

FOOD CONTACT

BYK Regulatory Information

AQUACER 1547

Wax emulsion for improved scratch resistance in aqueous can coating systems.

Summary

AQUACER 1547 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
China	GB9685-2016, table A.2 'Coatings'	Yes
MERCOSUR	GMC Resolution n. 39/19	Yes
	GMC Resolution n. 02/12	Yes
Printing inks		
Europe	Suitable for food contact printing inks	Yes
	Swiss Ordinance 817.023.21, Annex 10	Yes
	Nestlé Guidance Note on Packaging Inks (Oct. '18)	Yes
Industry	EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)	Yes
Adhesives		
EU	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	Yes
	German BfR XIV 'Polymer Dispersions'	Yes
	German BfR XXXVI 'Paper and board in contact with food'	Yes
USA	21 CFR 175.105 'Adhesives'	Yes
China	GB9685-2016, table A.5 'Adhesives'	No

Paper and paperboard		
EU	Suitable for food contact paper and paperboard	Yes
	Regulation (EU) No. 10/2011	Yes
	German BfR XXXVI 'Paper and paperboard in contact with food'	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

Without the full evaporation of 2-diethylaminoethanol, the food contact status for AQUACER 1547 is not valid.

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 active components of the product are directly listed in Annex 1-table 1 of Commission Regulation (EU) No. 10/2011 of 14 January 2011 (PIM) (as amended). There are SML values applicable.

AQUACER 1547 contains 2-diethylaminoethanol (DEAE). This amine is currently evaluated as a formulation aid thus a separate listing as an "additive" under the PIM-Regulation (EU) 10/2011 is not required. However, the classification as a formulation aid is connected to its boiling point at 163°C (evaporation is assumed) and its low toxicity (listing in national food contact coatings legislation). Therefore, evaporation and residual amount of this substance needs to be monitored by the final user. Art. 3 of Framework Regulation (EC) 1935/2004 applies.

Without the full evaporation of 2-diethylamino-ethanol, the food contact status for AQUACER 1547 is not valid.

German BfR XIV 'Polymer Dispersions'

The product is compliant with the compositional requirements of BfR XIV 'Polymer Dispersions'.

CoE ResAP (2004) 1

The wax base of this product is listed in CEPE "Code of practice for food contact coatings", Edition 4, Version, Feb. 2009.

Dual use additives

The product contains dual use additives for which restrictions apply:

- E914 – oxidized polyethylene (ca. 30%)
- E514 – sodium sulphate (ca. 0,3 %)

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

Formulation aids are not covered by the food contact status.

USA **21 CFR 175.300 'Resinous and polymeric coatings'**

The product can be used in compliance with the requirements of FDA 21 CFR 175.300 (Resinous and polymeric coatings).

Formulation aids are not covered by above statement.

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

The product can be used in compliance 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), since its components are listed in table A.2 (Additives for coatings).

Formulation aids are not covered by above statement.

MERCOSUR GMC Resolutions n. 39/19 & 02/12

The product is authorized for use under MERCOSUR GMC Resolution n. 39/19 and MERCOSUR GMC Resolution n. 02/12. Specific Migration Limits and/or restrictions apply.

Therefore, the product can be recommended for use in food contact coatings in MERCOSUR member states.

Printing inks

Europe Swiss Ordinance 817.023.21, Annex 10

This product is conform with the compositional requirements of the part for printing inks for packaging of the Swiss Ordinance 817.023.21 (Version of 1 December 2019) since all components are listed on the A-list in Annex 10. Specific migration limits apply.

Therefore, the product can be recommended for use in food contact printing inks in Europe.

Industry Nestlé Guidance Note on Packaging Inks (Oct. '18)

According to the recipe, the product does not contain any of the substances listed in Table 1 – Table 7 of the Nestlé Guidance note on Packaging Inks (dated October 2018).

EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018) are present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

Adhesives

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

The active components of the product are directly listed in Annex 1- table 1 of Commission Regulation (EU) No. 10/2011 of 14 January 2011 (PIM) (as amended). There are SML values applicable.

AQUACER 1547 contains 2-diethylaminoethanol (DEAE). This amine is currently evaluated as a formulation aid thus a separate listing as an "additive" under the PIM-Regulation (EU) 10/2011 is not required. However, the classification as a formulation aid is connected to its boiling point at 163°C (evaporation is assumed) and its low toxicity (listing in national food contact coatings legislation). Therefore, evaporation and residual amount of this substance needs to be monitored by the final user. Art. 3 of Framework Regulation (EC) 1935/2004 applies.

Without the full evaporation of 2-diethylamino-ethanol, the food contact status for AQUACER 1547 is not valid.

German BfR XIV 'Polymer Dispersions'

The product is compliant with the compositional requirements of the German BfR XIV 'Polymer Dispersions'.

German BfR XXXVI 'Paper and board in contact with food'

The product is compliant with the compositional requirements of the German BfR XXXVI 'Paper and paperboard in contact with food'.

Dual use additives

The product contains dual use additives for which restrictions apply:

- E914 – oxidized polyethylene (ca. 30%)
- E514 – sodium sulphate (ca. 0,3 %)

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

Formulation aids are not covered by the food contact status.

USA **21 CFR 175.105 'Adhesives'**

The product complies with the compositional requirements of 21 CFR FDA Sec 175.105.

Formulation aids are not covered by the food contact status.

China **GB9685-2016, table A.5 'Adhesives'**

The product is not compliant with table A.5 'Adhesives' 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 active components of the product are directly listed in Annex 1- table 1 of Commission Regulation (EU) No. 10/2011 of 14 January 2011 (PIM) (as amended). There are SML values applicable.

AQUACER 1547 contains 2-diethylaminoethanol (DEAE). This amine is currently evaluated as a formulation aid thus a separate listing as an "additive" under the PIM-Regulation (EU) 10/2011 is not required. However, the classification as a formulation aid is connected to its boiling point at 163°C (evaporation is assumed) and its low toxicity (listing in national food contact coatings legislation). Therefore, evaporation and residual amount of this substance needs to be monitored by the final user. Art. 3 of Framework Regulation (EC) 1935/2004 applies.

Without the full evaporation of 2-diethylamino-ethanol, the food contact status for AQUACER 1547 is not valid.

German BfR XXXVI 'Paper and paperboard in contact with food'

The product is compliant with the compositional requirements of the German BfR XXXVI 'Paper and paperboard in contact with food'.

Dual use additives

The product contains dual use additives for which restrictions apply:

- E914 – oxidized polyethylene (ca. 30%)
- E514 – sodium sulphate (ca. 0,3 %)

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

Formulation aids are not covered by the food contact status.

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

The product complies with the compositional requirements of 21 CFR FDA Sec 176.170.

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

The product complies with the compositional requirements of 21 CFR FDA Sec 176.180.

Formulation aids are not covered by the food contact status.

China **GB9685-2016, table A.6 'Paper'**

The product is not compliant 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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