



Allergen Servilab

C/ La Aldehuela 97, 05695,
La Horcajada (Ávila), España
Tel: 609 164 718
e.vega@allergenservilab.com

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Manufacturer's Declaration for:

Cat, Dog, Horse and other Mammals dander

This is to confirm that the biologic source materials, cat, dog, horse and other mammals dander have been prepared and tested in accordance with the requirements of the European Pharmacopoeia monograph 01/2017:2621, Animal Epithelia and Outgrowths for Allergen Products.

ALLERGEN SERVILAB reviews animal species, supplier's sources, countries of origin and supporting documentation for all materials of animal origin, especially regarding Transmissible Spongiform Encephalopathies (TSE) infection or contamination.

Dander is isolated from the hair of the animals that has been collected from approved suppliers. Animals are certified by animal health care practitioners to be healthy and free from contagious, infectious, or other detectable disease. The certification also confirms the identity of the materials, and that the skins of the animals from which the hair was collected without injuring the skin. Equipment used in the collection of the hair is certified to be cleaned between animals to help prevent the possibility of cross-contamination. Hair source materials with evidence of contamination with faeces, dirt or blood is not included or used. Each lot of animal hair received is documented and labelled to ensure identity and traceability throughout downstream processing.

Dander is collected by washing the hair through cycles of acetone, and then filtration of the acetone to isolate the dander. The dander is air-dried to remove acetone vapours, and the material is sieved, transferred to clean, tared and labelled containers, and stored at <0°C.

ALLERGEN SERVILAB Quality Department reviews and inspects all labelled containers and manufacturing records prior to release. The products are held in a dedicated freezer until released for distribution.

ALLERGEN SERVILAB S.L.
Quality Department.



Allergen Servilab
CIF: B-87925905
Calle La Aldehuela, 97
05695 La Horcajada (Ávila)
Telf.: +34 609 164 718