

FOOD CONTACT

BYK Regulatory Information

CERACOL 601

Wax dispersion based on carnauba wax for solvent-borne and aqueous can and coil coatings. Increases scratch-resistance and surface slip.

Summary

CERACOL 601 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
Europe	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 (max. 4%)
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

Europe **Regulation (EU) No. 10/2011**

The product is covered by the compositional requirements of Regulation (EU) No. 10/2011 (including all amendments).

German BfR XIV 'Polymer Dispersions'

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

CoE ResAP (2004) 1

The product is covered by the compositional requirements of the CEPE "Code of practice for food contact coatings", Version Feb. 2009.

Dual Use

The product contains dual use component E903.

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 can be used in compliance with the requirements of FDA 21 CFR 175.300, if used as recommended below. Based on studies and external consultation, we recommend following use conditions:

- Max. use level of 4% in wet coating formulations
- For formulations with a solid content of 40% and a dry thickness of 12 µm
- The use level can be adapted for deviating thickness and solid content.

Solvents are not covered by the food contact status.

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

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

Solvent

The product contains a significant amount of solvent [please refer to the SDS for more information]. 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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