



PRECISION SEALING  
O-RING DIVISION

**CONFORMITY CERTIFICATE**

Customer : **LABLABO**

Subject: **Conformity statement according to regulation (CE) n°1935/2004 clause 16 on materials and articles intended to come into contact with food.**

Document reference : 20200605\_1935\_PB701\_LABLABO

Elastomer : **PB701**

We, hereby certify, that the material intended to come into contact with foodstuffs and related part number listed below (1):

- belongs to the class : Rubber  Silicone

- complies with the requirements of European regulations CE n° 1935/2004 of 27<sup>th</sup> October, 2004 and n° 2023/2006 of 22<sup>nd</sup> December, 2006.

This conformity statement is given within the limit of document attached:

- Compliance with FDA - CFR § 177-2600 requirements. See Hutchinson certificate for NBR elastomer PB701 in date of June 5<sup>th</sup>, 2020.

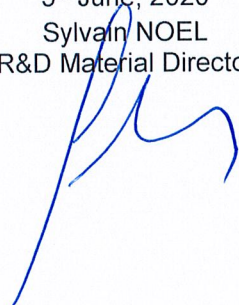
This conformity is given for new products and according to the respect of the usual rules about storage conditions.

This certificate is valid for 1 year. Moreover, it will be renewed in the case of a change material, regulation modification.

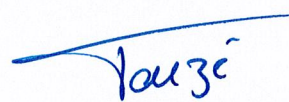
(1) Concerned parts:

HUTCHINSON Reference	LABLABO Reference	Dimension
103206	JT0009	3.25 x 1.25
105305	JT0013	5.00 x 1.00
111397	JT0037	11.10 x 1.60
113252	JT0014	13,10 x 1,60

5<sup>th</sup> June, 2020  
Sylvain NOEL  
R&D Material Director



Nathalie TOUZE  
Quality Manager





PRECISION SEALING

O-RING DIVISION

**CONFORMITY CERTIFICATE**

Customer : LABLABO

Subject : FDA certificate and others requirements

Document reference : 20200605\_PB701\_lablabo\_FDA certificate and other requirements

Compound : PB701

Based on our knowledge, we certify the composition of our elastomer PB701 and related parts numbers (1) comply with the following regulations and composition restrictions:

**1- Statement on transmissible bovine spongiform encephalopathy (BSE)**

We hereby confirm that we did receive statements regarding TSE/BSE from our current additive suppliers:

1/ Most additives that go into the composition of our products are not animal derived.

2/ Whilst the others could derive from tallow/lard, the suppliers have stated that they are in compliance with the monographs of the European Directorate for the Quality of Medicines (EDQM) and/or with the note for guidance on minimizing the risk of transmitting animal Encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev3 – Mars 2011) – Item 6-4 Tallow derivatives and/or with the regulation 1774/2002/EC laying down health's rules concerning animal by-products not intended for human consumption (Category 3 Material).

Based on the above, we are confident that our products are free of SRM (Specified Risk Material)

**2- FDA**

The composition does comply with the positive list of American regulation FDA - CFR 21 § 177-2600.

**3 – Heavy Metals (European Directive 94/62/EC)**

The composition does not contain any Cadmium, Lead, Mercury, Chromium VI compounds in accordance with the Directive requirements.

**4- Latex**

The composition does not contain any product with latex.

**5- PVC**

The composition does not contain any product with PVC.

**6- Phthalates, bisphenol A and nitrites**

No phthalate, bisphenol A and nitrites substances are intentionally incorporated in the rubber compound PB701. However, traces of phthalate substances may be found in this compound. The levels are in accordance with European Regulation EC 2005/84/CE requirements.

**7- CMR substances from European Directive 1272/2008/CE - categories 1 & 2**

The composition does not contain any product with these CMR substances cat 1&2.



Customer : **LABLABO**

Subject : **FDA certificate and others requirements**

Document reference : **20200605\_PB701\_lablabo\_FDA certificate and other requirements**

Compound : **PB701**

Furthermore, it is advisable to check within the framework of the final application:

- If other regulatory requirements apply
- The compatibility of material with fluids in contact and operating conditions
- The neutrality for products in contact

This declaration is determined by the ingredients that go into the composition of our product. It is based on our current knowledge and the information provided by our suppliers.

It considers new products and does not take into consideration compounds or reactions likely to occur during the degradation or decomposition of materials.

This declaration is valid for the regulations in force at the time of its issues.

This certificate must be renewed after 2 years.

(1) part numbers:

<b>HUTCHINSON Reference</b>	<b>LABLABO Reference</b>	<b>Dimension</b>
103206	JT0009	3.25 x 1.25
105305	JT0013	5.00 x 1.00
111397	JT0037	11.10 x 1.60
113252	JT0014	13,10 x 1,60

Chateau Gontier  
June 5<sup>th</sup>, 2020  
Sylvain NOEL  
R&D Materials Director



PRECISION SEALING  
O-RING DIVISION

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From Jérôme PICHOT  
Expéditeur

Date 21/04/2020 Pages 1  
Date Pages

**LABLABO – Directive 2011/65/EU and modification of the Annex II by the directive (UE) 2015/863**

### 1 - Object

Conformity of our products according to the directive 2011/65/EU of 8 June 2011 and the modification of the Annex II by the directive (UE) 2015/863, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS directive)

### 2 - General comments:

The information that we are releasing is determined by the ingredients going into the composition of our products. Our response considers new products and does not take into consideration compounds or reactions likely to occur during the degradation or decomposition of materials (incineration for example). It is based on our current knowledge and particularly on the information released by our suppliers.

### 3 - Conformity

The materials composing the products we supply to you do not contain any heavy metals, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) within the limits defined by the directive 2011/65/EU and the modification of the Annex II by the directive (UE) 2015/863.

Jérôme PICHOT  
Laboratory Technician



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