



KUREHA CORPORATION

3-3-2, Nihonbashi-Hamacho, Chuo-ku, Tokyo 103-8552, Japan

To whom it may concern

Date : 6 March, 2020

Re: Declaration of compliance

Issued by

Kureha Corporation (Hereinafter referred to as “We”, “Us”, “Our”),
3-3-2, Nihonbashi-Hamacho, Chuo-ku, Tokyo 103-8552, Japan

Identity of the product

CB-100E (Hereinafter referred to as “Product”)

Product type: Final plastic material or article

Product description: PVDC monolayer film

Intended food contact: Dry, wet, aqueous, acidic, and/or fatty foods

Confirmation for EU Regulation

We confirmed herewith that the “Product” complies with

- 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 and repealing Directives 80/590/EEC and 89/109/EEC and its amendment Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009.
- Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacture practice for materials and articles intended to come into contact with food and its amendment Commission Regulation (EC) No 282/2008 of 27 March 2008.
- Commission Regulation (EU) No 10/2011 of 14 January 2011 and its amendments up to and including Commission Regulation (EU) 2019/1338 of 8 August 2019.
- Concentration levels of heavy metals set forth in European Parliament and Council Directive 94/62/EC of 20 December 1994.

All monomers and additives used in the “Product” are listed in the Union list of authorized substances in “ANNEX I” in “COMMISSION REGULATION (EU) No.10/2011” and its amendments.

The “Product” complies with the overall and specific migration limits using the following simulants and test conditions listed below as defined in “Commission Regulation (EU) No.10/2011” and its amendments.

● Testing Conditions

<u>Food stimulant</u>		<u>Test time and temperature</u>
Simulant A	10%EtOH	OM-2 (10days at 40°C)
Simulant B	3% Acetic acid	OM-2 (10days at 40°C)
Simulant C	20%EtOH	OM-2 (10days at 40°C)
Simulant D1	50%EtOH	OM-2 (10days at 40°C)



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Simulant D2

Vegetable oil

OM-2

(10days at 40°C)

- The following monomers and additives with SML or other restrictions are used in the “Product”.

FCM No.	Cas No.	SML, SML(T), Restrictions and specifications
532	8013-07-8	60mg/kg , SML(T)(32)=60mg/kg
138	77-90-7	SML(T)(32)=60mg/kg
130	75-35-4	SML:ND
127	75-01-4	QM:1mg/kg and SML:ND
670	30899-62-8	SML(T)(32)=60mg/kg

Dual Use Additives

The following substances are used in the “Product”.

Number (E or FL)	Name
FL 09.511	Tributyl acetylcitrate
E 472a	Acetic acid esters of mono- and diglycerides of fatty acids
E 461	Methylcellulose
E 339	Sodium phosphates

Confirmation for FDA CFR Title 21

We confirmed herewith that the “Product” complies with

- Sec. 172.828
- Sec. 181.27

ISO 9001

KUREHA VIETNAM CO., LTD. that manufactures the “Product” above has obtained ISO 9001 certification.

This certificate is valid until the related regulations are changed.

Yours sincerely,

Ichiro Kitada

General Manager

Food Packaging Technology Department

Polymer Processing Research Laboratories

KUREHA CORPORATION