

FOOD CONTACT

BYK Regulatory Information

BYK-314

Summary

BYK-314 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'
China	GB9685-2016, table A.2 'Coatings'	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	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 component of this product is a polymer (polyester modified silicone) and manufactured using monomers 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. Restrictions apply. The main active component as such is not listed as a “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’

All components of this product are conform to the compositional requirements of 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.

Therefore, the product can be recommended for 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 silicone active compound is specifically cleared under Title 21 CFR (FDA) Sec. 175.300 “Polymeric and resinous coatings”. However, the use level is strongly restricted. Based on new data in regard to the molecular weight distribution a study on the bioavailability and the resulting potential dietary exposure has been subcontracted (Law firm Mayer-Brown, June, 2008). The outcome of this study (opinion letter available) extends the current FDA-clearance, so that the product can now be used under the following conditions:

- Use level up to 0.53 weight % BYK-314 in the wet coating formulation (for a solid content of 40 %; corresponding to a concentration of 1.33 % BYK-314 in the dried coating).
- The film thickness may not exceed 12 µm (0.5 mil).
- For coatings with other dry mass/ film thickness the use level need to be adapted accordingly.
- For solvents, FDA 21 CFR Sec. 174.5 applies; it should be removed during the manufacturing process to an extend leaving only technical unavoidable residues.

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

China **GB9685-2016, table A.2 'Coatings'**

This product is in compliance with table A.2 'Coatings' of the National Standard of the People's Republic of China, GB96852016.

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 apply.

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

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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This issue replaces all previous versions - Printed in Germany.

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