

FOOD CONTACT

BYK Regulatory Information

AQUACER 539

Summary

AQUACER 539 is suitable according to the following compositional provisions for food contact applications as indicated below:

Plastics		
EU	Regulation (EU) No. 10/2011	Yes
Paper and paperboard		
EU	German BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR 176.170 'Components of paper and paperboard in contact with aqueous and fatty foods'	Yes
	21 CFR 176.180 'Components of paper and paperboard in contact with dry food'	Yes
China	GB9685-2016, table A.6 'Paper'	No

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

Plastics

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.

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

The table below lists only substances that are used or known to be present and are relevant to be considered for compliance with the specific migration limits (SML) and/or any restrictions laid down in national legislation. For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS), where applicable.

FCM No.	CAS No	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
93	/	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	0,05	Not to be used for articles in contact with fatty foods for which simulant D1 and/or D2 is laid down
799	/	Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C 8-C 22) alcohols	1,8	Ethylene oxide residue < 0.1 mg/kg
NL	2634-33-5	1,2-Benzisothiazolin-3-one	0,5	/
NL	55965-84-9	5-Chloro-2-methyl-4-isothiazolin-3-one, mixture with 2-Methyl-4-isothiazolin-3-on (3:1)	0,15	/

NL: listed in National Legislation

To the best of our knowledge and understanding, additives authorized for use in both food contact plastics and as direct food additives according to Regulations (EC) No 1333/2008 are not present in this product.

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, residues of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out are not known or expected to be present in concentration exceeding the specific migration limits established by this regulation. Testing is not routinely performed for substances that are neither identified nor reasonably expected to be present.

In accordance with our role as a manufacturer of substances, non-intentionally added substances (NIAS) which have become known to us are assessed in accordance with internationally recognized scientific principles of risk assessment to ensure compliance with the requirements of Article 3(1)(a) of Regulation (EC) No 1935/2004. The assessments are carried out under the assumption that this product is used in accordance with BYK's recommendations for food contact applications and/or under normal or foreseeable conditions of use, and considering the following parameters: 100% migration, 1kg food in contact with 6 dm² of packaging, film thickness 1mm.

Paper and paperboard

EUROPE

German BfR XXXVI 'Paper and board for food contact'

This product may be used as a sizing agent in accordance with BfR Recommendation XIV. Polymer Dispersions, and as a surface refining or coating agent subject to the requirements of Regulation (EU) No. 10/2011.

USA

21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods

This product complies with the compositional requirements of 21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods. This product includes components that are listed in 21 CFR 176.170 as well as 21 CFR 181.30, which may be cross-referenced for use in compliance with 21 CFR 176.170.

21 CFR 176.180 Components of paper and paperboard in contact with dry food.

This product complies with the compositional requirements of 21 CFR 176.170 Components of paper and paperboard in contact with dry food. This product includes components that are listed in 21 CFR 176.170 as well as 21 CFR 181.30, which may be cross-referenced for use in compliance with 21 CFR 176.180.

China

GB9685-2016, table A.6 'Paper'

The product does not comply with table A.6 'Paper' 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.

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.

Food Contact Team
Regulatory Affairs
BYK-Chemie GmbH

The information contained herein is based on our current knowledge and experience. No warranties, guarantees and/or assurances of any kind, either express or implied, including warranties of merchantability or fitness for a particular purpose, are made regarding any products mentioned herein and data or information set forth, or that such products, data or information may be used without infringing intellectual property rights of third parties. Any information about suitability, use or application of the products is non-binding and does not constitute a commitment regarding the products' properties, use or application. Contractual terms and conditions, in particular agreed product specifications, always take precedence. We recommend that you test our products in preliminary trials to determine their suitability for your intended purpose prior to use. We reserve the right to make any changes and to update the information herein without notice.

This issue replaces all previous versions

ANTI-TERRA®, AQUACER®, AQUAMAT®, AQUATIX®, BENTOLITE®, BYK®, BYK-AQUAGEL®, BYK®-DYNWET®, BYK-MAX®, BYK®-SILCLEAN®, BYKANOL®, BYKCARE®, BYKETOL®, BYKJET®, BYKONITE®, BYKOPLAST®, BYKUMEN®, CARBOBYK®, CERACOL®, CERAFAK®, CERAFLOUR®, CERAMAT®, CERATIX®, CLAYTONE®, CLOISITE®, DISPERBYK®, DISPERPLAST®, FULACOLOR®, FULCAT®, GARAMITE®, GELWHITE®, HORDAMER®, LACTIMON®, LAPONITE®, NANOBYK®, OPTIBENT®, OPTIGEL®, PURABYK®, RECYCLOBYK®, RHEOBYK®, SCONA®, SILBYK®, TIXOGEL® and VISCOBYK® are registered trademarks of the BYK group.