Vertebrate Toxic Agent Product Data Sheet Guideline

ACVM guideline (March 2018)

Introduction

Use this guideline to help you complete the Vertebrate Toxic Agent Product Data Sheet (PDS) for registration of a VTA. The PDS form (ACVM 1-4) 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 and application form 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. Complete the footer on page 1. All other footers should then fill automatically. (If double clicking does not open the footer, put your mouse over the footer and right click on edit when it appears.)

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

Part A: General Information

A1 Trade Name of the Vertebrate Toxic Agent

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).

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 Product Type

Vertebrate toxic agent—already filled in on form.

A4 Formulation Type

Select the formulation type from the table below.

Formulation type	Definition
Aerosol	A container-held formulation that is dispersed generally as a propellant as fine droplets/particles upon the actuation of a valve.
Bait concentrate	A solid or liquid intended for dilution before use as a bait.
Bait (ready to use)	A formulation designed to attract and be eaten by the target pest (includes grain baits).
Dustable powder	A free flowing powder, suitable for dusting.
Emulsifiable concentrate	Liquid homogeneous formulation with emulsifiers in an organic solvent that forms a dispersion when added to water as a diluent.
Emulsifiable suspension	A stable emulsion for application to the seed either directly or after dilution.
Gas	A gas packed in a pressure bottle or pressure tank.
Gas-generating product	A product that generates gas by chemical reaction.
Gel	A homogeneous, gelatinous formulation to be applied as an emulsion after dilution in water.
Granule	Solid formulation comprising particles of defined size (>80µm diameter) for application without further dilution, usually to soil.

Grease	Very viscous formulation based on oil, solvent or fat.
Liquid (ready to use)	Self defining
Paste	Water-based, film forming composition.
Soluble concentrate	A liquid, homogeneous formulation to be applied as a true solution of the active ingredient after dilution in water.
Suspension concentrate	A stable suspension of active ingredient(s) in a fluid, which may contain other dissolved active ingredient(s), intended for dilution with water before use.
Tablet	Solid formulation in the form of small, flat plates for dissolution in water.
Technical concentrate	A technical material either in solution or diluted with solid adjuvants for use only in the preparation of formulations.
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.
Vapour releasing product	A formulated product containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable formulations and/or dispensers.
Wettable powder	A powder formulation to be applied as a suspension after dispersion in water.
Other	Please specify.

A5 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).

A6 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.

A7 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 1V).

A8 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 per package or number of solid dose forms (such as tablets, capsules) 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 1V).

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

B1 Active Ingredient Manufacturer

For each active ingredient list the details for each manufacturer 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. 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 %
Brodifacoum	C H Factory, 234 Mayfield Street, USA	98.0	2-(4-bromobiphenyl)-4'yl)1,2-dihydronaphthalene 2% max

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 trade name products are used as an ingredient, provide full formulations** of all trade name products used, or arrange to have complete formulations sent directly to MPI by the supplier.

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**.

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, such as active ingredient, emulsifier, surfactant, filler etc. Refer to table below.

NB: If the PDS includes a formulation change, include currently registered and proposed formulations.

For new registrations, or variations to the formulation, state the proposed 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 1V).

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 a VTA.
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; a soluble structure containing a dose of a pharmaceutical preparation.
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 (e.g. 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 (such as 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. This includes but is not limited to the following: bulk product formulation, filling, packaging and labelling, contract sterilisation, external analytical laboratory testing, re-packing/re-labelling* (secondary packaging), release for supply.

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 1V).

*Repacker(s)/relabeller(s) are restricted to activities that do not breach the primary packaging (that is, packaging in direct contact with the product). The term secondary packaging is used to describe the activities of a repacker/relabeller.

Quality control function
The quality control function, whether it is in house and/or external, must also be listed.

Products imported unfinished
Products imported unfinished for repacking or relabelling include any formulations, bulk products, unlabelled products or products labelled with foreign labels that require a change in the market packaging in New Zealand to complete them for sale as a New Zealand registered product. These products require an import certificate issued by MPI.

'Release for supply'
Provide the name of the main 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 (sometimes called 'stability 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. Refer to the Chemistry and Manufacturing Information Requirements for a more comprehensive list of relevant chemical and physical characteristics that should be covered in the specifications. The following is an example only.

Parameter	Range (include units if appropriate)	Method
Appearance	Description of acceptable parameters	
pH	5.0 – 7.0	CIPAC method 31
Active Ingredient concentration	45 – 55 mg/kg	HPLC method 23.1 (Company method, validation supplied).

As in the example above, include a volume or weight for quantifiable parameters wherever possible. The acceptable percentage range can also be included.

B7 Packaging Details

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.

B8 Distribution Process (if applicable)

Complete this section if there are special requirements to ensure the integrity of the product through the distribution chain. This would include restrictions on who may purchase the product or if defined transport conditions are required. Note: the registrant is not responsible for compliance with the distribution process beyond the point of market release.

Part C: Statement and Notices

Explained on form.