

FOOD CONTACT

BYK Regulatory Information

BYK-017

Silicone-containing defoamer for aqueous pigment concentrates and glycol pastes for use in printing inks and coatings. Prevents foam during grinding. Long-term stability. Particularly suitable for grinds that contain resins.

Technically recommended use level: 0.2 – 0.8%

Summary

BYK-017 is suitable according to the following compositional provisions for food contact applications, as indicated:

Adhesives		
EU	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	Yes
	BfR XIV 'Polymer Dispersions'	Yes
	BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 175.105 'Adhesives'	Yes
China	GB9685-2016, Table A.5 'Adhesives'	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 (dated 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

Adhesives

EU

Regulation (EU) No. 10/2011

All components of this product are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments). Specific Migration Limits and/or restrictions apply.

BfR XIV ‘Polymer Dispersions’

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

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 additives

The product contains a ‘dual use additive’ to which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321, < 0.1 %).

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

USA

21 CFR 175.105 ‘Adhesives’

This product complies with the compositional requirements of FDA 21 CFR 175.105 ‘Adhesives’.

Therefore, the product can be recommended for use in food contact adhesives according to 21 CFR FDA 175.105.

China

GB9685-2016, Table A.5 ‘Adhesives’

The active components of BYK-017 are not fully listed in GB9685-2016.

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 2019). The monomers/starting substances for manufacturing the active components and all other components are listed in Annex 10. Specific migration limits apply.

Note: The product contains Octamethylcyclotetrasiloxane (D4; CAS No. 556-67-2) as an impurity. Refer to our BRIEF document for its amount.

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

Industry **Nestlé Guidance note on Packaging Inks (dated 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.

Food Contact Team
Regulatory Affairs
BYK-Chemie GmbH

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This issue replaces all previous versions

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