

Division Caoutchouc de Précision
Precision Molded Division
Activité Etanchéité de Précision
Precision Sealing Systems Activity
Site de Saint Briec et Gamaches

Saint-Brieuc, le 23/05/2019

LABLABO
Esther Icart

COMPLIANCE STATEMENT

Subject : certificate for food contact, BSE, absence of substances
Compound : D706

On the basis of our knowledge, we assure that our D706 elastomer used for parts (1) :

1- FDA :

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

2- European Food Contact :

Complies with the requirements to European Regulation CE n°1935/2004 of 27/10/2004 and n°2023/2006 of 22 December 2006

3- 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 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 (EMEA/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)

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

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

5- Latex and PVC :

Does not contain any product with latex or PVC.

6- Phthalates, Bisphenol A and Nitrites :

Does not contain any Phthalate, Bisphenol A and Nitrites.

No Phthalate, Bisphenol A and Nitrites substances are intentionally incorporated in the rubber compound.

However traces of Phthalate substances may be found in this compound. The level are conform according to European Regulation EC 2005/84/CE requirements.

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



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(1) concerned parts:

Customer Reference	Hutchinson Reference	Material
JP0021	504140	D706
JP0012	503425	D706
JP0013	506144	D706
JC0203	509138	D706

Gilles Hartenstein
Material Development Manager
May 23th 2019

This document must be renewed after 2 years