

FOOD CONTACT

BYK Regulatory Information

BYK-A 501

Silicone-free defoamer on polymer-basis for solvent-borne and solvent-free coatings and printing inks.

Technically recommended use level: 0.1 – 1.5 %

Summary

BYK-A 501 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	No
	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'	No
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes
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 (October 2018)	No
	EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)	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

The main active components of this product are manufactured using monomers/starting substances which are 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.

However, the main active components as such are not listed as “polymeric additives” 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’

The active components of this product conform with the compositional requirements of the German BfR-Recommendation XIV. “Polymer Dispersions”.

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.

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

USA

21 CFR 175.300 ‘Resinous and polymeric coatings’

The product is compliant with the compositional requirements of Sec. 175.300 of 21 CFR FDA.

Therefore, the product can be recommended for use in food contact coatings in regards to Sec. 175.300 of 21 CFR FDA.

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

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).

MERCOSUR	<p data-bbox="403 409 826 443"><u>GMC Res. n. 39/19 & n. 02/12</u></p> <p data-bbox="403 450 1401 546">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.</p> <p data-bbox="403 553 1401 616">Therefore, the product can be recommended for use in food contact coatings in MERCOSUR member states.</p>
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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) since all 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 7 of the Nestlé Guidance note on Packaging Inks (dated October 2018). However, the solvent 2-Methoxy-1-methylethylacetat, which is listed in Table 7, 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.

The product contains a significant amount of solvent [Solvent naphtha (petroleum), heavy aromatic, with a boiling range from 160 °C – 220°C] and 2-methoxy-1-methylethyl acetate, with a boiling point of approximately 146°C]. Solvents are currently not regulated by food contact positive lists as it is assumed that solvents evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 in the EU, and FDA 21 CFR 174.5 in the US, should be fulfilled.

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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