Australian Government
Australian Pesticides and Veterinary Medicines Authority

This content is current only at the time of printing. This document was printed on **22 March 2022**. A current copy is located at https://apvma.gov.au/node/49261

Relevant data for module levels—agricultural chemical products

The following sets out the data that may be relevant to particular assessment modules detailed in the Agvet Regulations. This list is not exhaustive and is only intended to provide you with guidance in putting your application together. Please review this information in consultation with the Module Descriptors 6A guideline.

- Chemistry
- Toxicology
- Occupational Health and Safety
- Environment
- Efficacy and host crop safety

Chemistry

Detailed data guidelines for chemistry and manufacture are available in Part 2.

Module 2.1

Module 2.1(a)

For applications referred to at 2.1(a) of the Module Descriptors 6A guideline, a chemistry data package for comprehensive assessment may include submission of the following data or submission of valid scientific argument:

Active constituent

- identification (ISO common name, IUPAC chemical name, molecular and structural formula, spectral data, physicochemical properties)
- stability data
- manufacturer(s) name and physical address(es) of the site(s) of manufacture
- manufacturing process (including quality control, reaction scheme, and details of impurities (description of their formation and structures))
- Declaration of Composition (DoC) and/or manufacturer's specifications
- batch analysis data (for batches analysed in the past five years)
- analytical methods and validation data
- analytical reference standards, including impurities where required
- description of the primary packaging material for the technical active constituent.

Product

- active constituent approval number, site of manufacture and certificate of analysis product details

- distinguishing name
- formulation type
- name(s) of formulator(s) and physical address(es) of site(s) of formulation
- formulation composition
- non-active constituent specifications
- manufacturing process (including quality control)
- physicochemical properties
- product specifications
- batch analysis data (analysed within the past five years)
- stability data
- in-use stability data (where relevant)
- analytical methods and validation data
- description of the primary packaging material
- draft label.

Module 2.2

Module 2.2(a)(1), (2) or (3)

For applications referred to at 2.2(a)(1), (2) and (3) of the Module Descriptors 6A guideline, a chemistry data package for reduced assessment may include submission of the following data or submission of valid scientific argument:

Active constituent

- identification (ISO common name, IUPAC chemical name, molecular and structural formula, spectral data, physicochemical properties)
- information on active constituent consisting of or derived from GMOs (where relevant)
- stability data
- manufacturer(s) name(s) and physical address(es) of site(s) of manufacture
- manufacturing process (including quality control, reaction scheme, and details of impurities (description of their formation and structures)
- Declaration of composition (DoC) and/or manufacturer’s specifications
- batch analysis data (analysed in the past five years)
- analytical methods and validation data
- if applicable, analytical reference standards, including impurities (where required)
- description of the primary packaging material for the technical active constituent.

Product

- active constituent approval number, site of manufacture and certificate of analysis product details
- distinguishing name
- formulation type
- name(s) of formulator(s) and physical address(es) of site(s) of formulation
- formulation composition
- non-active constituent specifications
- manufacturing process (including quality control)
- physicochemical properties
- product specifications
- batch analysis data (analysed within the past five years)
- stability data
- in-use stability data (where relevant)
- analytical methods and validation data
- description of the primary packaging material
- draft label.

Module 2.3

Module 2.3(a)

For applications referred to at 2.3(a) of the Module Descriptors 6A guideline, a chemistry data package for assessment of a new source of an existing active may include submission of the following data or submission of valid scientific argument:

Active

- identification (ISO common name, IUPAC chemical name, molecular and structural formula, confirmation of identity through at least two spectral or chromatographic methods)
- manufacturer(s) name and physical address(es) of the site(s) of manufacture
- manufacturing process (including quality control, reaction scheme, and details of impurities (description of their formation and structures))
- Declaration of Composition (DoC) and/or manufacturer's specifications
- batch analysis data (for batches analysed in the past five years)
- analytical methods and validation data
- description of the primary packaging material for the technical active constituent.

