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TO WHOM IT MAY CONCERN

Release: January 2026
Revision: 2
Our ref.: JvL/os

C E R T I F I C A T E

We herewith certify that the product **AQUAVATE™ BIO SB 2383** is composed of raw materials which conform with requirements stipulated in the food contact legislation and recommendations stated below (for Biocide ingredients see separate section further down):

E.U. The components and/or monomers used in **AQUAVATE™ BIO SB 2383** are listed in Annex I of the Plastics Regulation (EU) No 10/2011 in the current valid version.

Known components with restrictions

Acetic acid, vinyl ester	FCM 231	SML 12 mg/kg
Acetaldehyde (traces)	FCM 128	SML(T) 6 mg/kg
PHA Oligomers (Mw < 1000 Da)	FCM no. undisclosed	SML 5 mg/kg
Crotonic acid	FCM 467	SML(T) 0,05 mg/kg

** for details please refer to EU regulation 10/2011*

Known Dual-use-components:
AQUAVATE™ BIO SB 2383 contains some “Dual Use” additives that have corresponding E-numbers:
E262, E415, E461.

U.S.A:

The main polymer is cleared by an affective Food Contact Notification (FCN).
It is approved for food types I-V, VIA, VIB, and VII-IX under Conditions of Use B through H, as identified in Table 2 of 21 CFR 176.170(c).
This polymer is not intended for use in contact with infant formula and human milk.

All other components of **AQUAVATE™ BIO SB 2383** are compliant with:

F.D.A – code of Federal Regulations, sections:
21 CFR 175.105 Adhesives.
21 CFR 175.300 Resinous and polymeric coatings.

The meaning of the above statement is to provide information on the listing of the ingredients in the positive lists of the mentioned legislation or recommendations. These ingredients have therefore been judged for their suitability for direct or indirect food contact.

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BIOCIDES (information compiled to the best of our knowledge)

AQUAVATE™ BIO SB 2383 contains allowed biocides. The constituents and levels of these biocides in the dispersion do not exceed:

BIT (1,2-benzisothiazol-3(2H)-one)	CAS no.: 2634-33-5	Level: ≤ 0.02%
Bronopol	CAS no.: 52-51-7	Level: ≤ 0.014%
CIT/MIT (3:1)	CAS no.: 55965-84-9	Level: ≤ 5 ppm

