

FOOD CONTACT

BYK Regulatory Information

DISPERBYK-195

Summary

DISPERBYK-195 is suitable according to the following compositional provisions for food contact applications, as indicated:

Printing inks		
Europe	Suitable for food contact printing inks	See explanation
	Swiss Ordinance 817.023.21, Annex 10	See explanation ⁽¹⁾
Industry	Nestlé Printing Inks for Food Packaging (07/04/2022)	Yes
	EuPIA Exclusion List (June 2023)	Yes

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)}:

The monomers/starting substances for manufacturing the active components and all other components are listed in Annex 10 of the part for printing inks for packaging of the Swiss Ordinance 817.023.21 (Version of 15 October 2022).

Specific migration limits apply.

Industry Nestlé Printing Inks for Food Packaging (07/04/2022)

According to the recipe, the product does not contain any of the substances listed in Table 5 – Table 7 of the Nestlé Printing Inks for Food Packaging (07/04/2022).

EuPIA Exclusion List (June 2023)

According to the recipe, none of the substances listed in Annex 1 (Group C – G) of the EuPIA Exclusion List (March 2021) are intentionally present. The product itself is not classified and labeled with any of the Hazard Statements given in Group A and B.

Notes

*(1)

The product contains according to the Swiss Ordinance 817.023.21, Annex 10, food contact material entry 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	II	III	IV	V	A	B	[mg/kg]	N°	
				M	C	S	AD	P					
5045	Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8-C22) 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 9 of entry no. 5045, 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.

- The emulsifier / alkyl ethoxylate is not in compliance with (EU) 231/2012.
- The emulsifier used in the manufacture may contain max. 10 ppm ethylene oxide which may contribute in > 2 ppm ethylene oxide in Disperbyk 195.
- 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. 59, 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 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/ink will still be significantly lower.

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

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 ink 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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Contractual terms and conditions, in particular agreed product specifications, always take precedence.

We recommend that you test our products in preliminary trials to determine their suitability for your intended purpose prior to use. To the extent we are not legally obliged to do so, any information herein regarding legal regulations reflect only our unbinding evaluation.

The evaluation does neither preclude compliant use in additional regions nor applications nor does it limit your responsibility to evaluate the compliance with any regulations applicable to you.

We reserve the right to make any changes and to update the information herein without notice.

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