

FOOD CONTACT

BYK Regulatory Information

CLAYTONE-AF

Organophilic bentonite for aliphatic solvent-borne systems. CLAYTONE-AF is self-activating and easy to disperse.

Summary

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

Coatings		
EU	Suitable for food contact coatings	Yes
	Regulation (EU) No. 10/2011	Yes (restricted)
	German BfR & Dutch Warenwet	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
Printing inks		
Europe	Suitable for food contact printing inks	Yes
	Swiss Ordinance 817.023.21, Annex 10	Yes
Industry	Nestlé Guidance Note on Packaging Inks (Oct. '18)	Yes
	EuPIA Exclusion List (Nov. '16 – Corr. Dec. '18)	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

Coatings	
EU	<u>Regulation (EU) No. 10/2011</u> The active component is listed in the PIM, but is restricted: only to be used up to 12 % (w/w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room temperature or below. The sum of the specific migration of 1-chlorohexadecane and 1-chlorooctadecane shall not exceed 0,05 mg/kg food. Can contain platelets in the nanoform that are only in one dimension thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer. <u>German BfR & Dutch Warenwet</u> Applying the principle "mutual recognition" of listing in accordance to "195. Mitteilung" of BfR and Dutch Warenwet, the formulation of CLAYTONE-AF is conform to the compositional requirements of the EU

regulation of Coatings. However, final legal compliance needs to be verified by the producer of the final article under consideration of the final application and the conditions of use of the product. Furthermore, we recommend migration testing to verify compliance.

Therefore, the product can be recommended for use in food contact coatings in the EU.

USA 21 CFR 175.300 'Resinous and polymeric coatings'

The chemical composition of CLAYTONE-AF is listed in §178.3297 "Colorants for polymers". Therefore, it can be used as indirect additive, a colorant, for all polymers (including metal-polymer coated (§175.300)).

Printing inks

Europe Swiss Ordinance 817.023.21, Annex 10

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 2019) 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 Guidance Note on Packaging Inks (Oct. '18)

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 – Corr. Dec. '18)

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.

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

Regulatory Affairs
BYK-Chemie GmbH

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This issue replaces all previous versions

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