

FOOD CONTACT

BYK Regulatory Information

BYK-3762

Summary

BYK-3762 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	-	See explanation
	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				
Europe	Regulation (EU) No. 10/2011	Yes	-	See explanation
	CoE ResAP (2004) 1			
USA	21 CFR 175.300 'Resinous and polymeric coatings'			Yes
China	GB9685-2016, table A.2 'Coatings'			No
Printing inks				
Europe	21st Amendment to Consumer Goods Ordinance (GIO)	Yes	-	See explanation
	Swiss Ordinance 817.023.21			
China	GB9685-2016, table A.4 "Inks"			No

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 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.

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 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 0.5% 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”.

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

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.

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 0.5% 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 may be used in can coatings that will contact 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

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.

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, 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)).

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.

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. 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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