

FOOD CONTACT

BYK Regulatory Information

BYK-3450

Silicone surfactant for aqueous printing inks and overprint varnishes, inkjet inks, aqueous coatings, adhesives, and care products providing a significant reduction in surface tension. Particularly suitable for improving the wetting of aqueous systems on very non-polar substrates. Does not increase the surface slip.

Summary

BYK-3450 is suitable according to the following compositional provisions for food contact applications, as indicated:

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

Paper and paperboard		
	Suitable for food contact paper and paperboard	Yes
Europe	Regulation (EU) No. 10/2011	See explanation
	German BfR XXXVI 'Paper and board for food contact'	Yes
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 (October 2018)	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

Adhesives

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

The components of this product or the monomers and starting substances used for manufacturing are either listed directly in Annex I – Table I of Regulation (EU) No. 10/2011 or are regulated by national legislation of a EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

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

German BfR XXXVI ‘Paper and board for food contact’

The product complies with the compositional requirements of BfR XXXVI ‘Paper and board for food contact’.

Therefore, the product can be recommended for use in food contact adhesives in the EU.

USA **21 CFR 175.105 ‘Adhesives’**

The product does not comply with the compositional requirements of Sec. 175.105 of 21 CFR FDA.

Therefore, the product cannot be recommended for use in food contact adhesives in regards to Sec. 175.105 of 21 CFR FDA.

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

Not all components are listed in table A.5 of the GB9685-2016.

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

Coatings

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

The components of this product or the monomers and starting substances used for manufacturing are either listed directly in Annex I – Table I of Regulation (EU) No. 10/2011 or are regulated by national legislation of a EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

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

CoE ResAP (2004) 1

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

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

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

The product does not meet the compositional requirements of Sec. 175.300 of 21 CFR FDA.

Therefore, the product cannot be recommended for use in food contact coatings in regards to Sec. 175.300 of 21 CFR FDA.

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.

Paper and paperboard

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

The components of this product or the monomers and starting substances used for manufacturing are either listed directly in Annex I – Table I of Regulation (EU) No. 10/2011 or are regulated by national legislation of a EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

German BfR XXXVI ‘Paper and board for food contact’

The product complies with the compositional requirements of BfR XXXVI ‘Paper and board for food contact’.

Therefore, the product can be recommended for use in food contact paper and paperboard 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) 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 (October 2018)**

According to the recipe, the product does not intentionally 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 (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 added. 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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