FOOD CONTACT

BYK Regulatory Information

SCONA TSKD 9103

Summary

SCONA TSKD 9103 is suitable for food contact applications under the following compositional provisions:

Plastics		
EU	Regulation (EU) No. 10/2011	Yes
USA	21 CFR FDA 177.1520 ‘Olefin polymers	No
China	GB9685-2016, table A.1 ‘Plastics’	Yes
Japan	Japan Food Sanitation Act Positive List System	Yes
MERCOSUR	GMC Resolution n. 02/12	Yes
	GMC Resolution n. 39/19	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

Plastic

EUROPE

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as amended as of the date of this document.

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 dm^2 of packaging, film thickness 1mm.

USA

21 CFR 177.1520 'Olefin polymers.'

This product does not comply with the compositional requirements of 21 CFR 177.1520 Olefin polymers for use as an additive to polymers.

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.

JAPAN

Japan Food Sanitation Act Positive List System

The ingredients in this product are listed in Japan's Food Sanitation Act Positive List (PL) system under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370. Please contact separately for use Limit by Synthetic Resin Group (%).

MERCOSUR

GMC Res No 02/12 and 39/19

The active components of this product are compositionally compliant with GMC Res No 39/19 with the polymeric components complying with GMC Res No 02/12 which allows this product to be recommended for use as an additive in food contact plastic materials in MERCOSUR member states.

The table below lists only the substances used or known to be present which are relevant to be considered for compliance with the specific migration limits (SML) laid down in GMC Res. GMC Res No 02/12 and 39/19:

Ref. No.	CAS-No.	Name	SML(T)
19960	108-31-6	Maleic anhydride	30 expressed as maleic acid

Therefore, the product is authorized for use in food contact plastics in MERCOSUR member states.

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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