

# FOOD CONTACT

## BYK Regulatory Information

### BYK-MAX D 4221

Solvent-free wetting and dispersing additive for thermoplastics applications for the dispersion and stabilization of solids in masterbatches and for compounding.

#### Summary

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

Plastics		
EU	Suitable for food contact plastics	Yes
	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 177.1520 'Olefin polymers'	No
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. Explanations below show details on considered regulations and evaluations.

## Explanation

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### Plastics

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**EU**      **Regulation (EU) No. 10/2011**

The active component as such is not listed as “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM) (as amended), however the polymeric additives are identical to a polymer that can form the main structural component of a plastic material and therefore the risk from the polymeric additive can be regarded as evaluated as the monomers have already been evaluated and authorized (REG. (EU) No. 10/2011; Art. 6 No.(3) c.) ).

Therefore, the product can be recommended for food contact plastics in the EU.

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

The components are not fully listed under section 177.1520 of 21 CFR FDA.

Therefore, the product cannot be recommended for use in applications described in Sec. 177.1520 of 21 CFR FDA.

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**China**      **GB9685-2016, table A.1 ‘Plastics’**

The product does not comply with 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).

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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**  
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*This issue replaces all previous versions*

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