

DECLARATION OF COMPLIANCE WITH FOOD CONTACT LEGISLATION

1. Identity and address of the business operator issuing the declaration of compliance

Name Mr/Mrs: AGAUD Justine

Position: Material engineer

Company Name and Address: TECHNE – ZA Les Haies – 69480 MORANCE

2. Identity and address of the business operator who manufactures or imports the materials and/or items covered by this declaration

Company Name and Address: TECHNE – ZA Les Haies – 69480 MORANCE

Specify: ☒ Operator ☐ Importer

3. Identity of the material and / or item covered by this declaration

Description RUBBER GASKETS

Trade name and reference : Aseptic seals

Indicate the component material(s) of the item:

Material 33466 – FKM80 Black

Statement issued on: 01/03/2022

4. Confirmation that those materials or items meet the relevant requirements of Food contact regulations

The materials and/or items covered by this DoC comply with the relevant requirements laid down in Framework Regulation (EC) N° 1935/2004/EC, Regulation (EC) N°2023/2006 and other European and national texts applicable, listed below:

Regulation CE 1935/2004

Regulation CE 2023/2006

Particularities (to be completed as of publication of the list)

☒ Not applicable

☐ (EC)Regulation N° 450/2009 on active and intelligent materials and items intended to come into contact with food, specify the substance used and the number mentioned in the Community list:

.....
.....

☐ (EC)Regulation N° 282/2008 on recycled plastic materials and items intended to come into contact with foods, specify the type of material and the authorization number of the recycling process, mentioned in the EC process register:

This declaration of compliance has been established in respect of the following (tick any appropriate boxes)

☐ Declarations by suppliers of raw materials

☒ Overall Migration testing

Simulants	Duration	Temperature	Results (mg/dm ²)	Limits (mg/ dm ²)
Simulant A – Ethanol 10%	4H	100°C	3,2	10±2
Simulant B – Acetic acid 3%	4H	100°C	117	10±2
Simulant C – Ethanol 20%	4H	100°C	5,0	10±2
Simulant D1 – Ethanol 50%	4H	Temp. reflux	1,6	10±2
Simulant D2 – Ethanol 95%	4,5H	60°C	1,9	10±3
Simulant D2 – Isooctan	2,5H	60°C	<1,0	

These global migration limits correspond to a gasket/equipment surface ratio of 1. If the application has lower gasket/equipment ratios, please refer to the formula below:

$$\text{Result Measured} \times \frac{\text{Seal area}}{\text{Seal area} + \text{Area of the container}} \leq : \text{Limits for overall migration by regulation CE 1935/2004}$$

☒ Migration of Aluminium, Baryum, Copper, Zinc, Lead

Metals	Duration	Temperature	Results (mg/kg)	Limits (mg/kg)
Aluminium	2H	100°C	<0,5	1
Baryum	2H	100°C	0,83	1,2
Copper	2H	100°C	<0,25	4
Zinc	2H	100°C	<1,0	5

☒ Extractable heavy metals contents

Metals	Results (mg/kg)	Limits (mg/kg)
Cadmium	<1	1
Lead	<1	1
Antimony	<1	1
Arsenic	<1	1
Mercury	<1	1

These tests have been performed by LNE French laboratory. Results have been received on 19/07/2021.

5. Information related to the intended use of the materials or items

Type of food intended to be placed in contact:

☒ All types of food products

Contact conditions (time and temperatures) corresponding to the input data

Tests were done at reflux temperature for 4 hours so valid for all conditions. According to the new French Arrêté of August 05, 2020, Annex III, these conditions correspond to a "hot contact followed, possibly, by a prolonged contact".

Maximum surface / volume ratio in contact with food used to establish compliance of the material or item (if applicable): *Conventional ratio area of material/weight of food : 6dm²/kg*

☐ Not applicable

This declaration is valid on condition that there is no modification of material composition, that its intended use has not changed and in the absence of regulatory changes.

Compliance is understood to be subject to compliance with the conditions of storage, handling and use, taking into account the specific characteristics of the material or item, and the conditions such as prescribed by professional practices or codes.

In the event of changes to the nature of the packaged product, its composition or its intended use, as well as in the event of a change in the conditions for using the material or the item, the person for whom this declaration is intended must ensure the compatibility packaging / content for which s/he then accepts responsibility.

Signed in Morancé on 01/03/2022


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