

FOOD CONTACT

BYK Regulatory Information

BYK-3771

Summary

BYK-3771 is suitable for food contact applications in accordance with the following compositional provisions, provided that its use does not exceed the maximum concentration indicated below:

| Adhesives | | |
|---------------|--|--------------|
| Europe | Regulation (EU) No. 10/2011 | Yes – max 2% |
| | German BfR XIV ‘Polymer Dispersions’ | Yes |
| USA | 21 CFR 175.105 ‘Adhesives’ | Yes – max 2% |
| China | GB9685-2016, table A.5 ‘Adhesives’ | No |
| Printing inks | | |
| Europe | 21 st Amendment to Consumer Goods Ordinance (GIO) | Yes – max 2% |
| | Swiss Ordinance 817.023.21 | |
| Industry | Nestlé Standard “Printing Inks for Food Packaging” | Yes |
| | 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 for use as an additive or as a polymer production aid. Substances used in its manufacture 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 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, residues of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out are not known or expected to be present in concentration exceeding the specific migration limits established by this regulation. Testing is not routinely performed for substances that are neither identified nor reasonably expected to be present.

In accordance with our role as a manufacturer of substances, 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, 1kg food in contact with 6 dm² of packaging, substrate weight of 15 g/m².

German BfR XIV 'Polymer Dispersions'

This product may be used in accordance with BfR Recommendation XIV, as it is manufactured with substances authorized under 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 cleared under 21 CFR 176.210 which may be cross-referenced for use under 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”.

This product contains a solvent, which is not considered in the food contact evaluation, and is the responsibility of the downstream user to remove prior to use in food contact application.

China

GB9685-2016, table A.5 ‘Adhesives’

The active components are not all listed in GB9685-2016 table A5 for adhesive applications. Therefore, this product cannot be recommended for use in food contact adhesives in China.

Printing inks

EUROPE

21st Amendment to Consumer Goods Ordinance (GIO)

This product may be used in the manufacture of printing inks for packaging intended for direct and indirect contact with food in accordance with the requirements of the German Consumer Goods Ordinance (Bedarfsgegenständeverordnung). All intentionally added 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.

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

Intentionally added substances used in this product are either listed in Annex 2 and/or Annex 10 of Swiss Ordinance 817.023.21 (version January 1, 2026) or subject to Article 35(b).

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)

None of the intentionally added substances in the product are listed in the exclusion and/or minimisation lists of the Nestlé Standard “Printing Inks for Food Packaging” (version St-80.001-01 of 02/04/2024).

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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