FOOD CONTACT

BYK Regulatory Information

CERACOL 604

Summary

CERACOL 604 is suitable for food contact applications under the following compositional provisions, provided that its use does not exceed the maximum concentration as indicated below:

Coatings		
Europe	Regulation (EU) No. 10/2011	Yes – max 5% (See explanation)
	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	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 or as a polymer production aid. No specific migration limit applies.

Polymer production aids used in this product, including solvents, fall under Article 6(1) and are subject to national legislation. The table below lists only the substances used or known to be present which are relevant to be considered for compliance with the specific migration limits (SML) and/or any restrictions laid down in national legislation, specifically 21st Amendment to Consumer Goods Ordinance (GIO):

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
144	111-76-2	Ethylene glycol monobutyl ether (Group restriction No 35)	5	Please refer to the provisions of the German Ink Ordinance

This product contains the following substance, which 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.

German BfR Recommendation XIV. Polymer Dispersions

This product is manufactured with substances permitted by reference to Regulation (EU) No. 10/2011, provided that solvents present in this product are completely removed from the intermediate or final materials and article.

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.

The product contains a significant amount of solvent. The solvent of this product is not included in this evaluation and must be completely removed by downstream users prior to use in food contact applications.

CHINA

GB9685-2016, table A.2 'Coatings'

The active components of the product are 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). Therefore, this product can be recommended for use in food contact coatings in China.

Solvents and other formulation aids are not covered by the 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. Solvents are not in scope of this evaluation. The restriction for the synthetic resin groups is "dose as needed" for Polymer Groups 1-5.

MERCOSUR

GMC Res. No. 39/19

The active components of this product are compositionally compliant with GMC Res. No. 39/19 MERCOSUR Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coatings that come into contact with food.

The table below lists only the substances used or known to be present which are relevant to be considered for compliance with the specific migration limits (SML) laid down in GMC Res. No. 39/19:

Ref. No.	CAS-No.	Name	SML
16993	111-76-2	Ethylene glycol monobutyl ether	SML = 3 mg/k. The limit refers to the sum of substances of number M18, M20, M23, M24, M25, M26, M83, M85. Only for use in adhesives and polymeric and resinous coatings.

Please note that it is the responsibility of both the 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.

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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