

FOOD CONTACT

BYK Regulatory Information

CERACOL 79

Summary

CERACOL 79 is suitable according to the following compositional provisions for food contact applications as indicated below:

Coatings		
Europe	Regulation (EU) No. 10/2011	Yes – max 2 %
	German BfR XIV. Polymer dispersions	
USA	21 CFR 175.300 ‘Resinous and polymeric coatings’	Yes
China	GB9685-2016, table A.2 ‘Coatings’	Yes
Japan	Japan Food Sanitation Act Positive List System	Yes
MERCOSUR	GMC Resolution n. 39/19	No- See explanation
Printing inks		
Europe	21 st Amendment to Consumer Goods Ordinance (GIO)	Yes – max. 2 %
	Swiss Ordinance 817.023.21	
Industry	Nestlé Standard “Printing Inks for Food Packaging”	Yes
	EuPIA Exclusion Policy	Yes

This summary only reflects conducted evaluations on existing regulations. It does not exclude compliant use in additional regions or applications.

Please refer to the explanation section below for detailed information on the regulations and assessment criteria considered.

Explanation

Coatings

EUROPE

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

This product is authorized for use as an additive and/or polymer production aid.

Polymer production aids, including solvents, used in this product are either listed in national legislation or are subject to risk assessment in accordance with Article 19 of this Regulation.

This product contains the following substance(s) listed in national legislation with a Specific Migration Limit (SML) and/or restrictions:

- Dipropylene glycol monomethyl ether (CASRN 34590-94-8)

Please note that it is the sole responsibility of downstream business operators to ensure that solvents are completely removed during downstream processing. For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS).

With reference to Article 11(3) of this Regulation, the following substance is also authorized for use as a food additive under Regulation (EC) No 1333/2008:

- Carnauba wax, E 903

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, presence of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out is not known or expected. The products are not regularly tested for substances that are neither identified nor reasonably foreseen to be present.

In accordance with our role as a manufacturer of substances, and when used in compliance with BYK's recommendations for food contact applications under normal or foreseeable conditions of use, this product is expected to meet the requirement set out in Article 3(1)(a) of Regulation (EC) 1935/2004.

It remains the responsibility of both manufacturers of finished food contact articles and downstream business operators to ensure compliance with the applicable provisions laid down in Regulation (EC) No. 1935/2004, particularly regarding the suitability of the material and articles for their intended use, prevent deterioration in the organoleptic properties of food and compliance with the applicable migration limits and restrictions.

German BfR Recommendation XIV. Polymer Dispersions

This product is manufactured with substances permitted by reference to Regulation (EU) No. 10/2011.

USA

21 CFR 175.300 'Resinous and polymeric coatings'

This product complies with the compositional requirements of 21 CFR 175.300 Resinous and polymeric coatings. This product includes components that are listed in 21 CFR 175.300 as well as components which are cleared under 21 CFR 184.1978 Carnauba wax, which may be cross-referenced for use in compliance with 21 CFR 175.300.

This product contains solvents which are not considered in the food contact evaluation and are the responsibility of the downstream user to remove prior to use in food contact applications.

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.

JAPAN

Japan Food Sanitation Act Positive List System

The ingredients in this product are listed in Japan's Food Sanitation Act Positive List (PL) system under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370. Please contact separately for use Limit by Synthetic Resin Group (%).

MERCOSUR

GMC Res No 39/19

The active components of this product are compositionally compliant with GMC Res No 39/19 which allows this product to be recommended for use as an additive in food contact plastic materials in MERCOSUR member states, with a restriction on one component for use only with adhesives.

Therefore, the product is authorized for use in adhesives in MERCOSUR member states as an adhesive and not supported for use in food contact coatings.

Printing inks

EUROPE

21st Amendment to Consumer Goods Ordinance (GIO)

Intentionally added substances in this product are either listed in Annex 14, Table 1 of the GIO, subject to derogation under §4, Abs. 5, Sentence 5 ("salt rule"), or are included in Regulation (EU) No 10/2011 without any restrictions indicated in columns 9 and/or 10. Substances used beyond the scope of paragraphs 5 and 6 of this Regulation and/or listed in Annex I of Regulation (EU) No 10/2011 are not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR) according to the criteria established in Regulation (EC) No 1272/2008 (CLP).

The table below lists only the substances used or known to be present that are relevant for compliance with the specific migration limits (SML) and/or any restrictions laid down in the German Ink Ordinance and/or Regulation (EU) No 10/2011:

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
123	34590-94-8	Dipropylene glycol monomethyl ether (Group restriction No 37)	5	Please refer to the provisions laid down in the German Ink Ordinance

In accordance with our role as a manufacturer of substances, and when used in compliance with BYK's recommendations for food contact applications under normal or foreseeable conditions of use, this product is expected to meet the requirement set out in Article 3(1)(a) of Regulation (EC) 1935/2004.

Therefore, this product can be considered suitable for use in food contact packaging inks that are not in contact with food (non-direct food contact inks).

Swiss Ordinance 817.023.21

Intentionally added substances in this product are either listed in Annex 2 and/or Annex 10 of Swiss Ordinance 817.023.21 (version January 1, 2026), subject to Article 35(b), or are not classified as carcinogenic, mutagenic, or toxic to reproduction (CMR).

The table below lists only the substances used or known to be present that are relevant for compliance with the specific migration limits (SML) and/or any restrictions laid down in the German Ink Ordinance and/or Regulation (EU) No 10/2011:

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
123	34590-94-8	Dipropylene glycol monomethyl ether (Group restriction No 37)	5	Please refer to the provisions laid down in the Swiss Ordinance Annex 10

Therefore, this product can be considered suitable for use in food contact packaging inks that are not in contact with food (non-direct food contact inks).

Industry

Nestlé Standard “Printing Inks for Food Packaging” (02/04/2024)

None of the intentionally added substances in the product are listed in the exclusion and/or minimisation lists of the Nestlé Standard “Printing Inks for Food Packaging” (version St-80.001-01 of 02/04/2024).

EuPIA Exclusion Charter (March 2026)

The product intentionally does not contain any of the substances listed in Annexes 1 and 2 of the ‘EuPIA Charter on Raw Material Selection and Exclusion for Printing Inks and Related Products’ (March 2026). The product itself as raw material is not classified and labeled with any of the Hazard Statements for Group I or Group II substances as defined in the section ‘Selection Criteria & Procedures’.

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. Please note that it is the responsibility of both manufacturers of finished food contact articles and downstream business operators to ensure compliance with the applicable migration limits and restrictions of the finished materials or articles under specific real and/or foreseeable conditions of use.

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 is in effect for three years commencing the date of issue.

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This issue replaces all previous versions

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