

FOOD CONTACT

BYK Regulatory Information

BYK-3560

Silicone- and fluorine-free surface additive for increasing the surface energy in aqueous, solvent-borne, UV-curable, and high-solid systems.

Summary

BYK-3560 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	No
EU	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	No
	CoE ResAP (2004) 1	No
	USA 21 CFR 175.300 'Resinous and polymeric coatings'	Yes (max. 0.14%, see below)
China	GB9685-2016, Table A.2 'Coatings'	No
Adhesives		
	Suitable for food contact adhesives	No
Europe	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	No
	German BfR XXXVI 'Paper and board in contact with food'	No
	USA 21 CFR 175.105 'Adhesives'	Yes (max. 0.14%, see below)
China	GB9685-2016, table A.5 'Adhesives'	No

Paper and paperboard		
	Suitable for food contact paper and paperboard	No
Europe	Regulation (EU) No. 10/2011	No
	German BfR XXXVI 'Paper and board for food contact'	No
USA	21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'	No
	21 CFR 176.180 'Components of paper and paperboard in contact with dry food'	No
China	GB9685-2016, table A.6 'Paper'	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 (07/04/2022)	Yes
	EuPIA Exclusion List (March 2021)	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

EU **Regulation (EU) No. 10/2011**

The main active component as such is not listed as a “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in compliance with this regulation.

German BfR XIV ‘Polymer Dispersions’

The product is not fully covered by the BfR XIV ‘Polymer Dispersions’.

CoE ResAP (2004) 1

The product is not fully covered by CoE ResAP (2004) 1.

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

USA **21 CFR 175.300 ‘Resinous and polymeric coatings’**

The product is not covered by a listing in Sec. 175.300 of 21 CFR FDA.

However, based on calculations, the product can still be recommended for use in food contact coatings, when the following restrictions are applied:

- In wet formulations up to 0.14% for food contact coatings with a solid content of 40% and a film thickness of 12 µm.
 - The use level can be adapted for other application conditions (e.g. solid content, film thickness)
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China **GB9685-2016, Table A.2 ‘Coatings’**

The active components of the product are not listed in GB9685-2016.

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

Adhesives

Europe **Regulation (EU) No. 10/2011**

The main active component as such is not listed as a “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in compliance with this regulation.

German BfR XIV ‘Polymer Dispersions’

The product is not fully covered by the BfR XIV ‘Polymer Dispersions’.

German BfR XXXVI ‘Paper and board in contact with food’

The product is not covered by the compositional requirements of BfR XXXVI ‘Paper and board in contact with food’.

In summary, the product cannot be recommended for food contact adhesive applications in the Europe.

USA **21 CFR 175.105 ‘Adhesives’**

The product can be used in compliance with the requirements of FDA 21 CFR 175.105, if used as recommended below. Based on studies and external consultation, we recommend following use conditions:

- Max. use level of 0.14% 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.

Formulation aids are not covered by the food contact status.

China **GB9685-2016, table A.5 ‘Adhesives’**

This product is not in compliance with the National Standard of the People’s Republic of China, GB9685-2016.

Paper and paperboard

Europe **Regulation (EU) No. 10/2011**

The main active component as such is not listed as a “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in compliance with this regulation.

German BfR XXXVI ‘Paper and board for food contact’

The product is not covered by the compositional requirements of BfR XXXVI ‘Paper and board in contact with food’.

Therefore, the product cannot be recommended for use in food contact adhesives in the EU.

USA **21 CFR 176.170 ‘Components of paper and paperboard in contact with aqueous and fatty foods’**

The product does not comply with the compositional requirements of 21 CFR 176.170.

21 CFR 176.180 ‘Components of paper and paperboard in contact with dry food’

The product does not comply with the compositional requirements of 21 CFR 176.180.

Therefore, the product cannot be recommended for paper and paperboard in contact with food.

China **GB9685-2016, table A.6 ‘Paper’**

This product is not in compliance with the National Standard of the People’s Republic of China, 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 2020). 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 Printing Inks for Food Packaging (07/04/2022)**

According to the recipe, the product does not intentionally contain any of the substances listed in 4. 'General Nestlé Exclusions and Minimisations' and Table 5 – Table 8 of the Nestlé Printing Inks for Food Packaging (07/04/2022).

EuPIA Exclusion List (March 2021)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (March 2021) are intentionally 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.

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