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# Occupational health and safety (Part 6)

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This document sets out the recommendations and guidelines for submitting data in addition to the toxicological data recommended in [Part 3](#) to enable the characterisation of the human health risks associated with the use of agricultural chemical products, as part of applications for registration or extensions of use and for permit applications.

The human exposure, hazard and risk data provide essential information on:

- the human health hazards of the product
- potential exposure during handling or use of the product by professional and/or household users
- potential post-application exposure, such as during re-entry to treated crops or areas or re-handling of treated commodities such as seed, grain or treated timber products

Risks to people's health and safety are assessed by taking into account the hazard and the potential for exposure, using the following approach:

- Hazard identification—The identification of the type and nature of adverse effects that a substance has an inherent capacity to cause in an organism, animal species or human. The data relating to hazard identification are discussed in detail in [Part 3 \(Toxicology\)](#).
- Hazard characterisation (often referred to as the dose response characterisation)—The qualitative and, wherever possible, quantitative description of the inherent property of a substance having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.
- Exposure assessment—Evaluation of human exposure to a substance based on measured, extrapolated and/or modelled exposure data for the situation.
- Risk characterisation—The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability that the adverse effect will occur in a given organism, animal species or humans under defined exposure conditions.

Based on the risk assessment, risk management measures can be undertaken to reduce human health risks to an acceptable level where necessary. Those measures include engineering controls, safety directions (including for personal protective equipment), use restraints, re-entry intervals, and scheduling recommendations.

## 1. Types of applications

The nature of your application determines which types of data you should provide. Each [data module](#) below lists a number of data elements.

You should submit data to provide a comprehensive view of the hazard, exposure and risk throughout the lifecycle of the product.

A comprehensive assessment comprises of a full occupational health and safety data package, containing all of the data elements; a reduced or limited assessment comprises a subset of the data elements in a comprehensive assessment.

Exposure studies should be conducted and interpreted using Organization for Economic Co-operation and Development (OECD), or similar, testing guidelines.

## 2. Data elements

The data elements for a comprehensive assessment are listed and, where necessary, explained in this section.

For some applications, certain studies may not be relevant because of the type of active constituent or product, or because of the intended use of the product. However, for certain agricultural products, there may be specific considerations, recommendations, or both. You should address these considerations on a case-by-case basis and provide specific information as appropriate.

If you do not believe that a particular data element is necessary, you may leave the data heading in and provide a valid scientific argument for the exclusion of the data element. The regulatory value of scientific arguments will be determined based on their merits and reliability.

Additional regulatory information, including recommendations made by other governments and internationally recognised organisations, may also be considered during the assessment.

The data elements for a comprehensive part 6 occupational health and safety submission are shown below. All data elements should be addressed with the submission of data or scientific argument.

The data elements are:

- Contents
- Data summary
- Hazard
  - Physical and chemical properties: (see '[chemistry and manufacture](#)')
    - Active constituent
    - Product
    - Individual constituents
  - Toxicology (see '[toxicology](#).')
- Exposure
  - Mixing and loading
  - Product application
  - Re-entry and re-handling
  - Dermal absorption
- Risk characterisation
  - Margin of exposure (MOE)
  - Further requirements where the MOE is inadequate
  - Risk assessment proposed by the applicant (acute and repeat dose)
- 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
  - Proposed label wording
  - Safety data sheet (SDS)

- Training requirements
- Occupational exposure monitoring
  - Exposure standard
  - Ambient air monitoring
  - Health surveillance
- Tank mixing
- Contraindications

If any of this information has been supplied elsewhere in the application, it need not be repeated. You may simply cross-reference its location in the application.

Tables may be used as a means of summarising the information. If studies are cited, they should be cross-referenced in the main body of the application.

In the following sections we discuss briefly the information we expect under the headings we provided.

## 2.1. Contents

A table of contents should be provided.

