



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

Instructions for using APVMA Data List Form in RTF Format

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INSTRUCTIONS FOR USING APVMA DATA LIST IN RTF FORMAT

1. Obtaining The Data List Template

Click on the RTF Data List template link on the Data Protection Application Requirements page. This will open the form. Save the document to your computer by selecting **File, Save As**. Choose where you would like to save the form and select an appropriate file name.

2. Entering Information Into The Data List

2.1 Identifying Information

- In the **Applicant's Name** field, enter the Applicant name exactly as it's written on your application form.
- In the **Product Name or Name of Active Constituent** field;
 - a) If applying for a product (or a combined product and active constituent application), enter the name of the product exactly as it's written on your application form.
 - or**
 - b) If applying for an active constituent that is not combined with a product application, enter the name of the active constituent as it's written on your application form.
- In the **Product Number or Active Constituent Number** field, enter the APVMA number if known. If not known please leave the field blank.
- In the **Application Number** field, enter the current APVMA application number for the application if known. If not known please leave the field blank.

2.2 Data List Table

In the **Data List Table** provide the required details for every piece of information submitted with the application that meets the following criteria:

- a report (document) describing one or more tests, analyses, trials or studies (eg, a stability trial, toxicology study, metabolism study, residue processing study, worker exposure study, ecotoxicology study, efficacy trial etc);
- a report (document) summarising information necessary to meet APVMA requirements (eg, a report summarising the toxicological properties and case histories of a particular active constituent with respect to target animal safety);
- a description of a method of analysis (including validation methods); and
- an expert opinion provided on a data requirement by someone other than the applicant.

A guideline specifically addressing the **types of chemistry data that must be included in the Data List Table** is available from the Data Protection page of the APVMA website.

The details of the submitted information must be entered as per the instructions below. Where more than one type of information is included in the same report (e.g. multiple trials in the one report, or analytical methods included in a stability or residues trial report) the report must not be entered into the table twice and should only be identified in the table by the primary (main) Data Type and Sub-Type. Similarly if other information is attached to a report in an appendix (referred to in the document/report), separate entries for the appendices must not be included in the table. One entry of the report/document will be sufficient to identify the information.

Other information provided to the APVMA (e.g. specification sheets, certificates of analysis, MSDS's, formulation details, container specifications etc) should not be listed in the Data List table (see **Chemistry Data Guideline**).

2.3 Details To Be Entered Into The Table

2.3.1 Ref Num

Enter your reference number as shown on the report/document provided. For published documents, applicants may choose to use the journal reference (eg. volume, chapter and/or page numbers as relevant). If there is no appropriate reference number on the document/report, applicants must create one and add it to the document.

Where possible it is preferable for applicants to use the volume and/or page number where the document/study can be found in the data package as the reference number. This assists the APVMA to locate the piece of information when considering the application.

Importantly, the reference number included in the Data List Table must correspond to an obvious reference number on the actual document/report. As an identifier, the reference number should be unique to the document/report and should not be identical for all entries in the data list.

2.3.2 Data Type

Enter the data type in the correct format, exactly as it is written in the table at the bottom of this document.

For data that is relevant to more than one requirement, select the primary (main) data type only. Do Not create two entries for one report.

2.3.3 Data Sub-Type

Enter the data sub-type in the correct format, exactly as it is written in the table at the bottom of this document. If you are unsure, check the Data Requirements and Guidelines in Volume 3 of the relevant Agricultural or

Veterinary Manual of Guidelines and Requirements (MORAG) available from the **MORAG Page of the APVMA website**.

2.3.4 Author(s)

Enter the name of the author(s) as provided on the report/document. The sponsor of a report is not considered the author. The author is usually the person or persons responsible for the production of the report. However, in the case of privately conducted research, the company producing the report may be considered the legal author as they are responsible for its contents. If unsure please enter the name of both the person and company. If there is no author given, then use the following options in this order:

- i) Enter the editor's name(s) with the suffix (Ed.);
- ii) If no editors, enter the compilers name(s) with the suffix (Comp.); or
- iii) If neither editors nor compilers, enter 'Anon'.

2.3.5 Title

Enter the title as it appears on the report/document.

2.3.6 Publication

If the report/document is publicly available, enter the name of the publication that it was published in. Please use the full journal name rather than the common abbreviation. If it was published on the Internet, then provide the Internet address (URL). (For example, the URL for the current page is http://www.apvma.gov.au/registration/downloads/DP_datalist_instructionsRTF.pdf).

