



Guideline for Completing Application Purpose and Description of Use

February 2007

Guideline for Completing “Application Purpose and Description of Use”

The APVMA application forms include the field ‘Application Purpose and Description of Use’. This information provides a quick explanation of the application and where required will be included in the Application Summary published to the APVMA’s website.

Applicants must complete the purpose and description field of the application form in accordance with the relevant type/style below to ensure the APVMA has the necessary information to expediently process the application. Applicants should use the examples below as templates when preparing purpose and description statements for their applications.

1. Active constituent approval only:

The statement must include the active constituent name and the type of product it is intended for use in (i.e. agricultural and/or veterinary chemical products).

Examples:

- a) Approval of Imipyradin for use in agricultural and veterinary chemical products.
- b) Approval of Imipyradin for use in agricultural chemical products.

2. Product registration:

The statement must include the concentration of all active constituents in the proposed product (e.g. g/L, g/kg, mg/g etc.), the formulation or dose type and a description of intended use/s.

Examples:

- a) Registration of a 100 g/L Imipyradin, aqueous concentrate for use in brassica (head) vegetables for the control of various Lepidopteran pests.
- b) Registration of a 2 g/L Imipyradin, electrolyte for oral hydration therapy in sheep.

3. Active constituent approval in conjunction with product registration (i.e. Category 1 and 2 applications only):

Active Constituent component

The statement must include the name of the new active constituent requiring approval, the type of product it is intended for use in (i.e. agricultural and/or veterinary chemical products), the name of the associated product (except in the case of companion animal products where the product name should not be included) and the application number of the associated product (if known).

Examples:

a) Approval of Imipyradin for use in agricultural chemical products in conjunction with the registration of Smith's Imipyradin Insecticide (application XXXXX).

b) Approval of Imipyradin for use in veterinary chemical products in conjunction with the registration of Smith's Imipyradin Oral Hydration Therapy for Sheep (application XXXXX)

(Companion animal products)

c) Approval of Imipyradin for use in veterinary chemical products in conjunction with application XXXXX

Product Registration component

The statement must include the concentration of all active constituents in the proposed product (eg g/L, g/kg, mg/g etc.), the formulation or dose type, a description of intended use/s, as well as the name and the application number of the associated active constituent (if known).

Examples:

a) Registration of a 100 g/L Imipyradin, aqueous concentrate for use in brassica (head) vegetables for the control of various Lepidopteran pests, in conjunction with the approval of Imipyradin (application XXXXX).

b) Registration of a 2 g/L Imipyradin, electrolyte for oral hydration therapy in sheep, in conjunction with the approval of Imipyradin (application XXXXX).

4. Variation of product registration only:

The statement must summarise the proposed variation of registration (e.g. formulation, names and addresses of registrant or manufacturer, States and Territories registered and or conditions of registration).

NOTE: Due to the confidential nature of many of these changes, these applications will rarely require an application summary to be published. Application summaries are only published for variation applications that involve a change to the use or dealing with a product.

Example:

- a) Variation of registration to add an additional formulator.

5. Variation of the label only:

The statement must summarise the proposed variation of the label approval (e.g. new pests, diseases, crops, hosts, directions and instructions for use and or conditions of label approval).

Examples:

- a) Variation of the label approval to extend the use to include the control of blue cereal aphid on wheat, oats, triticale and barley.
- b) Variation of the label approval to allow subcutaneous administration.
- c) Variation of the label approval to copy uses from a closely similar reference product and update the label in accordance with the Labelling Code.

6. Variation of both the product and the label:

The statement must summarise the proposed variation of registration and the label approval.

Examples:

- a) Variation of registration and label approval to extend registration to Queensland and the Northern Territory and to include use in pastures for the control of *Mimosa pigra*.
- b) Variation of registration and label approval to add a new pack size (50g) and packaging material (HDPE).