FOOD CONTACT

BYK Regulatory Information

BYK-3761

Silicone-containing surface additive for thermosets and solvent-borne coating systems with a strong reduction in the surface tension. Excellent substrate wetting, prevents cratering and increases surface slip.

Summary

BYK-3761 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	Suitable for food contact coatings	See explanation
	Regulation (EU) No. 10/2011	See explanation
	German BfR XIV ‘Polymer Dispersions’	See explanation
	CoE ResAP (2004) 1	See explanation
USA	21 CFR 175.300 ‘Resinous and polymeric coatings’	See explanation (max. 0.24%)
China	GB9685-2016, table A.2 ‘Coatings’	No
MERCOSUR	GMC Resolution n. 39/19	No
	GMC Resolution n. 02/12	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 (07/04/22)	No
	EuPIA Exclusion List (March 2021)	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

Coatings

EU

Regulation (EU) No. 10/2011[*(1)]

The main active component of this product is directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments).

German BfR XIV 'Polymer Dispersions'[*(1)]

The main active component complies with the compositional requirements of the BfR XIV 'Polymer Dispersions'.

CoE ResAP (2004) 1[*(1)]

The main active component is covered by the CoE ResAP (2004) .

Dual use additive

The product contains a 'dual use additive' (< 0.01%) for which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321).

[*(1)] Solvents and other formulation aids are not covered by the food contact status. Please see the note for 'Solvents'.

USA

21 CFR 175.300 'Resinous and polymeric coatings'[*(1)]

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 0.24% 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.

[*(1)] Solvents and other formulation aids are not covered by the food contact status. Please see the note for 'Solvents'.

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

GMC Resolutions n. 39/19 & 02/12

The product does not comply with the compositional requirements of MERCOSUR GMC Resolution n. 39/19 and MERCOSUR GMC Resolution n. 02/12.

Therefore, the product is not authorized for use in coatings.

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.

Additional note: the non-listed D4 (CAS 556-67-2) is present, as an impurity. Its amount is referred to in our BRIEF document.

Therefore, the product can be recommended for use in food contact printing inks in Europe.

Industry

Nestlé Printing Inks for Food Packaging (07/04/2022)

According to the recipe, the product contains the substances D4 (CAS 556-67-2), D5 (CAS 541-02-6), xylene (CAS 1330-20-7) and benzene (CAS 71-43-2) which are mentioned under 4. 'General Nestlé Exclusions and Minimisations'. Additionally, the product contains the solvent toluene (CAS 108-88-3), which is also mentioned in Table 8.1 'Exclusion list for Solvents' and the solvent ethylbenzene (CAS 100-41-4), which is also mentioned in Table 8.2 'Minimisation list for Solvents' of the Nestlé Printing Inks for Food Packaging (07/04/2022).

EuPIA Exclusion List (March 2021)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (March 2021) are present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

(*1) **Solvents**

The product contains a significant amount of solvents; 2-phenoxyethanol [boiling point: 244,3 °C] & xylene [boiling point ranges from: 136 – 145 °C]. More information about present solvents can be found in the Safety Data Sheet. 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 21 CFR 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
BYK-Chemie GmbH

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