

# FOOD CONTACT

## BYK Regulatory Information

### ANTI-TERRA-U 80

Wetting and dispersing additive for solvent-borne systems to stabilize inorganic pigments.

#### Summary

ANTI-TERRA-U 80 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
China	GB9685-2016, table A.2 'Coatings'	No

Solvents and 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

#### 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 Migration Limits and/or restrictions apply.

#### BfR XIV ‘Polymer Dispersions’

The components of this product are covered by the compositional requirements of the German BfR-Recommendation XIV. ‘Polymer Dispersions’.

#### CoE ResAP (2004) 1

The product is conform with the compositional requirements of the Council of Europe Framework Resolution ResAP (2004) 1 on coatings intended to come into contact with foodstuffs.

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

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#### 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 Sec. 175.300 of 21 CFR FDA.

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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).

## Solvents

The product contains a significant amount of solvent [2-butoxyethanol, with a boiling point of approximately 171 °C]. Solvents are considered to evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 should be fulfilled.

## 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

Regulatory Affairs  
BYK-Chemie GmbH

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*This issue replaces all previous versions*

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