

FOOD CONTACT

BYK Regulatory Information

BYK-1642

Polymer-based, VOC- and silicone-free defoamer for aqueous coatings, printing inks, adhesives, paper coatings and construction chemicals. Optimum performance at the lowest dosage.

Summary

BYK-1642 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	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 'Resinous and polymeric coatings'	Yes
China	GB9685-2016, table A.2 'Coatings'	No
Adhesives		
EU	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymers Dispersions'	Yes
	German BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 175.105 'Adhesives'	Yes
China	GB9685-2016, table A.5 'Adhesives'	No
Paper & paperboard		
EU	Suitable for food contact paper & paperboard	Yes
	Regulation (EU) No. 10/2011	No
	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	
Suitable for food contact printing inks	Yes
Swiss Ordinance 817.023.21, Annex 10	Yes
Nestlé Guidance Note on Packaging Inks (Oct. '18)	Yes
EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)	Yes

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 components of this product are either manufactured using monomers/starting substances which are fully evaluated as SCF - list 0-4 and directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments), or are directly listed themselves. Restrictions apply. One active component of this product is not listed as a “polymeric additive” in Annex I – Table I of Regulation (EU) No. 10/2011 and therefore the product can formally not be used as an additive in compliance with this regulation.

German BfR XIV ‘Polymer Dispersions’

For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by the German BfR-Recommendation XIV “Polymer Dispersions”.

CoE ResAP (2004) 1

For this product, either the components themselves or the monomers and starting substances used for manufacturing are listed in the CEPE ‘Code of practice for food contact coatings’, Edition 4, Version Feb. 2009.

Dual use

The product contains a ‘dual use additive’:

Sorbitan oleate (CAS-No. 1338-43-8, E494, amount < 10%).

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

Formulation aids are not covered by the food contact status.

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

The product is covered by the compositional requirements of 21 CFR Sec. 175.300.

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

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 food contact coatings in China.

Adhesives

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

The components of this product are either manufactured using monomers/starting substances which are fully evaluated as SCF - list 0-4 and directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments), or are directly listed themselves. Restrictions apply. One active component of this product is not listed as a “polymeric additive” in Annex I – Table I of Regulation (EU) No. 10/2011 and therefore the product can formally not be used as an additive in compliance with this regulation.

German BfR XIV ‘Polymers Dispersions’

For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by the German BfR-Recommendation XIV “Polymer Dispersions”.

German BfR XXXVI ‘Paper and board for food contact’

For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by the German BfR-Recommendation XXXVI “Paper and board for food contact”.

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

Formulation aids are not covered by the food contact status.

USA **21 CFR 175.105 ‘Adhesives’**

The product can be recommended for applications described in 21 CFR Sec. 175.105, since the components for manufacturing of the product, are listed within that respective section.

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

China **GB9685-2016, table A.4 ‘Adhesives’**

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

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

Paper & paperboard

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

The components of this product are either manufactured using monomers/starting substances which are fully evaluated as SCF - list 0-4 and directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments), or are directly listed themselves. Restrictions apply. One active component of this product is not listed as a “polymeric additive” in Annex I – Table I of Regulation (EU) No. 10/2011 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’

For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by the German BfR-Recommendation XXXVI “Paper and board for food contact”.

Therefore, the product can be recommended for use in food contact paper and paperboard in the EU.

Formulation aids are not covered by the food contact status.

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

The product is not covered by the compositional requirements of Sec. 176.170 of 21 CFR FDA.

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

The product is not covered by the compositional requirements of Sec. 176.180 of 21 CFR FDA.

Therefore, the product cannot be recommended for use in paper and paperboard, in regards to Sec. 176.170 and Sec. 176.180 of 21 CFR FDA.

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

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

Therefore, the product cannot be recommended for 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 2020). The monomers/starting substances for manufacturing the active components and all other components are listed on the A-list 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 (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 (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.

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
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