

FOOD CONTACT

BYK Regulatory Information

BYK-3155

Summary

BYK-3155 is suitable for food contact applications under the following compositional provisions, as indicated below:

Plastics		
EU	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 177.1520 'Olefin polymers.'	Yes
China	GB9685-2016, Table A.1 'Plastics'	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

Plastic

EUROPE

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

This product is manufactured with substances that are either directly listed in Annex I - Table I of Regulation (EU) No 10/2011 or are subject to derogation as per Article 6(3).

The table below lists only substances that are used or known to be present and that are relevant for compliance with the specific migration limits (SML) and/or any restrictions set out in Annex I of this Regulation or in national legislation.

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
140	77-93-0	citric acid, triethyl ester	SML(T) = 60	expressed as the sum of the substances (32)

To our knowledge and understanding, additives authorized for use in both food contact plastics and as direct food additives according to Regulations (EC) No 1333/2008 are not present in this product.

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, residues of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out are not known or expected to be present in concentration exceeding the specific migration limits established by this regulation. Testing is not routinely performed for substances that are neither identified nor reasonably expected to be present.

In accordance with our role as a manufacturer of substances, non-intentionally added substances (NIAS) which have become known to us are assessed in accordance with internationally recognized scientific principles of risk assessment to ensure compliance with the requirements of Article 3(1)(a) of Regulation (EC) No 1935/2004. The assessments are carried out under the assumption that this product is used in accordance with BYK's recommendations for food contact applications and/or under normal or foreseeable conditions of use, and considering the following parameters: 100% migration, 1kg food in contact with 6 dm² of packaging, film thickness 1mm.

USA

21 CFR 177.1520 'Olefin polymers.'

This product complies with the compositional requirements of 21 CFR 177.1520 Olefin polymers for use as an additive to polymers. This product includes components that are listed in 21 CFR regulations including 21 CFR 184 and 21 CFR 178 which may be cross-referenced for use in compliance with 21 CFR 177.1520.

China

GB9685-2016, table A.1 'Plastics'

The product does not comply with table A.1 'Plastic' 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.

Food Contact Team
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This issue replaces all previous versions

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