

FOOD CONTACT

BYK Regulatory Information

BYK-MAX CT 4260

Organophilic bentonite for aliphatic solvent-borne systems. BYK-MAX CT 4260 is a conventional organoclay requiring a polar activator.

Summary

BYK-MAX CT 4260 is suitable according to the following compositional provisions for food contact applications, as indicated:

Plastics		
EU	Suitable for food contact plastics	Yes (restricted)
	Regulation (EU) No. 10/2011	Yes (restricted)
USA	21 CFR 177.1520 'Olefin polymers'	Yes
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

Plastics	
EU	<p><u>Regulation (EU) No. 10/2011</u></p> <p>The active component is listed in the PIM, but is restricted: only to be used up to 12 % (w/w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room temperature or below. The sum of the specific migration of 1-chlorohexadecane and 1-chlorooctadecane shall not exceed 0,05 mg/kg food. Can contain platelets in the nanoform that are only in one dimension thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer.</p> <p>Therefore, the product can be recommended for use in food contact plastics in the EU, as described above.</p>
USA	<p><u>21 CFR 177.1520 'Olefin polymers'</u></p> <p>The chemical composition of BYK-MAX CT 4260 is listed in §178.3297 "Colorants for polymers". Therefore, it can be used as indirect additive, a colorant, for all polymers.</p> <p>Therefore, the product can be recommended for use in regards to Sec. 177.1520 of 21 CFR FDA.</p>

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

The active components of the product are not listed in GB9685-2016.

Therefore, we cannot recommend the product in regards to the China 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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This issue replaces all previous versions

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