

FOOD CONTACT

BYK Regulatory Information

CERACOL 624

Carnauba wax based wax dispersion for solvent-borne can coatings.

Summary

CERACOL 624 is suitable according to the following compositional provisions for food contact applications, as indicated:

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

The wax-base of the product is directly listed in Annex 1- table 1 of Commission Regulation (EU) No. 10/2011 of 14 January 2011 (PIM) (as amended). No SML value applicable.

German BfR XIV 'Polymer Dispersions'

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.

CoE ResAP (2004) 1

The wax-base of this product is listed in the CEPE "Code of practice for food contact coatings", Edition 4, Version, Feb. 2009.

The product contains a significant amount of the solvent *dipropylene glycolmonomethylether* (boiling point ca. 185°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.

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**

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 table A.2 'Coatings' of 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.

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This issue replaces all previous versions