



PRECISION SEALING SYSTEM O-RINGS AND BONDED SEALS

CONFORMITY CERTIFICATE

Customer : LABLABO

Subject : Food contact certificate and others requirements

Document reference : 20231010_6SL2387_Lablabo_Food contact and others requirements Compound : 6SL2387

On the basis of our knowledge, we assure that our VMQ rubber 6SL2387 and related part numbers (1):

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 (EMEA/410/01 rev3 – Mars 2011) – Item 6-4 Tallow derivatives and/or with the regulation 1774/2002/EC laying down health 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 – Food contact:

Composition in agreement:

- with German requirements BFR (Federal Institute for the risks assessment) chapter XV
- with the French decree of November 25th, 1992
- with the positive list of American requirement FDA CFR 21 § 177-2600

6SL2387 answers to the following inertia requirements:

- compliance with inertia requirements according to French decree of November 25, 1992 in particular with global migration requirements for simulator liquids which represent aqueous food, acid and alcohols until 20°. The results don't comply with fatty simulator (olive oil) but allow the contact with meats, cheeses, fishes and backer foods (report IANESCO report n° E18-07452-3),

- compliance with inertia requirements according to American requirement FDA – CFR 21 § 177-2600. (Report n° E18-07452-1).







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3 - Heavy Metals (European Directive 94/62/EC)

- Does not contain any Cadmium, Lead, Mercury, Chromium VI compounds in accordance with the Directive requirements

4- Latex,

- Does not contain any product with latex

<u>5- PVC</u>

- 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 6SL2387.

- However traces of phthalate substances may be found in this compound. The levels are in accordance with European Regulation EC 2005/84/CE requirements.

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 certificate must be renewed after 2 years.

(1) part numbers:

HUTCHINSON Reference	LABLABO Reference	Dimension
104392	JT0076	4.00 x 1.50
108689	JT0075	8.10 x 1.60

Chateau Gontier Tuesday, 10th October 2023 Eric FORSTER R&D Materials Manager

HUTCHINSON ZI ouest de Bazouges. 53200 Château-Gontier Tel : + 33 2 43 09 23 23 - Fax : + 33 2 43 07 84 15 Page 2/2







Precision Sealing Systems Activity Precision Molding Division Saint-Brieuc

To	LABLABO	From			
Destinataire (s)		Marie MANGAVEL		
		Expéditeur			
Copy (ies)		<u>Date</u>		<u>Pages</u>	
Copie (s)			13/10/2023	1	
		Date		Pages	
<u>Object</u>	Restrictions on perfluorooctanoic acid (PFOA)				

1 - Object

Compliance with general directives concerning the absence of PFOA-type substances in our products

<u>2 – General comments</u>

The elements we communicate are determined by the ingredients used in the composition of our materials. Our response considers products in their new state and does not take into account compounds or reactions that may occur during the degradation or decomposition of the material(s) (e.g. incineration). It is based on current knowledge and in particular information from our suppliers. The declaration is valid for the regulations in force at the time of issue.

<u>3 – Compliance</u>

- In general, our products comply with directive (EC) 2019/1021 and its amendment (EU) 2020/784 with regard to PFOA-type substances (levels below 25 ppb).
- Some of our products may contain PTFE powder. The PFOA contained in PTFE powders is also regulated by Directive (EC) 2019/1021 and its amendment (EU) 2020/784. Our products comply with the limits specified in these regulations (less than 1000ppb).

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Marie Mangavel Material Development Manager

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