

# FOOD CONTACT

## BYK Regulatory Information

### BYK-MAX P 4102

#### Summary

BYK-MAX P 4102 is suitable for food contact applications under the following compositional provisions, provided that its use does not exceed the maximum concentration as indicated below:

Plastics		
EU	Regulation (EU) No. 10/2011	Yes – See explanation
	21 CFR 177.1520 ‘Olefin polymers’	Yes – max. 0.1%
USA	21 CFR 177.2420 ‘Polyester resins, cross-linked’	Yes
China	GB9685-2016, table A.1 ‘Plastics’	No
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	No

This summary reflects evaluations conducted based on existing regulations. It does not preclude the possibility of compliant use in other regions or applications. The explanations below provide details on the regulations and evaluations 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 manufactured with substances listed in Annex I - Table I of Regulation (EU) No 10/2011 and/or subject to derogation as per Article 6(3). No Specific Migration Limits and/or restrictions 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 our current knowledge of the standard recipe, product specifications, and data provided by raw material suppliers, substances for which genotoxicity has not been ruled out and which meet the requirements according to Annex IV point 6 are not known or not expected to be present in the product. Routine analysis for substances that are not known or expected to be present is not performed.

In accordance with our role as manufacturer of substances, and based on information provided to us by raw material suppliers, the following non-intentionally added substances (NIAS) with restrictions set forth in Annex II of this Regulation may be present in this product:

Name	Maximum concentration in the product [mg/kg]	SML [mg/kg food or food simulant]
Nickel	7	0,02

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.

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#### USA

#### **21 CFR 177.1520 ‘Olefin polymers’**

All components of this product are listed in part 178. Due to cross-reference, the product can be used for the manufacturing of polyolefins in contact with food in accordance with Sec.177.1520 “Olefin polymers” of Title 21 CFR (FDA) as an optional adjuvant/release agent. A use concentration of 1% by weight in the final plastic can be recommended.

#### **21 CFR 177.2420 ‘Polyester resins, cross-linked’**

The components of this product comply with the compositional requirements of 21 CFR 177.2420. Therefore, the product can be used in compliance with this section.

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#### China

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**GB9685-2016, table A.1 'Plastics'**

The active components are not listed in GB9685-2016.

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**MERCOSUR**

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**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**

The active components of this product are compositionally compliant with GMC Res. No. 39/19 which allow this product to be recommended for use as an additive in food contact coatings in MERCOSUR member states.

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**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. 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 deems to be actual 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 - Printed in Germany.*

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