

FOOD CONTACT

BYK Regulatory Information

BYK-088

Summary

BYK-088 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'	Yes
China	GB9685-2016, table A.2 'Coatings'	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes
Adhesives		
EU	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 175.105 'Adhesives'	Yes
Printing inks		
Europe	Suitable for food contact printing inks	Yes
	Swiss Ordinance 817.023.21, Annex 10	Yes
	Nestlé Printing Inks for Food Packaging (02/04/2024)	See explanation
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'	Yes

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

EU **Regulation (EU) No. 10/2011**

All components of this product are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments). Specific Migrations Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by the German BfR-Recommendation XIV. “Polymer Dispersions”.

CoE ResAP (2004) 1

For this product, either the 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.

Dual use

The product contains a ‘dual use additive’ to which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321, amount < 0.1 %).

Solvent

Additionally, the product contains a significant amount of volatile solvent, which is not in scope of the regulation. Solvents are expected to evaporate while producing the finished food contact article resulting in traces of no toxicological concern. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of Framework Regulation (EC) 1935/2004 applies.

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 can be recommended for applications described in 21 CFR Sec. 175.300, since the components for manufacturing of the product, are listed within that respective section.

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

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

All active components of BYK-088 are listed in GB9685-2016 table A2 for coating application.

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

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 and/or restrictions apply.

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

Adhesives

EU **Regulation (EU) No. 10/2011**

All components of this product are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments). Specific Migrations Limits and/or restrictions apply.

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

USA **21 CFR 175.105 'Adhesives'**

The product can be recommended for applications described in 21 CFR Sec. 175.105, since the components for manufacturing of the product, are listed within that respective section.

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 manufactured from components listed in Swiss Ordinance 817.023.21 (Version of 1 February 2024) Annex 10, as well as non-listed components. The non-listed components are self-controlled substances with a Specific Migration Limit of 10 ppb. In addition, this product may contain Non-Intentionally Added Substances such as those listed in the SML Disclosure Form, which may be Risk Assessed in the final material.

If migration limits are respected, the product can be recommended for use in food contact printing inks in Europe. For additional information on applicable migration limits, please contact us via our webform: <https://www.byk.com/en/contact?topic=regulatory-affairs>

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

Nestlé Printing Inks for Food Packaging (02/04/2024)

According to the recipe, the product contains naphtha (petroleum) (CAS 64741-65-7) which is defined as a mineral oil saturated hydrocarbons (MOSH), a component which should be minimised and for which its residual value must be below 0.1% of the dry film, and SVHC impurity D4 (CAS 556-67-2) as mentioned under 4. 'General Nestlé Exclusions and Minimisations'.

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

The product cannot be recommended for applications described in 21 CFR Sec. 176.170, since not all components for manufacturing of the product, are listed within that respective section.

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

The product can be recommended for applications described in 21 CFR Sec. 176.180, since the components for manufacturing of the product, are listed within that respective section.

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

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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