

# FOOD CONTACT

## BYK Regulatory Information

### BYK-2616

Low-emission additive for PVC plastisols to eliminate moisture.

#### Summary

BYK-2616 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	Suitable for food contact coatings	See explanation
	Regulation (EU) No. 10/2011	See explanation
	German BfR XIV 'Polymer Dispersions'	See explanation
	CoE ResAP (2004) 1	See explanation
USA	21 CFR 175.300 'Resinous and polymeric coatings'	No
China	GB9685-2016, table A.2 'Coatings'	No
Adhesives		
EU	Suitable for food contact adhesives	See explanation
	Regulation (EU) No. 10/2011	See explanation
USA	21 CFR 175.105 'Adhesives'	No
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

### Coatings

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- EU**      **Regulation (EU) No. 10/2011**<sup>\*(1)</sup>  
For this product, either the components themselves or the monomers and starting substances used for manufacturing are listed in the Regulation (EU) No. 10/2011. One active component of this product is not listed as a “polymeric additive” in Annex I – Table I of Regulation (EU) No. 10/2011 and therefore the product can formally not be used as an additive in compliance with this regulation.
- German BfR XIV ‘Polymer Dispersions’**<sup>\*(1)</sup>  
For this product, either the components themselves or the monomers and starting substances used for manufacturing are covered by the German BfR-Recommendation XIV. “Polymer Dispersions” .
- CoE ResAP (2004) 1**<sup>\*(1)</sup>  
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.
- Please refer to the ‘Notes’ section (<sup>\*(1)</sup>).
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- USA**      **21 CFR 175.300 ‘Resinous and polymeric coatings’**  
The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives. The components are not fully listed under section 175.300.
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- China**      **GB9685-2016, table A.2 ‘Coatings’**  
The product does not comply with 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).
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**Adhesives**

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**EU**      **Regulation (EU) No. 10/2011<sup>\*(1)</sup>**

For this product, either the components themselves or the monomers and starting substances used for manufacturing are listed in the Regulation (EU) No. 10/2011. One active component of this product is not listed as a “polymeric additive” in Annex I – Table I of Regulation (EU) No. 10/2011 and therefore the product can formally not be used as an additive in compliance with this regulation.

Please refer to the ‘Notes’ section (<sup>\*(1)</sup>).

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**USA**      **21 CFR 175.105 ‘Adhesives’**

The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives. The components are not fully listed under section 175.105.

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**China**      **GB9685-2016, table A.5 ‘Adhesives’**

The product does not comply with 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).

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## 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 <sub>8</sub> -C <sub>22</sub> ) 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 [mg/kg]	SML (T) N°	Restrictions and specifications	
				I M	II C	III S	IV AD	V P					
5045	Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C <sub>8</sub> -C <sub>22</sub> ) 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  $\leq 0.2$  ppm to  $\leq 0.1$  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.

**Food Contact Team**  
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