

# FOOD CONTACT

## BYK Regulatory Information

### BYK-3741

#### Summary

BYK-3741 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:

| Coatings |                                                  |                                   |
|----------|--------------------------------------------------|-----------------------------------|
| Europe   | Regulation (EU) No. 10/2011                      | Yes – max 0.6%<br>See explanation |
|          | German BfR XIV ‘Polymer Dispersions’             | Yes<br>See explanation            |
| USA      | 21 CFR 175.300 ‘Resinous and polymeric coatings’ | Yes – max 0.18%                   |
| China    | GB9685-2016, table A.2 ‘Coatings’                | No                                |

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

### Coatings

#### EUROPE

#### **Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food**

This product may be used as a polymer production aid subject to national legislation or risk assessment in accordance with Article 19 of this Regulation. Substances used in its manufacture are either listed in Annex I, authorized under national legislation or have been assessed in accordance with internationally recognized scientific principles on risk assessment.

To 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, 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 dm<sup>2</sup> of packaging, substrate weight of 15 g/m<sup>2</sup>.

#### **German BfR XIV 'Polymer Dispersions'**

This product may be used as a defoaming agent in accordance with Section I, No. 1 of BfR Recommendation XV. It remains the responsibility of downstream business operators to ensure that its use complies with the restrictions and/or specifications set out in BfR Recommendation XIV.

---

**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 0.18% 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.

---

**China**

---

**GB9685-2016, table A.2 'Coatings'**

The active components of the product are not listed in GB9685-2016.

Therefore, the product cannot be recommended for use in food contact coatings in China.

---

## 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.

## Food Contact Team

Regulatory Affairs  
BYK-Chemie GmbH

*The information contained herein is based on our current knowledge and experience. No warranties, guarantees and/or assurances of any kind, either express or implied, including warranties of merchantability or fitness for a particular purpose, are made regarding any products mentioned herein and data or information set forth, or that such products, data or information may be used without infringing intellectual property rights of third parties. Any information about suitability, use or application of the products is non-binding and does not constitute a commitment regarding the products' properties, use or application. Contractual terms and conditions, in particular agreed product specifications, always take precedence. We recommend that you test our products in preliminary trials to determine their suitability for your intended purpose prior to use. We reserve the right to make any changes and to update the information herein without notice.*

*This issue replaces all previous versions*

ANTI-TERRA®, AQUACER®, AQUAMAT®, AQUATIX®, BENTOLITE®, BYK®, BYK-AQUAGEL®, BYK®-DYNWET®, BYK-MAX®, BYK®-SILCLEAN®, BYKANOL®, BYKCARE®, BYKETOL®, BYKJET®, BYKONITE®, BYKOPLAST®, BYKUMEN®, CARBOBYK®, CERACOL®, CERAFAK®, CERAFLLOUR®, CERAMAT®, CERATIX®, CLAYTONE®, CLOISITE®, DISPERBYK®, DISPERPLAST®, FULACOLOR®, FULCAT®, GARAMITE®, GELWHITE®, HORDAMER®, LACTIMON®, LAPONITE®, NANOBYPK®, OPTIBENT®, OPTIGEL®, PURABYPK®, RECYCLOBYPK®, RHEOBYPK®, SCONA®, SILBYPK®, TIXOGEL® and VISCOBYPK® are registered trademarks of the BYK group.