

GUIDELINE FOR CHEMISTRY DATA IN DATA LISTS

From 1 October 2006 the APVMA will require the details of chemistry data provided with applications to be included in a data list that accompanies the application.

The 'Instructions for using APVMA data list' documents state that information considered 'data' for the purposes of a data list include:

- A report describing one or more tests, analyses, trials or studies
- A report summarising information necessary to meet APVMA data requirements
- A description of a method of analysis
- Expert opinion on a data requirement provided by someone other than the applicant

With respect to chemistry data, the items that **will be considered 'data'** for the purposes of a data list include reports of:

- physico-chemical properties
- stability studies (including in-use stability trials)
- analytical methods details
- validation data
- batch analysis results for active constituents and/or formulated products
- manufacturing/formulation process (including quality control during manufacture)

This information should be presented in report form. These data items must be included in the application data list.

Other information that may be required to be supplied in the Part 2 Chemistry and Manufacture data package, but **will not be considered 'data'** for the purposes of a data list include:

- certificates of analysis (non-active constituents)
- specification sheets
- Declaration of Composition (DoC)
- Material Safety Data Sheets (MSDS)
- formulation composition details
- product specifications
- container specifications

As such these items should not be included as individual items in a data list.

Items not mentioned above

Any other items not mentioned above should only be included in a data list where they constitute a report on a scientific body of work intended to demonstrate a result to support a data requirement (i.e. a report with an intellectual property value).

If unsure whether certain data should or should not be included in a data list, please contact the APVMA.

Attachment 1 contains an example data list including chemistry data.

ATTACHMENT 1

Applicant's List of Submitted Data

Please email this document to: DataList@apvma.gov.au with the Product Name or Active Constituent Name in the subject heading.

Applicant's Name: Company X

Product Name or Name of Active Constituent: Company X Chemical Product

Product Number or Active Constituent Approval Number (if known):

Application Number (if known):

Office Use Only	Ref Num	Data Type	Data Sub-Type	Author(s)	Title	Publication	Date	Authorising Party	Name of Other Party	Details of Other Party
<input type="checkbox"/>	P2, 57-99	Chemistry and Ma	Product, Stability	Jones, J. K. and Fred, S.	Storage stability of 'Company X Chemical Product' stored at 54 degrees C for 2 weeks	-	1 April 2006	Applicant		
<input type="checkbox"/>	P2, 22-56	Chemistry and Ma	Product, Stability	Hall, S	Cold stability of 'Company X Chemical Product'	-	1 May 2006	Applicant		
<input type="checkbox"/>	P2, 2-10	Chemistry and Ma	Product, Batch Analysis	Jones, J	Batch analysis for batch Y23XYZ, Company X Chemical product	-	17 August 2006	Applicant		
<input type="checkbox"/>	P2, 11-21	Chemistry and Ma	Product, Manufacturing and Quality Control	Tims, S	Manufacturing process and quality control for YBF6XYZ.	-	20 May 2006	Applicant		
<input type="checkbox"/>	P2 100-131	Chemistry and Ma	Product, Analytical Method	Burns, H	Chem ADB123 analytical method description and validation	-	30 March 2006	Other Party	Company Y	21 Company Y Drive, Smithfield 9057.