

FOOD CONTACT

BYK Regulatory Information

CERACOL 80

Wax dispersion based on a carnauba wax to improve the transfer properties of solvent-borne formulations for thermal transfer ribbons.

Technically recommended use level:

70-80 % additive (as supplied) based on the total formulation in the release layer.

20-30 % additive (as supplied) based on the total formulation in the pigmented layer.

Summary

CERACOL 80 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

All components of this product are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments).

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.

Dual Use

The product contains a dual use additive.

- Carnauba wax, ca. 17,5%, CAS No 8015-86-9, E903, no restrictions apply

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

The product can be recommended for applications described in 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

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
Regulatory Affairs

BYK-Chemie GmbH

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