

FOOD CONTACT

BYK Regulatory Information

GARAMITE-1958

Powdered rheology additive for solvent-borne and solvent-free systems to increase storage stability and sag resistance.

Technically recommended use level: 0.3 – 5%

Summary

GARAMITE-1958 is suitable according to the following compositional provisions for food contact applications, as indicated:

Coatings		
EU	Suitable for food contact coatings	No
	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	No
	CoE ResAP (2004) 1	No
USA	21 CFR 175.300 'Resinous and polymeric coatings'	No
	Keller and Heckman Opinion (January 2011)	Yes (restricted)
China	GB9685-2016, table A.2 'Coatings'	No
Adhesives		
EU	Suitable for food contact adhesives	No
	Regulation (EU) No. 10/2011	No
	German BfR XIV 'Polymer Dispersions'	No
	German BfR XXXVI 'Paper and board for food contact'	No
USA	21 CFR 175.105 'Adhesives'	No
	Keller and Heckman Opinion (January 2011)	Yes (restricted)
China	GB9685-2016, table A.5 'Adhesives'	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

Coatings

EU

Regulation (EU) No. 10/2011

This product does not comply with Regulation (EU) No. 10/2011.

German BfR XIV 'Polymer Dispersions'

The product is not covered by the compositional requirements of BfR XIV 'Polymer Dispersions'.

CoE ResAP (2004) 1

The product is not covered by the compositional requirements of CoE ResAP (2004) 1.

The product is currently not compliant for direct food contact applications in the EU.

USA

21 CFR 175.300 'Resinous and polymeric coatings'

The product does not comply with Title 21 CFR (FDA) Regulations for indirect food additives.

However, for one specific application the use of GARAMITE®-1958 has been cleared by a Keller & Heckman opinion letter, dated January 14, 2011. In this opinion it was stated, that GARAMITE-1958 may be used at levels up to 1.5 % in cross-linked polyester resins that, in turn, will be used to make repeated-use food-contact articles containing a maximum of 60 % of the polyester resin. The use of GARAMITE®-1958 will not limit the finished article with regard to food type or temperature conditions of use. When used as such, GARAMITE®-1958 may be said to comply fully with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.

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).

Adhesives

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

This product does not comply with Regulation (EU) No. 10/2011.

German BfR XIV 'Polymer Dispersions'

The product is not covered by the compositional requirements of BfR XIV 'Polymer Dispersions'.

German BfR XXXVI 'Paper and board for food contact'

The product is not covered by the compositional requirements of BfR XXXVI 'Paper and board for food contact'.

The product is currently not compliant for direct food contact applications in the EU.

USA **21 CFR 175.105 'Adhesives'**

The product cannot be used in compliance with the requirements of FDA 21 CFR 175.105.

However, for one specific application the use of GARAMITE®-1958 has been cleared by a Keller & Heckman opinion letter, dated January 14, 2011. In this opinion it was stated, that GARAMITE-1958 may be used at levels up to 1.5 % in cross-linked polyester resins that, in turn, will be used to make repeated-use food-contact articles containing a maximum of 60 % of the polyester resin. The use of GARAMITE®-1958 will not limit the finished article with regard to food type or temperature conditions of use. When used as such, GARAMITE®-1958 may be said to comply fully with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.

China **GB9685-2016, table A.5 'Adhesives'**

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

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