

FOOD CONTACT

BYK Regulatory Information

CERACOL 83

Wax dispersion to improve the transfer properties of solvent-borne formulations for thermal transfer ribbons.

Summary

CERACOL 83 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
Printing inks		
Europe	Suitable for food contact printing inks	Yes
	Swiss Ordinance 817.023.21, Annex 10	Yes
Industry	Nestlé Printing Inks for Food Packaging (07/04/22)	See explanation
	EuPIA Exclusion List (March 2021)	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

This product complies with the COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food (including all amendments).

German BfR XIV ‘Polymer Dispersions’

This product complies with the compositional requirements of the German BfR-Recommendation XIV “Polymer Dispersions”.

CoE ResAP (2004) 1

The active component of this product is listed in CEPE “Code of practice for food contact coatings”, Edition 4, Version Feb. 2009.

Therefore, the product can be recommended for use in 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 active component of the product is listed. Therefore, the product can be recommended for use in applications described in Sec. 175.300.

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 is listed in GB9685-2016 table A2 ‘Coatings’.

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

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

Printing inks

Europe **Swiss Ordinance 817.023.21, Annex 10**

This product is conform with the compositional requirements of the part for printing inks for packaging of the Swiss Ordinance 817.023.21 (Version of 1 October 2022). Since all components are listed on the A-list in Annex 10. Specific migration limits apply.

Therefore, the product can be recommended for use in food contact printing inks in Europe.

Industry **Nestlé Printing Inks for Food Packaging (07/04/22)**

According to the recipe, the product does not intentionally contain any of the substances listed in Table 5 – Table 8 of the Nestlé Printing Inks for Food Packaging (07/04/2022). However, the product contains a wax (CAS 8002-74-2), which is considered a MOSH, as stated in 4. 'General Nestlé Exclusions and Minimisations'

EuPIA Exclusion List (March 2021)

The product is conform with the compositional requirements of the EuPIA Exclusion List (March 2021).

The product contains a significant amount of isopropanol (CAS No. 67-63-0; boiling point ca. 82,5 °C). Volatile solvents are expected to 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.

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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