

# FOOD CONTACT

## BYK Regulatory Information

### RHEOBYK-7410 ET

Liquid rheology additive to generate highly thixotropic flow behavior for medium-polarity solvent-borne and solvent-free systems.

Technically recommended use level: 0.2 – 2.5%

#### Summary

RHEOBYK-7410 ET 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'	No
Adhesives		
EU	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	Yes
	German BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 175.105 'Adhesives'	No
China	GB9685-2016, table A.5 'Adhesives'	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 (dated October 2018)	Yes
	EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)	Yes

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

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

The monomers and starting substances used for manufacturing of the product are 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. However, the main active component is not listed as “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in plastics in compliance with this regulation.

#### **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 covered by the compositional requirements of CoE ResAP (2004) 1. For this product, either the active 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.

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

Solvents 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. The components are not fully listed under section 175.300.

Therefore, the product cannot be recommended for use in food contact coatings in regards to Sec. 175.300, as described above.

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#### **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).

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**Adhesives**

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

The monomers and starting substances used for manufacturing of the product are 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. However, the main active component is not listed as “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in plastics in compliance with this regulation.

**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’.

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

Solvents are not covered by the food contact status.

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**USA**      **21 CFR 175.105 ‘Adhesives’**

The product does not comply with Sec. 175.105 of Title 21 CFR (FDA) Regulations for indirect food additives. The components are not fully listed under section 175.105.

Therefore, the product cannot be recommended for use in food contact coatings in regards to Sec. 175.105, as described above.

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

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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**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 2019). 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.

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**Industry**    **Nestlé Guidance note on Packaging Inks (dated October 2018)**

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 (November 2016 - Corrigendum Dec. 2018)**

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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## Solvents

The product contains a significant amount of solvent [N-Formylmorpholin, with a boiling point of 244 °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.

## 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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