

FOOD CONTACT

BYK Regulatory Information

BYK-037

VOC-free defoamer on the basis of a mineral oil emulsion for aqueous emulsion paints, plasters and adhesives. Contains silicone.

Technically recommended use level: 0.1 – 0.5%

Summary

BYK-037 is suitable according to the following compositional provisions for food contact applications, as indicated:

Adhesives		
EU	Suitable for food contact adhesives	Yes (0.1%)
	Regulation (EU) No. 10/2011	Yes (0.1%)
	German BfR XIV 'Polymer Dispersions'	No
	German BfR XXXVI 'Paper and board for food contact'	No
USA	21 CFR 175.105 'Adhesives'	Yes (0.1%)
China	GB9685-2016, table A.5 'Adhesives'	No
Coatings		
EU	Suitable for food contact coatings	Yes (0.1%)
	Regulation (EU) No. 10/2011	Yes (0.1%)
	German BfR XIV 'Polymer Dispersions'	No
	CoE ResAP (2004) 1	No
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes (0.1%)
China	GB9685-2016, table A.2 'Coatings'	No

Note: BYK-037 contains a significant amount of solvent [petroleum hydrocarbons, boiling area > 200 °C]. Solvents are assumed to evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Consequently, solvents and other formulation aids are exempted from our evaluation and not covered by the food contact status.

Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 and 174.5 of 21 CFR FDA should be fulfilled..

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 an EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

To meet defined restrictions, we recommend following use conditions:

- max. use level of 0.1% in wet adhesive formulations
- formulations with a solid content of 40%
- resulting dry thickness of 12 µm

The use level can be adapted for deviating thickness and solid content.

German BfR XIV ‘Polymer Dispersions’

The product does not comply with the compositional requirements of the BfR recommendation XIV ‘Polymer Dispersions’.

German BfR XXXVI ‘Paper and board for food contact’

The product does not comply with the compositional requirements of the BfR recommendation XXXVI ‘Paper and board for food contact’.

Dual use additive

The product contains a dual use additive: Sorbitan monooleic acid ester (E494), CAS No. 1338-43-8.

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

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 0.1% in wet adhesive formulations
- formulations with a solid content of 40%
- resulting dry thickness of 12 µm

The use level can be adapted for deviating thickness and solid content.

China

GB9685-2016, table A.5 ‘Adhesives’

The components of BYK-037 are not fully listed in 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 an EU member state as Polymer Production Aid (PPA). Specific Migrations Limits and/or restrictions apply.

To meet defined restrictions, we recommend following use conditions:

- max. use level of 0.1% in wet coating formulations
- formulations with a solid content of 40%
- resulting dry thickness of 12 µm

The use level can be adapted for deviating thickness and solid content.

German BfR XIV ‘Polymer Dispersions’

The product does not comply with the compositional requirements of the BfR recommendation XIV ‘Polymer Dispersions’.

CoE ResAP (2004) 1

The product does not comply with the compositional requirements of the Council of Europe ResAP (2004) 1, Version of Feb. 2009.

Dual use additive

The product contains a dual use additive: Sorbitan monooleic acid ester (E494), CAS No. 1338-43-8.

Therefore, the product can be recommended for food contact coatings in the EU, as described above.

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 studies and external consultation, we recommend following use conditions:

- max. use level of 0.1% in wet coating formulations
- formulations with a solid content of 40%
- resulting dry thickness of 12 µm

The use level can be adapted for deviating thickness and solid content.

China **GB9685-2016, table A.2 ‘Coatings’**

The components of BYK-037 are not fully listed in GB9685-2016.

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

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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