

FOOD CONTACT

BYK Regulatory Information

AQUACER 561

Beeswax-based wax emulsion to improve surface protection in aqueous care products and coating systems.

Summary

AQUACER 561 is suitable according to the following compositional provisions for food contact applications, as indicated:

Paper and paperboard		
EU	Suitable for food contact paper and paperboard	See explanation
	Regulation (EU) No. 10/2011	See explanation
	German BfR XXXVI 'Paper and board for food'	See explanation
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'	No
China	GB9685-2016, table A.6 'Paper'	No
MERCOSUR	GMC Resolution n. 39/19	No
	GMC Resolution n. 02/12	No
	GMC Resolution n. 40/15	No
	GMC Resolution n. 41/15	No

Solvents and other 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

Paper and paperboard

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

All components of this product are directly listed in Annex I – Table I of Regulation (EU) No. 10/2011 (including all amendments). Specific Migrations Limits and/or restrictions apply.

German BfR XXXVI ‘Paper and board for food contact’^{*(1)}

The product is covered by the compositional requirements of BfR-Recommendation XXXVI.

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

Please refer to the ‘Notes’ section (^{*(1)}).

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. Not all active components are 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 cannot be recommended for applications described in FDA 21 CFR 176.180. Not all active components are fully listed under section 176.180 (components of paper and paperboard in contact with dry food).

Therefore, the product cannot be recommended for paper and paperboard as described in 21 CFR 176.170 & 176.180.

Solvents and other 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).

MERCOSUR GMC Resolutions n. 39/19, 02/12, 40/15 & 41/15

The product does not comply with the compositional requirements of MERCOSUR GMC Resolution n. 39/19, MERCOSUR GMC Resolution n. 02/12, MERCOSUR GMC Resolution n. 40/15, and MERCOSUR GMC Resolution n. 41/15.

Therefore, the product is not authorized for use under these regulations.

Solvents

The product contains a significant amount of solvent [with a boiling range from 100°C – 184°C]. Solvents are currently not regulated by food contact positive lists as it is assumed that solvents evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 should be fulfilled.

Notes

*(1):

The products mentioned contain emulsifiers according to EU/10/2011, Annex 1, food contact material entry no. 799 and according to the Swiss Ordinance 817.023.21, Annex 19, food contact material entry no. 5045:

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
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.	

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

As indicated in the restrictions (column 10) of entry no. 799, the purity criteria are linked to (EU) 231/2012 and have recently been changed ((EU) 2022/1396) from a tolerable residual content of ethylene oxide ≤ 0.2 ppm to ≤ 0.1 ppm.

In our opinion, this limit is too strict and also not in line with the other entries of EU/10/2011:

- Alcohol ethoxylates are not food additives and are not consumed as such. Therefore, the limits of EO in our products should not be the same as those in food additives.
- Other ethoxylates not covered by the above description must be in compliance with FCM No. 129, Ethylene Oxide. The limit for this is 1 mg/kg EO (= 1 ppm) in the final product.
- The production and processing of the final product, the Food Contact Material, involves a heat treatment in which ethylene oxide evaporates. 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.

But due to these new purity requirements, our suppliers have withdrawn the positive food contact ratings for the emulsifiers described above at short notice.

There are currently no suitable analytical methods for these low residues of ethylene oxide.

However, based on information from our suppliers and worst-case calculations, we can confirm that the products mentioned contain EO residues significantly below 0.1 ppm.

For you as a customer, this means that you can carry out your own food assessment of your product based on this maximum possible ethylene oxide residue.

Efforts are currently being made by CEFIC (European Chemical Industry Council) with regard to the EU Commission to restore the old status quo. However, it is not foreseeable if and when this will succeed.

Please do not hesitate to contact us if you have any questions.

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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