

FOOD CONTACT

BYK Regulatory Information

ANTI-TERRA-U

Wetting and dispersing additive for solvent-borne industrial and architectural coatings to stabilize inorganic pigments.

Summary

ANTI-TERRA-U is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	Yes
Europe	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'
China	GB9685-2016, table A.2 'Coatings'	No
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes
Printing inks		
Europe	Suitable for food contact printing inks	Yes
	Swiss Ordinance 817.023.21, Annex 10	Yes
Industry	Nestlé Guidance Note on Packaging Inks (Oct. '18)	No
China	GB9685-2016, table A.4 'Inks'	No

Solvents and other 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 monomers and starting materials used to manufacture the components of the product are listed directly in Annex I - Table I of Regulation (EU) No 10/2011. The main active component as such is not listed as a “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in compliance with this regulation.

German 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.

Dual use additive

The product contains the following dual use additives, for which restrictions apply:

- 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321);
- Propylene glycol (CAS-No. 57-55-6, E1520).

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

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

The active components are conform to the compositional requirements of Sec. 175.300 of Regulations for indirect food additives as laid down in 21 CFR.

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

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).

MERCOSUR **GMC Res. n. 39/19 & n. 02/12**

The product is authorized for use under MERCOSUR GMC Resolution n. 39/19 and MERCOSUR GMC Resolution n. 02/12. Specific migration limits apply.

Therefore the product can be recommended for use in food contact coatings in MERCOSUR member states.

Solvents and other formulation aids are not covered by the food contact status.

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 2019). 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.

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). However, the solvent toluene (CAS 108-88-3), which is listed in Table 6, and ethylbenzene (CAS 100-41-4), which is listed in Table 7, are present.

China GB9685-2016, table A.4 'Inks'

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 [see Safety Datasheet]. 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.

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This issue replaces all previous versions

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