

# FOOD CONTACT

## BYK Regulatory Information

### BYK-044

Silicone-containing defoamer for aqueous printing inks and overprint varnishes.

Technically recommended use level: 0.05 – 0.5%

#### Summary

BYK-044 is suitable according to the following compositional provisions for food contact applications, as indicated:

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 (March 2021)	See explanation
Adhesives		
EU	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	Yes
	BfR XIV 'Polymer Dispersions'	Yes
	BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 175.105 'Adhesives'	No
China	GB9685-2016, Table A.5 'Adhesives'	No
Paper and paperboard		
EU	Suitable for food contact paper and paperboard	Yes
	Regulation (EU) No. 10/2011	Yes
	German BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'	No
	21 CFR 176.180 'Components of paper and paperboard in contact with dry food'	No
China	GB9685-2016, table A.6 'Paper'	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.

## Explanation

### Printing inks

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#### 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). The monomers/starting substances for manufacturing the active components and all other 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.

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

According to the recipe, the product does not intentionally contain any of the substances listed in Table 5 – Table 8 of the Nestlé Printing Inks for Food Packaging (07/04/2022). The product contains CMIT/MIT (3:1) [CAS no. 55965-84-9] (< 0.01 %), which itself is classified with the Hazard Statements given in Group A and B of the EuPIA Exclusion Policy, as mentioned under 4. 'General Nestlé Exclusions and Minimisations'. The product itself is not classified with the Hazard Statements given in Group A and B of the EuPIA Exclusion Policy.

#### **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 intentionally present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B, although the product contains CMIT/MIT (3:1) [CAS no. 55965-84-9] (< 0.01 %), which itself is classified with the Hazard Statements given in Group A and B.

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**Adhesives**

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- EU**      **Regulation (EU) No. 10/2011**  
For this product is compliant with the compositional requirements of Regulation (EU) No. 10/2011.
- BfR XIV ‘Polymer Dispersions’**  
The product is compliant with the compositional requirements of BfR XIV ‘Polymer Dispersions’.
- BfR XXXVI ‘Paper and board for food contact’**  
The product is compliant with the compositional requirements of BfR XXXVI ‘Paper and board for food contact’.
- Dual use additive (restricted)**  
This product contains the ‘dual use additive’ (< 0.03%) 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 use in food contact adhesives in the EU.
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- USA**      **21 CFR 175.105 ‘Adhesives’**  
The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives.
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- China**      **GB9685-2016, Table A.5 ‘Adhesives’**  
Not all active components of BYK-044 are listed in GB9685-2016.
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## Paper and paperboard

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

For this product is compliant with the compositional requirements of Regulation (EU) No. 10/2011.

**German BfR XXXVI 'Paper and board for food contact'**

The product is compliant with the compositional requirements of BfR XXXVI 'Paper and board for food contact'.

Therefore, the product can be recommended for use in food contact paper and paperboard in the EU.

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**USA**      **21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'**

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

**21 CFR 176.180 'Components of paper and paperboard in contact with dry food'**

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

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**China**      **GB9685-2016, Table A.6 'Paper'**

Not all active components of BYK-044 are listed in 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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