

# FOOD CONTACT

## BYK Regulatory Information

### BYK-P 104

Controlled flocculating wetting and dispersing additive for solvent-borne, medium-polarity to high-polarity coatings to prevent the flooding/floating of titanium dioxide in combination with colored pigments.

Technically recommended use level: 0.5 – 20 % (based upon pigment)

#### Summary

BYK-P 104 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	No
	German BfR XIV 'Polymer Dispersions'	Yes
	CoE ResAP (2004) 1	Yes
USA	21 CFR 175.300 'Resinous and polymeric coatings'	Yes
China	GB9685-2016, table A.2 'Coatings'	No

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	
<b>EU</b>	<p><b><u>Regulation (EU) No. 10/2011</u></b></p> <p>The main active component of this product is manufactured using 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. A specific migration limit applies. The main active component as such is not listed as an additive in a.m. REG. (EU) No. 10/2011 (PIM), and therefore the product can formally not be used as an additive in compliance with this regulation.</p> <p><b><u>German BfR XIV 'Polymer Dispersions'</u></b></p> <p>The active component of this product is conform to the compositional requirements of the German BfR-Recommendation XIV "Polymer Dispersions".</p>

---

**CoE ResAP (2004) 1**

The monomers and starting substances used for manufacturing of the active component are listed in the CEPE 'Code of practice for food contact coatings', Edition 4, Version Feb. 2009.

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

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

---

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

The product complies with Title 21 CFR (FDA) Regulations for indirect food additives. The components are fully listed under section 175.300, but restrictions apply.

Therefore, the product can be recommended for use in food contact coatings in regards to Sec. 175.300, as described above.

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

---

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

The product does not comply with the National Food Safety Standard of the People's Republic of China, Standard for Uses of Additives in Food Contact Materials and Articles (GB9685-2016).

---

**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*

ADD-MAX<sup>®</sup>, ADD-VANCE<sup>®</sup>, ANTI-TERRA<sup>®</sup>, AQUACER<sup>®</sup>, AQUAMAT<sup>®</sup>, AQUATIX<sup>®</sup>, BENTOLITE<sup>®</sup>, BYK<sup>®</sup>, BYK-AQUAGEL<sup>®</sup>, BYK<sup>®</sup>-DYNWET<sup>®</sup>, BYK-MAX<sup>®</sup>, BYK<sup>®</sup>-SILCLEAN<sup>®</sup>, BYKANOL<sup>®</sup>, BYKCARE<sup>®</sup>, BYKETOL<sup>®</sup>, BYKJET<sup>®</sup>, BYKO2BLOCK<sup>®</sup>, BYKONITE<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>, MINERPOL<sup>®</sup>, NANOBYK<sup>®</sup>, OPTIBENT<sup>®</sup>, OPTIFLO<sup>®</sup>, OPTIGEL<sup>®</sup>, POLYAD<sup>®</sup>, PRIEX<sup>®</sup>, PURABYK<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> and VISCOBYK<sup>®</sup> are registered trademarks of the BYK group.