If the report/document is not publicly available enter a dash (eg. -)

2.3.7 Date

Enter the date as included on the report/document. If no date is included, applicants are required to enter the following:

- i) If published, the date it was published; or if not published
- ii) The date the preparation of the report / document was completed; or if unknown
- iii) the date the report / document was received by the applicant; or if unknown
- iv) the date the report / document was included in the application.

2.3.8 Authorising Party

The 'authorising party' is the person or persons that may give consent for protected data to be used for subsequent applications. Typically the 'authorising party' will be the 'owner' of the information.

The only possible options are Applicant; Public Domain; Other Party; Prev Sub, Not Protected and Prev Sub, Protected. These options must be entered in the correct format, exactly as written here. The Five options are explained below:

- **Applicant**

The applicant as identified on the data list and application form is the authorising party

- **Public Domain**

The information is available in the public domain (for example it has been published and could be freely accessed by anyone).

Data protection will **not** apply to information that is available in the public domain.

- **Other Party**

A party other than the applicant is the authorising party. Where this applies see also section 3.3.9 below.

Where the authorising party is both the 'Applicant' and an 'Other Party', please use 'Other Party' and insert both the applicant and other party's name and address in the 'Details of Other Party Field'.

- **Prev Sub, Not Protected**

The information has been previously submitted to the APVMA by the applicant but is not subject to data protection. For example the information may have been originally submitted before 1 January 2005 (when data protection began), or was submitted after 1 January 2005 but was not 'required' or not 'relied-on' by the APVMA to grant the application with which the information was submitted. Such information may need to be supplied again to make an application for a new proposal complete (i.e a study that contains information relevant and required for the current application).

Data protection will **not** apply to information identified as 'Prev Sub, Not Protected'.

- **Prev Sub, Protected**

The information has been previously submitted to the APVMA by the applicant and is currently subject to data protection. It may be necessary for a study to be resubmitted with a subsequent application where it contains information relevant to that application (eg. the study reports on 2 different products). Where this applies see also section 2.3.11 below.

Note: It is the applicant's responsibility to ensure the correct authorising party/ies are provided in the data list. The APVMA will only accept Consent for Use from the nominated authorising party/ies. Multiple authorising parties can be nominated using "other party". If more than one Authorising Party is nominated, Consent for Use will be accepted from any of the Authorising Parties. However, there are criminal penalties for providing false information to the APVMA.

2.3.9 Name of Other Party

When 'Other Party' is selected as the Authorising Party, enter the name of the Authorising Party.

If 'Other Party' is not selected as the Authorising Party please leave this section completely blank (i.e. **Do Not** insert a dash).

2.3.10 Details of Other Party

When 'Other Party' is selected as the Authorising Party, enter the contact address details of the Authorising Party.

If 'Other Party' is not selected as the Authorising Party please leave this section completely blank (i.e. **Do Not** insert a dash).

2.3.11 APVMA Ref Data No.

When 'Prev Sub, Protected' is selected as the Authorising Party (indicating that the data has been previously submitted and is already subject to data protection) you must enter the 'APVMA data number' that the piece of information was assigned by the APVMA when it was previously submitted.

The APVMA data number will be apparent from the APVMA data list that you would have received for the application with which the information was first submitted. It may also be obtained from the **PUBCRIS** record of the relevant registered product or approved active constituent.

If 'Prev Sub, Protected' is not selected as the Authorising Party please leave this section completely blank (i.e. **Do Not** insert a dash or any numbers).

3. To Add A New Record

To add another record, place your cursor in the last row, then press the Tab key.

4. To Delete A Record

To delete a row, place your cursor in the row you wish to delete, then select **Table**, then **Delete** then **Rows**. This may be different if you are not using Microsoft Word.

5. Submitting The Data List

Once all the information has been entered into the Data List, save the document and then send the file via;

a) Email

From Microsoft Word click on the **File** menu, then select **Send To**, then **Mail Recipient (as attachment)**. Put the product name/active constituent name and if known the APVMA product or active number and application number in the Subject heading and send to DataList@apvma.gov.au.

or

b) Disk/CD

Save to disk or CD and enclose with your application. Write the product/active constituent name and if known the APVMA product or active number and application number on the label.

