

FOOD CONTACT

BYK Regulatory Information

BYK-MAX P 4200

Summary

BYK-MAX P 4200 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'	Yes
Japan	Japan Food Sanitation Act Positive List System	No
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes

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

Plastics

Europe

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

This product is authorized for use as an additive or polymer production aid. Substances used in its manufacture are either listed in Annex I - Table I of Regulation (EU) No 10/2011, authorized under national legislation or have been risk-assessed in accordance with Article 19 of this Regulation. No Specific Migration Limits (SML) apply.

To the best of 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 177.1520 as well as 21 CFR 181.24 Antioxidants, which may be cross-referenced for use in compliance with 21 CFR 177.1520. This product is permitted for use as an extrusion aid in the production of olefin polymers that comply with 21 CFR 177.1520. The finished polymer may be used in contact with foodstuffs under the conditions of use B through H described in table 2 of Sec. 176.170 of this chapter.

China

GB9685-2016, table A.1 'Plastics'

The active components are listed in GB9685-2016 table A1 for plastic applications.

Japan

Japan Food Sanitation Act Positive List System

The ingredients in this product are not all listed in Japan's Food Sanitation Act Positive List (PL) system under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370.

MERCOSUR

GMC Res No 02/12 and GMC Res. No. 39/19

The active components of this product are compositionally compliant with GMC Res. No. 39/19 MERCOSUR Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coatings that come into contact with food with the polymer components complying with GMC Res No 02/12 MERCOSUR Technical Regulation on the positive list of monomers, other starting substances and polymers authorized for the manufacturing of plastic packaging and equipment in contact with food which allow this product to be recommended for use as an additive in food contact plastic material in MERCOSUR member states.

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
Regulatory Affairs
BYK-Chemie GmbH

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This issue replaces all previous versions

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