

Food Contact Certificate

Product: ULTRASON® P 3010 NATURAL

Revision: 01.03.2021

Version: 1.0

Contact:

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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 and repealing Directives 80/590/EEC and 89/109/EEC).

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 given limitations, 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.

The composition of the product complies with the requirements of the Commission 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 following restrictions have to be ensured:

- 4,4'-Dihydroxybiphenyl (FCM-No 170): SML = 6 mg/kg
- 4,4'-Dichlorodiphenyl sulphone (FCM-No 152): SML = 0,05 mg/kg

Additional information and/or restrictions are mentioned in Commission Regulation (EU) No 10/2011 as amended for the substances under the respective FCM-No.
(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>).

The meaning of the abbreviations is:

SML = specific migration limit expressed in mg per kg food
FCM-No = unique identification number of the substance

The product is suitable for repeated use applications but not intended for single use applications like food packaging.

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Dual Use Additives

No additives are used in the manufacture of the product which are listed in 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 and which are also listed as food additives or flavourings in Regulations (EC) No 1333/2008 and (EC) No 1334/2008 and their implementing measures.

We confirm that the product is manufactured according to the requirements of 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. BASF meets the demands for risk minimization in the value chain which are required.

USA

Since October, 9th 2007 Food Contact Notification (FCN) No 725 for the above specified ULTRASON® P is effective.

Hence, the product fully complies with the requirements of the Federal Drug and Cosmetic Act, 21 CFR when used in articles intended for repeat-use in contact with Food Types I-IX under Conditions of Use A-H, and J, (cooking temperatures above 250°F).

The listing of effective notifications for food contact substances is available on the FDA website.

CHINA

The above specified BASF resin is based on PPSU.

We herewith confirm, that the resin complies with the "National food safety standard – Plastic resins for food contact use" GB 4806.6 provided the following limitations are ensured:

- 4,4'-Dihydroxybiphenyl (CAS No. 92-88-6): SML = 6 mg/kg
- 4,4'-Dichlorodiphenyl sulphone (CAS No. 80-07-9): SML = 0.05 mg/kg

The meaning of the abbreviations is:

SML = specific migration limit expressed in mg per kg food

The composition of the above referenced product fulfills "National food safety standard – Food Contact Plastic Material and Articles" GB 4806.7.

Compliance with the provisions of GB 4806.7 and above stated limitations in the final article must be ensured by the person who introduces the articles into circulation.

Standard GB9685-2016 for Uses of Additives in Food Contact Materials and Articles is not applicable, because no additives are used in this product.

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China:

The product is in accordance with "National food safety standard – General safety requirements of food contact materials and articles" GB 4806.1-2016 in so far as:

- the product is deemed not to endanger human health as required in Article 3.1 of GB 4806.1-2016
- the product is produced in the pre-established specifications and purity limits
- the production of the above product is carried out in production units with the necessary quality control systems, which enables traceability through all stages of production.

Compliance with the provisions of GB 4806.1-2016, especially the suitability of the articles for the given application, the effect on smell and taste of the food, and observance of any given limitations, must be ensured by the person who introduces the articles into circulation (see the last paragraph).

The product is suitable for repeated use applications but not intended for single use applications like food packaging.

The above referenced product is manufactured outside of China.

We confirm that the product is manufactured under good manufacturing practice according to the requirements of 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. BASF meets the demands for risk minimization in the value chain which are required.

Heavy Metals

The sum of lead, cadmium, chromium-VI and mercury does not exceed the maximum value of 100 ppm (i.e. 0.01%) as required by the CONEG (Coalition of North Eastern Governors) for the January 1, 1994. Thus, also the maximum value for these elements laid down in Directive 94/62/EEC is met.

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.

We give no warranties, expressed or implied, concerning the suitability of above-mentioned product for use in any medical device and pharmaceutical applications.

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

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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.