

FOOD CONTACT

BYK Regulatory Information

BYK-1740

“Green” defoamer based on environmentally friendly and sustainable raw materials for aqueous architectural coatings as well as adhesives with excellent defoaming effect. VOC-free and biodegradable.

Technically recommended use level: 0.2 – 0.5 %

Summary

BYK-1740 is suitable according to the following compositional provisions for food contact applications, as indicated:

| Adhesives | | |
|----------------------|---|--------------|
| Europe | Suitable for food contact adhesives | Yes (0.1 %) |
| | 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 (0.15 %) |
| China | GB9685-2016, table A.5 ‘Adhesives’ | No |
| Coatings | | |
| Europe | Suitable for food contact coatings | Yes (0.1 %) |
| | Regulation (EU) No. 10/2011 | Yes |
| | German BfR XIV ‘Polymer Dispersions’ | Yes |
| | ResAP (2004) 1 | Yes |
| USA | 21 CFR 175.300 ‘Resinous and polymeric coatings’ | Yes (0.15 %) |
| 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’ | 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. '18) | Yes |
| | EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018) | Yes |

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

Adhesives

Europe Regulation (EU) No. 10/2011

The components of this product or the monomers and starting substances used for manufacturing are either listed directly in Annex I – Table I of Regulation (EU) No. 10/2011 or are regulated by national legislation of a EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

Scientific Committee on Food (SCF)

The two main active components representing > 90 % of the product are evaluated by EFSA/SCF as SCF 0-4. The product also contains an additional defoaming component, which is classified by EFSA as SCF-list 3 and is permitted for adhesives in contact with food. The use of this substance is subject to restrictions, which limits the maximum use level of the product in full surface adhesive formulations to 0.1 % (solid content 40 %, film thickness 12 µm).

German BfR XIV 'Polymer Dispersions'

The product is covered by the compositional requirements of BfR XIV 'Polymer Dispersions', except for one component with defoaming activity.

German BfR XXXVI 'Paper and board for food contact'

The product is covered by the compositional requirements of BfR-Recommendation XXXVI 'Paper and board for food contact', except for one component with defoaming activity.

In summary, the product can be recommended for use in food contact adhesives in the Europe, if a maximum use level of 0.1 % is maintained (solid content 40 %, film thickness 12 µm).

USA 21 CFR 175.105 'Adhesives'

The product complies with the compositional requirements for materials used for adhesives in contact with foodstuffs, under following use conditions:

- maximum use level of 0.15 % in wet coating formulations
- for formulations with a solid content of 40 %
- final film thickness of 12 µm

The use level can be adapted for deviating film thickness and solid content.

China GB9685-2016, table A.5 'Adhesives'

The active components of BYK-1740 are not listed in GB9685-2016, table A.5 'Adhesives'. Therefore, the product is not approved.

Coatings

Europe

Regulation (EU) No. 10/2011

The components of this product or the monomers and starting substances used for manufacturing are either listed directly in Annex I – Table I of Regulation (EU) No. 10/2011 or are regulated by national legislation of a EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

Scientific Committee on Food (SCF)

The two main active components representing > 90 % of the product are evaluated by EFSA/SCF as SCF 0-4. The product also contains an additional defoaming component, which is classified by EFSA as SCF-list 3 and is permitted for coatings in contact with food. The use of this substance is subject to restrictions, which limits the maximum use level of the product in coating formulations to 0.1 % (solid content 40 %, film thickness 12 µm).

German BfR XIV ‘Polymer Dispersions’

The product is covered by the compositional requirements of BfR XIV ‘Polymer Dispersions’, except for one component with defoaming activity.

Framework Resolution ResAP (2004) 1

The product complies with the compositional requirements of the Framework Resolution ResAP (2004) 1 as part of the Council of Europe Policy Statement concerning ‘Coatings intended to come into contact with foodstuffs’, Version 3, Feb 12th, 2009, except for one component with defoaming activity.

Dual use additive

The product contains a ‘dual use additive’ (< 0.5 %) for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321).

In summary, the product can be recommended for use in food contact coatings in the Europe, if a maximum use level of 0.1 % is maintained (solid content 40 %, film thickness 12 µm).

USA

21 CFR 175.300 ‘Resinous and polymeric coatings’

The product complies with the compositional requirements for materials used for coatings in contact with foodstuffs (‘Resinous and polymeric coatings’), under following use conditions:

- maximum use level of 0.15 % in wet coating formulations
- for formulations with a solid content of 40 %
- final film thickness of 12 µm

The use level can be adapted for deviating film thickness and solid content.

China

GB9685-2016, table A.2 ‘Coatings’

The components of the product are not fully listed in GB9685-2016, table A.2 ‘Coatings’. Therefore, the product is not approved.

Paper and paperboard

Europe Regulation (EU) No. 10/2011

The components of this product or the monomers and starting substances used for manufacturing are either listed directly in Annex I – Table I of Regulation (EU) No. 10/2011 or are regulated by national legislation of a EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

German BfR XXXVI ‘Paper and board for food contact’

The product is covered by the compositional requirements of BfR-Recommendation XXXVI ‘Paper and board for food contact’, except for one component with defoaming activity.

In summary, the product can be recommended for use in food contact paper and paperboard in Europe Specific Migrations Limits and/or restrictions apply.

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

The product complies with the compositional requirements for materials used for components of paper and paperboard in contact with aqueous and fatty foods in contact with foodstuffs.

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

The product complies with the compositional requirements for materials used for components of paper and paperboard in contact with dry food in contact with foodstuffs.

China GB9685-2016, table A.6 ‘Paper’

The active components of BYK-1740 are not listed in GB9685-2016, table A.6 ‘Paper. Therefore, the product is not approved.

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 Dec 2019) since all components are listed on the A-list in Annex 10. Specific migration limits apply.

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

Industry Nestlé Guidance Note on Packaging Inks (Oct. '18)

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 (November 2016 - Corrigendum Dec. 2018)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018) are present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

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.

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This issue replaces all previous versions

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