Agricultural Chemical Product Data Sheet Guideline

ACVM guideline: Feb 2014

Introduction

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Introduction

Use this guideline to help you complete the Agricultural Chemical Product Data Sheet (PDS) for registration of an agricultural chemical. The PDS form (ACVM 1-3) is available on our website.

The completed and MPI-approved PDS is part of the "product and manufacturing specifications" referred to in the conditions of registration for your product.

The following information from the PDS will appear on the Public Register:

- trade name of product
- registration number
- registrant's name and address
- New Zealand agent's name and address (if applicable)
- product type(s)
- the nominal content of the active ingredient(s), not including overages.

Identification Table

At the bottom of each page (except the last) you will find a product identification table that includes date and electronic signature, which can be a hand-written signature that has been scanned. This footer will be used to simplify the procedure for making any future variations. When you apply for a variation, you will just need to include the page(s) with the requested change(s) and the new date rather than sending the entire PDS with the application. In order to change a date without changing the date on all the other pages, the footers are not linked—in other words, each one needs to be filled in. There is an easy way to do this. If you complete the footer on page 1, you can copy and paste it to complete the rest of the pages.

1. Go into page 1 footer by double clicking on it.
2. Complete identification row—number (if known), name, electronic signature (see above) and date.
3. Drag mouse across the completed table to highlight. Click copy or press Control C.
4. Go to next page, highlight identification table on that page and click paste or press Control V.
5. Repeat step 4 for the rest of the pages except the last.

If you have any questions, contact us (approvals@mpi.govt.nz).

Part A: General Information

A1 Trade Name of the Agricultural Chemical

The wording of the trade name **must be identical** on the PDS and the label you supply. The registration number will be assigned by MPI (if not previously assigned).

Prohibited substances

In the ACVM (Exemptions and Prohibited Substances) Regulations 2011, the following substances are prohibited from use as agricultural chemicals or as ingredients in agricultural chemicals. MPI will not register a product containing any of these substances.

Aldrin

Chlordane

Chlordecone

DDT including DDD (also known as TDE) and DDE

Dieldrin

Technical endosulfan and its related isomers

Endrin

HCB (also known as hexachlorobenzene) except as an impurity in other active ingredients

HCH (also known as hexachlorocyclohexane or benzenehexachloride)

Heptachlor

Lindane

Mirex

Pentachlorobenzene

Check with the EPA (http://www.epa.govt.nz/) about their phasing out of substances.

A2 Registrant Information

The registrant is the person/company who applies to register a trade name product or the person to whom a registration is transferred.

In the Full Legal Name box, put the registered company name or partnership names (including the trading name) or individual name.

If you are an overseas company applying to be a product registrant, you must be registered as an overseas company under section 334 of the New Zealand Companies Act 1993 to carry out business in New Zealand. You must also provide a New Zealand contact (name, address and phone number) on your product label.

A3 New Zealand Agent

When registering as an overseas company with the New Zealand Companies Office, you must provide the full name and address of one or more people resident or incorporated in New Zealand who are authorised to accept service of documents on your behalf. Any official MPI documents (such as certificates of registration, suspension of registration, prohibition notices, recall notices) will be sent to this person/organisation. If you are in New Zealand, you may also nominate an agent to accept service of documents on your behalf.

This agent is only a contact person and is not legally responsible for the product. The responsibility remains with you, as registrant.

A4 New Zealand Consultant

If you appoint a consultant to help with the registration process, email us a Letter of Authorisation so we know the consultant has the authority to act on your behalf. If this person is to be the point of contact during the registration process, provide details. Otherwise, leave this section blank.

A5 Product Type

Select the product type from the table below.

Product type	Definition
Anti-sap stain (timber)	To control sap stain fungi on timber (including sawn) and logs
Bactericide	To control bacteria
Fungicide	To control fungi
Herbicide	To control weeds
Insecticide	To control insects
Miticide (Acaricide)	To control mites
Molluscicide	To control slugs and snails
Nematicide	To control nematodes
Piscicide	To control fish
Plant growth regulator	To alter the behaviour of crop plants, eg it may accelerate or retard growth, prolong or break dormancy, promote rooting or other physiological changes
Viricide	To control viruses
Other	Please specify.