Module 2.3(b)

For applications referred to at 2.3(b) of the Module Descriptors 6A guideline, a chemistry data package for assessment of a new product containing existing active constituent(s) may include submission of the following data or submission of valid scientific argument:

Product

- active constituent approval number, site of manufacture and certificate of analysis confirming compliance with the standard
- product details
- distinguishing name
- formulation type
- name(s) of formulator(s) and physical address(es) of site(s) of formulation
- formulation composition
- non-active constituent specifications
- manufacturing process (including quality control)
- product specifications
- batch analysis data
- stability data
- in-use stability data (where relevant)
- analytical methods and validation data
- description of the primary packaging material
- draft label.

Module 2.3(c)(1), (2) or (3)

For applications referred to at 2.3(c)(1) or (2) of the Module Descriptors 6A guideline, a chemistry data package for limited assessment may include submission of the following data or submission of valid scientific argument:

Product (extension of shelf life for a date controlled product, extension of in-use shelf life, or change to storage temperature)

- product details
- distinguishing name
- product specifications
- stability data
- in-use stability data (where relevant)

- analytical methods and validation data.

Module 2.3(c)(4)

For applications referred to at 2.3(c)(4) of the Module Descriptors 6A guideline, a chemistry data package for limited assessment may include submission of the following data or submission of valid scientific argument:

Product (formulation change or additional formulation)

- active constituent approval number, site of manufacture and certificate of analysis confirming compliance with the standard
- product details
- distinguishing name
- formulation type
- name(s) of formulator(s) and physical address(es) of site(s) of formulation
- formulation composition
- non-active constituent specifications
- manufacturing process (including quality control)
- product specifications
- batch analysis data
- stability data
- in-use stability data (where relevant)
- analytical methods and validation data
- description of the primary packaging material
- draft label.

Module 2.3 (active constituent variations)

Active (replacement or additional manufacturing site, change in active constituent specifications)

- identification (ISO common name, IUPAC chemical name, molecular and structural formula, confirmation of identity through at least two spectral or chromatographic methods)
- manufacturer(s) name and physical address(es) of the site(s) of manufacture
- manufacturing process (including quality control, reaction scheme, and details of impurities (description of their formation and structures))
- Declaration of Composition (DoC) and/or manufacturer's specifications
- batch analysis data (for batches analysed in the past five years)
- analytical methods and validation data
- description of the primary packaging material for the technical active constituent.

Return to top of page.

Toxicology

Detailed data guidelines for toxicology are available in Part 3.

Module 3.1

Module 3.1(a) and (b)

For applications referred to at 3.1(a) and (b) of the Module Descriptors 6A guideline, a toxicology data package for comprehensive assessment may include submission of the following data or submission of valid scientific argument:

- chemistry and manufacture (data Part 2)
- absorption, distribution, metabolism and excretion (toxicokinetics, pharmacokinetics) (data Part 4);
- acute toxicity studies:
- studies on the active constituent;

- studies on the product;
- short-term toxicity studies (repeat-dose);
- sub-chronic toxicity studies (repeat dose);
- long-term (chronic) toxicity studies (repeat dose):
- chronic toxicity studies
- carcinogenicity studies
- combined chronic toxicity and carcinogenicity studies
- reproduction studies;
- developmental studies (including developmental neurotoxicity)
- genotoxicity studies
- neurotoxicity studies
- additional studies
- toxicity of metabolites and impurities
- other adverse effects
- toxicity of mixtures
- mechanistic studies and mode of action
- immunotoxicity
- human toxicological data;
- no-observed-adverse-effect level (NOAEL);
- acceptable daily intake (ADI);
- acute reference dose (ARfD);
- first aid instructions and safety directions;
- toxicological database/bibliography.

