

FOOD CONTACT

BYK Regulatory Information

BYK-141

Silicone defoamer for solvent-borne and solvent-free coating systems as well as ambient curing plastic systems on polyurethane basis.

Summary

BYK-141 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	No
	German BfR XIV 'Polymer Dispersions'	Yes
	CoE ResAP (2004) 1	Yes
USA	21 CFR 175.300	Yes (max. 0.9%)
	'Resinous and polymeric coatings'	
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 2018)	No
	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	
Europe	<p><u>Regulation (EU) No. 10/2011</u></p> <p>The main active components of this product are polymers and manufactured using monomers/starting substances, which are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011, but they are themselves not listed as “polymeric additives”. Therefore, the product can formally not be used as an additive in compliance with this regulation.</p>

German BfR XIV 'Polymer Dispersions'

This product is covered by the compositional requirements of BfR XIV 'Polymer Dispersions'.

CoE ResAP (2004) 1

The components of this product are polymers and manufactured using monomers/starting substances which are fully evaluated as SCF-list 0-4.

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

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 the "no migration exemption", we recommend following use conditions:

- Max. use level of 0.9% in wet coating formulations
- For formulations with a solid content of 40% and a dry film thickness of 12 µm
- The use level can be adapted for deviating film thickness and solid content.

Therefore, the product can be recommended in food contact coatings in regards to Sec. 175.300 of 21 CFR FDA.

Solvents and other 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.

Therefore, the product cannot be recommended for use in food contact coatings in China.

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.

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

Industry **Nestlé Guidance note on Packaging Inks (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). However, the solvent toluene, which is listed in Table 6, and the solvent ethylbenzene, 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.

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

Not all components of the product are listed in GB9685-2016.

Therefore, the product cannot be recommended for use in food contact inks in China.

Solvents

The product contains a significant amount of solvents [solvent naphtha with a boiling range from 140 °C – 200°C and isobutanol with a boiling point of 108°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.

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This issue replaces all previous versions

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