

FOOD CONTACT

BYK Regulatory Information

CERAFAK 140 N

Dispersion of a carnauba wax for solvent-borne can coatings, to improve the surface slip and the scratch resistance.

Technically recommended use level: 1.3-6 % additive (as supplied) based upon total formulation.

Summary

CERAFAK 140 N 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	
Europe	<u>Regulation (EU) No. 10/2011</u> The product is covered by the compositional requirements of Regulation (EU) No. 10/2011 (including all amendments). <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 for coating commodities intended to come into contact with Foods and Resins and Plastics. <u>CoE ResAP (2004) 1</u> The wax-base of this product is listed in the CEPE "Code of practice for food contact coatings", Edition 4, Version, Feb. 2009.

Solvents

Additionally, the product contains a significant amount of volatile solvent, which is not in scope of the regulation (See safety data sheet and/or BRIEF).

Solvents are expected to evaporate while producing the finished food contact article resulting in traces of no toxicological concern. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of Framework Regulation (EC) 1935/2004 applies.

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 product can be used in compliance with the requirements of FDA 21 CFR 175.300. The wax-base is fully listed under sections 175.300 (Resinous and polymeric coatings).

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

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

The active component of the product complies with 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 it is listed in table A.2 (additives for coatings).

Solvents and other formulation aids are not covered by above statement.

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
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