Table of Data Types and Sub-Types

Data Type	Data Sub-Type
Chemistry and Manufacture	Active Constituent, Stability
Chemistry and Manufacture	Active Constituent, Manufacturing/Quality Control
Chemistry and Manufacture	Active Constituent, Batch Analysis
Chemistry and Manufacture	Active Constituent, Analytical Methods
Chemistry and Manufacture	Active Constituent, Other Information
Chemistry and Manufacture	Product, Manufacturing/Quality Control
Chemistry and Manufacture	Product, Batch Analysis
Chemistry and Manufacture	Product, Stability
Chemistry and Manufacture	Product, Analytical Methods
Chemistry and Manufacture	Product, Other Information
Toxicology	Acute Oral Studies, Active
Toxicology	Acute Dermal Studies, Active
Toxicology	Acute Inhalation Studies, Active
Toxicology	Acute Skin Irritation Studies, Active
Toxicology	Acute Eye Irritation Studies, Active
Toxicology	Acute Skin Sensitisation Studies, Active
Toxicology	Acute Oral Studies, Product
Toxicology	Acute Dermal Studies, Product
Toxicology	Acute Inhalation Studies, Product
Toxicology	Acute Skin Irritation Studies, Product
Toxicology	Acute Eye Irritation Studies, Product
Toxicology	Acute Skin Sensitisation Studies, Product
Toxicology	Short-term Studies
Toxicology	Sub-chronic Studies
Toxicology	Chronic Studies
Toxicology	Carcinogenicity Studies
Toxicology	Chronic/Carcinogenicity Studies
Toxicology	Reproduction Studies
Toxicology	Developmental (Teratology) Studies
Toxicology	Genotoxicity (Mutagenicity) Studies
Toxicology	Metabolites and Impurities Studies
Toxicology	Studies of Other Special Effects

Toxicology	Studies of Mixtures
Toxicology	Studies in Humans
Toxicology	Other Information
Metabolism and Kinetics	Plants
Metabolism and Kinetics	Laboratory Animals
Metabolism and Kinetics	Target Animals
Metabolism and Kinetics	Other Information
Residues	Crop Residues Human Consumption
Residues	Crop Residues Livestock Feed
Residues	Animal Commodity Residues Direct Application
Residues	Animal Commodity Residues Crop Transfer
Residues	Animal Commodity Residues Wool Residues
Residues	Analytical Methods
Residues	Fate - Storage, Processing and Cooking
Residues	Other Information
OH and S	Worker Exposure
OH and S	Air Monitoring
OH and S	Dislodgable foliar residues
OH and S	Other information
Environment Fate	Physicochemical Degradation Hydrolysis
Environment Fate	Physicochemical Degradation Photodegradation
Environment Fate	Biodegradation Soils
Environment Fate	Biodegradation Water
Environment Fate	Mobility Volatility
Environment Fate	Mobility Adsorption/Desorption
Environment Fate	Mobility Leaching Potential
Environment Fate	Field Dissipation Soils
Environment Fate	Field Dissipation Water
Environment Fate	Field Dissipation Air
Environment Fate	Field Dissipation Plants
Environment Fate	Accumulation/Metabolism Aquatic Organisms
Environment Fate	Accumulation/Metabolism Soils
Environment Fate	Accumulation/Metabolism Soils
Environment Fate	Accumulation/Metabolism Other
Environment Fate	Modelling Studies
Environment Fate	Storage and Disposal Information
Environment Toxicology	Vertebrates Acute
Environment Toxicology	Vertebrates Short-term
Environment Toxicology	Vertebrates Other
Environment Toxicology	Aquatic Organisms Acute
Environment Toxicology	Aquatic Organisms Short-term
Environment Toxicology	Aquatic Organisms Other
Environment Toxicology	Non-target Invertebrates (terrestrial) Predators

Environment Toxicology	Non-target Invertebrates (terrestrial) Parasites
Environment Toxicology	Non-target Invertebrates (terrestrial) Bees
Environment Toxicology	Non-target Invertebrates (terrestrial) Earthworms
Environment Toxicology	Non-target Invertebrates (terrestrial) Soil micros
Environment Toxicology	Non-target Invertebrates (terrestrial) Other
Environment Toxicology	Non-target Vegetation - Laboratory
Environment Toxicology	Non-target Vegetation - Field
Environment Toxicology	Other Information
Efficacy and Safety	Efficacy
Efficacy and Safety	Phytotoxicity and Crop Safety
Efficacy and Safety	Target Animal Safety Studies
Efficacy and Safety	Pharmacological Data/Studies
Efficacy and Safety	Other Information
Other Trade Aspects	Residues in Fibre/Wool
Other Trade Aspects	Presence of Disease
Other Trade Aspects	Endocrine and Related Substances
Other Trade Aspects	Genetically Modified Produce
Other Trade Aspects	Other Information
Special Data Requirements	Antibiotics
Special Data Requirements	Other Information