

FOOD CONTACT

BYK Regulatory Information

BYK-093

Summary

BYK-093 is suitable according to the following compositional provisions for food contact applications, as indicated:

Adhesives		
EU	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	No
USA	21 CFR 175.105 'Adhesives'	Yes
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.

Please refer to the explanation section below for detailed information on the regulations and assessment criteria considered.

Explanation

Adhesives

EUROPE

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

This product is not authorized to be used as an additive under Commission Regulation (EU) No 10/2011.

BfR Recommendations XIV. Polymer dispersions

The components of this product are not fully covered by the German BfR-Recommendation XIV. "Polymer Dispersions".

Therefore, the product cannot be recommended for food contact adhesives in the EU.

USA

Adhesives 21 CFR 175.105

The product complies with the compositional requirements of 21 CFR 175.105 Adhesives. This product includes components that are listed in 21 CFR 175.105 and substances which are Generally Recognized As Safe (GRAS) allowing use in adhesives in accordance with 21 CFR 175.105 under the following use conditions:

- Max. use level of 1.04% in wet coating formulations
- For formulations with a solid content of 40% and a dry thickness of 12 µm
- The use level can be adapted for deviating thickness and solid content.

This product has been evaluated for use in food contact formulations for the general population and may not be appropriate for sensitive applications, such as infant formula and human milk or medical devices.

Therefore, the product can be recommended for use in food contact adhesives in compliance with 21 CFR 175.105 Adhesives. As per the limitations outlined in that regulation, the final adhesive must either be separated from the food by a functional barrier or used subject to the following additional limitations:

- In dry foods: The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.
- In fatty and aqueous foods:
 - The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.
 - Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement "food-packaging adhesive".

China

GB9685-2016, table A.5 'Adhesives'

The product does not comply with table A.5 'Adhesives 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.

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. Please note that it is the responsibility of both manufacturers of finished food contact articles and downstream business operators to ensure compliance with the applicable migration limits and restrictions of the finished materials or articles under specific real and/or foreseeable conditions of use.

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 is in effect for three years commencing the date of issue.

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This issue replaces all previous versions

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