Module 3.2

Module 3.2(a), (c) and (e)

For applications referred to at 3.2(a), (c) and (e) of the Module Descriptors 6A guideline, a toxicology data package for reduced assessment may include submission of the following data or submission of valid scientific argument:

- chemistry and manufacture (data Part 2)
- absorption, distribution, metabolism and excretion (toxicokinetics, pharmacokinetics) (data Part 4);
- acute toxicity studies:
- studies on the active constituent;
- studies on the product;
- short-term toxicity studies (repeat-dose studies of less than 90 days duration);
- sub-chronic toxicity studies (90 days to less than 12 months);
- developmental studies (including developmental neurotoxicity)
- genotoxicity studies
- additional studies:
- toxicity of metabolites and impurities
- other adverse effects
- toxicity of mixtures
- mechanistic studies and mode of action
- immunotoxicity
- human toxicological data;
- no-observed-adverse-effect level (NOAEL);
- first aid instructions and safety directions;
- toxicological database/bibliography.

Module 3.2(b) and (d)

For applications referred to at 3.2(b) and (d) of the Module Descriptors 6A guideline, in addition to submission of the studies listed above, or submission of valid scientific argument, the following data may be included:

- long-term (chronic) toxicity studies (12 months or longer):
- chronic toxicity studies
- carcinogenicity studies
- combined chronic toxicity and carcinogenicity studies
- reproduction studies;
- acceptable daily intake (ADI);
- acute reference dose (ARfD).

Module 3.3

Module 3.3(a), (b), (d), (e) and (g)

For applications referred to at 3.3(a), (b), (d), (e) and (g) of the Module Descriptors 6A guideline, a toxicology data package for limited assessment may include submission of the following data or submission of valid scientific argument:

- chemistry and manufacture (data Part 2)
- acute toxicity studies:
- studies on the active constituent;
- studies on the product.

Notes:

Overseas health report

Please note for applications for a new product or permit with a new active constituent, a toxicology data package for limited assessment may include submission of an acceptable overseas health report and a data package comprising all of the studies associated with that report.

The provision of a comprehensive toxicological assessment report on the active constituent, which is of acceptable quality and dated from 1 July 2005, would enable classification of the application as a limited toxicology assessment. Please note that summary reports would not be sufficient to modify the level of assessment required.

Definition of a major formulation change

For the purposes of module 3.3 a major formulation change is a change to the formulation of an agricultural or veterinary chemical product, including new combinations of existing active constituents, such that safety to humans may need separate assessment. Some examples include:

- where there has been a significant increase in the concentration of active constituent which could affect the hazard potential, poison scheduling, safety directions or residues;
- where a major change in non-active constituent significantly affects the performance, stability or other attributes of the product; or
- where the formulation has been changed significantly to accommodate a new application method/use-pattern (eg changing from a wettable powder to an emulsifiable concentrate; changing from an oral drench to a topical pour-on dosage form).

Definition of a biological chemical product

Biological chemical products may be either agricultural or veterinary chemical products. A biological chemical product is a chemical product where the active constituent comprises or is derived from a living organism (plant, animal, micro-organism, etc), with or without modification.

Definition of a biotechnology chemical product

A biotechnology chemical product is one that is developed by means of one of the following biotechnological processes:

- recombinant DNA technology.

- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells
- hybridoma and monoclonal antibody methods.

Module 4

This is an additional module that applies to any application for either an agricultural or veterinary chemical, where the application must be referred to Therapeutic Goods Administration (TGA) for poisons scheduling. Data relevant to scheduling is covered by toxicology modules 3.1, 3.2 or 3.3.

Return to top of page

Occupational Health and Safety

Detailed data guidelines for occupational health and safety are in Part 6.

Module 6.1

Module 6.1(a)

For applications referred to at 6.1(a) (new product, new active) of the Module Descriptors 6A guideline, an OH&S data package for assessment may include submission of the following data or submission of valid scientific argument:

Hazard:

- physical and chemical properties:
- active constituent;
- product;
- individual constituents;
- toxicology.

Exposure:

- mixing and loading;
- product application;
- re-handling;
- dermal absorption.

