



Division Caoutchouc de Précision
 Precision Molding Division
 Activité Etanchéité de Précision
 Precision Sealing Systems Activity
 Site de Saint Brieuc et Gamaches

Saint-Brieuc, le 20/07/2021

LABLABO

COMPLIANCE STATEMENT

Subject : BSE, FDA, Heavy metal, Latex certificate
Compound : 7EP1197

On the basis of our knowledge, we assure that our 7EP1197 elastomer used for parts (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 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-March 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- FDA

Has a composition in accordance with the positive list of American regulation FDA 21 CFR §177.2600

2- Heavy Metals (European Directive 94/62/EC) :

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

3- Latex :

Does not contain any product with latex.

Note: Furthermore it is necessary to check in the framework of the final application:

- Any additional requirement related to regulations
- The material compatibility with fluids in contact, the operating conditions
- The neutrality for products in contact

(1) concerned parts:

Customer Reference	Hutchinson Reference	Material
JP0049	597100	7EP1197
JP0051	597101	7EP1197

Gilles Hartenstein
 Material Development Manager
 July 20th 2021

This document must be renewed after 2 years