

January 31st, 2023

Christian Dully
Director Operations and Supply Chain
christian.dully@basf-3dps.com

Food Contact Certificate Ultrasint PA11

European Union:

Presuming appropriate processing the product can be used in the countries of the European Community for food contact materials or articles according to article 3 of Regulation (EC) No 1935/2004 (Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27th October 2004 on materials and articles intended to come into contact with food).

Compliance with the provisions of Regulation (EC) No 1935/2004, especially the suitability of the articles for the given application, the effect on smell and taste of the food, and observance of any limitations that are specified, must be ensured by the person who introduces the articles into circulation (see the last paragraph).

The specific restrictions mentioned in Commission Regulation (EU) No 10/2011 most recently amended by Commission Regulation (EU) 2020/1245 of 2 September 2020 have to be ensured.

Substances	FCM Reference	SML
11-aminoundecanoic acid	443	5 mg/kg
1,6-hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	631	45 mg/kg ¹

¹ Fat Reduction Factor is applicable

100% calculation for migration carried out on the above mentioned Product (or a specimen representative of this material) have shown that the specific migration limit was not exceeded for the mentioned Additives:

- 1,6-hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide) with 6 dm² surface and a thickness of 125 µm.
- 11-aminoundecanoic acid with 6 dm² surface and a thickness of 250 µm.

Aids to Polymerization may be present in the product in accordance with Article 6(4)(b) and Article 19 of Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food most recently amended by Commission Regulation (EU) 2020/1245 of 2 September 2020.

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.



The product complies with the GMP requirements laid down in Regulation (EU) No 2023/2006 on the Good Manufacturing Practices applicable to materials and articles intended to come into contact with foodstuffs.

USA:

We confirm that this product fulfils the requirements on materials used for articles or components of articles intended to come into contact with food as described in Code of Federal Regulations Food and Drugs Title 21- 2017 - §177.1500:

For use only in articles intended for repeated use in contact with food or side-seam cements for articles intended for 1-time use in contact with food and which are in compliance with 21 CFR §175.300.

This product may be used as articles or component of articles used in contact with all food types under Conditions of Use B through H, as described in Table 2 of 21 CFR 176.170(c).

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.



For notice:

Appropriate conditions have to be applied when processing the product. The suitability of the articles for the application concerned, including their effect on smell and taste of the food, and observance of any given limitations (for example overall migration, specific limits and other analytical requirements) must be tested and ensured in each case by the person who places any finished food contact article on the market. The product is strictly not recommended for any medical or pharmaceutical application. We give no warranties, expressed or implied, concerning the suitability of above-mentioned products for these applications. Formulation disclosure for medical and pharmaceutical applications is not supported

All information contained in this document is given in good faith and is based on sources believed to be reliable and accurate at the date of publication of this document.

THIS STATEMENT EXPIRES 18 MONTHS AFTER THE DATE OF ISSUE or in case of regulatory changes before such date. Please ask for a new confirmation if needed.

It is the responsibility of those to whom we supply our products to ensure that any proprietary rights and existing laws and legislation are observed.

The certificate is exclusively for our customers and respective competent authorities. It is not intended for publication either in printed or electronic form (e.g. via Internet) by others. Thus, neither partial nor full publication is allowed without written permission.

This product information was generated electronically and is valid without signature.

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.

