

FOOD CONTACT

BYK Regulatory Information

BYK-MAX D 4221

Summary

BYK-MAX D 4221 is suitable according to the following compositional provisions for food contact applications, as indicated:

Plastics		
Europe	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 177.1520 'Olefin Polymers'	No
China	GB9685-2016, table A.1 'Plastics'	No
Japan	Japan Food Sanitation Act Positive List System	Yes
MERCOSUR	GMC Resolution No. 39/19	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

Regulation (EU) No 10/2011

The product may be used for the manufacturing of materials and articles within the scope of Regulation (EU) N° 10/2011 and its amendments, since the components are fully listed in Annex I, table 1. Specific Migration Limits (SML) or restrictions apply.

USA

21 CFR 177.1520 Olefin polymers

This product does not comply with the compositional requirements of 21 CFR 177.1520 Olefin polymers for use as an additive to polymers. Therefore, the product is not recommended for use in plastic food contact applications under 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. 39/19

The product may be used for the preparation of plastic materials and polymeric coatings intended to contact food according to MERCOSUR GMC/RES. N° 39/19, since the components are fully listed in the positive list of additives. Specific Migration Limits (SML) or restrictions apply.

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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