

FOOD CONTACT

BYK Regulatory Information

BYK-3410

Silicone-free surface additive for aqueous coatings, printing inks as well as adhesives and sealants to improve substrate wetting.

Technically recommended use level: 0.2 - 2%

Summary

BYK-3410 is suitable according to the following compositional provisions for food contact applications, as indicated:

| Coatings | | |
|----------------------|---|-----|
| Europe | Suitable for food contact coatings | Yes |
| | Regulation (EU) No. 10/2011 | Yes |
| | German BfR XIV 'Polymer Dispersions' | Yes |
| | CoE ResAP (2004) 1 | Yes |
| USA | 21 CFR 175.300 'Resinous and polymeric coatings' | Yes |
| China | GB9685-2016, table A.2 'Coatings' | No |
| Paper and paperboard | | |
| Europe | Suitable for food contact paper and paperboard | Yes |
| | Regulation (EU) No. 10/2011 | Yes |
| | 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 |
| China | GB9685-2016, table A.6 'Paper' | Yes |
| MERCOSUR | GMC Resolution n. 40/15 | No |
| | GMC Resolution n. 41/15 | No |
| | GMC Resolution n. 42/15 | No |
| | GMC Resolution n. 39/19 | No |
| | GMC Resolution n. 02/12 | No |
| Printing inks | | |
| Europe | Suitable for food contact printing inks | Yes |
| | Swiss Ordinance 817.023.21 (Annex 10) | Yes |
| Industry | Nestlé Guidance Note on Packaging Inks (Oct. 2018) | Yes |
| | EuPIA Exclusion List (March 2021) | Yes |

| Adhesives | | |
|------------------|---|-----------------------|
| | Suitable for food contact adhesives | Yes |
| Europe | Regulation (EU) No. 10/2011 | Yes |
| | German BfR XIV 'Polymer Dispersions' | Yes |
| | German BfR XXXVI 'Paper and board for food contact' | Yes |
| | | |
| USA | 21 CFR 175.105 'Adhesives' | Yes |
| China | GB9685-2016, table A.5 'Adhesives' | No |
| MERCOSUR | GMC Resolution n. 27/99 | Yes (See explanation) |
| | GMC Resolution n. 39/19 | No (See explanation) |
| | GMC Resolution n. 02/12 | No (See explanation) |
| | GMC Resolution n. 40/15 | No (See explanation) |
| | GMC Resolution n. 28/99 | No (See explanation) |

This summary only reflects conducted evaluations on existing regulations. It does not exclude compliant use in additional regions or applications. Explanations below show details on considered regulations and evaluations.

Explanation

Coatings

Europe

Regulation (EU) No. 10/2011

The components of this product, or the monomers and starting materials used to manufacture the components of the product, are directly listed in Annex I – Table I of Regulation (EU) No 10/2011. Specific Migration Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by the German BfR-Recommendation XIV. ‘Polymer Dispersions’.

CoE ResAP (2004) 1

For this product, either the components themselves or the monomers and starting substances used for manufacturing are listed in the CEPE ‘Code of practice for food contact coatings’, Edition 4, Version Feb. 2009.

Dual use additive (restricted)

The product contains ‘dual use additives’, for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT, E321) and Sorbitan monooleate (E494).

Therefore, BYK-3410 can be recommended for food contact coatings in the EU.

USA

21 CFR 175.300 ‘Resinous and polymeric coatings’

The product complies with the compositional requirements of 21 CFR 175.300, since all components are listed within the respective section.

Therefore, BYK-3410 can be recommended for food contact coatings as described in 21 CFR 175.300.

China

GB9685-2016, table A.2 ‘Coatings’

The 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, table A.2 (Additives for coatings).

Paper and paperboard

Europe **Regulation (EU) No. 10/2011**

The components of this product, or the monomers and starting materials used to manufacture the components of the product, are directly listed in Annex I – Table I of Regulation (EU) No 10/2011. Specific Migration Limits and/or restrictions apply.

German BfR XXXVI ‘Paper and board for food contact’

For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by the German BfR-Recommendation XXXVI. ‘Paper and board for food contact’.

Dual use additive

The product contains ‘dual use additives’, for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT, E321) and Sorbitan monooleate (E494).

Therefore, BYK-3410 can be recommended for food contact paper and paperboard in the EU.

USA **21 CFR 176.170 ‘Components of paper and paperboard in contact with aqueous and fatty foods’**

The product complies with the compositional requirements of 21 CFR 176.170, since all components are listed within the respective section.