## 2.2. Data summary

You should include an overall summary of the information and the rationale for any conclusions you make. The summary should contain:

- a brief description of the product (including formulation type, hazard classification and packaging)
- a brief description of the use pattern of the product (including purpose of application, equipment used and maximum area treated or quantity of product handled per day)
- an outline of the potential for workplace and/or domestic exposure (for example, during mixing, loading, application, re-entry or re-handling)
- an assessment of health risks to all exposed populations (workers)
- a description of risk mitigation or reduction measures, where possible (such as safety directions, use restraints or restrictions, re-handling intervals or engineering controls).

## 2.3. Hazard

### 2.3.1. Physical and chemical properties

#### 2.3.1.1. Active constituent

You should provide the following data elements for an active constituent and/or product:

- International Union of Pure and Applied Chemistry (IUPAC) name
- Chemical Abstract Service (CAS) number
- purity
- colour and physical appearance
- odour
- vapour pressure or volatility
- octanol–water partition coefficient (Log  $P_{ow}$ )
- molecular weight
- hazard classification
- Australian Code for the Transport of Dangerous Goods by Roads and Rail (ADG Code)
- packaging information.

#### 2.3.1.2. Product

You should provide the following information:

- formulation type
- colour and physical appearance
- odour
- vapour pressure
- volatility
- hazardous properties
- ADG code
- for particulate formulations:
  - particle size distribution
  - dust or fines content
  - attrition and friability
- packaging information.

### **2.3.1.3. Individual constituents**

You should provide the following information:

- name (active constituents first, followed by non-active constituents)
- CAS number
- hazard classification
- exposure standard (Safe Work Australia Hazardous Substances Information System, HSIS)
- concentration.

#### **2.3.1.3.1. IUPAC name, CAS number, purity, colour and physical appearance, odour, vapour pressure or volatility**

In some instances, the data may be descriptive (colour, appearance, odour, etc.), whereas quantitative data for other properties (such as vapour pressure or volatility) should be provided.

#### **2.3.1.3.2. Hazardous properties**

Hazardous properties include properties adverse to human health recognised under the Safe Work Australia guidance to classifying hazardous chemicals (Safe Work Australia 2018), or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), such as corrosive, carcinogenic, mutagenic and irritant.

Also included are physicochemical properties recognised under the ADG Code, such as explosive, flammable and oxidiser.

#### **2.3.1.3.3. ADG Code**

The ADG Code is implemented by state and territory legislation. For current information on the code, visit the National Transport Commission website.

#### **2.3.1.3.4. Packaging information**

This should include the container volume or weight, the container construction material, and the neck size of the container if its contents are a liquid. Any unique packaging information should also be provided (such as child-proof packaging or unique nozzles or applicators).

#### **2.3.1.3.5. Formulation type**

This should be consistent with types listed in the Handbook of first aid instructions and safety directions for agricultural and veterinary chemicals (FAISD handbook).

#### **2.3.1.3.6. Dry particulate formulations**

Dusts, powders and granulates may be a risk to workers as a potential source of respirable particles. Therefore, you should provide the following information:

- the particle size distribution (or nominal size range) for solid products intended for either direct application or for dispersion in water

- the dust or fine content of particulate products in order to determine the percentage of respirable particles for classification purposes
- estimates for attrition and friability for granular products to determine whether the capacity for dust generation meets the criteria for classification as a hazardous substance.

#### **2.3.1.4. Hazard classification**

Classification of hazardous substances is required under state and territory legislation. In the first instance, you should check the [Safe Work Australia HSIS](#) to determine whether the chemical has been previously classified as hazardous. If it has not been classified, it should be classified by referring to the Approved Criteria for Classifying Hazardous Substances (Safe Work Australia 2018, or the latest edition).

The GHS came into effect with new work health and safety laws on 1 January 2012. The GHS is an internationally agreed system designed to harmonise the diverse systems of classification and hazard communication currently in use throughout the world. Manufacturers and importers of hazardous chemicals will need to reclassify their products, re-label them and prepare new safety data sheets to meet the new requirements. There will be a five-year transitional period for moving to the new GHS-based system, during which manufacturers and importers can use either the GHS system or the current classification and labelling system for workplace hazardous substances and dangerous goods. After 1 January 2017, all chemicals supplied for use must comply with the new requirements. These changes do not apply to requirements under the ADG Code for the transport of dangerous goods. For more information about the changes, visit the hazardous chemicals pages on the [Safe Work Australia website](#).

