

FOOD CONTACT

BYK Regulatory Information

BYK-331

Silicone surface additive for solvent-borne, solvent-free, and aqueous coatings and printing inks with a medium reduction of surface tension and a medium increase of slip.

Technically recommended use level: 0.025 – 0.2 %

Summary

BYK-331 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
Europe	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. 0.5 %)
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)	Yes
	EuPIA Exclusion List (Nov.'16 – Corrigendum Dec.'18)	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

Europe

Regulation (EU) No. 10/2011

The product complies with the compositional requirements of Regulation EU/10/2011.

German BfR XIV 'Polymer Dispersions'

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

CoE ResAP (2004) 1

The product complies with the compositional requirements of CoE ResAP (2004) 1.

Dual use additive

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

Therefore, the product can be recommended for 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 studies and external consultation, we recommend following use conditions:

- Max. use level of 0.5 % in wet coating 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.

Formulation aids are not covered by the food contact status.

China

GB9685-2016, table A.2 'Coatings'

Not all components of the product are 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) 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 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).

EuPIA Exclusion List (Nov.'16 – Corrigendum Dec.'18)

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
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This issue replaces all previous versions

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