

DECLARATION OF COMPLIANCE

Version date 4.11.2022

Version 4.0

Product name: Sulapac Flow v 1.7 – EX1013

Product description: Granules**Color: Natural**

1. EUROPE

1.1 APPLICABLE LEGISLATION

REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food.

COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, amended up to COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008.

COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended up to COMMISSION REGULATION (EU) 2020/1245 of 2 September 2020.

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, amended up to DIRECTIVE (EU) 2018/852.

Compliance with the requirements of the Framework Regulation

- Regulation (EC) No 2023/2006; Good Manufacturing Practice (GMP): YES
- Article 3 of Regulation (EC) No 1935/2004; General Safety Aspects: YES
- Article 17 of Regulation (EC) No 1935/2004; Traceability: YES

Compliance with the requirements of the Plastics Regulation

- Regulation (EU) No 10/2011: YES

Raw materials used to produce this product are manufactured from only monomers, other starting substances, macro-molecules obtained from microbial fermentation, additives and polymer production aids authorized under Annex I of Regulation (EU) 10/2011.

1.2 MEMBER STATE LEGISLATION

Intentionally added substances not subject to listing in Annex I according to Article 6 of Regulation (EU) No 10/2011, and other components made from non-plastic materials, are either risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004 or comply with the requirements of the legislation listed below.

Member state legislation not considered.

1.3 NON-INTENTIONALLY ADDED SUBSTANCES

Based on our current supplier documentation, non-intentionally added substances according to Article 6(4a) of Regulation No 10/2011 are risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004. Further processing of this material by converters would require an appropriate risk assessment.

1.4 OVERALL MIGRATION LIMIT

Representative samples made from this product and tested according to the requirements of Annex V of regulation (EU) 10/2011 complied with the overall migration limit of 10 mg/dm² tested under the following conditions:

Simulant	Test conditions
10% ethanol (simulant A)	10 d at 40°C
3 % acetic acid (simulant B)	24 h at 40°C
50 % ethanol (simulant D1)	24 h at 40°C
95% ethanol (simulant D2)	2 d at 20°C*
Iso-octane (simulant D2)	10 d at 40°C
MPPO (simulant E)	10 d at 40°C

*With 95% ethanol, testing conditions were adjusted according to those defined for non-polyolefin materials in Table 2 of JRC Technical Guidelines for Compliance testing: testing 2 days at 20°C covers 10 days at 40°C.

1.5 ORGANOLEPTIC PROPERTIES

Testing performed on representative samples has shown that this material will not induce unacceptable changes to the composition of food/beverages or to their organoleptic properties. It is however responsibility of the manufacturer of the finished items to ensure compliance with the relevant regulations in their intended end use.

1.6 LIMITS AND RESTRICTIONS

Limits and restrictions of non-listed substances

This product does not contain non-listed substances with restrictions.

Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

This product contains substances with limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I. All substances comply with applicable limitations.

More information on request.

Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex II, Metals

This product does not contain metals with restrictions listed in Annex II.

Limits and restrictions as listed in Regulation (EC) No 10/2011, Annex II, Primary Aromatic Amines

This product does not contain Primary Aromatic Amines according to Annex II.

1.7 DUAL USE ADDITIVE(S)

A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring, regardless of its purity or whether or not the substance is subject to restriction in food and/or plastic.

This product contains Dual Use Additives. More information available on request.

1.8 SPECIFICATIONS FOR USE

Specifications of use as regards of time and temperature of treatment and storage of food

Based on the above, we can state that the above-mentioned product, when used to produce final food contact articles, can be compliant with the following testing requirements:

Short term contact with all food types at conditions that include heating up to:

- 40°C for contact time up to 24 hours,
- 70°C for up to 2 hours and
- 100°C for 15 min,

Long term contact at room or refrigerated temperature storage with all food types except acidic foods.

For acidic foods short term contact is recommended as described above.

This refers only to migration compliance and not to technical fitness-for-use.

Any other limitation of use

Surface/volume ratio used for compliance assessment: 6 dm² FCM / kg food

Compliance with specific migration limits, NIAS and other restrictions, has been documented through testing. All substances have been risk assessed according to Regulation (EC) No 1935/2004, article 3.

2. USA

The products listed herein are manufactured in accordance with the applicable regulations of the U.S. Federal Food, Drug, and Cosmetic Act (Act), and are made in facilities that are in compliance with 21 CFR 117 Subpart B - Current Good Manufacturing Practice. The components of the raw materials used in the manufacture of our products have been evaluated by our suppliers for food contact applications within the U.S. using the following clauses of the Act: 21 CFR Indirect Food Additives, Prior Sanctioned letters, Food Contact Notifications (FCN), Generally Recognized as Safe (GRAS), and for suitability of use using 21 CFR 176.170(c) Table 1 (types of food) and Table 2 (conditions of use). Final articles manufactured using this product are suitable for use with all food types at conditions of use B through H with the exception of infant formula and human milk. Such uses are not covered as part of the intended use of substances intentionally added which are covered by US FDA FCN.

Component	Food Contact Applications	21 CFR 176.170(c) Table 1	21 CFR 176.170(c) Table 2
Resin	Yes 21 CFR 178-186, FCN	I-IX	B - H

This refers only to compositional compliance and not to technical fitness-for-use. The verification if the manufactured final articles are suitable for the intended purpose of use and food contact is subject to the manufacturer. The manufacturer of the final article is responsible for its compliance with the requirements of the relevant parts of the U.S. FDA Food & Drugs Act.

3. JAPAN

Based on the documentation provided by the suppliers all the materials used in the above-mentioned material can be considered compositionally compliant with the Japanese Food Sanitation act as issued by the Japan Ministry of Health Labour and Welfare (MHLW).

The components are listed on Appended Table dated April 28th 2020 and come into effect on June 1st 2020, hereinafter referred to as the Positive List (PL), provided under the Specifications and Standards for Food and Food Additives, etc. (MHLW Notification No.370, 1959).

4. MERCOSUR

Based on the documentation provided by the suppliers all the materials used in this product can be considered compositionally compliant with the requirements of MERCOSUR/GMC/RES. No. 03/92 on the General Criteria of Packaging and Food Equipment in Contact with Foods, as amended.

The main starting substances are listed in MERCOSUR/GMC/RES. No. 02/12 MERCOSUR Technical Regulation on positive list of monomers, other starting substances and polymers authorised for the manufacture of food-contact plastic packaging and equipment. All additives are listed in the Positive list (Annex 1) of MERCOSUR GMC RES. 39/19 on additives to be used in articles in contact with food.

5. GENERAL

This declaration is based on a typical product sample produced under standard production conditions as required by our manufacturing standards. Conversion conditions at our customers may change the profile of potential migrants and lead to different results on the final article. Any such changes are beyond our knowledge. Therefore, please be informed that it is the responsibility of the producer of the finished food-contact articles to make certain that such articles, under actual conditions of use, meet the above referenced requirements.

No representation or warranty is made as to the truth or accuracy of any data, information or opinions contained herein or as to their suitability for any purpose, condition, or application.

This certificate is valid for two years or until there is a change in the products, manufacturing processes or legislation.

*Sulapac Ltd
Iso Roobertinkatu 21
FI-00120 Helsinki
Finland*

Sulapac
is proud
to be an
ISO 9001
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