

# FOOD CONTACT

## BYK Regulatory Information

### BYK-370

Silicone-containing surface additive, polyester-modified, for solvent-borne coating systems and UP gel coats. OH-functional. Strongly reduces surface tension.

#### Summary

BYK-370 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
	Suitable for food contact coatings	Yes
	Regulation (EU) No. 10/2011	No
EU	German BfR XIV 'Polymer Dispersions'	Yes
	German BfR XV 'Silicones'	Yes
	CoE ResAP (2004) 1	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes (max. 0.1%)
China	GB9685-2016, table A.2 'Coatings'	No
Printing inks		
Europe	Suitable for food contact printing inks	Yes
	Swiss Ordinance 817.023.21, Annex 10	Yes
	Nestlé Guidance Note on Packaging Inks (Oct. '18)	No
Industry	EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)	Yes

Solvents and other formulation aids are not covered by the food contact status.

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

---

#### Europe Regulation (EU) No. 10/2011

The main active component of this product is a polymer (polyester-modified siloxane) and is manufactured using monomers/starting substances which are fully evaluated as SCF - list 0-4 and directly listed in Annex I – Table I of COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 (PIM) on plastic materials and articles intended to come into contact with food (including all amendments). Restrictions apply. The active polymeric silicone component as such is not listed as a “polymeric additive” in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive.

#### German BfR XIV ‘Polymer Dispersions’

The product is conform with the compositional requirements of the German BfR-Recommendation XIV ‘Polymer Dispersions’.

#### German BfR XV ‘Silicones’

The active component of this product is listed in the German BfR-Recommendation XV “Silicones”.

#### CoE ResAP (2004) 1

The components themselves or the monomers and starting substances used for manufacturing are listed in in the Framework Resolution ResAP (2004) 1 on coatings intended to come into contact with foodstuffs.

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

Solvents and other formulation aids are not covered by the food contact status.

---

#### USA 21 CFR 175.300 ‘Resinous and polymeric coatings’

The product can be used in compliance with the requirements of FDA 21 CFR 175.300, if used as recommended below. Based on the “no migration exemption”, we recommend following use conditions:

- Max. use level of 0.1% in wet coating formulations
- For formulations with a solid content of 40% and a dry film thickness of 12 µm
- The use level can be adapted for deviating film thickness and solid content.

Solvents and other formulation aids are not covered by the food contact status.

---

---

**China**     **GB9685-2016, table A.2 'Coatings'**

The active components of BYK-370 are not listed in GB9685-2016.

---

**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). The monomers/starting substances for manufacturing the active components and all other components are listed in Annex 10. Specific migration limits apply.

Additional note: the non-listed D4 (CAS 556-67-2) is present, as an impurity. Its amount is referred to in our BRIEF document.

Therefore, the product can be recommended for use in 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). However, the solvent toluene, which is listed in Table 6, and the solvent ethylbenzene, which is listed in Table 7, are present.

**EuPIA Exclusion List (November 2016 - Corrigendum Dec. 2018)**

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.

---

### **Solvents**

The product contains a significant amount of solvents. Solvents are currently not regulated by food contact positive lists as it is assumed that solvents evaporate from the finished product so that only residues or traces of no toxicological concern should remain. Evaporation needs to be monitored by the manufacturer of the final product. Article 3 of the Framework Regulation (EC) 1935/2004 should be fulfilled.

### **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

*The information herein is based on our present knowledge and experience. The information merely describes the properties of our products but no guarantee of properties in the legal sense shall be implied. We recommend testing our products as to their suitability for your envisaged purpose prior to use. No warranties of any kind, either express or implied, including warranties of merchantability or fitness for a particular purpose, are made regarding any products mentioned herein and data or information set forth, or that such products, data or information may be used without infringing intellectual property rights of third parties. We reserve the right to make any changes according to technological progress or further developments.*

*This issue replaces all previous versions*

ACTAL<sup>®</sup>, ADD-MAX<sup>®</sup>, ADD-VANCE<sup>®</sup>, ADJUST<sup>®</sup>, ADVITROL<sup>®</sup>, ANTI-TERRA<sup>®</sup>, AQUACER<sup>®</sup>, AQUAMAT<sup>®</sup>, AQUATIX<sup>®</sup>, BENTOLITE<sup>®</sup>, BYK<sup>®</sup>, BYK<sup>®</sup>-DYNWET<sup>®</sup>, BYK<sup>®</sup>-MAX<sup>®</sup>, BYK<sup>®</sup>-SILCLEAN<sup>®</sup>, BYKANOL<sup>®</sup>, BYKETOL<sup>®</sup>, BYKJET<sup>®</sup>, BYKO2BLOCK<sup>®</sup>, BYKOPLAST<sup>®</sup>, BYKUMEN<sup>®</sup>, CARBOBYK<sup>®</sup>, CERACOL<sup>®</sup>, CERAFAK<sup>®</sup>, CERAFLOUR<sup>®</sup>, CERAMAT<sup>®</sup>, CERATIX<sup>®</sup>, CLAYTONE<sup>®</sup>, CLOISITE<sup>®</sup>, DISPERBYK<sup>®</sup>, DISPERPLAST<sup>®</sup>, FULACOLOR<sup>®</sup>, FULCAT<sup>®</sup>, GARAMITE<sup>®</sup>, GELWHITE<sup>®</sup>, HORDAMER<sup>®</sup>, LACTIMON<sup>®</sup>, LAPONITE<sup>®</sup>, MINERAL COLLOID<sup>®</sup>, MINERPOL<sup>®</sup>, NANOBYK<sup>®</sup>, OPTIBENT<sup>®</sup>, OPTIFLO<sup>®</sup>, OPTIGEL<sup>®</sup>, PAPERBYK<sup>®</sup>, PERMONT<sup>®</sup>, POLYAD<sup>®</sup>, PRIEX<sup>®</sup>, PURE THIX<sup>®</sup>, RECYCLOBLEND<sup>®</sup>, RECYCLOBYK<sup>®</sup>, RECYCLOSSORB<sup>®</sup>, RECYCLOSTAB<sup>®</sup>, RHEOBYK<sup>®</sup>, RHEOCIN<sup>®</sup>, RHEOTIX<sup>®</sup>, SCONA<sup>®</sup>, SILBYK<sup>®</sup>, TIXOGEL<sup>®</sup>, VISCOBYK<sup>®</sup> and Y 25<sup>®</sup> are registered trademarks of the BYK group.