

# FOOD CONTACT

BYK Regulatory Information

## CLAYTONE-HY

### Summary

CLAYTONE-HY is suitable for food contact applications under the following compositional provisions, as indicated:

Coatings		
Europe	Regulation (EU) No. 10/2011	Yes (restricted)
	German BfR Recommendation XIV	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	As a colorant

Printing Inks		
Europe	GIO – German Ink Ordinance, part of BedGgstV	Yes
	Swiss Ordinance 817.023.21	Yes
Industry	Nestlé Standard 'Printing Inks for Food Packaging'	Yes
	EuPIA Exclusion Policy	Yes

This summary only reflects conducted evaluations on existing regulations. It does not exclude compliant use in additional regions or applications. Please refer to the explanation section below for detailed information on the regulations and assessment criteria considered.

## Explanation

### Coatings

#### Europe

##### **Regulation (EU) No 10/2011**

The product may be used for the manufacturing of materials and articles within the scope of Regulation (EU) N° 10/2011 and its amendments, since the components are fully listed in Annex I, table 1. The following restrictions apply:

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.

##### **German BfR Recommendation XIV**

The product may be used for the manufacturing of materials and articles according to the German BfR Recommendation XIV 'Polymer dispersions'. The following restrictions apply:

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.

#### USA

##### **21 CFR 175.300 'Resinous and polymeric coatings'**

The chemical composition of CLAYTONE-HY is listed in §178.3297 "Colorants for polymers". This may be cross-referenced to allow the use of this product as a colorant in polymeric coatings on a metal substrate under 21 CFR 175.300.

### Printing Inks

#### Europe

##### **GIO – German Ink Ordinance, part of the Consumer Goods Regulation (BedGgstV)**

The product may be used for the manufacturing of printing inks for packaging not intended for direct contact with food as defined in the German BedGgstV. Migration of single components must not exceed 10 µg/kg food.

### **Swiss Ordinance 817.023.21**

The product may be used for the manufacturing of printing inks for packaging according to Swiss Ordinance 817.023.21 (Version as of 1 January 2026), since the components are fully listed in Annexes 2 or 10.

The following restrictions apply:

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 4 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.

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### **Industry**

#### **Nestlé Standard 'Printing Inks for Food Packaging' (02 April 2024)**

The product complies with the Nestlé Standard 'Printing Inks for Food Packaging' (02 April 2024), since substances listed in the tables of sections 4 – 8 are not added intentionally.

#### **EuPIA Exclusion Charter (March 2026)**

The product intentionally does not contain any of the substances listed in Annexes 1 and 2 of the 'EuPIA Charter on Raw Material Selection and Exclusion for Printing Inks and Related Products' (1<sup>st</sup> edition, March 2026). The product itself as raw material is not classified and labeled with any of the Hazard Statements for Group I or Group II substances as defined in the section 'Selection Criteria & Procedures'.

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### **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. Please note that it is the responsibility of both manufacturers of finished food contact articles and downstream business operators to ensure compliance with the applicable migration limits and restrictions of the finished materials or articles under specific real and/or foreseeable conditions of use.

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 is in effect for three years commencing the date of issue.

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*This issue replaces all previous versions*

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