

## **DECLARATION OF COMPLIANCE**

To European legislation EC 1935/2004 Art. 3
To FDA regulation 21 CFR 177.2600
To BfR XV III
To CH BGV 817.023.21







Product/material: Silicone L-7200

Date of declaration: 23.02.2021

We confirm that the above mentioned material is compliant to the below mentioned regulation and legislations.

## To European legislation EC 1935/2004 Art. 3

In the current absence of EU legislation which specifies the requirements to prove that a silicone article is safe for food contact, we have conducted extraction testing to the requirements of FDA 21CFR 177.2600 "Rubber articles intended for repeated contact with foodstuff" and BfR XV "Silicones" on the above materials to support the statement that our silicones are safe for food contact.

The material has been manufactured from monomers, polymers and additives that are authorized on one or more of the positive lists of FDA 21 CFR 177.2600, and BfR XV III

The material is suitable for repeated use.

ERIKS guarantees that all products of this material are produced according the directive for GMP (Good Manufacturing Practice) 2023/2006/EC, which is part of the Framework regulation EC1935/2004. The traceability of the products derived from this material is secured and the regulations for documentation and labelling protocol have been fulfilled.

### To FDA regulation 21 CFR 177.2600

This material formulation has been evaluated according to the requirements of FDA 21 CFR 177.2600 (a-d) and extraction tested according to FDA 21 CFR 177.2600 (e-f).

Test	Requirements	Result
Extraction Hexane 7 hours	Max. 175 mg/inch²	PASS
Extraction Hexane 2 hours	Max. 4 mg/inch <sup>2</sup>	PASS
Extraction in boiling water 7 hours	Max. 20 mg/inch <sup>2</sup>	PASS
Extraction in boiling water 2 hour supplementary	Max. 1 mg/inch <sup>2</sup>	PASS

#### Conditions of use

This material can be used for aqueous and fatty foods as per 21 CFR 177.2600.



## To BfR XV III

This material formulation has been evaluated according to the requirements of BfR XV and migration tested according to BfR XXI

Test	Requirements	Result
Mass of extracted residues (extraction in distilled water, 10 min. at 40°C)	Max. 10 mg/dm²	PASS
Mass of extracted residues (extraction in 3% Acetic acid, 10 min. at 40°C)	Max. 50 mg/dm²	PASS
Mass of extracted residues (extraction in 10% Ethanol, 10 min. at 40°C)	Max. 10 mg/dm²	PASS

As per the requirements of BFR recommendation XV III, all samples have complied with their respective global limits in all simulants and no peroxides have been detected. All samples have also complied with the volatiles limit (0.5%).

All samples are therefore compliant with the testing requirements set out in BFR recommendation XV III.

#### Conditions of use

This material can be used for contact with foodstuffs for periods up to 10 Minutes accordingly to BfR XXI category 3.

# To Swiss Bedarfsgegenständeverordnung 817.023.21

Based on the results of the tests and the compliance with ingredients listed in the BfR XV III, we confirm compliance with the Swiss Consumer Goods Ordinance 817.023.21.

This declaration is not intended as technical documentation, the suitability of this product for a specific application should be verified with ERIKS. This declaration is valid without signature until revocation or renewal.