

FOOD CONTACT

BYK Regulatory Information

AQUACER 1063

Summary

AQUACER 1063 is suitable according to the following compositional provisions for food contact applications, as indicated:

Printing inks		
Europe	Suitable for food contact printing inks	Yes
	Swiss Ordinance 817.023.21, Annex 10	See explanation ⁽¹⁾
Industry	Nestlé Printing Inks for Food Packaging (02/04/2024)	Yes
	EuPIA Exclusion List (March 2024)	Yes
Paper and paperboard		
EU	Suitable for food contact paper and paperboard	Yes
	Regulation (EU) No. 10/2011	See explanation ⁽¹⁾
	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'	No
	21 CFR 176.180 'Components of paper and paperboard in contact with dry food'	Yes
China	GB9685-2016, table A.6 'Paper'	No
Adhesives & Sealants		
EU	Suitable for food contact adhesives	Yes
	Regulation (EU) No. 10/2011	See explanation ⁽¹⁾
	German BfR XIV 'Polymer Dispersions'	Yes
USA	21 CFR FDA 175.105 'Adhesives'	Yes
China	GB9685-2016, table A.5 'Adhesives'	No

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

Printing inks

Europe **Swiss Ordinance 817.023.21, Annex 10**⁽¹⁾

This product is conform⁽¹⁾ with the compositional requirements of the part for printing inks for packaging of the Swiss Ordinance 817.023.21 (Version February 2024) since all components are listed in Annex 10. Specific migration limits apply.

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

Industry **Nestlé Printing Inks for Food Packaging (02/04/2024)**

According to the recipe, the product does not intentionally contain any of the substances listed in 4. 'General Nestlé Exclusions and Minimisations' and Table 5 – Table 8 of the Nestlé Printing Inks for Food Packaging (02/04/2024).

EuPIA Exclusion List (March 2024)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (March 2024) are intentionally present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

Paper and paperboard

EU **Regulation (EU) No. 10/2011**⁽¹⁾

This product is conform⁽¹⁾ with the compositional requirements of Regulation (EU) No. 10/2011.

German BfR XXXVI 'Paper and board for food contact'

The components of this product are conform to the compositional requirements of the German BfR-Recommendation XXXVI 'Paper and board for food contact'

Therefore, the product can be recommended for use in adhesive applications in the EU.

Qm & Specific migration limits apply.

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

The product cannot be recommended for applications described in FDA 21 CFR 176.170. The components are not fully listed under section 176.170 (components of paper and paperboard in contact with aqueous and fatty foods).

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

The product can be recommended for applications described in FDA 21 CFR 176.180. The active components are fully listed under section 176.180 (components of paper and paperboard in contact with dry food).

Therefore, the product can be recommended for paper and paperboard as described in 21 CFR 176.180.

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

The active components of AQUACER 1063 are listed in GB9685-2016 but under different application scope, therefore we can confirm AQUACER 1063 for neither of specific application under GB9685-2016.

Therefore the product cannot be recommended for adhesives as described in GB9685-2016, table A.6

Adhesives & Sealants

EU **Regulation (EU) No. 10/2011**^{*(1)}

This product is conform⁽¹⁾ with the compositional requirements of Regulation (EU) No. 10/2011.

Qm & Specific migration limits apply.

German BfR XIV 'Polymer Dispersions'

All the components of this product are conform to the compositional requirements of the German BfR-Recommendation XIV. "Polymer Dispersions".

Therefore, the product can be recommended for use in adhesive applications in the EU. Qm & Specific migration limits apply.

USA **21 CFR FDA 175.105 'Adhesives'**

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

Therefore, the product can be recommended for food contact adhesives, as described in Sec. 175.105 'Adhesives' of 21 CFR FDA.

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

The active components of AQUACER 1063 are listed in GB9685-2016 but under different application scope, therefore we can confirm AQUACER 1063 for neither of specific application under GB9685-2016.

Therefore the product cannot be recommended for adhesives as described in GB9685-2016, table A.5

Note ⁽¹⁾

Due to the purity requirement of (EU) 231/2012, our supplier does not confirm compliance/ a positive food contact ratings for the emulsifier used in the manufacture of the product.

The product contains according to the Swiss Ordinance 817.023.21, Annex 10, Substance No.5045 / FCM 799 of Regulation (EU) No. 10/2011.

1	2	3	4	5					6	7	8	9		
N°	Denomination of the substance	N° CAS	N° Ref.	Use					Part		SML	SML (T)	Restrictions and specifications	
				I M	II C	III S	IV AD	V P	A	B	[mg/kg]	N°		
5045	Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols		77708	M			AD			A		1.8		In compliance with the maximum ethylene oxide content as laid down in the purity criteria for food additives in Commission Regulation (EU) No 231/2012

▼ M6												
799	77708		polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	yes	no	no	1,8					In compliance with the maximum ethylene oxide content as laid down in the purity criteria for food additives in Commission Regulation (EU) No 231/2012.

As indicated in the restrictions (Swiss ordinance entry no. 5045 / (EU) No. 10/2011 FCM 799), the purity criteria are linked to (EU) 231/2012 and have a tolerable residual content of ethylene oxide of ≤ 0.1 ppm.

In our opinion, this limit is too strict and also not in line with the other entries of Swiss Ordinance 817.023.21 and Regulation (EU) No. 10/2011.

- The emulsifier / alkyl ethoxylate is not in compliance with (EU) 231/2012.
- The purity criteria of (EU) 231/2012 are not applicable to the substance for use in coatings and adhesives.
- The limits of EO in our products/raw materials should not be the same as those in food additives.
Other ethoxylates not covered by the above description must be in compliance with Swiss ordinance Annex 10 Substance No 59 & Regulation (EU) No. 10/2011 FCM Substance No No. 129, Ethylene Oxide.
The limit for this is 1 mg/kg for Ethylene oxide (= 1 ppm) in the packaging material / final product.
- The production and processing of the final product, the Food Contact Material, involves a heat treatment in which ethylene oxide is assumed to evaporate. Furthermore, due to its reactivity, ethylene oxide can react with other components of the formulation, especially with water.
- Therefore, the content of ethylene oxide in the final product will still be significantly lower.

For you as a customer, this means that you can carry out your own food assessment of your product based on this maximum possible for ethylene oxide residue in the final packaging material of 1 ppm.

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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