

FOOD CONTACT

BYK Regulatory Information

ANTI-TERRA-U 100

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

Summary

ANTI-TERRA-U 100 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 | No |
| | GMC Resolution n. 02/12 | No |
| Printing inks | | |
| Europe | Suitable for food contact printing inks | Yes |
| | Swiss Ordinance 817.023.21 (Annex 10) | 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.4 'Inks' | No |
| Industry | Nestlé Guidance note on Packaging Inks (dated October 2018) | Yes |
| | EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018) | Yes |

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.

Dual use additive (restricted)

This product contains ‘dual use additives’ for which restrictions apply:

- 2,6-Di-tert-butyl-p-cresol (BHT; CAS No. 128-37-0, E321).
- Sorbitan oleate (CAS No. 1338-43-8, E494).

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

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.

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 Resolution n. 39/19 & 02/12**

The product does not comply with the compositional requirements of MERCOSUR GMC Resolution n. 39/19 and MERCOSUR GMC Resolution n. 02/12.

Therefore, the product is not authorized for use in coatings.

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 2020). 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.

USA **21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'**

The product does not comply with Sec. 176.170 of Title 21 CFR (FDA) Regulations for indirect food additives, since not all components are fully listed under Sec. 176.170.

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

The product does not comply with Sec. 176.180 of Title 21 CFR (FDA) Regulations for indirect food additives, since not all components are fully listed under Sec. 176.180.

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).

Industry **Nestlé Guidance note on Packaging Inks (dated October 2018)**

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).

EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018) are present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

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
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This issue replaces all previous versions

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