

FOOD CONTACT

BYK Regulatory Information

BYK-346

Silicone surfactant for aqueous coatings, printing inks and overprint varnishes with strong reduction in surface tension resulting in significantly improved substrate wetting. No increase in surface slip. Solution of BYK-345.

Technically recommended use level: 0.1 – 1 %

Summary

BYK-346 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	Yes
	Regulation (EU) No. 10/2011	No
EU	German BfR XIV 'Polymer Dispersions'	Yes (active ingredient)
	Dutch Warenwet - Chapter X	Yes
	CoE ResAP (2004) 1	Yes (active ingredient)
	USA 21 CFR 175.300 'Resinous and polymeric coatings'	No
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 (October 2016)	Yes
	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 product does not comply with the 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).

German BfR XIV 'Polymer Dispersions'

The active component is covered by the compositional requirements of BfR XIV 'Polymer Dispersions'.

Dutch Warenwet – Chapter X

The product is covered by the compositional requirements of the Dutch Warenwet – Chapter X.

CoE ResAP (2004) 1

The active component (polyether modified silicone) of this product is listed in the CoE ResAP (2004) 1, Version Feb. 2009.

Dual use additive

The product contains a 'dual use additive' (< 0.03%) 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 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 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 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.

Solvents

The product contains a significant amount of solvent [(2-methoxymethylethoxy)propanol, boiling point: approximately 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.

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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