

# FOOD CONTACT

## BYK Regulatory Information

### BYK-019

Silicone-containing defoamer for aqueous pigment concentrates for use in coatings, printing inks and overprint varnishes. Prevents foam during grinding. Long-term and shear stability. Particularly suitable for resin-free grinds (slurries).

Technically recommended use level: 0.1 – 1 %

#### Summary

BYK-019 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'	No
China	GB9685-2016, table A.2 'Coatings'	Yes
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 (07/04/2022)	See explanation
	EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)	Yes
China	GB9685-2016, table A.4 'Inks'	No

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

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

The monomers and starting materials used to manufacture the components of the product are listed directly in Annex I - Table I of Regulation (EU) No 10/2011.

#### **German BfR XIV 'Polymer Dispersions'**

For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by 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.

#### **Solvents**

The product contains a significant amount of solvent 2-methoxymethylethoxy – propanol, boiling point: approx.. 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.

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.

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#### **USA**      **21 CFR 175.300 'Resinous and polymeric coatings'**

The product does not comply with Sec. 175.300 of Title 21 CFR (FDA) Regulations for indirect food additives.

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

The active components of BYK-019 are listed in GB9685-2016 table A2 for coating application.

Therefore, the product can be recommended for use in food contact coatings in China.

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

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<b>MERCOSUR</b>	<b><u>GMC Res. n. 39/19 &amp; n. 02/12</u></b> 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.
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## Printing inks

<b>Europe</b>	<b><u>Swiss Ordinance 817.023.21, Annex 10</u></b> 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 the EU.
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<b>Industry</b>	<b><u>Nestlé Printing Inks for Food Packaging (07/04/2022)</u></b> According to the recipe, the product contains D4 (CAS 556-67-2) (amount: $\geq 0.01 - < 0.1$ %), D5 (CAS 541-02-6) (amount: $\geq 0.01 - < 0.1$ %), D6 (CAS 540-97-6) (amount: $\geq 0,1 - < 0,25$ ), which are mentioned under 4. 'General Nestlé Exclusions and Minimisations' of the Nestlé Printing Inks for Food Packaging (07/04/2022).  <b><u>EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)</u></b> 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.
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<b>China</b>	<b><u>GB9685-2016, table A.4 'Inks'</u></b> 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).
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## 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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