

# FOOD CONTACT

## BYK Regulatory Information

# HORDAMER PE 35

Modified primary polyethylene dispersion for improving the surface characteristics of aqueous printing inks and overprint varnishes.

## Summary

HORDAMER PE 35 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
Industry	Nestlé Guidance Note on Packaging Inks (Oct. '18)	See explanation
	EuPIA Exclusion List (Nov. '16 – Corrigendum Dec. '18)	See explanation
China	GB9685-2016, table A.4 'Additives for Inks'	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

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**Europe** **Swiss Ordinance 817.023.21, Annex 10<sup>\*(1)</sup>**

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 2020) since all components are listed in Annex 10. Migration limits apply.

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

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**Industry** **Nestlé Guidance Note on Packaging Inks (Oct. '18)<sup>\*(1)</sup>**

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 (Nov. '16 – Corrigendum Dec. '18)<sup>\*(1)</sup>**

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.

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

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**China** **GB9685-2016, table A.4 'Additives for Inks'**

This product is not in compliance with the National Standard of the People's Republic of China, GB96852016.

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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	SML (T)	Restrictions and specifications	
				I	II	III	IV	V	A	B	[mg/kg]	N°	
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.

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