FOOD CONTACT

BYK Regulatory Information

BYK-306

Silicone-containing surface additive for ambient-curing plastic systems and solvent-borne coating systems with a strong reduction of surface tension. Excellent substrate wetting, prevents cratering and increases surface slip.

Technically recommended use level: 0.1 – 0.5%

Summary

BYK-306 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 (max. 0.26%)
China	GB9685-2016, table A.2 ‘Coatings’	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)	No
	EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)	Yes

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

Regulation (EU) No. 10/2011

The main active component of this product is directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments).

German BfR XIV 'Polymer Dispersions'

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

CoE ResAP (2004) 1

The main active component is covered by the CoE ResAP (2004) .

Dual use additive

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.

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

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 studies and external consultation, we recommend following use conditions:

- Max. use level of 0.26% in wet adhesive formulations.
- For formulations with a solid content of 40% and a dry thickness of 12 µm.
- The use level can be adapted for deviating thickness and solid content.

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

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 (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) 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 Europe.

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). However, the solvent toluene (CAS 108-88-3), which is listed in Table 6, and ethylbenzene (CAS 100-41-4), which is listed in Table 7, are present.

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.

Solvents

The product contains a significant amount of solvents; 2-phenoxyethanol [boiling point: 244,3 °C] & xylene [boiling point ranges from: 136 – 145 °C]. More information about present solvents can be found in the Safety Data Sheet. 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 and 174.5 of 21 CFR FDA should be fulfilled.

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