Risk management and workplace information:

- measures to control user exposure:
- before and during end-use;
- re-entry or re-handling;
- measures to control public and bystander exposure:
- during end-use
- re-entry or re-handling
- product label;
- Safety Data Sheet (MSDS);
- training requirements;
- occupational exposure monitoring:
- exposure standard
- ambient air monitoring;
- health surveillance;
- tank mixing
- contraindications.

Risk characterisation:

- margin of exposure (MOE);
- further requirements where the MOE is inadequate;
- risk assessment proposed by the applicant (acute and repeat dose).

Module 6.2

Module 6.2(c), (d) and (e)

For applications referred to at 6.2(c), (d) and (e) of the Module Descriptors 6A guideline, an OH&S data package for reduced assessment may include submission of the following data or submission of valid scientific argument:

Hazard:

- physical and chemical properties:
- active constituent;
- product;
- individual constituents;
- toxicology.

Exposure:

- mixing and loading;
- product application;
- re-entry or re-handling;
- dermal absorption.

Risk management and workplace information:

- measures to control user exposure:
- before and during end-use;
- re-entry or re-handling;
- measures to control public and bystander exposure:
- during end-use
- re-entry or re-handling
- product label;
- Safety Data Sheet (MSDS);
- training requirements;
- occupational exposure monitoring:
- exposure standard
- ambient air monitoring;
- health surveillance;
- tank mixing
- contraindications.

Risk characterisation:

- margin of exposure (MOE);
- further requirements where the MOE is inadequate;
- risk assessment proposed by the applicant (acute and repeat dose).

Module 6.3

Module 6.3(c)

For applications referred to at 6.3(c) of the Module Descriptors 6A guideline, an OH&S data package for limited assessment may include submission of the following data or submission of valid scientific argument:

Hazard:

- physical and chemical properties:
- active constituent;
- product;
- individual constituents.

Exposure:

- mixing and loading;
- product application;
- re-entry or re-handling;
- dermal absorption.

Risk management and workplace information:

- measures to control user exposure
- before and during end use
- re-entry or re-handling
- measures to control public and bystander exposure:
- during end-use
- re-entry or re-handling
- product label;
- Safety Data Sheet (MSDS);
- training requirements;
- contraindications.

Module 6.3(b)

For applications referred to at 6.3(b) of the Module Descriptors 6A guideline, an OH&S data package for limited assessment may include submission of the following data or submission of valid scientific argument:

Hazard:

- physical and chemical properties:
- active constituent;
- product;
- individual constituents.

Occupational exposure:

- mixing and loading;
- product application;
- re-entry and re-handling.

Risk management and workplace information:

- measures to control occupational exposure:
- before and during end-use;
- re-handling;
- product label;
- Material Safety Data Sheet (MSDS);
- training requirements;
- tank mixing;
- contraindications.

Return to top of page

Environment

Detailed data guidelines for environment are in Part 7.

Modules 7.1, 7.2 and 7.3 Environment

Module 7.1(a), 7.2(a),(b),(c) and (d), and 7.3(a) and (c)

For applications referred to at 7.1(a), 7.2(a),(b),(c) and (d), and 7.3(a) and (c) of the Module Descriptors 6A guideline, an environment data package for comprehensive, reduced or limited assessment may include submission of the following studies or submission of valid scientific argument and/or reference to previous assessments:

Environmental chemistry and fate

- physical and chemical properties of the active constituent (solubility in water, vapour pressure, low Kow, dissociation constant, UV-visible absorption)
- rate and route of degradation
- abiotic degradation (hydrolysis, soil photolysis, aqueous photolysis)
- biodegradation under aerobic and anaerobic conditions in soil and water/sediment systems
- mobility (volatility, adsorption/desorption, leaching potential)
- field accumulation/ dissipation (terrestrial, aquatic).

Environmental toxicology

- terrestrial vertebrates
- aquatic species
- bees and other non-target arthropods
- soil organisms
- non-target terrestrial plants.

