

FOOD CONTACT

BYK Regulatory Information

CERAMAT 258

Wax dispersion based on an oxidized HDPE wax for solvent-borne coatings to improve the scratch resistance, for matting and to generate a soft-feel effect.

Summary

CERAMAT 258 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
	CoE ResAP (2004) 1	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	No
China	GB9685-2016, table A.2 'Coatings'	Yes

Solvents are not covered by the food contact status.

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

Coatings

EU

Regulation (EU) No. 10/2011

The components of this product are listed directly in Annex I – Table I of Regulation (EU) No. 10/2011. Specific Migrations Limits and/or restrictions apply.

German BfR XIV ‘Polymer Dispersions’

The product is covered by the compositional requirements of BfR-Recommendation XIV “Polymer Dispersions”.

CoE ResAP (2004) 1

The product is covered by the CoE ResAP (2004) 1, Edition 4, Version, Feb. 2009.

Dual use additives

The product contains dual use additives for which restrictions apply:

- E914 – oxidized polyethylene (ca. 20%)

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

Solvents are not covered by the food contact status.

USA

21 CFR 175.300 ‘Resinous and polymeric coatings’

The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives. The components are not fully listed under section 175.300.

Solvents are not covered by the food contact status.

China

GB9685-2016, table A.2 ‘Coatings’

The active component of CERAMAT 258 is listed in GB9685-2016 table A2 coating application.

Solvents are not covered by the food contact status.

Solvents

The product contains a significant amount of solvent [n-butyl acetate, with a boiling point of approximately 126 °C]. Solvents are currently not regulated by food contact positive lists as it is assumed that solvents evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 should be fulfilled.

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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