

FOOD CONTACT

BYK Regulatory Information

SCONA TSPOE 1002 GBLL

Summary

SCONA TSPOE 1002 GBLL is suitable for food contact applications under the following compositional provisions as indicated below:

Adhesives		
	Regulation (EU) No. 10/2011	Yes
EU	German BfR XIV 'Polymer Dispersions'	Yes
	German BfR XXXVI 'Paper and board for food contact'	Yes
USA	21 CFR FDA 175.105 'Adhesives'	Yes

Plastics		
EU	Regulation (EU) No. 10/2011	Yes
USA	21 CFR FDA 177.1520 'Olefin polymers	No

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

Adhesives

EUROPE

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

This product can be considered suitable for use in food contact adhesives. Additional information is available in the 'Plastics' section.

Please note that the assessments for adhesives are based on the following parameters: 100% migration, 1 kg of food in contact with 6 dm² of packaging material, substrate weight of 15 g/m².

German BfR XIV 'Polymer Dispersions'

This product may be used in accordance with BfR Recommendation XIV, as it is manufactured with substances authorized under Regulation (EU) No. 10/2011.

German BfR XXXVI 'Paper and board for food contact'

This product may be used as a sizing agent in accordance with BfR Recommendation XIV. Polymer Dispersions, and as a surface refining or coating agent subject to the requirements of Regulation (EU) No. 10/2011.

USA

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".

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), where applicable.

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
234	108-31-6	Maleic anhydride	30 expressed as maleic acid	-
264	111-66-0	1-Octene	15	-
433	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6	-

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.

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.

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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