

FOOD CONTACT

BYK Regulatory Information

DISPERBYK-182

Wetting and dispersing additive for aqueous and solvent-borne coating systems and printing inks. For all-purpose pigment concentrates of non-polar through to aqueous systems.

Summary

DISPERBYK-182 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	Suitable for food contact coatings	No
	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	No
	CoE ResAP (2004) 1	No
USA	21 CFR 175.300 'Resinous and polymeric coatings'	No
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
	EuPIA Exclusion List (Nov. '16 – Corrigendum Dec. '18)	Yes

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	<p><u>Regulation (EU) No. 10/2011</u> This product does not comply with the Regulation (EU) No. 10/2011.</p> <p><u>German BfR XIV 'Polymer Dispersions'</u> The components of this product are not fully covered by the German BfR-Recommendation XIV. "Polymer Dispersions".</p> <p><u>CoE ResAP (2004) 1</u> For this product, not all components 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.</p>

Therefore, the product cannot 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 sections 175.300.

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 in Annex 10. Specific migration limits apply.

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

USA **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 2-Methoxy-1-methylethylacetat (CAS 108-65-6), which is listed in Table 7, is present.

EuPIA Exclusion List (Nov. '16 – Corrigendum Dec. '18)

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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