

FOOD CONTACT

BYK Regulatory Information

BYK-028

VOC-free silicone-containing defoamer for aqueous high gloss emulsion systems and adhesives. Easy incorporation.

Summary

BYK-028 is suitable according to the following compositional provisions for food contact applications, as indicated:

| Coatings | | |
|---------------|---|------------|
| EU | 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 (0.9%) |
| China | GB9685-2016, table A.2 'Coatings' | No |
| Adhesives | | |
| EU | Suitable for food contact adhesives | Yes |
| | Regulation (EU) No. 10/2011 | Yes |
| | German BfR XIV 'Polymer Dispersions' | Yes |
| | German BfR XXXVI 'Paper and board in contact with food' | Yes |
| USA | 21 CFR 175.105 'Adhesives' | Yes (0.9%) |
| 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 |
| 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 (October 2018) | 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

Coatings

EU 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 an EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

All components of this product (excluding the active defoamer component, which has been evaluated by EFSA as stated above) are conform to the compositional requirements of the German BfR-Recommendation XIV ‘Polymer Dispersions’.

CoE ResAP (2004) 1

The main active components are listed in the CoE ResAP (2004) 1, Version Feb. 2009.

Dual use

The product contains a ‘dual use additive’ (< 0.01%) for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321).

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

USA 21 CFR 175.300 ‘Resinous and polymeric coatings’

The product can be used in compliance with the requirements of FDA 21 CFR 175.300, if used as recommended below. Based on the “no migration exemption”, we recommend following use conditions:

- Max. use level of 0.9% in wet coating formulations.
- For formulations with a solid content of 40% and a dry film thickness of 12 µm.
- Component of can coatings that will contact dry, aqueous, acidic and alcoholic foods (up to 50% ethanol content) under temperatures corresponding to FDA’s Conditions of Use B (“boiling water sterilized”).
- The use level can be adapted for deviating film thickness and solid content.

China GB9685-2016, table A.2 ‘Coatings’

Not all active components of BYK-028 are listed in GB9685-2016.

Adhesives

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

The main active components of the product, and/or its monomers/starting substances are listed in Annex I – Table I of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food (including all amendments). Furthermore, the product contains an active defoamer 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.

German BfR XIV ‘Polymer Dispersions’

All components of this product (excluding the active defoamer component, which has been evaluated by EFSA as stated above) are conform to the compositional requirements of the German BfR-Recommendation XIV ‘Polymer Dispersions’.

German BfR XXXVI ‘Paper and board in contact with food’

All components of this product (excluding the active defoamer component, which has been evaluated by EFSA as stated above) are conform to the compositional requirements of the German BfR-Recommendation XXXVI ‘Paper and board for food contact’.

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

USA **21 CFR 175.105 ‘Adhesives’**

The product can be used in compliance with the requirements of FDA 21 CFR 175.105, if used as recommended below. Based on the “no migration exemption”, we recommend following use conditions:

- Max. use level of 0.9% in wet coating formulations.
 - For formulations with a solid content of 40% and a dry film thickness of 12 µm.
 - Component of can coatings that will contact dry, aqueous, acidic and alcoholic foods (up to 50% ethanol content) under temperatures corresponding to FDA’s Conditions of Use B (“boiling water sterilized”).
 - The use level can be adapted for deviating film thickness and solid content.
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China **GB9685-2016, table A.5 ‘Adhesives’**

Not all active components of BYK-028 are listed in GB9685-2016.

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.

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). The monomers/starting substances for manufacturing the active components and all other components are listed in Annex 10. Specific migration limits apply.

Additional note: the non-listed D4 (CAS 556-67-2) is present, as an impurity. Its amount is referred to in our BRIEF document.

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

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 (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 - Printed in Germany.

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