

# FOOD CONTACT

## BYK Regulatory Information

### BYK-014

VOC-free, silicone-free polymer-based defoamer for aqueous architectural coatings, plasters, adhesives as well as care products and polishes. Optimum performance at the lowest dosage.

#### Summary

BYK-014 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
Europe	Suitable for food contact coatings	Yes
	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
	CoE ResAP (2004) 1	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes (max. 0.32%)
China	GB9685-2016, table A.2 'Coatings'	No
Adhesives		
Europe	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
	German BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 175.105 'Adhesives'	Yes (max. 0.8%)
China	GB9685-2016, table A.5 'Adhesives'	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

### Coatings

#### Europe

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

This product is covered by the compositional requirements of Regulation (EU) No. 10/2011.

##### **German BfR XIV 'Polymer Dispersions'**

The product is covered by the compositional requirements of BfR XIV 'Polymer Dispersions', except for one component with defoaming activity.

##### **CoE ResAP (2004) 1**

Either the components themselves or the monomers and starting substances used for manufacturing are covered by the CoE ResAP (2004) 1, Version Feb. 2009, except for one component with defoaming activity.

##### **Dual use**

The product contains the 'dual use additive' (< 0.3%) for which restrictions apply: 2,6-Di-tert-butylp-cresol (BHT; CAS-No. 128-37-0, E321).

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

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#### USA

##### **21 CFR 175.300 'Resinous and polymeric coatings'**

An ingredient of BYK-014 is regulated by a FCN for use in coatings while all other ingredients are directly listed in 175.300 or can be cross-referenced from other applicable sections. Therefore, the product can be used in compliance with the requirements of FDA 21 CFR 175.300. We recommend the following use conditions:

- Max. use level of 0.32% in wet coating 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.

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#### China

##### **GB9685-2016, table A.2 'Coatings'**

The product does not comply with the National Food Safety Standard of the People's Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles (GB9685-2016).

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**Adhesives**

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

This product is covered by the compositional requirements of Regulation (EU) No. 10/2011.

**German BfR XIV 'Polymer Dispersions'**

The product is covered by the compositional requirements of BfR XIV 'Polymer Dispersions', except for one component with defoaming activity.

**German BfR XXXVI 'Paper and board for food contact'**

The product is covered by the compositional requirements of BfR-Recommendation XXXVI 'Paper and board for food contact', except for one component with defoaming activity.

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

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**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 0.8% 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.
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**China**     **GB9685-2016, table A.5 'Adhesives'**

The product does not comply with the National Food Safety Standard of the People's Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles (GB9685-2016).

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## 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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