



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Pre-clearance application for animal-derived ingredients

This form is to assist users of the Electronic Listing Facility (ELF) seeking pre-clearance for animal-derived ingredients by detailing what the TGA is looking for and what supporting documents need to be provided.

1. Name of sponsor

2. Sponsor ID

3. Address

4. Name of contact person

5. Telephone number

6. Facsimile number

Supporting documents required to issue a pre-clearance certificate:

- Veterinary certificate indicating animals have been subjected to ante- and post-mortem examination and satisfy health requirements for human consumption.
- Evidence that the tissues have been procured in Government approved facilities. Tissues collected in the field (e.g. placenta collected in paddocks) are not acceptable.
- Imported animal-derived raw materials should be accompanied by a permit from the Australian Biosecurity Import Conditions (BICON)

Completed application should be forwarded to:

Infectious Diseases Safety Unit
Biological Sciences Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Enquiries should be directed to: infectiousdiseasesafety@health.gov.au

Post: PO Box 100 Woden ACT 2606 ABN: 40 939 406 804

Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au <https://www.tga.gov.au>

Reference/Publication #

Section 1. Ruminants[§] – TSE and viral safety

| Ingredient | Animal Species (e.g. cattle, sheep) | Tissue [#] (e.g. bone, hide) | Tissue Category [§] | Preparation (e.g. powder, extract, capsule) | Country(ies) of origin* |
|------------|---|---|---------------------------------|---|-------------------------|
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[§] **Ruminants** are any of various hoofed, even-toed, usually horned mammals such as cattle, sheep, goats, deer, camels and giraffes, characteristically having a stomach divided into four compartments and chewing a cud consisting of regurgitated, partially digested food.

[#] If the ingredient is manufactured from more than one tissue, please list all tissues.

[§] Please see Appendix 1, page 19 of the **TGA's Supplementary Requirements for Therapeutic Goods for Minimising the Risk of Transmissible Spongiform Encephalopathies (TSEs)** document <<https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/guidelines-sterility-testing-therapeutic-goods/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure>>.

* List all countries from which raw material for the ingredient is sourced.

Section 2. Non-ruminants[§] – Viral safety

| Ingredient | Animal Species (e.g. pig, chicken) | Tissue [#] (e.g. bone, hide) | Preparation (e.g. powder, extract, capsule) | Country(ies) of origin* |
|------------|---------------------------------------|--|--|-------------------------|
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[§] **Non-ruminants** are animals like pigs, chickens, tigers, etc.

[#] If the ingredient is manufactured from more than one tissue, please list all tissues.

* List all countries from which raw material for the ingredient is sourced.

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