

FOOD CONTACT

BYK Regulatory Information

AQUACER 513

HDPE-based VOC-free wax emulsion for improving the surface protection in aqueous coatings and printing inks as well as in aqueous care products and polishes.

Summary

AQUACER 513 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	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'	No
China	GB9685-2016, table A.2 'Coatings'	Yes
Printing inks		
Europe	Suitable for food contact printing inks	Yes
	Swiss Ordinance 817.023.21, Annex 10	Yes
Industry	Nestlé Printing Inks for Food Packaging (07/04/2022)	See explanation
	EuPIA Exclusion List (March 2021)	See explanation

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

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

German BfR XIV ‘Polymer Dispersions’

The product is covered by the compositional requirements of BfR-Recommendation XIV.

CoE ResAP (2004) 1

The product is covered by the compositional requirements of CoE ResAP (2004) 1. For this product, either the active components themselves or the monomers and starting substances used for manufacturing are listed in the CEPE ‘Code of practice for food contact coatings’, Edition 4, Version Feb. 2009.

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 does not comply with Title 21 CFR (FDA) Regulations for indirect food additives. The components are not fully listed under section 175.300.

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

All active components of AQUACER 513 are listed in GB9685-2016 table A2 for coating applications.

Therefore, the product can be recommended for use in food contact printing inks in China.

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.

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

Industry **Nestlé Printing Inks for Food Packaging (07/04/2022)**

According to the recipe, the product does not intentionally contain any of the substances listed in Table 5 – Table 8 of the Nestlé Printing Inks for Food Packaging (07/04/2022). The product contains CMIT/MIT (3:1) [CAS no. 55965-84-9] (< 0.01 %), which itself is classified with the Hazard Statements given in Group A and B of the EuPIA Exclusion Policy, as mentioned under 4. 'General Nestlé Exclusions and Minimisations'. The product itself is not classified with the Hazard Statements given in Group A and B of the EuPIA Exclusion Policy.

EuPIA Exclusion List (March 2021)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (March 2021) are intentionally present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B, although the product contains CMIT/MIT (3:1) [CAS no. 55965-84-9] (< 0.01 %), which itself is classified with 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.

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