

FOOD CONTACT

BYK Regulatory Information

DISPERBYK-103

Wetting and dispersing additive for solvent-borne matting agent pastes.

Summary

DISPERBYK-103 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	Yes
EU	Regulation (EU) No. 10/2011	No
	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'	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	No
	EuPIA Exclusion List	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

Regulation (EU) No. 10/2011

The main active component of above mentioned product is manufactured using starting materials which are fully evaluated as SCF-list 0-4 and directly listed in Annex I – Table I of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food (as amended). Specific migration limits apply. The main active component as such is not listed as “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’

This product is covered by the compositional requirements of BfR XIV ‘Polymer Dispersions’.

CoE ResAP (2004) 1

This product is covered by the compositional requirements of CoE ResAP (2004) 1.

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 the compositional requirements of 175.300 ‘Resinous and polymeric coatings’.

Therefore, the product cannot 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).

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.

Industry Nestlé Guidance note on Packaging Inks (October 2018)

According to the recipe, the product does not contain any of the substances listed in Table 1 – Table 6 of the Nestlé Guidance note on Packaging Inks (dated October 2018). However, the solvent 2-Methoxy-1-methylethylacetat, which is listed in Table 7 'Minimize list for solvents, is present.

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
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This issue replaces all previous versions

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