

FOOD CONTACT

BYK Regulatory Information

BYK-378

Summary

BYK-378 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)
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. 0.5% (see explanation)
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	21 st Amendment to Consumer Goods Ordinance (GIO)	Yes – max. 0.5% (see explanation)
	Swiss Ordinance 817.023.21	
Industry	Nestlé Standard “Printing Inks for Food Packaging”	See explanation
	EuPIA Charter	Yes

This summary only reflects conducted evaluations on existing regulations. It does not exclude compliant use in additional 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

This product is authorized to be used as an additive or polymer production aid.

Polymer production aids and/or aids to polymerization other than those included in the Union list are either listed in national legislation or subject to risk assessment in accordance with Article 19 of this Regulation.

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 I of Regulation (EU) No 10/2011 or in national legislation.

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

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.

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 coatings intended for food contact applications. Additional regulatory information is provided in the 'Adhesives' section.

Please note that the assessments for coatings are based on a maximum use level of 0.5% 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.

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.

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)

Intentionally added substances in this product 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 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 the German Ink Ordinance and/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 is manufactured with substances either listed in Annex 2 and/or Annex 10 of Swiss Ordinance 817.023.21 (version January 1, 2026), 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	/

Therefore, this product may be used in printing inks that are not intended to come into direct contact with food.

Industry

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

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], Decamethylcyclo-pentasiloxane (D5) [CAS 541-02-6] and Dodecamethylcyclohexasiloxane (D6) [CAS 540-97-6] which are mentioned under 4. 'General Nestlé Exclusions and Minimisations'.

Therefore, the use of the above-mentioned product is not an obstacle for the compliance to the Nestlé Guidance Note.

EuPIA Exclusion Charter (March 2026)

The product intentionally does not contain any of the 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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