

FOOD CONTACT

BYK Regulatory Information

BYK-MAX D 4220

Summary

BYK-MAX D 4220 is suitable according to the following compositional provisions for food contact applications, provided that its use does not exceed the maximum concentration as indicated below:

Plastics		
EU	Regulation (EU) No. 10/2011	Yes – max 1%
USA	21 CFR 177.1520 ‘Olefin Polymers’	Yes
China	GB9685-2016, table A.1 ‘Plastics’	No
Japan	Japan Food Sanitation Act Positive List System	Yes
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 a polymer production aid. Substances used in its manufacture are either listed in Annex I - Table I of Regulation (EU) No 10/2011 or subject to derogation as per Article 6(3). No Specific Migration Limits (SML) and/or restrictions apply.

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, 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 chapters including 21 CFR 172, 184 and 178.3740 'Plasticizers in polymeric substances', 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 1 'Plastics' 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).

Japan

Japan Food Sanitation Act Positive List System

The ingredients in this product are listed in Japan's Food Sanitation Act Positive List (PL) system under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370. Please contact separately for use Limit by Synthetic Resin Group (%).

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 and 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 as applicable. This allows this product to be recommended for use as an additive in food contact plastics 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

The information contained herein is based on our current knowledge and experience. No warranties, guarantees and/or assurances of any kind, either express or implied, including warranties of merchantability or fitness for a particular purpose, are made regarding any products mentioned herein and data or information set forth, or that such products, data or information may be used without infringing intellectual property rights of third parties. Any information about suitability, use or application of the products is non-binding and does not constitute a commitment regarding the products' properties, use or application. Contractual terms and conditions, in particular agreed product specifications, always take precedence. We recommend that you test our products in preliminary trials to determine their suitability for your intended purpose prior to use. We reserve the right to make any changes and to update the information herein without notice.

This issue replaces all previous versions

ANTI-TERRA®, AQUACER®, AQUAMAT®, AQUATIX®, BENTOLITE®, BYK®, BYK-AQUAGEL®, BYK®-DYNWET®, BYK-MAX®, BYK®-SILCLEAN®, BYKANOL®, BYKCARE®, BYKETOL®, BYKJET®, BYKONITE®, BYKOPLAST®, BYKUMEN®, CARBOBYK®, CERACOL®, CERAFAK®, CERAFLLOUR®, CERAMAT®, CERATIX®, CLAYTONE®, CLOISITE®, DISPERBYK®, DISPERPLAST®, FULACOLOR®, FULCAT®, GARAMITE®, GELWHITE®, HORDAMER®, LACTIMON®, LAPONITE®, NANOBYPK®, OPTIBENT®, OPTIGEL®, PURABYK®, RECYCLOBYK®, RHEOBYK®, SCONA®, SILBYK®, TIXOGEL® and VISCOBYK® are registered trademarks of the BYK group.