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

The product complies with the compositional requirements of 21 CFR 176.180, since all components are listed within the respective section.

Therefore, BYK-3410 can be recommended for paper and paperboard as described in 21 CFR 176.170 & 176.180.

China **GB9685-2016, table A.6 ‘Paper’**

The active components of BYK-3410 are listed in GB9685-2016 table A6 for paper application.

Therefore, BYK-3410 can be recommended for paper and paperboard as described in GB9685-2016, table A.6.

MERCOSUR **GMC Resolutions n. 40/15, 41/15, 42/15, 39/19 & 02/12**

The product does not meet the compositional requirements of MERCOSUR GMC Resolutions n. 40/15, n. 41/25, n. 42/15, n. 39/19 or n. 02/12.

Therefore, BYK-3410 is not authorized for use in paper and paperboard in MERCOSUR member states.

Printing inks

Europe **Swiss Ordinance 817.023.21 (Annex 10)**

This product is conform with the compositional requirements of the part for printing inks for packaging of the Swiss Ordinance 817.023.21 (Version of 1 December 2020) since all components are listed in Annex 10. Specific migration limits apply.

Therefore, the product can also be recommended for use in food contact printing inks in the EU.

Industry **Nestlé Guidance Note on Packaging Inks (October 2018)**

According to the recipe, the product does not contain any of the substances listed in Table 1 – Table 7 of the Nestlé Guidance note on Packaging Inks (dated October 2018).

EuPIA Exclusion List (March 2021)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (March 2021) are present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

Adhesives

EU Regulation (EU) No. 10/2011

The components of this product, or the monomers and starting materials used to manufacture the components of the product, are directly listed in Annex I – Table I of Regulation (EU) No 10/2011. Specific Migration Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

The product complies with the compositional requirements of BfR XIV ‘Polymer Dispersions’.

German BfR XXXVI ‘Paper and board for food contact’

The product complies with the compositional requirements of BfR XXXVI ‘Paper and board for food contact’.

Dual use additive (restricted)

The product contains ‘dual use additives’, for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT, E321) and Sorbitan monooleate (E494).

Therefore, the product can be recommended for use in food contact adhesives.

USA 21 CFR 175.105 ‘Adhesives’

The product complies with the compositional requirements of 21 CFR 175.105, since all components are listed within the respective section.

Therefore, BYK-3410 can be recommended for food contact adhesives as described in 21 CFR 175.105.

China GB9685-2016, table A.5 ‘Adhesives’

The 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, table A.5 (Additives for adhesives).

MERCOSUR GMC Res. n. 27/99, n. 39/19, n. 02/12, n. 40/15, & n. 28/99

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 product complies with the compositional requirements of Resolution n. 27/99. Specific migration limits and/or restrictions apply.

Therefore, the product can be recommended for use in food contact adhesives in MERCOSUR member states.

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
Regulatory Affairs
BYK-Chemie GmbH

The information herein is based on our present knowledge and experience. The information merely describes the properties of our products but no guarantee of properties in the legal sense shall be implied. We recommend testing our products as to their suitability for your envisaged purpose prior to use. No warranties 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. We reserve the right to make any changes according to technological progress or further developments.

This issue replaces all previous versions - Printed in Germany.

ADD-MAX®, ADD-VANCE®, ANTI-TERRA®, AQUACER®, AQUAMAT®, AQUATIX®, BENTOLITE®, BYK®, BYK-AQUAGEL®, BYK-DYNWET®, BYK-MAX®, BYK-SILCLEAN®, BYKANOL®, BYKCARE®, BYKETOL®, BYKJET®, BYKO2BLOCK®, BYKONITE®, BYKOPLAST®, BYKUMEN®, CARBOBYK®, CERACOL®, CERAFAK®, CERAFLLOUR®, CERAMAT®, CERATIX®, CLAYTONE®, CLOISITE®, DISPERBYK®, DISPERPLAST®, FULACOLOR®, FULCAT®, GARAMITE®, GELWHITE®, HORDAMER®, LACTIMON®, LAPONITE®, MINERPOL®, NANOBYPK®, OPTIBENT®, OPTIFLO®, OPTIGEL®, POLYAD®, PRIEX®, PURABYPK®, PURE THIX®, RECYCLOBLEND®, RECYCLOBYK®, RECYCLOSSORB®, RECYCLOSTAB®, RHEOBYK®, RHEOCIN®, RHEOTIX®, SCONA®, SILBYK®, TIXOGEL® and VISCOBYK® are registered trademarks of the BYK group.