

FOOD CONTACT

BYK Regulatory Information

AQUACER 1061

Emulsion of an ethylene-acrylic acid copolymer wax for improving the surface characteristics of paper.

Technically recommended use level: 1 – 3 %

Summary

AQUACER 1061 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	Suitable for food contact coatings	Yes
	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 (restricted)
China	GB9685-2016, table A.2 'Coatings'	No

Paper and paperboard		
EU	Suitable for food contact paper and paperboard	Yes
	Regulation (EU) No. 10/2011	Yes
	German BfR XXXVI 'Paper and board for food contact'	Yes
	21 CFR 175.300 'Resinous and polymeric coatings'	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

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

The main active component of this product is a polymer and manufactured using monomers which are fully evaluated as SCF - list 0-4 and directly listed in Annex I – Table I of 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). The basic copolymer of AQUACER 1061, which is compliant with this regulation due to the listing of the monomers and its high molecular weight, has been further modified with an in Annex I of above mentioned regulation listed additive. This subsequent salinization is not regarded to change the regulatory status. Migration limits apply.

German BfR XIV ‘Polymer Dispersions’

The active component of AQUACER 1061 is listed in BfR-recommendations XXXV. “Copolymers of Ethylene, Propylene, Butylene, Vinyl Esters and unsaturated Aliphatic Acids, and their Salts and Esters “. Therefore, due to cross references the active component can also be used in accordance with BfR XIV.

CoE ResAP (2004) 1

For this product, either the components themselves or the monomers and starting substances used for manufacturing are listed in the CEPE ‘Code of practice for food contact coatings’, Edition 4, Version Feb. 2009, and in the Dutch Warenwet – Chapter X for coatings.

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

USA 21 CFR 175.300 ‘Resinous and polymeric coatings’

The basic copolymer of AQUACER 1061 is compliant with 21 CFR, 175.300(b)(3) and 175.320(b)(2), provided the following limitations are observed:

1. The finished food-contact layer made with this resin cannot exceed a thickness of 2.5 mils (0.0025 inch, 63.5 µm).
2. Under Conditions of use B, C, D, and H, the article may be in contact only with food types I, II, IV B, VI A, VI B, VII B, and VIII.
3. Under Conditions of use E, F, and G, the article may be in contact with all types of food except VI C.

The subsequent salinization is not regarded to change this regulatory status.

Therefore, the product can be recommended for use in regards to Sec. 175.300 of 21 CFR FDA, as described above.

Formulation aids are not covered by the food contact status.

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

The product does not comply with table A.2 '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).

Paper and paperboard

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

The main active component of this product is a polymer and manufactured using monomers which are fully evaluated as SCF - list 0-4 and directly listed in Annex I – Table I of 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). The basic copolymer of AQUACER 1061, which is compliant with this regulation due to the listing of the monomers and its high molecular weight, has been further modified with an in Annex I of above mentioned regulation listed additive. This subsequent salinization is not regarded to change the regulatory status. Migration limits apply.

German BfR XXXVI 'Paper and board for food contact'

The product is covered by the compositional requirements of BfR XXXVI 'Paper and board for food contact'.

Therefore, the product can be recommended for use in food contact paper and paperboard in the EU.

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

The basic copolymer of AQUACER 1061 is compliant without limitations with 21 CFR 176.170(b).

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

The basic copolymer of AQUACER 1061 is compliant without limitations with 21 CFR 176.180.

The subsequent salinization is not regarded to change this regulatory status.

Therefore, the product can be recommended in regards to Sec. 176.170 and 176.180, as described above.

Formulation aids are not covered by the food contact status.

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. 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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