

FOOD CONTACT

BYK Regulatory Information

SCONA TSPE 2102 GAHD

Summary

SCONA TSPE 2102 GAHD is suitable according to the following compositional provisions for food contact applications as indicated below:

| Plastics | | |
|----------|-----------------------------------|-----|
| Europe | Regulation (EU) No. 10/2011 | Yes |
| China | GB9685-2016, table A.1 'Plastics' | 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

Plastics

EUROPE

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

This product is manufactured with monomers/other starting substances and additives listed in Annex I - Table I of Regulation (EU) No 10/2011 or subject to derogation as per Article 6(3).

Aids to polymerization used in this product are either authorized under national legislation or have been risk assessed in accordance with Article 19 of this Regulation.

The table below lists only substances that are used or known to be present and that are relevant for compliance with the specific migration limits (SML) and/or any restrictions set out in Annex I of Regulation (EU) No 10/2011 or in national legislation. For additional information on substance concentrations, please refer to the Safety Data Sheet (SDS).

| FCM No. | CAS-No. | Name | SML / SML(T) [mg/kg] | Restrictions / Specifications |
|---------|----------|------------------|-----------------------------------|----------------------------------|
| 234 | 108-31-6 | Maleic anhydride | 30 expressed as maleic acid | - |

To the best of our knowledge and understanding, additives authorized for use in both food contact plastics and as direct food additives according to Regulations (EC) No 1333/2008 are not present in this product.

Based on the current knowledge of the product composition, product specifications, and information provided by raw material suppliers, residues of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out are not known or expected to be present in concentration exceeding the specific migration limits established by this regulation. Testing is not routinely performed for substances that are neither identified nor reasonably expected to be present.

In accordance with our role as a manufacturer of substances, non-intentionally added substances (NIAS) which have become known to us are assessed in accordance with internationally recognized scientific principles of risk assessment to ensure compliance with the requirements of Article 3(1)(a) of Regulation (EC) No 1935/2004. The assessments are carried out under the assumption that this product is used in accordance with BYK's recommendations for food contact applications and/or under normal or foreseeable conditions of use, and considering the following parameters: 100% migration, 1kg food in contact with 6 dm² of packaging, film thickness 1mm.

CHINA

GB9685-2016, table A.1 'Plastics'

The product complies with compositional requirements of 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), since its components are listed in table A.1 (Additives for plastics).

Therefore, the product can be recommended for use in plastics, according to 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. 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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