

CERTIFICATE OF COMPLIANCE

CH U530-B95-LT – Light blue (FDA)

CERTIFICATE FOR FOOD CONTACT

Reg (EC) No 1935/2004

Reg (EC) No 2023/2006

Reg (EC) No 10/2011

FDA § 21 CFR 177.2600



CARSTEN HOLM A/S certifies the suitability for repeated contact directly or indirectly with food based on technical information and component analysis. According to the regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 directives 80/590/EEC and 89/109/ECC.

All articles are produced in compliance with good manufacturing standards so that they do not transfer their constituents to food and gives a high level of protection to human health.

According to the regulation (EC) No 2023/2006 of 22 December 2006 (GMP) for materials and articles intended to come into contact with food.

According to the Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs and the Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011

The articles were tested and is in compliance with the demands of the Food and Drug Administration (FDA) Regulations §21 cfr 177.2600 (1. April 2009 edition).

Total migration:

The following migration tests have been conducted at the Austrian Research Institute (Osterreiches Forschungsinstitut - OFI):

Overall migration according to ÖN EN 1186-14 respectively EU No 10/2011

Simulant	Surrogate for	Duration	Temperature	Overall migration [mg/dm ²]	Acceptable ratio of volume/surface [ml/dm ²]
Acetic acid 3%	aqueous / acidic	2 hrs	70°C	1.6	27
Isooctane	aliphatic	0.5 hrs	40°C	5.3	88
Ethanol 95%		2 hrs	60°C	32.4	540

Overall migration according FDA 21 CFR 177.1600*

Test conditions	Limit according to FDA 21CFR177.2600 [mg/inch ²]	Total extractives [mg/inch ²]
distilled water 1 st extraction 7 hr	20	<1
distilled water 2 nd extraction 2 hr	1	<1
n-hexane 1 st extraction 7 hr	175	1
n-hexane 2 nd extraction 2 hr	4	<1

Specific migration Residual content of isocyanate according to DIN EN 13130-8

The maximum residual content of isocyanate (calculated as NCO) concerning (EU) 10/2011 may not exceed 1 mg/kg material. The determined amount is under the detection limit (<0,2 mg/kg)

Specific migration Primary aromatic amines according EU No 10/2011 ANNEX II

The specific migration limit of primary aromatic amines is 0,01 mg/kg foodstuff. The determined amount is under the detection limit (< 0,2 mg/kg).

*the test was carried out on a similar compound.

Specifications and/or limitations on intended use

Seals usually have a small contact area and also a short exposure time (< 1hr) with foodstuffs. Therefore the overall migrations tests was performed appropriate the standardised test conditions OM3 (EU 10/2011 Annex V, table 3). That correspond to any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.

The calculation of the acceptable ratio of volume foodstuffs per seal surface is based on the verification of compliance by residual content per food contact surface area as indicated in EU 10/2011 Annex I and Annex V 2.1.8.

The migration tests according to FN EN 1186-3 and -14 respectively EU 10/2011 with the aforementioned simulant cover the groups of foodstuff stated in EU 10/2011 Annex III table 2. To verify applicability with pure fats or oils and for foodstuffs with a fat reduction factors FRF < 2 it is recommended to carry out additional tests.

This declaration of conformity only applies to appropriate use. As producer of semi-finished products Carsten Holm A/S has no influence on subsequent processing. It is the users responsibility to verify the suitability of the product for a specific foodstuff in case of requirements surpassing the aforementioned guidelines.

This declaration is in effect until further notice.

The contents of this document are valid until our suppliers retract their corresponding declarations.

The regulations for documentation and labeling protocol have been fulfilled.

Signed by



Ulrik Holm
Manager
CARSTEN HOLM A/S

Note:

For further information please see the CH U5530-B95-LT datasheet on Carsten Holm homepage or contact the Carsten Holm A/S sales department.

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