Declaration of Compliance | BSE, TSE & ADI

1. Introduction

Filcoflex B.V. hereby declares that the products named in chapter 2, hereinafter referred to as the "products", do not contain substances which are in violation with any animal derivative rules and regulations as listed in chapter 3, hereinafter referred to as the "rules and regulations". This means that the products do not contain any Haram materials, such as the ones listes in chapter 4, hereinafter referred to as the "haram materials".

2. Products

This declaration applies to all end products manufactured by Filcoflex from roll and/or sheet materials with the following Filcoflex brand or type names;

- PU-TEX

3. Rules and regulations

As the rules and regulations of the animal derivative products can be categorized, Filcoflex B.V. declares that all of the substances in violation with the below listed rules and regulations are absent within the products.

- BSE & TSE
- Animal derived fat or components (tallow)
- Animal derived products
- Products from genetically modified organisms GMO's
- Human derived products
- Human or animal components

4. Haram materials

The products do not contain any Haram materials. Listed below is a small amount of examples that are proven to be absent from the products.

- Animal derivative, such as;
  - Blood
  - Carron
  - Pork
  - Animals slaughtered without mentioning the name of Allah/God
  - Wild animal/carnivore
  - Animal with sharp teeth and/or claws
  - Amphibia
- Khamr
- Part of human body

5. Supplier addition

For the PU-PWW material, Filcoflex B.V. has received additional information.

5.1 Information from the TPU supplier

Based on the available information from the raw material supplier of the material, the main ingredients of the formulation are not of animal source.

However, some additive ingredients are produced from animal tallow.
The animal sourced raw materials used in these additives are produced in accordance with Regulation (EC) No 1069/2009 of the European parlement and of the Council of the 21st of october 2021 laying down health rules as regards animal by-products and derived products not intended for human consumption.

Filcoflex's raw material supplier has also confirmed compliance with EMEA 410/01 rev 3 and ISO 224421 standards (Annex C section C.5 on tallow derivatives).

Therefore the raw material supplier declares a negligible BSE risk based on the annual reconfirmation assessment report for the maintenance of official disease status and the approval of national control programs (Annex 16)

The supplier also confirms compliance with the guidelines aimed at minimizing the risk of TSE transmission:

- EU 722/2012, which in turn references EU 1069/2009
- EU guideline 2004/C 24 /03
- US 21 CFR 189.5 and 21 CFR 700.27

The excessive processing conditions applied to the tallow renders tallow non-viable.

It is therefore reasonable to consider, based on the supplier's declarations, that the risk of TSE transmission with use of these raw materials is negligible.

5.2 Information from the White MB supplier

Based on information of the raw material supplier, the White MB may contain substances of animal origin.

Filcoflex's raw material supplier declares that all raw materials used in the process and/or production, comply with the provisions of Regulation (EC) No 1774/2002, Directive 2000/6/EC and Commission Decision 2000/48/EC.

Furthermore, plastic materials, when processed at temperatures above 200°C, pose an additional safety factor with respect to the risk of BSE transmission. In fact, any active prions still present would be incorporated into the polymer matrix.

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Disclaimer
The information contained herein is believed to be accurate as of the date of this document. If any of the above mentioned regulations change after the date of declaration, this information is no longer valid.

The manner in which you use our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you test our products to determine suitability for your processing and intended use. Your analysis must at least include testing to determine suitability from a technical health, safety and environmental and regulatory standpoint.

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