

FOOD CONTACT

BYK Regulatory Information

BYK-378

Solvent-free silicone surface additive for aqueous, solvent-borne, and solvent-free coatings and adhesives to increase surface slip and to greatly reduce surface tension. Minor foam stabilization and low dosage.

Technically recommended use level: 0.01 – 0.3%

Summary

BYK-378 is suitable according to the following compositional provisions for food contact applications, as indicated:

Adhesives		
Europe	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
	German BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 175.105 'Adhesives'	Yes (max. 0.048%)
China	GB9685-2016, table A.5 'Adhesives'	No
Coatings		
Europe	Suitable for food contact coatings	Yes
	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
	CoE ResAP (2004) 1	No
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes (max. 0.048%)
China	GB9685-2016, table A.2 'Coatings'	No
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 (Oct. '18)	Yes
	EuPIA Exclusion List (Nov. '16 – Corrigendum Dec. '18)	Yes

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

Adhesives

Europe Regulation (EU) No. 10/2011

The components of this product or the monomers and starting materials used to manufacture the components of this product are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments). Specific Migrations Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

The product is covered by the compositional requirements of BfR XIV ‘Polymer Dispersions’.

German BfR XXXVI ‘Paper and board for food contact’

The product is covered by the compositional requirements of BfR XXXVI ‘Paper and board for food contact’.

Dual use

The product contains a ‘dual use additive’ to which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321, amount < 0.1%).

In summary, the product can be recommended for use in food contact adhesives in the EU.

Formulation aids are not covered by the food contact status.

USA 21 CFR 175.105 ‘Adhesives’

The product can be used in compliance with the requirements of FDA 21 CFR 175.105, if used as recommended below. Based on studies and external consultation, we recommend following use conditions:

- Max. use level of 0.048% 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.

Formulation aids are not covered by the food contact status.

China GB9685-2016, table A.5 ‘Adhesives’

Not all components are listed in GB9685-2016.

Coatings

Europe **Regulation (EU) No. 10/2011**

The components of this product or the monomers and starting materials used to manufacture the components of this product are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments). Specific Migrations Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

The product is covered by the compositional requirements of BfR XIV ‘Polymer Dispersions’.

CoE ResAP (2004) 1

The product is not fully covered by the CoE ResAP (2004) 1, Version Feb. 2009.

Dual use

The product contains a ‘dual use additive’ to which restrictions apply: 2,6-Di-tert-butyl-p-cresol (BHT; CAS-No. 128-37-0, E321, amount < 0.1%).

In summary, the product can be recommended for use in food contact coatings in the EU.

Formulation aids are not covered by the food contact status.

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 0.048% 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.

Formulation aids are not covered by the food contact status.

China **GB9685-2016, table A.2 ‘Coatings’**

Not all components are listed in GB9685-2016.

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 2019) 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 food contact printing inks in Europe.

Industry **Nestlé Guidance Note on Packaging Inks (Oct. '18)**

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).

EuPIA Exclusion List (Nov. '16 – Corrigendum Dec. '18)

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.

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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