#### **2.3.1.5. Toxicology**

A full description of the relevant toxicological data elements is provided in [Part 3 of the data guidelines \(Toxicology\)](#). If these data have been supplied elsewhere in the application, you need only make a cross-reference to their location.

## **2.4. Exposure**

Your submission should contain information relevant to all potential sources of occupational and/or domestic exposure to the active constituent and/or product. The data should allow a detailed assessment of the exposure, which is needed to assess the risk to human health. Data that do not enable independent evaluation may be of reduced or no regulatory value.

Exposure-related data may be derived from various sources, such as measured user exposure, bystander exposure and dislodgeable residues studies, or from extrapolations based on surrogate data or suitable data models.

In general, data obtained from studies conducted under normal use conditions are preferred. However, calculations based on modelling or surrogate data may show that potential exposure levels associated with a particular use pattern are low enough not to warrant measured exposure studies. Where the calculations reveal a cause for concern, it may be appropriate to conduct measured studies to confirm or eliminate those concerns.

A variety of databases and models, which continue to be developed and improved, are used to estimate exposure. If you submit data derived from surrogate data or modelling, you should provide full disclosure of the source. Measured exposure data may also be drawn from published and unpublished studies. The exposure studies should contain sufficient data to allow independent evaluation of the findings, but published reports often do not have data to that level of detail and may be of reduced or no regulatory value.

#### **2.4.1. Mixing and loading**

Many products require preparation before application or end use. In most cases, this simply involves diluting the concentrated product with water. The risk of exposure for the worker doing the mixing is often significant.

Data elements to supply for agricultural products are:

- equipment or system
- container volume(s)
- tank volume(s)
- average number of mixing or loading operations per day

- duration of treatment season
- volume of product used per day
- proposed personal protective equipment
- exposure studies (if available) or modelled exposure data
- other relevant information.

You should address any issues relevant to the use pattern described in the relevant particulars for a label and other activities that may result in exposure to the chemical. For submissions requesting consideration for a number of use patterns in different crops and/or situations you should address the above elements for each. If there are unusual circumstances in which additional information is needed for an effective assessment, you should submit that information.

#### **2.4.1.1. Equipment or system**

You should propose measures to control exposure.

Mixing and loading systems may be closed or open. Closed systems use engineering control measures to minimise the release of the product during mixing and loading. An example is the use of specifically designed product containers that fit directly to enclosed mixing tanks. Systems such as those may effectively mitigate the potential for exposure, such as through splashing or evaporation, that exists with open systems.

#### **2.4.1.2. Container volume**

This refers to the product container and need not be submitted again if provided earlier.

#### **2.4.1.3. Tank volume**

This refers to the volume of the mixing tank.

#### **2.4.1.4. Average number of mixing or loading operations per day**

This should be based on the typical use pattern of the product. A number of examples may be provided.

#### **2.4.1.5. Duration of treatment season**

Information on the treatment season for all crops or situations indicated on the label will make the risk assessment more accurate. If a simple statement of a period of time does not adequately describe the situation, you should provide parameters such as the length of the treatment season (treatment months) or the number of operations per season (single application per season, regularly repeated treatments, etc.).

#### **2.4.1.6. Volume of product used per day**

This should be consistent with the information above, based on the proposed use pattern described on the label.

#### **2.4.1.7. Proposed personal protective equipment**

This should be selected to minimise exposure to the chemical in question.

### **2.4.2. Product application**

Agricultural chemicals may be applied using many different methods and techniques, all of which have the potential to expose workers to them. Data relevant to the specific use pattern on the label makes it possible to assess potential exposure.

Data elements to supply for agricultural products are:

- crop or use situation
- application method and equipment
- application rate (litres or kilograms of product per hectare) and spray volume (litres of water per hectare)
- concentration of active constituent in the spray mix
- total time (hours) of application per day

- area treated per day (considering maximum farm size for a particular crop)
- proposed personal protective equipment
- worker exposure studies (if available) or modelled exposure data
- other relevant information.