A6 Formulation Type

Select the formulation type from the table below.

The formulation types below are the current formulation types and codes as defined in the Croplife *International Catalogue of Pesticide Formulation Types and International Coding System* Technical Monograph No. 2, 6th Edition. This and subsequent updates can be found on the Croplife International website (http://www.croplife.org/view_document.aspx?docId=1281).

Formulation code and type	Definition

(AB) Grain bait	Special form of bait.
(AE) Aerosol dispenser	A container-held formulation that is dispersed generally by a propellant as fine droplets or particles upon the actuation of a valve.
(AL) Any other liquid	A liquid not yet designated by a specific code, to be applied undiluted.
(AP) Any other powder	A powder not yet designated by a specific code, to be applied undiluted.
(BB) Block bait	Special form of bait.
(BR) Briquette	Solid block designed for controlled release of active ingredient into water.
(CB) Bait concentrate	A solid or liquid intended for dilution before use as a bait.
(CF) Capsule suspension for seed treatment	A stable suspension of capsules in a fluid to be applied to the seed, either directly or after dilution.
(CG) Encapsulated granule	A granule with a protective or granule release-controlling coating.
(CL) Contact liquid or gel	Rodenticidal or insecticidal formulation in the form of a liquid/gel for direct application, or after dilution in the case of gels.
(CP) Contact powder	Rodenticidal or insecticidal formulation in powder form for direct application. Formerly known as tracking powder (TP).
(CS) Capsule suspension	A stable suspension of capsules in a fluid, normally intended for dilution with water before use.
(DC) Dispersible concentrate	A liquid homogeneous formulation to be applied as a solid dispersion after dilution in water. (Note there are some formulations that have characteristics intermediate between DC and EC).
(DP) Dustable powder	A free-flowing powder suitable for dusting.
(DS) Powder for dry seed treatment	A powder for application in the dry state directly to the seed.
(DT) Tablet for direct application	Formulation in the form of tablets to be applied individually and directly in the field, and/or bodies of water, without preparation of a spraying solution or dispersion.
(EC) Emulsifiable concentrate	A liquid, homogeneous formulation to be applied as an emulsion after dilution in water.
(ED) Electrochargeable liquid	Special liquid formulation for electrostatic (electrodynamic) spraying.
(EG) Emulsifiable granule	A granular formulation, which may contain water insoluble formulants, to be applied as an oil-in-water emulsion of the active ingredient(s) after disintegration in water.
(EO) Emulsion, water in oil	A fluid, heterogeneous formulation consisting of a solution of pesticide in water dispersed as fine globules in a continuous organic liquid phase.
(EP) Emulsifiable powder	A powder formulation, which may contain water insoluble formulants, to be applied as an oil-in-water emulsion of the active ingredient after dispersion in water.
(ES) Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
(EW) Emulsion, oil in water	A fluid, heterogeneous formulation consisting of a solution of pesticide in an organic liquid dispersed as fine globules in a continuous water phase.
(FD) Smoke tin	Special form of smoke generator.

(FG) Fine granule	A granule in the particle size range from 300 to 2500 µm.
(FK) Smoke candle	Special form of smoke generator.
(FP) Smoke cartridge	Special form of smoke generator.
(FR) Smoke rodlet	Special form of smoke generator.
(FS) Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or after dilution.
(FT) Smoke tablet	Special form of smoke generator**.**
(FU) Smoke generator	A combustible formulation, generally solid, which upon ignition releases the active ingredient(s) in the form of smoke.
Special forms of smoke generators	
(FK) Smoke candle	
(FP) Smoke cartridge	
(FW) Smoke pellet	
(FR) Smoke rodlet	
(FT) Smoke tablet	
(FD) Smoke tin	
(FW) Smoke pellet	
(GA) Gas	A gas packed in pressure bottle or pressure tank.
(GB) Granular bait	Special form of bait.
(GE) Gas generating product	A formulation that generates a gas by chemical reaction.
(GF) Gel for seed treatment	A homogeneous gelatinous formulation to be applied directly to the seed.
(GG) Macrogranule	A granule in the particle size range from 2000 to 6000 µm.
(GL) Emusifiable gel	A gelatinised formulation to be applied as an emulsion in water.
(GP) Flo-dust	Very fine dustable powder for pneumatic application in greenhouses.
(GR) Granule	A free-flowing solid formulation of a defined granule size range ready for use.
Special forms of granules	
(CG) Encapsulated granule	A granule with a protective or release-controlling coating.
(FG) Fine granule	Particle size range from 300 to 2500 µm.
(GG) Macrogranule	Particle size range from 2000 to 6000 µm.
(MG) Microgranule	Particle size range from 100 to 600 µm.
(GS) Grease	Very viscous formulation based on oil or fat.