Country/State	Regulation	Comments
Europe	EU 10/2011	Not applicable. Adhesives, coatings and printing inks are not subject of this regulation.
Switzerland	Swiss Ordinance Annex 2-Plastics	Swiss Ordinance 817.023.211-Annex 2, table 1: Not applicable. Adhesives, coatings and printing inks are not subject of this regulation.
Switzerland	Swiss Ordinance Annex 10 - packaging inks	Swiss Ordinance 817.023.211-Annex 10, table 1: Bronopol: Listed under PM Ref. no. 40460 in annex 10 as additive for printing inks, SML=0.05 mg/kg; CIT/MIT: Listed under PM Ref. no. 43730 in annex 10, as additive for printing inks, SML=0.15 mg/kg BIT: Listed under PM Ref. no. 37520 in annex 9 and 10 as additive for silicons and printing inks, SML=0.5 mg/kg
China	GB 9685-2016 Additives in food contact materials and articles	BIT: FCA0041: listed as additive in rubber and inks (max.level 0.02%), adhesives (dosage as necessary), paper (max. level 0.16 mg/dm²). SML 1.2 mg/kg CIT/MIT: FCA 0365: listed as additive in adhesives (dosage as necessary), plastics (PA, PE, PP, PS, ABS, PET, PC: dosage as necessary), paper (max. level 0.005%), coatings (max. level 0.0025%). Bronopol: FCA0301: listed as additive in adhesives (dosage as necessary), coatings and papers (max. level 0.01%);
Germany	BfR XIV – polymer dispersions	BIT: max. 80 µg/dm² in dispersion film; CIT/MIT: max 4 µg/dm² in dispersion film; inputs from other uses have to fulfill the criteria of the appropriate restriction, total content in extract of finished product: BIT: max. 80 µg/dm² CIT/MIT: max 25 µg/dm² Bronopol: maximum 0.032 mg/dm² dispersion film;
Germany	BfR XXXVI - paper and board for food contact	For use as slimicide and preservative in paper production: BIT: max. 10 µg/dm^2 detectable in extract of final product; CIT/MIT: max 0.5 µg/dm² detectable in extract of final product. Inputs from other uses have to fulfill the criteria of the appropriate restriction, total content in extract of finished product: BIT: max. 80 µg/dm^2. CIT/MIT: max 25 µg/dm² Bronopol: <0,003% rel. to dry fibre. (not detectable in extract of final product);
Netherlands	Warenwet	Bronopol: listed in CAT : HFDST: 10, par 3, 6 CIT/MIT/BIT: listed in HFDST II – Papier en Karton 1.2.2. and HFDST: 10, par 3. BIT: SML 30 mg/kg. MIT: SML 0.01 mg/kg (alone or together with CMIT)
USA	FDA 21 CFR 175.105	Substances for use as components of adhesives: BIT: for use as preservative only; CIT/MIT: for use only as an antimicrobial agent in polymer latex emulsions. Bronopol: for use only as an antibacterial preservative only. Shall be in accordance with 21 CFR 175.105;
USA	FDA 21 CFR 175.300	Substances for use as components of resinous and polymeric coatings: BIT: As an antimicrobial agent in can-end cements. For limitations/specifications see FCN No. 1256. As preservative in aqueous latex/silicone formulations for coatings on metal substrates. For limitations/specifications see FCN No. 1453. Slimicides; Bronopol: at a maximum level of 0.6 pound per ton of dry weight fiber; CIT/MIT: At a level of 2.5 pounds per ton CIT/MIT of dry weight fiber.
USA	FDA 21 CFR 176.170	Components of paper and paperboard in contact with aqueous and fatty food: BIT: only as preservative in paper coating compositions … at a level not to exceed 0.01 mg/in^2 (0.0016 mg/cm^2) of finished paper and paperboard. See also FCN 1446; CIT/MIT: for use only as an antimicrobial agent (based on isothiazolone a.i.) at a level not to exceed 1) 50 ppm for polymer latex emulsions in paper coatings in the coating formulation. 2) 25 ppm for finished coating formulations and for additives. Bronopol: for use only as an antimicrobial/preservative in fillers, pigment slurries, starch sizing solutions, and latex coatings at levels not to exceed 0.01% by weight of those components.
USA	FDA 21 CFR 176.180	Components of paper and paperboard in contact with dry food: BIT: only as preservative in paper coating compositions … at a level not to exceed 0.02 mg/in^2 (0.0031 mg/cm^2) of finished paper and paperboard. See also FCN 1446; CIT/MIT: for use only as an antimicrobial agent (based on isothiazolone a.i.) at a level not to exceed 1) 50 ppm for polymer latex emulsions in paper coatings in the coating formulation. 2) 25 ppm for finished coating formulations and for additives. Bronopol: for use only as a microbial/preservative in fillers, pigment slurries, starch sizing solutions, and latex coatings at levels not to exceed 0.01% by weight of those components (wet end applications).

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In framework regulation (EC) No 1935/2004 is announced that 17 different groups of materials have to be regulated. These groups include e.g. plastic materials, glass, wood, adhesives, coatings and wax. Till now only regulations for Ceramics, Plastic materials intended for food contact and Regenerated cellulose exist. Regulations concerning the other use areas are announced to come into effect in the future. Until then the regulations of the different Member States stay in force.

AQUAVATE™ BIO SB 2383 complies with framework regulation (EC) No 1935/2004.

AQUAVATE™ BIO SB 2383 is produced by Paramelt B.V. in accordance with regulation (EC) No 2023/2006 on Good Manufacturing Practice (packaging).

PARAMELT BV

J. van Langerak (Senior Regulatory Affairs Officer)

End users of finished materials and articles intended to come into contact with food have the responsibility to ensure that limitations and requirements described in these chapters are met for the finished products.
Moreover end users must comply in all countries with the general regulatory requirements, that food-contact materials do not bring about an unacceptable change in composition of the food-stuffs or a deterioration in the organoleptic characteristics thereof.

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