

FOOD CONTACT

BYK Regulatory Information

CLOISITE-116

Microgranuled Clay based on a natural mineral for aqueous polymers having optimized surface properties and cations composition for exfoliation in aqueous systems. The product is microscaled in its delivery form and exfoliates to nano scale in the matrix only.

Summary

CLOISITE-116 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' | 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

Plastics

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

The product complies with the compositional requirements of REG EU/10/2011.

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

USA **21 CFR 177.1520 'Olefin polymers'**

The product complies with the compositional requirements of Sec. 177.1520 of 21 CFR FDA.

Therefore, the product can be recommended for use in food contact plastics in regards to Sec. 177.1520 of 21 CFR FDA.

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

The active components of CLOISITE-116 are listed in GB9685-2016 table A1 for plastic applications.

Therefore, the product can be used in plastics in regards to 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.

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This issue replaces all previous versions

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