

FOOD CONTACT

BYK Regulatory Information

RHEOBYK-425

VOC-free, liquid rheology additive for aqueous dispersion-based systems to improve anti-sagging and to adjust in-can viscosity. The additive is suitable for increasing the grinding viscosity of aqueous pigment pastes.

Technically recommended use level: 0.1 – 2%

Summary

RHEOBYK-425 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	Yes
EU	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	No
China	GB9685-2016, table A.2 'Coatings'	No
Adhesives		
	Suitable for food contact adhesives	Yes
EU	Regulation (EU) No. 10/2011	No
USA	21 CFR 175.105 'Adhesives'	No
China	GB9685-2016, table A.5 'Adhesives'	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

Coatings

EU Regulation (EU) No. 10/2011

The main active components of this product are manufactured using monomers/starting substances, which are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011, but they are themselves not listed as “polymeric additives”. Therefore, the product can formally not be used as an additive in compliance with this regulation.

German BfR XIV ‘Polymer Dispersions’

For this product, either the components themselves or the monomers and starting substances used for manufacturing are listed in the German BfR-Recommendation XIV. “Plastic Dispersions”.

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

USA 21 CFR 175.300 ‘Resinous and polymeric coatings’

The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives. The components are not fully listed under sections 175.300.

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).

Adhesives

EU Regulation (EU) No. 10/2011

The main active components of this product are manufactured using monomers/starting substances, which are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011, but they are themselves not listed as “polymeric additives”. Therefore, the product can formally not be used as an additive in compliance with this regulation.

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

USA 21 CFR 175.105 ‘Adhesives’

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

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).

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
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This issue replaces all previous versions

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