You should address any issues relevant to the use pattern described on the label and other activities that may result in exposure to the chemical. While these data elements may be adequate for most exposure assessments, there may be unusual circumstances in which additional information is needed for an effective assessment. Where that is the case, you should submit that information.

#### **2.4.2.1. Use situation**

The use situation is a description of the area or location under treatment. You should provide enough information on the use of the substance to enable an accurate exposure assessment (such as indoor or outdoor use, greenhouses, parks, rights of way, playing fields). Also specify whether the product is being applied on land accessible to members of the public (or whether the product will only be used on land where restricted access can reasonably be expected, such as on farms, golf courses or bowling greens).

#### **2.4.2.2. Application method and equipment**

Many application methods and types of equipment are used for agricultural applications. The application method should be clearly indicated (for example, aerial, ground-based or hand-held spraying, misting, fogging, painting, chemigation, stem injection, fumigation).

The type of application equipment should also be clearly described (for example, ground-boom or air-blast equipment, hand-held, foggers).

The method of droplet production should also be described (hydraulic nozzle, rotary disc atomiser, air blast, etc.) and should include dimensions where relevant.

Diagrams and/or photographs should be provided for product-specific application equipment (this is not necessary for common agricultural spray equipment).

#### **2.4.2.3. Application rate and spray volume**

The maximum and minimum product application rates (litres per hectare, grams per square metre or grams per cubic metre) should be provided to determine the volume of product or concentration of active constituent applied per unit area or volume of air.

The maximum and minimum spray volumes should also be provided to estimate the maximum possible active constituent concentration in the spray (spray dilution).

Where an application rate per unit area or volume of air is not possible, you should provide a total quantity of product handled per day, along with information supporting or justifying the figure.

#### **2.4.2.4. Total time for application per day**

This should be based on a typical or representative use situation, considering the differences in use situations and equipment used. This information should be supported by data, where such data are available.

#### **2.4.2.5. Area or volume treated per day**

This should be provided in hectares per day for crop spraying or grams per cubic metre for space spraying or fumigations, and may vary with the application equipment to be used or the use situation. Where it is not possible to supply that information, you should provide the quantity of product handled per day. This information should be supported by data if data are available.

#### **2.4.2.6. Proposed personal protective equipment**

This should be selected to protect users from identified acute and chronic health effects from the chemical in question.

If a specific glove type is required, the properties of the recommended type should be provided, taking into account the formulation characteristics, the breakthrough time of the glove material and practical issues for the user (such as availability and the feasibility of wearing the gloves during use of the product).

Details of respirators or any other equipment should be provided, taking into account practical issues for the user.

If you have additional information about the use of personal protective equipment for a particular use pattern or information on the standard practice for a particular industry, you should provide it.

The safe use of domestic pesticide products should not require safety equipment that is not readily available to the householder. Protective equipment other than gloves is not considered a mitigation option for domestic pesticide handlers because they are not trained and their compliance is not expected. Pesticide products may not be supported for domestic use if protective equipment other than gloves is required for their safe use.

### **2.4.3. Re-entry and re-handling**

Exposure to agricultural chemical residues or their degradation products is possible after a treatment has been completed. For example, re-entry to a treated crop to inspect the efficacy of the pesticide application or for general crop management activities (irrigation, pruning, etc.) may result in contact with the chemical (or a degradation product) if it is still present at a high enough level. The APVMA has validated the 2012 US EPA crop re-entry calculator (updated in March 2014) as being suitable for use in Australia for assessing crop re-entry exposure.

Occupational activities such as unloading fumigated materials (such as timber or grain) and bagging treated seed are further examples where exposure from re-entry or re-handling may occur.

Data elements to provide are:

- task-specific worker exposure studies
- dislodgeable foliar residue studies
- dislodgeable residue studies
- air or soil dispersion or dissipation studies
- proposed personal protective equipment
- proposed restricted entry or re-handling period.

#### **2.4.3.1. Task-specific worker or user exposure studies**

These should be submitted if available. Studies should be based on the specific re-entry or re-handling tasks in question and should address the relevant routes of human exposure.

In the absence of exposure studies, you may use default parameters, such as generic crop transfer coefficients and modelled air dispersion data.

