FOOD CONTACT

BYK Regulatory Information

SCONA TPPP 8112 GA

Summary

SCONA TPPP 8112 GA is suitable for food contact applications under the following compositional provisions, as indicated below:

Plastics		
EU	Regulation (EU) No. 10/2011	Yes
USA	21 CFR 177.1520 ‘Olefin polymers’	No
	21 CFR 175.105 ‘Adhesives’ and 21 CFR § 177.1395 ‘Laminate structures for use at temperatures between 120 °F and 250 °F.’ as an adhesive	Yes-See explanation
China	GB9685-2016, table A.1 ‘Plastics’	Yes
Japan	Japan Food Sanitation Act Positive List	Yes
MERCOSUR	GMC Resolution n. 02/12	Yes
	GMC Res. No. 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

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, the following non-intentionally added substances (NIAS) with restrictions set forth in Annex II of this Regulation may be present:

- Aluminium; SML = 1 mg/kg food or food simulant

Substances for which genotoxicity has not been ruled out are not known or expected in this product. Testing is not routinely performed for substances that are neither identified nor reasonably expected to be present.

Other 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.

21 CFR 175.105 'Adhesives.'

The product complies with the compositional requirements of 21 CFR 175.105 Adhesives. This product includes components that are listed in 21 CFR 175.105 as well as components which are cleared under 178.2010 Antioxidants and stabilizers for polymers and 21 CFR 177.1520 which may be cross-referenced for use in compliance with 21 CFR 175.105.

Therefore, the product can be recommended for use in food contact adhesives in compliance with 21 CFR 175.105 Adhesives. As per the limitations outlined in that regulation, the final adhesive must either be separated from the food by a functional barrier or used subject to the following additional limitations:

- In dry foods: The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.
- In fatty and aqueous foods:
    - The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.
    - Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement "food-packaging adhesive".

This clearance also allows the use of this product in accordance with 177.1395 'Laminate structures for use at temperatures between 120 °F and 250 °F'. as an adhesive so long as a functional barrier is present and under FDA Condition of Use A-H as outlined in 21 CFR 176.170(c), Table 2.

Japan

Japan Food Sanitation Act Positive List System

The ingredients 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, Appended Table 1 and Table 2, as applicable, published by MHLW, as Polymer Group 2.

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.

MERCOSUR

GMC Res. No. 39/19 & GMC Res No 02/12

The active components of this product are compositionally compliant with GMC Res. No. 39/19 MERCOSUR Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coatings that come into contact with food with the polymeric components complying with GMC Res No 02/12 MERCOSUR Technical Regulation on the positive list of monomers, other starting substances and polymers authorized for the manufacturing of plastic packaging and equipment in contact with food.

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. No. 39/19 and GMC Res No 02/12:

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

Please note that it is the responsibility of both the 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.

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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