

FOOD CONTACT

BYK Regulatory Information

BYK-A 500

Silicone-free air release additive for unsaturated polyester resins as well as polyurethane and epoxy systems; particularly recommended for transparent systems. Also suitable for epoxy floorings.

Technically recommended use level: 0.1 – 0.5%

Summary

BYK-A 500 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

Solvents and other formulation aids are not covered by the food contact status. For further details, please refer to the 'Explanation'.

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, or the monomers/starting substances used for the manufacture of those components, 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 (including all amendments). 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 the product are conform with the compositional requirements of the German BfR-Recommendation XIV “Plastic 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 CoE ResAP (2004) 1, Version Feb. 2009.

Dual use additive

The product contains a “dual use additive” (< 0.5%) for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321).

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 active components of the product are listed in 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, as described above.

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).

The product contains a significant amount of solvents (boiling range ca. 140 - 200°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 and 174.5 of CFR 21 FDA 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
Regulatory Affairs
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