

FOOD CONTACT

BYK Regulatory Information

BYK-1745

Summary

BYK-1745 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
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR 175.105 'Adhesives'	Yes
China	GB9685-2016, table A.5 'Adhesives'	Yes
MERCOSUR	GMC Resolution n. 27/99	Yes
	GMC Resolution n. 39/19	Yes
Coatings		
Europe	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes
Paper and paperboard		
Europe	German BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'	Yes
	21 CFR 176.180 'Components of paper and paperboard in contact with dry food'	Yes
MERCOSUR	GMC Resolution n. 40/15	Yes
	GMC Resolution n. 41/15	No
	GMC Resolution n. 42/15	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 as a polymer production aid. No specific migration limit applies.

Polymer production aids used in this product are either listed in Annex I, authorized under national legislation, or have been risk assessed in accordance with Article 19 of this Regulation.

The table below lists only the substances used or known to be present which are relevant to be considered for compliance with the specific migration limits (SML) and/or any restrictions laid down in Regulation (EU) No 10/2011:

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
315	128-37-0	2,6-di-tert-butyl-p-cresol	3	Not applicable

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.

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.

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 as well as components which are cleared under 21 CFR 184.1555, 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’**

The product complies with the compositional requirements of the National Food Safety Standard of the People’s Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles, table A.5 (Additives for adhesives).

MERCOSUR**GMC Res. No. 27/99 MERCOSUR Technical Regulation on Adhesives**

According to GMC Resolution n. 27/99 on Adhesives, adhesives may be made from one or more of the substances mentioned in GMC Resolution n. 39/19, n. 02/12, n. 40/15 and n. 28/99. The components of this product are compositionally compliant with GMC Res. No. 39/19.

The table below lists only the substances used or known to be present which are relevant to be considered for compliance with the specific migration limits (SML) laid down in GMC Res. No. 39/19:

Ref. No.	CAS-No.	Name	SML
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46640	128-37-0	2,6-di-tert-Butyl-p-cresol	SML = 3 mg/kg
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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.

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.

German BfR Recommendation XIV. Polymer Dispersions

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

USA

21 CFR 175.300 'Resinous and polymeric coatings'

The product complies with the compositional requirements of 21 CFR 175.300. This product includes components that are listed in 21 CFR 175.300 as well as components which are cleared under 21 CFR 184.1555, which may be cross-referenced for use in compliance with 21 CFR 175.300.

MERCOSUR

GMC Res. No. 39/19 MERCOSUR Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coatings that come into contact with food

The components of this product are compositionally compliant with GMC Res. No. 39/19.

The table below lists only the substances used or known to be present which are relevant to be considered for compliance with the specific migration limits (SML) laid down in GMC Res. No. 39/19:

Ref. No.	CAS-No.	Name	SML
46640	128-37-0	2,6-di-tert-Butyl-p-cresol	SML = 3 mg/kg

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.

Paper and Paperboard

EUROPE

German BfR XXXVI 'Paper and board for food contact'

This product is permitted for use as a sizing agent in accordance with BfR Recommendation XIV. Polymer Dispersions, and as a surface refining and coating agent, as it is manufactured using substances authorized under Regulation (EU) No. 10/2011.

USA

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

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

This product complies with the compositional requirements of 21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods' which may be cross-referenced for use under 21 CFR 176.180 'Components of paper and paperboard in contact with dry food' for use in coatings on paper and paperboard. This product includes components listed in 21 CFR 176.170 as well as components which are listed under 21 CFR 184.1555, which may be cross-referenced for use in compliance with 21 CFR 176.170 and 21 CFR 176.180.

MERCOSUR

GMC Res. No. 40/15 MERCOSUR Technical Regulation on Cellulosic Materials

This product meets the compositional requirements of GMC Resolution n. 40/15 on Cellulosic Materials. The product does not meet the compositional requirements of MERCOSUR GMC Resolutions n. 41/15 or n. 42/15.

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 the date of issue.

Food Contact Team
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