BYK Regulatory Information

BYK-348

Summary

BYK-348 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. 0.5% (see explanation)
China	GB9685-2016, table A.5 'Adhesives'	No
Coatings		
Europe	Regulation (EU) No. 10/2011 CoE ResAP (2004) 1	Yes – max 0.5% (see explanation)
China	GB9685-2016, table A.2 'Coatings'	No
Printing inks		
Europe	21st Amendment to Consumer Goods Ordinance (GIO) Swiss Ordinance 817.023.21	Yes – max. 0.5% (see explanation)
Industry	Nestlé Printing Inks for Food Packaging (April 2024) EuPIA Exclusion Policy (April 2025)	Yes – 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 or as polymer production aid. No specific migration limit applies.

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.

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 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.

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.

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 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 (CAS 556-67-2), decamethylcyclopentasiloxane (CAS 541-02-6) and dodecamethylcyclohexasiloxane (CAS 540-97-6) which are mentioned under 4.

Therefore, the use of the above-mentioned product is not an obstacle for the compliance with 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
Regulatory Affairs
BYK-Chemie GmbH

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This issue replaces all previous versions

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