(GW) Water soluble gel	A gelatinised formulation to be applied as an aqueous solution.
(HN) Hot fogging concentrate	A formulation suitable for application by hot fogging equipment, either directly or after dilution.
(KK) Combi-pack solid/liquid	A solid and a liquid formulation, separately contained within one outer pack, intended for simultaneous application in a tank mix.
(KL) Combi-pack liquid/liquid	Two liquid formulations, separately contained within one outer pack, intended for simultaneous application in a tank mix.
(KN) Cold fogging concentrate	A formulation suitable for application by cold fogging equipment, either directly or after dilution.
(KP) Combi-pack solid/solid	Two solid formulations, separately contained within one outer pack, intended for simultaneous application in a tank mix.
(LA) Lacquer	Solvent-based, film forming composition.
(LS) Solution for seed treatment	A clear to opalescent liquid to be applied to the seed either directly or as a solution of the active ingredient after dilution in water. The liquid may contain water insoluble formulants.
(LV) Liquid vaporizers	A liquid formulation in a cartridge/bottle, designed to fit a suitable heater unit, from which the formulation passes up a heated wick and evaporates into the local atmosphere.
(MC) Mosquito coil	A coil which burns (smolders) without producing a flame and releases the active ingredient into the local atmosphere as a vapour or smoke.
(ME) Micro-emulsion	A clear to opalescent, oil and water containing liquid, to be applied directly or after dilution in water, when it may form a diluted micro-emulsion or a conventional emulsion.
(MG) Microgranule	A granule in the particle size range from 100 to 600 µm.
(MV) Vaporizing mats	A mat, made from pulp or other suitable inert materials, and impregnated with an active ingredient. The mat is intended for use in a heating unit designed to produce slow volatilisation of the active ingredient.
(OD) Oil dispersion	A stable suspension of active ingredient(s) in a water-immiscible fluid, which may contain other dissolved active ingredient(s), intended for dilution with water before use.
(OF) Oil miscible flowable concentrate (oil miscible suspension)	A stable suspension of active ingredient(s) in a fluid intended for dilution in an organic liquid before use.
(OL) Oil miscible liquid	A liquid, homogeneous formulation to be applied as a homogeneous liquid after dilution in an organic liquid.
(OP) Oil dispersible powder	A powder formulation to be applied as a suspension after dispersion in an organic liquid.
(PA) Paste	Water-based, film-forming composition.
(PB) Plate bait	Special form of bait.
(PC) Gel or paste concentrate	A solid formulation to be applied as a gel or paste after dilution with water.
(PO) Pour-on	Solution for pouring on the skin of animals in a high volume (normally more than 100ml per animal).
(PR) Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter, containing an active ingredient.
(PS) Seed coated with a pesticide	Self-defining.