#### **2.4.3.2. Dislodgeable residue studies**

These studies are used in calculating the levels of substance present and potentially transferable to users following treatment (for example, dislodgeable foliar residues, or transfer coefficient values or dissipation rates).

#### **2.4.3.3. Air or soil dispersion or dissipation studies**

These are of use where soils are fumigated, and provide information on levels of chemical in air and soil to estimate exposure.

#### **2.4.3.4. Proposed personal protective equipment**

For workers involved in re-entry and re-handling activities, equipment should be selected to protect them from acute and chronic health effects identified for the chemical in question.



Re-entry or re-handling considerations for pesticides or pesticide-treated products used in the domestic environment should not require any protective equipment other than gloves.

#### 2.4.3.5. Proposed restricted entry or re-handling period

You may propose a restricted entry or re-handling period in order to protect workers from acute and chronic health effects identified for the substance in question.

#### 2.4.4. Dermal absorption

An investigation of the extent of dermal absorption of the active constituent or product is desirable for risk assessment. In the absence of dermal absorption data, a default value of 100% substance applied to the skin is assumed as a worst case value. Applicants can refine the dermal absorption value by exploring further sources of information to estimate dermal absorption. For instance, the amount considered absorbable may be reduced by an applicant giving consideration to a substance's specific physicochemical properties; so, for example, if a substance has a molecular weight of greater than 500 and a partition coefficient ( $\log P_{ow}$ ) less than -1 or greater than 4, the default will be reduced from 100 to 10 per cent dermal absorption.

For dermal absorption studies provided in support of an application, the tested formulation should be identical to, or closely resemble, the product under consideration. The adequacy of this similarity will be determined on a case-by-case basis. Tested concentrations should represent expected human exposure concentrations (for example, the concentration of chemical in the product and the proposed end-use concentration[s] should be tested). Submission of 'triple pack' *in vitro* dermal absorption studies (using rat skin, human skin and an *in vivo* rat dermal study) is recommended to enable likely human dermal absorption to be estimated. The adequacy of dermal absorption data that does not follow the 'triple pack' approach will be assessed on a case-by-case basis, but those data may be of reduced value for risk assessment.

Further guidance on conducting and interpreting dermal absorption studies is in the [OECD Guidance notes on dermal absorption](#).

### 2.5. Risk characterisation

#### 2.5.1. Margin of exposure

A deterministic approach should be adopted for the risk assessment if adequate toxicological and exposure data are available. An acceptable margin between the relevant toxicological end-point (no-observed-effect level, or NOEL) and the measured or estimated repeated exposure is relevant in demonstrating the safety of the product. This is often called the margin of safety (MOS) or margin of exposure (MOE) and accounts for a range of uncertainties in the human health risk assessment. The acceptable margin varies depending on a range of factors, including:

- the quality of the data on which the predicted margin is based
- the toxicokinetics and/or toxicodynamics of a compound
- the nature and severity of the toxic effects
- the dose–response relationship
- the type of data (for example, animal or human toxicology data).

As a general rule, for human health risk assessment purposes an MOE greater than 100 is required when using animal toxicology data and an MOE greater than 10 is required when using human toxicology data.

#### 2.5.2. Further requirements where the MOE is inadequate

If your preliminary risk assessment (for example, using surrogate data or an exposure model) indicates an unacceptable MOE, and all available risk management options (including personal protective equipment) have been taken into account, we recommend that you collect further data and refine the risk assessment. Refinements may include:

- a percutaneous absorption study
- a worker exposure study using the product submitted for registration
- re-entry residue dissipation information on the product

- additional risk management strategies (such as engineering controls to reduce worker exposure).

Human exposure studies should be conducted in accordance with current best practice.

The OECD's Guidance document for the conduct of studies of occupational exposure to pesticides during agricultural application (OECD 1997) provides guidance on worker exposure studies and general guidance on minimum requirements for studies. This guidance is not as prescriptive as the United States Environmental Protection Agency's Occupational and residential exposure test guidelines (US EPA 2013), and requires study authors to design the details of studies to suit the particular situation to be assessed.

