

FOOD CONTACT

BYK Regulatory Information

CERAMAT 250

Aromatic-free wax dispersion based on a polyethylene wax for solvent-borne coatings to improve surface protection. It has a soft-feel effect, matting effect and reduces settling.

Technically recommended use level: 2 – 5 %

Summary

CERAMAT 250 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	Suitable for food contact coatings	Yes
	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'	Yes
China	GB9685-2016, table A.2 'Coatings'	Yes

Solvents and other formulation aids 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	<p><u>Regulation (EU) No. 10/2011</u> The wax-base of the wax-additive is evaluated and classified as SCF-list 0-4 and directly listed in Annex 1- table 1 of Commission Regulation (EU) No. 10/2011 of 14 January 2011 (PIM).</p> <p><u>German BfR XIV 'Polymer Dispersions'</u> The product can be used in compliance with national legislation for coatings, incl. BfR-Recommendation XIV 'Polymer Dispersions'.</p> <p><u>CoE ResAP (2004) 1</u> The wax-base of this product is in compliance with the CEPE "Code of practice for food contact coatings", Edition 4, Version, Feb. 2009.</p>

Dual use additive (restricted)

CERAMAT 250 contains a wax that meets the criteria for E905. This wax is not considered as a dual-use additive for normal uses with one exception: for use as surface treatment of confectionary excluding chocolate, chewing gum, melons, papaya, manga and avocado. (1995/2/EC and amendments - on food additives other than colours and sweeteners).

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

Solvents and other formulation aids are not covered by the food contact status.

USA **21 CFR 175.300 'Resinous and polymeric coatings'**

The wax-base of this product is listed in Sec. 175.300 for indirect food additives as laid down in 21 CFR.

Therefore, the product can be recommended for food contact coatings in regards to Sec. 175.300 of 21 CFR FDA.

Solvents and other formulation aids are not covered by the food contact status.

China **GB9685-2016, table A.2 'Coatings'**

The active components of CERAMAT 250 are listed in GB9685-2016, table A2.

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

Solvents and other formulation aids are not covered by the food contact status.

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
BYK-Chemie GmbH

The information herein is based on our present knowledge and experience. The information merely describes the properties of our products but no guarantee of properties in the legal sense shall be implied. We recommend testing our products as to their suitability for your envisaged purpose prior to use. No warranties of any kind, either express or implied, including warranties of merchantability or fitness for a particular purpose, are made regarding any products mentioned herein and data or information set forth, or that such products, data or information may be used without infringing intellectual property rights of third parties. We reserve the right to make any changes according to technological progress or further developments.

This issue replaces all previous versions

ACTAL[®], ADD-MAX[®], ADD-VANCE[®], ADJUST[®], ADVITROL[®], ANTI-TERRA[®], AQUACER[®], AQUAMAT[®], AQUATIX[®], BENTOLITE[®], BYK[®], BYK[®]-DYNWET[®], BYK[®]-MAX[®], BYK[®]-SILCLEAN[®], BYKANOL[®], BYKETOL[®], BYKJET[®], BYKO2BLOCK[®], BYKOPLAST[®], BYKUMEN[®], CARBOBYK[®], CERACOL[®], CERAFAK[®], CERAFLOUR[®], CERAMAT[®], CERATIX[®], CLAYTONE[®], CLOISITE[®], DISPERBYK[®], DISPERPLAST[®], FULACOLOR[®], FULCAT[®], GARAMITE[®], GELWHITE[®], HORDAMER[®], LACTIMON[®], LAPONITE[®], MINERAL COLLOID[®], MINERPOL[®], NANOBYK[®], OPTIBENT[®], OPTIFLO[®], OPTIGEL[®], PAPERBYK[®], PERMONT[®], POLYAD[®], PRIEX[®], PURE THIX[®], RECYCLOBLEND[®], RECYCLOBYK[®], RECYCLOSSORB[®], RECYCLOSTAB[®], RHEOBYK[®], RHEOCIN[®], RHEOTIX[®], SCONA[®], SILBYK[®], TIXOGEL[®], VISCOBYK[®] and Y 25[®] **are registered trademarks of the BYK group.**