

# FOOD CONTACT

## BYK Regulatory Information

### BYK-358 N

Polyacrylate-based surface additive for solvent-borne coating systems and ambient curing plastic systems to improve leveling. For semi-polar to polar systems.

#### Summary

BYK-358 N is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
Europe	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'	No
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes

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 – Corr. Dec. '18)	Yes
China	GB9685-2016, table A.4 'Inks'	No

Formulation aids and solvents 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

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

The active component of this product is a poly acrylate polymer and manufactured using monomers which are fully evaluated as SCF-list 0-4 and directly listed 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). Restrictions apply. The active component as such is not listed as a “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive.

#### **German BfR XIV ‘Polymer Dispersions’**

The product is conform with the compositional requirements of BfR-Recommendation XIV ‘Polymer Dispersions’.

#### **CoE ResAP (2004) 1**

The product is conform with the compositional requirements of the Council of Europe Framework Resolution ResAP (2004) 1 on coatings intended to come into contact with foodstuffs.

In summary, the product can be recommended for food contact coating applications in the Europe.

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#### **USA**     **21 CFR 175.300 ‘Resinous and polymeric coatings’**

The product does not comply with the compositional requirements of 21 CFR Sec. 175.300.

Therefore, the product cannot be recommended for food contact coatings as described in Sec. 175.300 of 21 CFR FDA.

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

The product does not comply with table A.2 ‘Coatings’ of 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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#### **MERCOSUR**     **GMC Resolutions n. 39/19 & 02/12**

The product is authorized for use under MERCOSUR GMC Resolution n. 39/19 and MERCOSUR GMC Resolution n. 02/12. Specific migration limits apply.

Therefore, the product can be recommended for use in food contact coatings in MERCOSUR member states.

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## 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 October 2022). The monomers/starting substances for manufacturing the active components and all other components are listed in Annex 10. Specific migration limits apply.

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

### Industry

#### **Nestlé Guidance Note on Packaging Inks**

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 (07/04/2022).

#### **EuPIA Exclusion List**

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.

### China

#### **GB9685-2016, table A.4 'Inks'**

The product does not comply with table A.4 'Inks' of 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).

## Solvents

The product contains a significant amount of solvent [see SDS for more info]. 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.

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