Australian studies involving workers must comply with National Health and Medical Research Council guidelines, including the National statement on ethical conduct in research involving Humans (NHMRC 2007).

### **2.5.3. Risk assessment proposed by the applicant**

We encourage you to undertake a risk assessment using the information provided in your application. This can be done by comparing relevant toxicological end points and exposure information (either measured or extrapolated) for all likely workers and general public.

Publicly available assessment reports provide examples of the human health and safety risk assessment process. They will be most relevant if they are on a similar product type and are recent (because methods have improved over time).

Documents that provide some advice on risk assessment include:

- From the International Programme on Chemical Safety's (IPCS)
  - Environmental Health Criteria 222, Biomarkers in risk assessment: validity and validation (IPCS 2001)
  - Environmental Health Criteria 214, Human exposure assessment (IPCS 2000)
  - Environmental Health Criteria 210, Principles for the assessment of risks to human health from exposure to chemicals (IPCS 1999)
  - Environmental Health Criteria 170, Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits (IPCS 1994)
  - Environmental Health Criteria 155, Biomarkers and risk assessment: concepts and principles (IPCS 1993)
- EnHealth (2012), [Environmental health risk assessment: guidelines for assessing human health risks from environmental hazards](#)
- WHO/IPCS (2010), [Human health risk assessment toolkit: chemical hazards](#).

## **2.6. Risk management and workplace information**

### **2.6.1. Measures to control user exposure**

We encourage you to submit risk management strategies and propose specific use information. Where indicated by the risk assessment, measures may be needed to control exposure to the substance before, during and/or after end use.

Where possible, you should quantify the level of protection afforded by controls (including the use of personal protective equipment) using available risk assessment methods. The controls should be sufficient to reduce exposure to a level that provides an acceptable MOE, as outlined above.

We encourage you to consider various measures to minimise exposure in accordance with the hierarchy of control measures in the National code of practice for the control of workplace hazardous substances (NOHSC 2007).

### **2.6.2. Proposed label wording**

#### **2.6.2.1. New active constituents**

For new active constituents, if the isolated active constituent will be handled by Australian workers, you should provide a copy of the proposed label wording required under national and state and territory regulations.

#### **2.6.2.2. Existing active constituents**

For existing active constituents, a copy of the proposed label wording need not be submitted.

### **2.6.2.3. New products**

For new products, the proposed label wording should be submitted.

### **2.6.3. Safety data sheet**

A safety data sheet (SDS) should be included for:

- new active constituents that are classified as hazardous according to the NOHSC Approved criteria or the GHS and will be handled by Australian workers
- products classified as hazardous according to the NOHSC approved criteria and according to the GHS.

The SDS for the active constituent and product should be written in accordance with the National code of practice for the preparation of material safety data sheets (NOHSC–ASCC 2011).

The health effects information in the SDS for a new active constituent should be consistent with the information in the relevant particulars for a label. The label also contains first aid instructions and safety directions from the [FAISD handbook](#).

### **2.6.4. Training requirements**

In some circumstances, training in the use of a product may be required for workplace safety reasons or under state and territory legislation (such as for Schedule 7 substances listed in Appendix J of the Standard for the Uniform Scheduling of Medicines and Poisons). For example, the product may require the use of dedicated application equipment, or it may be very toxic.

You should provide information on appropriate industry guidelines or any special training or accreditation required by a relevant authority for the use of the product.

### **2.6.5. Occupational exposure monitoring**

Occupational exposure monitoring may be recommended in order to confirm that exposure is controlled. This may be by means of atmospheric monitoring, health surveillance, or both. Inhalation exposure monitoring should be part of any worker exposure study, unless inhalation has been shown to be a minor route of exposure.

For new active constituents, you should indicate whether exposure monitoring is appropriate. If so, provide an exposure limit, a justification for the limit and the proposed monitoring method.

### **2.6.6. Exposure standard**

This refers to national exposure standards declared under the Adopted national exposure standards for atmospheric contaminants in the occupational environment (Safe Work Australia, 2019). These values are established for the airborne concentration of an individual chemical at a level that should not cause adverse health effects or cause undue discomfort to nearly all workers.

