

FOOD CONTACT

BYK Regulatory Information

BYK-1794

Summary

BYK-1794 is suitable according to the following compositional provisions for food contact applications, as indicated:

Adhesives		
	Suitable for food contact adhesives	Yes
Europe	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR FDA 175.105 'Adhesives'	Yes
China	GB9685-2016, table A.5 'Adhesives'	No
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 (02/04/2024)	See explanation
	EuPIA Exclusion List (March 2024)	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

Adhesives

Europe Regulation (EU) No. 10/2011

The main active component as such is not listed as a “polymeric additive” in REGULATION (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’

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

Dual use additive

The product contains a ‘dual use additive’ (< 0.4%) for which restrictions apply: 2,6-Di-tertbutyl-p-cresol (BHT; CAS-No. 128-37-0, E321).

Therefore, BYK-1794 can be recommended for use in adhesive applications in the EU.

USA 21 CFR FDA 175.105 ‘Adhesives’

The product complies with the compositional requirements of 21 CFR FDA Sec. 175.105.

Therefore, the product can be recommended for food contact adhesives, as described in Sec. 175.105 ‘Adhesives’ of 21 CFR FDA.

China GB9685-2016, table A.5 ‘Adhesives’

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 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 on our product BRIEF 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.

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

According to the recipe, the product contains n-hexane and cyclohexane, which is mentioned under 4. 'General Nestlé Exclusions and Minimisations', as MOSH. The product contains the solvent cyclohexane (< 0,1%), which is mentioned in Table 8.2 'Minimisation list for Solvents' of the Nestlé Printing Inks for Food Packaging (02/04/2024).

EuPIA Exclusion List (March 2024)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (March 2024) are intentionally 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
BYK-Chemie GmbH

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