(RB) Bait (ready for use)	A formulation designed to attract and be eaten by the target pests.
Special forms of baits	
(BB) Block bait	
(AB) Grain bait	
(GB) Granular bait	
(PB) Plate bait	
(SB) Scrap bait	
(SA) Spot-on	Solution for spot application on the skin of animals in a low volume (normally less than 100ml per animal).
(SB) Scrap bait	Special form of bait.
(SC) Suspension concentrate (=flowable concentrate)	A stable suspension of active ingredient(s) in water, intended for dilution with water before use.
(SD) Suspension concentrate for direct application	A stable suspension of active ingredient(s) in a fluid, which may contain other dissolved active ingredient(s), intended for direct application to rice paddies, for example.
(SE) Suspo-emulsion	A fluid, heterogeneous formulation consisting of a stable dispersion of active ingredients in the form of solid particles and fine globules in a continuous water phase.
(SG) Water soluble granule	A formulation consisting of granules to be applied as a true solution of the active ingredient after dissolution in water, but which may contain insoluble inert ingredients.
(SL) Soluble concentrate	A clear to opalescent liquid to be applied as a solution of the active ingredient after dilution in water. The liquid may contain water insoluble formulants.
(SO) Spreading oil	Formulation designed to form a surface layer on application to water.
(SP) Water soluble powder	A powder formulation to be applied as a true solution of the active ingredient after dissolution in water, but which may contain insoluble inert ingredients.
(SS) Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
(ST) Water soluble tablet	Formulation in form of tablets to be used individually, to form a solution of the active ingredient after disintegration in water. The formulation may contain water insoluble formulants.
(SU) Ultra-low volume (ULV) suspension	A suspension ready for use through the ULV equipment.
(TB) Tablet	Pre-formed solids of uniform shape and dimensions, usually circular, with either flat or convex faces, the distance between faces being less than the diameter.
Special forms of tablets	
(DT) tablets for direct application	
(ST) tablets for dissolution in water	
(WT) tablets for dispersion in water	

(TC) Technical material	A material resulting from a manufacturing process comprising the active ingredient, together with associated impurities. This may contain small amounts of necessary additives.
(TK) Technical concentrate	A material resulting from a manufacturing process comprising the active ingredient, together with associated impurities. This may contain small amounts of necessary additives and appropriate diluents. For use only in the preparation of formulations.
(TP) (Tracking powder)	(Discontinued term. Refer to CP)
(UL) Ultra-low volume (ULV) liquid	A homogeneous liquid ready for use through ULV equipment.
(VP) Vapour releasing product	A formulation containing one or more volatile active ingredients, the vapours of which are released into the air. Evaporation rate is normally controlled by using suitable formulations and/or dispensers.
(WG) Water dispersible granules	A formulation consisting of granules to be applied after disintegration and dispersion in water.
(WP) Wettable powder	A powder formulation to be applied as a suspension after dispersion in water.
(WS) Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
(WT) Water dispersible tablet	Formulation in the form of tablets to be used individually, to form a dispersion of the active ingredient after disintegration in water.
(XX) Others	Temporary categorisation of all other formulations not listed above.
(ZC) A mixed formulation of CS and SC	A stable suspension of capsules and active ingredient(s) in fluid, normally intended for dilution with water before use.
(ZE) A mixed formulation of CS and SE	A fluid, heterogeneous formulation consisting of a stable dispersion of active ingredient(s) in the form of capsules, solid particles, and fine globules in a continuous water phase, normally intended for dilution with water before use.
(ZW) A mixed formulation of CS and EW	A fluid, heterogeneous formulation consisting of a stable dispersion of active ingredient(s) in the form of capsules and fine globules in a continuous water phase, normally intended for dilution with water before use.

A7 Overseas Regulatory Status

List the countries where the identical trade name product is already registered. This information is used if there is an urgent product recall.

General Information that is Part of the Product and Manufacturing Specifications

The product and manufacturing specifications are the collective description of the characteristics of the product and how it is to be manufactured, as proposed by the applicant, detailed in the PDS and approved as part of the registration. In effect, they include:

- all of the chemistry and manufacturing details, including labelling, that specify what the product is (formulation and specific detailing regarding packaging)
- how the product is made and handled from sourcing materials through to the point at which the registrant is no longer responsible
- the approved ACVM label content, including all specifically approved use claims and contraindications (if applicable).

A8 Label Information

You must provide an electronic copy of the label as part of your application. The label information, including all claims, warnings, contraindications, and application methods, is considered part of the product and manufacturing specifications.

A9 Shelf Life of the Formulated Product

For new registrations state the proposed shelf life. Include in-use shelf life if appropriate.

For variations to registrations state the approved shelf life. If a variation application is submitted to amend the currently approved shelf life, list both the approved and proposed shelf life on the application form (ACVM 1-1).