You should check Safe Work Australia's [Hazardous Substances Information System](#) to determine whether there is an Australian exposure standard for a particular chemical. Where no such exposure standard has been established for Australia, you may submit a value set by an overseas regulatory authority.

### **2.6.7. Ambient air monitoring**

Monitoring of ambient air levels of highly toxic volatile pesticides (such as fumigants) may also be recommended for the assessment of exposure to re-entry workers.

### **2.6.8. Health surveillance**

Australian and state or territory law establishes health surveillance requirements for certain substances or substance classes. For information on substances nationally recommended for health surveillance, refer to the current Schedule and guidelines for health surveillance (NOHSC–ASCC 1995).

For new active constituents, you should indicate whether health surveillance is appropriate. If so, provide a biological index, a justification for the index and the proposed monitoring method.

### 2.6.9. Tank mixing

You should comment on any tank mixes that may affect the risk assessment (such as tank mixing of cholinesterase inhibitors or known synergists), based on available data.

### 2.6.10. Contraindications

You should list any health or other circumstances that are peculiar to the product and would contraindicate its use in particular circumstances.

## 3. References

EnHealth 2012, [Environmental health risk assessment: guidelines for assessing human health risks from environmental hazards](#).

IPCS 1993, [Environmental Health Criteria 155: Biomarkers and risk assessment: concepts and principles](#), International Programme on Chemical Safety, World Health Organization, Geneva.

IPCS 1994, [Environmental Health Criteria 170: Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits](#), International Programme on Chemical Safety, World Health Organization, Geneva.

IPCS 1999, [Environmental Health Criteria 210: Principles for the assessment of risks to human health from exposure to chemicals](#), International Programme on Chemical Safety, World Health Organisation, Geneva.

IPCS 2000, [Environmental Health Criteria 214: Human exposure assessment](#), International Programme on Chemical Safety, World Health Organization, Geneva.

IPCS 2001, [Environmental Health Criteria 222, Biomarkers in risk assessment: validity and validation](#), International Programme on Chemical Safety, World Health Organization, Geneva.

NHMRC 2007, [National statement on ethical conduct in research involving humans](#), National Health and Medical Research Council, Canberra.

Safe Work Australia, 2019, [Workplace Exposure Standards for Airborne Contaminants](#), Safe Work Australia, Canberra.

Safe Work Australia 2013, [Guidance note on the interpretation of workplace exposure standards for airborne contaminants](#), Safe Work Australia, Canberra.

Safe Work Australia, 2018, [Classifying hazardous chemicals National Guide](#), Safe Work Australia, Canberra.

NOHSC 2007, [National code of practice for the control of workplace hazardous substances](#), 2nd edition, National Occupational Health and Safety Commission, Safe Work Australia, Canberra.

NOHSC–ASCC 1994, [National code of practice for the labelling of workplace substances](#), National Occupational Health and Safety Commission and Australian Safety and Compensation Council, Safe Work Australia, Canberra.

NOHSC–ASCC 1995, [Schedule and guidelines for health surveillance](#), National Occupational Health and Safety Commission and Australian Safety and Compensation Council, Safe Work Australia, Canberra.

Safe Work Australia, 2018, [Preparation of safety data sheets for hazardous chemicals Code of Practice](#), Safe Work Australia, Canberra.

OECD 1997, [Guidance document for the conduct of studies of occupational exposure to pesticides during agricultural application, Series on Testing and Assessment no. 9](#), Environment Directorate, Organisation for Economic Cooperation and Development, Paris.

Safe Work Australia, Hazardous Substances Information System (HSIS), Safe Work Australia, Canberra.

UNECE 2013, Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 5th revised edition, United Nations Economic Commission for Europe.

US EPA 2013, Occupational and residential exposure test guidelines, OCSPP 875 Series, United States Environmental Protection Agency, Washington DC, United States.

WHO/IPCS 2010, Human health risk assessment toolkit: chemical hazards, World Health Organization and International Programme on Chemical Safety.

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#### Version history

Version	Date	Description
3	20 July 2020	Minor updates
2	19 February 2015	Revision to account for adoption of 2012 US EPA re-entry interval calculator
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.