

FOOD CONTACT

BYK Regulatory Information

BYK-MAX P 4200

Polymer processing additive for thermoplastics (particularly on the basis of PE and PP) to reduce odors and VOC in the end product.

Technically recommended use level: 0.5 - 2%

Summary

BYK-MAX P 4200 is suitable according to the following compositional provisions for food contact applications, as indicated:

Plastic		
EU	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 177.1520 'Olefin polymers'	Yes
China	GB9685-2016, table A.1 'Plastics'	Yes

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

Plastic

EU Regulation (EU) No. 10/2011

For this product, the components themselves or the monomers and starting substances used for manufacturing are listed in the Regulation (EU) No. 10/2011, with the exception of a residual amount of polyether.

It is assumed, that during processing, the residual polyether is evaporated.

Additionally, the carrier polymer as such is not listed as "polymeric additive" in a.m. REG. (EU) No. 10/2011 (PIM). 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, BYK-MAX P 4200 can be recommended for use in plastics in the EU.

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

The product is compliant with the compositional requirements of 21 CFR 177.1520, since the components of the product are directly listed, or due to cross-reference with other sections of 21 CFR.

Additionally, the active component as such is listed in 21 CFR Sec. 177.1520 ‘Olefin polymers’ and is permitted for use as an extrusion aid in the production of olefin polymers that comply with Sec. 177.1520. The finished polymer is used in contact with foodstuffs under the conditions of use B through H described in table 2 of Sec. 176.170 of this chapter.

Therefore, BYK-MAX P 4200 can be recommended for use in plastics, according to 177.1520, with the above described conditions of use.

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

The product complies with compositional requirements of 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), since its components are listed in table A.1 (Additives for plastics).

Therefore, BYK-MAX P 4200 can be recommended for use in plastics, according to the GB9685-2016.

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
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