

# FOOD CONTACT

BYK Regulatory Information

## SCONA 12031 N

### Summary

SCONA 12031 is suitable for food contact applications under the following compositional provisions, as indicated below:

Plastics		
Europe	Regulation (EU) No. 10/2011	Yes
China	GB9685-2016, table A1 "Plastic", A3 "Rubber" and A5 "Adhesive"	Yes
Japan	Japan Food Sanitation Act Positive List System	Yes
MERCOSUR	GMC Resolution n. 02/12	Yes
	GMC Res No 39/19	Yes

This summary reflects evaluations conducted based on existing regulations. It does not preclude the possibility of compliant use in other regions or applications. The explanations below provide details on the regulations and evaluations considered.

## Explanation

### Plastics

#### Europe

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

Aids to polymerization used in this product are subject to Art. 6(4) and listed in national legislation and/or self-risk assessed in accordance with Art. 19 of this Regulation.

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) and/or any restrictions laid down in Regulation (EU) No 10/2011:

FCM No.	CAS-No.	Name	SML / SML(T) [mg/kg]	Restrictions / Specifications
234	108-31-6	Maleic anhydride	30 expressed as maleic acid	Not applicable
433	2082-79-3	Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, octadecyl ester	6	Not applicable

To 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, presence of substances listed in Annex II with restrictions and/or substances for which genotoxicity has not been ruled out is not known or expected. The products are not regularly tested for substances that are neither identified nor reasonably foreseen to be present.

In accordance with our role as manufacturer of substances, and based on information provided to us by raw material suppliers, 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, 1 kg of food in contact with 6 dm<sup>2</sup> of packaging material, film thickness 1 mm.

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.

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## China

### **GB9685-2016, table A1 “Plastic”, A3 “Rubber” and A5 “Adhesive”**

The active components of SCONA 12031 N are listed in GB9685-2016 table A1, A3 and A5 for plastic, rubber and adhesive applications.

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## 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 published by MHLW on September 24<sup>th</sup>, 2024. Please contact separately for use Limit by Synthetic Resin Group (%).

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## MERCOSUR

### **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 & 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 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.

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
19960	108-31-6	Maleic anhydride	SML(T) = 30 mg/kg (expressed as maleic acid)
68320	2082-79-3	3-(3,5-Di-tert-butyl-4-hydroxyphenyl) octadecyl propionate	SML = 6 mg/kg

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. 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 from the date of issue.

**Food Contact Team**  
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*This issue replaces all previous versions - Printed in Germany.*

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