

FOOD CONTACT

BYK Regulatory Information

BYK-375

Silicone surface additive for aqueous systems. Hydroxy-functional. Medium reduction of surface tension.

Summary

BYK-375 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 (max: 0.1%) |
| China | GB9685-2016, table A.2 'Coatings' | No |

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.

Solvents are not covered by above statement.

Explanation

Coatings

EU Regulation (EU) No. 10/2011

The active polymeric silicone component as such is not listed as a “polymeric additive” 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), and therefore the product can formally not be used as an additive.

German BfR XIV ‘Polymer Dispersions’

The product is 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’, Version Feb. 2009.

Dual use additive

The product contains a ‘dual use additive’ (< 0.3%) 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 food contact coatings in the EU.

Solvents are not covered by above statement.

USA 21 CFR 175.300 ‘Resinous and polymeric coatings’

The product can be used in compliance with the requirements of FDA 21 CFR 175.300, if used as recommended below. Based on studies and external consultation, we recommend following use conditions:

- Max. use level of 0.1% in wet coating formulations.
- For formulations with a solid content of 40% and a dry thickness of 12 µm.
- The use level can be adapted for deviating thickness and solid content.

Solvents are not covered by above statement.

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).

Solvent

The product contains a significant amount of solvent [Dipropylene glycolmonomethylether CAS No. 34590-94-8; boiling point 190°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 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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