7.2 Note:

Definition of a major formulation change

For the purposes of module 7.2 a major formulation change is a change to the formulation of an agricultural or veterinary chemical product, including new combinations of existing active constituents, such that safety to the environment and/or target species may need separate assessment. Some examples include:

- where there has been a significant increase in the concentration of active constituent which could affect the hazard potential;
- where a major change in non-active constituent significantly affects the environmental fate, ecotoxicity or other attributes of the product; or
- where the formulation has been changed significantly to accommodate a new application method/use pattern (eg changing from a seed treatment to an emulsifiable concentrate).

Return to top of page.

Efficacy and host crop safety

Detailed data guidelines for efficacy and safety are in Part 8.

Module 8.1

Module 8.1(a), (b) and (c)

For applications referred to at 8.1(a), (b) and (c) of the Module Descriptors 6A guideline, an efficacy and crop safety data package for comprehensive assessment should include submission of the following Australian and/or international data or submission of valid scientific argument:

Efficacy studies

- efficacy studies for every host and pest combination claimed on the label;
- studies to demonstrate the optimum application rate for each host/pest combination.

Host crop safety studies

- safety to host crops including yield data;
- safety to following crops;
- safety to non-target or adjacent crops;
- effects on taste of produce (organoleptic effects).

Other related studies (where relevant)

- compatibility/tank mix tests;
- effects of residues on subsequent processing (such as wine or malting barley);
- implications for resistance management;
- effects on other industries;
- compatibility with integrated pest management strategies.

Module 8.2

Module 8.2(a) and (b)

For applications referred to at 8.2(a) and (b) of the Module Descriptors 6A guideline, an efficacy and host safety data package for reduced assessment should include submission of the following Australian and/or international data or submission of valid scientific argument:

Efficacy studies

- efficacy studies for any new host or pest claimed on the label;
- studies to demonstrate the optimum application rate for the new host/pest combination.

Host safety studies (if a new host or higher application rate is proposed)

- safety to host crop including yield data;
- safety to following crops;
- safety to non-target crops;
- effects on taste of produce (organoleptic effects)
- effects of residues on subsequent processing (such as wine and malting barley);
- compatibility with integrated pest management strategies
- effects on other industries.

Module 8.3

Module 8.3(a), (b) and (c)

For applications referred to at 8.3(a), (b), and (c) of the Module Descriptors 6A guideline, an efficacy and host crop safety data package for limited assessment may include submission of the following data or submission of valid scientific argument:

Efficacy studies

- target efficacy studies to demonstrate comparable efficacy with the registered reference product.

Host safety studies

- host crop safety studies to demonstrate that any phytotoxicity and yield effects are comparable to the registered reference product.

Notes—major formulation change

Efficacy and/or safety to the host will be assessed when there is a change to the formulation of an agricultural or veterinary chemical product, including new combinations of existing active constituents. Major changes in formulation require assessment under module 8.1. However, applicants may provide valid scientific argument regarding submission of relevant efficacy/safety data to justify a different level of assessment, such as a bioequivalence assessment under module 8.3. Some examples of major changes in formulation include:

- where there has been a significant change(>10 per cent) in the concentration of active constituent and where the application/dose rate to the crop is changed; or
- where a major change in non-active constituent significantly affects the performance, stability or other attributes of the product; or
- where there has been a significant change in product specifications; or
- where the formulation has been changed significantly to accommodate a new application method/use-pattern (eg changing from a wettable powder to an emulsifiable concentrate); or
- where the new formulation is not identical, not closely similar, and not similar to a registered reference product.

Return to top of page

Content last updated: 27 April 2020
Content last reviewed: 27 April 2020
URL: https://apvma.gov.au/node/49261
Version: 3

Version history

Version	Date	Description
3	27 April 2020	Reviewed with minor edits
2	14 February 2018	Review of page with minor edits and update names of Departments
1	1 July 2014	First version

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator of agricultural and veterinary (agvet) chemical products.

We acknowledge the traditional owners and custodians of country throughout Australia and acknowledge their continuing connection to land, sea and community. We pay our respects to the people, the cultures and the elders past, present and emerging.