A10 Pack Sizes and Ranges

For new registrations state the requested pack sizes.

For variations to registrations list each individual pack size currently approved, or the range of sizes/volumes (such as 1L to 20L) if applicable. The currently approved pack sizes for a product must be listed by volume or weight per package. If a variation application is submitted to amend the currently approved pack sizes, list both the approved and proposed pack sizes on the application form (ACVM 1-1). Indicate which pack sizes will be/are marketed (use an X or a tick or **bold** type or any other clear identifier).

Part B: Product and Manufacturing Specifications-- Commercially Sensitive Information

Note: If you cross-reference another product, you still must provide the relevant information in the PDS. For information that is confidential to another party, you cannot put “refer to PXXX”.

B1 Active Ingredient Manufacturer/Formulator

For each active ingredient list the details for each manufacturer/formulator and each manufacturing site if there is more than one. Attach additional page if more space needed.

B2 Active Ingredient Minimum Purity and Impurities

State for each manufacturer/formulator. List all impurities present at levels:

- greater than or equal to 10 g/kg (1%) regardless of toxicity/ecotoxicity
- less than 10 g/kg (1%) for toxic/ecotoxic impurities
- any level where toxicity/ecotoxicity is unknown.

The following is an example only.

Active Ingredient	Manufacturer	% Minimum Purity	Impurity and Amount
Glyphosate	XYZ Ltd	95%	Formaldehyde 1.3g/kg N-nitroso-N-phosphonomethylglycine 1mg/kg

If the manufacturer is approved by the APVMA for production of the Technical Grade Active Constituent, supply the APVMA approval number in brackets next to the manufacturer’s name.

Attach additional page if needed.

B3 Formulation Details

Provide details of the full composition of the final formulated trade name product. Use the information below to complete the table.

Ingredient name
Enter the accepted ISO common name or IUPAC name for the active ingredient or, where this has not been established, provide the chemical name. **If proprietary or trade name products are used as an ingredient, provide full formulations** of all proprietary or trade name products used, or arrange to have complete formulations sent directly to MPI by the supplier in confidence. Also indicate how much is being added to the formulation.

CAS number
Enter the CAS registry or colour index number, where assigned.

Quantity
The concentration of all ingredients must be provided.

Chemical-based formulations are to be expressed in **g/L for liquids** and **g/kg for solids**. Do not use percentages.

Biological-based formulations are to be expressed in appropriate international units ensuring consistency (eg cfus/ml).

Function
Describe the purpose for each of the ingredients. Refer to table below.

For new registrations, state the proposed formulation.

For variations to registrations state the approved formulation. If a variation application is submitted to amend the currently approved formulation, list both the approved and proposed formulations on the application form (ACVM 1-1).

Include the amount of active ingredient *added* to the formulation and also the amount of active *in* the formulation if this is different. For example, copper oxychloride (as the active) and the claim is for copper.

Use the following table to complete the questions on purpose/function of each ingredient.

Function	Definition
Active ingredient	The substance or substances in a formulated product that is/are primarily responsible for the biological or other effects that make the product an agricultural chemical.
Adjuvant	A substance added to a formulation to assist the action of the principal ingredient or base.
Buffer	A weak acid and its conjugate base that is used to maintain the pH at a desired level.
Diluent	A chemically inert substance added to a solution to increase the volume and reduce the concentration.
Emulsifier	A surface active agent used to enable the dispersion of one liquid in another when one is not dissolvable in the other.
Filler	An inert bulking agent used to assist in measurement or distribution of an end use product.
Preservative	Any chemical additive that prevents or retards spoilage (such as sodium benzoate).
Surfactant	A substance that aids or enhances the surface modifying properties of a formulation (also known as wetting agent).
Suspending agent	A substance that evenly disperses solid or liquid material in a liquid or gas phase.
Other	Please specify.

Specific gravity
If the formulation is a liquid, state its specific gravity.

