

Food Contact Compliance Statements

Company: Bluepha Co., Ltd

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This statement contains the declarations of compliance with food contact regulations throughout the world and is valid for the following products produced at Bluepha Co., Ltd:

- Bluepha® BP330
- Bluepha® BP350

The statements do not cover converters and/or final product manufacturers in the case of:

- modification of our product by any addition of any other product to it.
- modification of the product resulting from the processing of the product.
- inadequate use and / or storage of the material and of the finished article.

Europe

The above-mentioned products [hereinafter called Bluepha®] as supplied by Bluepha, have been evaluated and were found to be suitable for use in food contact applications in the European Union. Our assessment of compliance is given per relevant regulation topic.

General safety regulations and Good manufacturing practice

The evaluation was in line with the requirements of Regulation (EC) No 10/2011, as amended by 2019/1338, applying to all EU member states.

Bluepha® is manufactured, processed, and distributed according to Good Manufacturing Practice (GMP) principles.

Regulations covering specific materials and articles

Bluepha® consists of Polyhydroxyalkanoate (PHA), which is included in Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. PHA is listed under number 1059, and CAS number 147398-31-0 for use temperatures up until 100°C and no SML/QM or SML(T) applies.

Compliance OML/SML test methods

Although Bluepha® is not subject to any SML/QM or SML(T), EC 10/2011 specifies that plastic materials and articles to come into contact with food have to meet an overall migration limit (OML) of 10 mg/dm².

Based on testing that Bluepha® has performed, Bluepha® is suitable for use with all food types for long-term storage at room temperature including heating up to 40°C for 10 days or heating up to 100°C for up to 30 minutes.

Screening-assessment results on non-intentional added substances

Bluepha® would also test substances that are introduced into the product unintentionally in the process of production and use, namely non-intention added substances. The testing results on these substances are listed as below:

NIAS	CAS No.	Standards	Results
3-Hydroxybutanoic acid (3-HB)	300-85-6	Hasn't been listed into European Commission Regulation	Risk acceptable
3-Hydroxyhexanoic acid (3-HH)	10191-24 -9	Hasn't been listed into European Commission Regulation	Risk acceptable
LMWO	NA	No requirements on limitations according to European Commission Regulation	Risk acceptable
Trans-2-hexenoic acid	13419-69-7	Hasn't been listed into European Commission Regulation, but no genotoxicity was found in the collective assessment of aromatic substances by EFSA	Risk acceptable

Crotonic acid	3724-65- 0	Hasn't been listed into European Commission Regulation	Risk acceptable
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Non-intentional added substances result from the heating process of extraction and drying. According to the International risk assessment standards, the food safety risks of these substances are acceptable.

The package of products and the storage environments might affect the sensory properties of the final products. Therefore, it is the responsibility of manufacturer of the final product, which is intended as the food contact product, to ensure that the residual substances which are not mentioned in this statement are safe and also suitable for intended applications.

While it's Bluepha's conclusion that the Bluepha® is permitted, it is the final product which must meet the given regulations and the manufacturer should take responsibility to check if the final product comply with the regulations.

United States of America

In progress

China

In progress



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