

FOOD CONTACT

BYK Regulatory Information

BYK-1709

Silicone-containing defoamer for aqueous pigment concentrates for use in coatings, printing inks and overprint varnishes. Prevents foam during grinding. Long-term and shear stability. Particularly suitable for resin-free grinds (slurries).

Technically recommended use level: 0.1 – 1 %

Summary

BYK-1709 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	No
	German BfR XIV 'Polymer Dispersions'	Yes
	CoE ResAP (2004) 1	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	No
China	GB9685-2016, table A.2 'Coatings'	Yes
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 2016)	Yes
	EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)	Yes
China	GB9685-2016, table A.4 'Inks'	No

Solvents and other formulation aids are not covered by the food contact status.

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	<u>Regulation (EU) No. 10/2011</u> The monomers and starting materials used to manufacture the components of the product are listed directly in Annex I - Table I of Regulation (EU) No 10/2011.

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.

Solvents

The product contains a significant amount of solvent 2-methoxymethylethoxy – propanol, boiling point: approx.. 190 °C. Solvents are currently not regulated by food contact positive lists as it is assumed that solvents evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 should be fulfilled.

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

Solvents and other formulation aids are not covered by the food contact status.

USA 21 CFR 175.300 'Resinous and polymeric coatings'

The product does not comply with Sec. 175.300 of Title 21 CFR (FDA) Regulations for indirect food additives.

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

The active components of BYK-1709 are listed in GB9685-2016 table A2 for coating application.

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

Solvents and other formulation aids are not covered by the food contact status.

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) since all 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 the EU.

Industry **Nestlé Guidance Note on Packaging Inks (October 2016)**

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.

China **GB9685-2016, table A.4 'Inks'**

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 (GB9685-2016).

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
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This issue replaces all previous versions

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