Other information
Include any other physicochemical parameters or information that is important to the identity of the product, manufacturing consistent of the product, or areas of ACVM concern. If there is an active ingredient overage included in the formulation, state the amount of overage per active ingredient and the reason for its inclusion (for example, manufacturing loss or degradation of the active in product storage).

B4 Manufacturer(s) of the Formulated Product

Provide the name, site address and function of all facilities involved in any step of manufacture/formulation. This includes but is not limited to the following: bulk product formulation, filling, packaging and labelling, contract sterilisation, external analytical laboratory testing, and re-packing/re-labelling.

For new registrations, list all proposed manufacturers.

For variations to registrations state the approved manufacturers. If a variation application is submitted to amend the currently approved manufacturer information, list both the approved and proposed manufacturers on the application form (ACVM 1-1).

Products imported unfinished
Products imported unfinished for repacking or relabelling that require a change in the market packaging in New Zealand to complete them for sale as a New Zealand registered product require an import certificate issued by MPI.

'Release for supply'
Provide the name of the primary company responsible for conducting the final product checks and ensuring the product meets the registration conditions before it is released for supply.

B5 Manufacturing Process

Explained on form.

B6 Specifications of the Formulated Product

Release specifications are those parameters that are tested before the product is to be released for sale. They are intended to confirm the quality of the product and batch-to-batch consistency.

Expiry specifications are those parameters that the product must meet at the end of its shelf life to remain fit for purpose. These parameters may be identical to the release specifications, with adjustments to acceptable values if appropriate.

The following is an example only.

Parameter	Range (include units if appropriate)	Method
Glyphosate	585 – 615 g/L	HPLC-64
pH	8.0 – 9.0	In-house
Emulsion characteristics	1% max cream	CIPAC MT 36.3

B7 Packaging Details

Give details of the exact packaging for each pack size in which the formulated product is distributed and marketed. Include composition (such as PP, HDPE) and construction of the container(s), and details of stoppers and closures.

Include material and thickness. If the packaging material is formed from layers, all layers should be included and it should be clear which layer is in direct contact with the product.

If packaging is recycled*, provide details about the recycling process and explain the verification methods to ensure the packaging is fit for purpose.

If more space is required, attach additional sheet.

*Recycled packaging includes:
1. reused existing packaging
2. containers with single use liners
3. packaging made from recycled materials.

B8 Distribution Process (if applicable)

Complete this section if there are special requirements to ensure the integrity of the product through the distribution chain, such as transport or storage conditions.

Note: the registrant is not responsible for compliance with the distribution process beyond the point of market release.

B9 Biosecurity Authorisation

If the product contains an ingredient(s) originating from an organism (for example plant, animal, fungus, bacteria, virus) and the product is being imported for manufacture, sale or use in New Zealand, biosecurity authorisation is required.

See the MPI Biosecurity New Zealand website or contact the Animal Imports Group (animalimports@mpi.govt.nz) for further information.

B10 HSNO Approval

Section 21(5) of the ACVM Act states: “Where a trade name product contains an agricultural compound that is also a hazardous substance or new organism, the Director-General must not register that product under this section, unless an approval for that substance or organism has been issued under the Hazardous Substances and New Organisms Act 1996”.

Hazardous substances or new organisms
If your product contains a hazardous substance or a new organism, or if you are unsure whether it does, contact the EPA (http://www.epa.govt.nz/). EPA NZ will provide informal advice, based on information provided, on whether or not a substance is hazardous and/or whether it is covered by an existing approval. If you choose this option, provide a status of substance (SOS) number and the EPA approval code on the PDS, and attach a copy of the SOS letter.

Non-hazardous substances
MPI will accept a declaration if you have self-determined that the agricultural compound you wish to register is not a hazardous substance*. (The declaration must be in writing on company letterhead.) We may require you to provide a technical argument why the ingredients in the product are non-hazardous to support your declaration. If MPI is not certain that the determination is correct, we will advise you to obtain a determination by EPA NZ. If you choose this option, place an X in the relevant box on the PDS.

* For a product to be considered non-hazardous, it must either contain no hazardous substances as defined under the HSNO Act OR contain a hazardous substance at a low enough level that the product as a whole is considered non-hazardous.

Part C: Statement and Notices

Explained on form.