

FOOD CONTACT

BYK Regulatory Information

BYK-012

VOC-free and silicone-free defoamer on polymer-basis for aqueous coatings, adhesives, and paper coatings. Particularly suitable for premium high-gloss architectural coatings. Optimal effect despite addition of smallest amounts only.

Summary

BYK-012 is suitable according to the following compositional provisions for food contact applications, as indicated:

Adhesives		
	Suitable for food contact adhesives	Yes
EU	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR 175.105 'Adhesives'	No
China	GB9685-2016, table A.5 'Adhesives'	No
Paper and paperboard		
	Suitable for food contact paper and paperboard	Yes
EU	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

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	<p><u>Regulation (EU) No. 10/2011</u></p> <p>The monomers and starting substances used for manufacturing of the product are listed in Annex I – Table I of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food, excluding the active defoamer component, which has been evaluated by EFSA. However, a main active component is not listed as “polymeric additive” in a.m. REG.</p>

(EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in plastics in compliance with this regulation.

German BfR XIV ‘Polymer Dispersions’

All components of this product (excluding the active defoamer component, which has been evaluated by EFSA) are conform to the compositional requirements of the German BfR-Recommendation XIV. ‘Polymer Dispersions’.

In order to meet the restrictions for the active defoamer component, the maximum use level in wet adhesive formulations is 0.3% (solid content 40%, dry film thickness of 12 µm). Furthermore, we recommend migration testing to verify compliance.

Therefore, the product can be recommended for use in food contact adhesives, as described above.

USA **21 CFR 175.105 ‘Adhesives’**

The product does not comply with the compositional requirements of Title 21 CFR (FDA) Regulations for indirect food additives.

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

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

The monomers and starting substances used for manufacturing of the product are listed in Annex I – Table I of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food, excluding the active defoamer component, which has been evaluated by EFSA. However, a main active component is not listed as “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in plastics in compliance with this regulation.

German BfR XXXVI ‘Paper and board for food contact’

All components of this product (excluding the active defoamer component, which has been evaluated by EFSA) are conform to the compositional requirements of the German BfR-Recommendation XXXVI ‘Paper and board for food contact’.

In order to meet the restrictions for the active defoamer component, the maximum use level in wet paper and board formulations is 0.3% (solid

content 40%, dry film thickness of 12 µm). Furthermore, we recommend migration testing to verify compliance.

Therefore, the product can be recommended for use in food contact adhesives, as described above.

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 Title 21 CFR (FDA) Regulations for indirect food additives.

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

The product does not comply with the compositional requirements of Title 21 CFR (FDA) Regulations for indirect food additives.

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.

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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This issue replaces all previous versions

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