FOOD CONTACT

BYK Regulatory Information

BYK-016

Summary

BYK-016 is suitable for food contact applications under the following compositional provisions:

Adhesives		
EU	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 175.105 ‘Adhesives’	Yes
China	GB9685-2016, table A.5 ‘Adhesives’	No
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes
Coatings		
EU	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 175.300 ‘Resinous and polymeric coatings’	Yes
China	GB9685-2016, table A.2 ‘Coatings’	Yes
Japan	Japan Food Sanitation Act Positive List System	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes
Paper and paperboard		
EU	German BfR XXXVI ‘Paper and paperboard in contact with food’	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
China	GB9685-2016, table A.6 ‘Paper’	Yes
MERCOSUR	GMC Resolution n. 40/15	No

Printing inks		
Europe	21st Amendment to Consumer Goods Ordinance (GIO)	Yes
	Swiss Ordinance 817.023.21	Yes
Industry	Nestlé Standard “Printing Inks for Food Packaging”	Yes
	EuPIA Charter	Yes
China	GB9685-2016, table A.4 ‘Inks’	No

This summary reflects only the regulations assessed to date and does not preclude permitted uses in other regions or applications. Please refer to the explanation section below for detailed information on the regulations and assessment criteria considered.

Explanation

Adhesives

EUROPE

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as amended as of the date of this document

This product is manufactured with monomers or other starting substances and additives listed in Annex I - Table I of Regulation (EU) No 10/2011 or subject to derogation as per Article 6(3).

Polymer production aids and/or aids to polymerization used in this product are either authorized under national legislation or subject to risk assessment 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	/

This product contains the following substance, which is also authorized for use as a food additive under Regulation (EC) No 1333/2008:

- 2,6-di-tert-butyl-p-cresol, E 321

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.

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.

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.

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.

JAPAN

Japan Food Sanitation Act Positive List System

The ingredients in this product are listed in Japan's Food Sanitation Act Positive List (PL) system under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370. Please contact separately for use Limit by Synthetic Resin Group (%).

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, as well as one additive that complies GMC Res No 02/12.

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 and GMC Res No 02/12:

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

Coatings

EUROPE

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as amended as of the date of this document

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 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.

USA

21 CFR 175.300 'Resinous and polymeric coatings'

This 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 or notified as Generally Recognized as Safe (GRAS).

MERCOSUR

GMC Res. No. 39/19 and **02/12**

The components of this product are compositionally compliant with 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 & GMC Res No, as well as one additive that complies GMC Res No 02/12 MERCOSUR Technical Regulation on the positive list of monomers, other starting substances and polymers authorized for the manufacturing of plastic packaging and equipment in contact with food.

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 and GMC Res No 02/12:

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.

CHINA

GB9685-2016, table A.2 'Coatings'

The active components are listed in table A.2 'Coatings' of GB9685-2016.

Paper and Paperboard

EUROPE

German BfR XXXVI 'Paper and board for food contact'

This product is permitted for use as a surface refining and coating agent, as it is manufactured with 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 that conform with the below provisions:

- 21 CFR 176.210 'Defoaming agents used in the manufacture of paper and paperboard'

China

GB9685-2016, table A.6 'Paper'

The active components of BYK-016 are listed in GB9685-2016 table A6 for paper application.

MERCOSUR

GMC Resolutions n. 40/15, 41/15, 42/15

The product does not meet the compositional requirements of MERCOSUR GMC Resolutions n. 40/15, n. 41/25, n. 42/15. As such, this product is not recommended for cellulosic applications

Printing Inks

EUROPE

21st Amendment to Consumer Goods Ordinance (GIO)

This product may be used in the manufacture of printing inks for packaging intended to come into direct contact with food in accordance with the requirements laid down in the German Consumer Goods Ordinance (Bedarfsgegenständeverordnung). Its components are either listed in Annex 14, Table 1 of the GIO, subject to derogation under §4, Abs. 5, Sentence 5 ("salt rule"), or are included in Regulation (EU) No 10/2011 without any restrictions indicated in columns 9 and/or 10.

The table below lists only the substances used or known to be present that are relevant for compliance with the specific migration limits (SML) and/or any restrictions laid down in the German Ink Ordinance or 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	/

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

This product may be used in the manufacture of printing inks for packaging that are not intended to come into direct contact with food according to Swiss Ordinance 817.023.21 (as of 1 January 2026) since intentionally added substances in this product are either listed in Annex 2 and/or Annex 10 of this Ordinance, subject to Article 35(b), or are not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR).

The table below lists only substances that are used or known to be present and that are relevant for compliance with the specific migration limits (SML) and/or any restrictions set out in Annex 2 and/or Annex 10 of this Ordinance.

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
721	128-37-0	2,6-di-tert-butyl-p-cresol	3	/

Industry

Nestlé Standard "Printing Inks for Food Packaging" (02/04/2024)

Based on the current knowledge of the product composition and manufacturing process, this product does not intentionally contain any substances listed in Section 4 ("General Nestlé Exclusions and Minimisations") or Tables 5–8 of the Nestlé document Printing Inks for Food Packaging.

EuPIA Exclusion Charter (March 2026)

The product does not intentionally contain any substances listed in Annexes 1 and 2 of the 'EuPIA Charter on Raw Material Selection and Exclusion for Printing Inks and Related Products' (March 2026). The product itself as raw material is not classified and labeled with any of the Hazard Statements for Group I or Group II substances as defined in the section 'Selection Criteria & Procedures'

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. 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.
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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This issue replaces all previous versions

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