Identification of Confidential Information for the   
Purpose of Data Protection

ACVM 1DP (November 2020)

* This form is to be completed by the Applicant/Registrant or their nominated New Zealand Agent/Consultant, or any other party supplying confidential information eligible for protection under Part 6 and section 29 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
* Registration (section 21) of a non-exempt ACVM trade name product is required to avoid committing an offence (section 8) under the ACVM Act.
* Send this completed form and all required supporting documentation electronically to [approvals@mpi.govt.nz](mailto:approvals@mpi.govt.nz)
* Refer to the Privacy Act 2020 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

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| Trade Name of Product | Reg Number (if known) |
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| 1. Confidential Supporting Information Provided (Click on appropriate box to tick.) |
| Confidential Supporting Information **has been** provided in support of the application(s) detailed below.  Confidential Supporting Information **has not been** provided in support of the application(s) detailed below. |

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| 1. Application Type (Click on appropriate box to tick the relevant application type(s). Include proposed use.) | |
| Application Type  Note: innovative trade name product refers to a product containing an innovative active ingredient, which means that the active ingredient is not in any previous registered product. | Requested Data Protection Period  Note: Data protection commences on granting or refusing of an application. |
| **New Registration** | |
| **A1 New product with new active ingredient**: Data supplied for an innovative2 trade name product containing a new active ingredient.  **Proposed use**: | 10 years  [Protected period starts when application is received, ends 10 years after the date the application is granted or refused] |
| **A2 New product containing known active ingredient with new risk profile:** Data supplied for a new product that does not contain a new active ingredient.  **Proposed use**: | 5 years  [Protected period starts when application is received, ends 5 years after the date the application is granted or refused] |
| **B2 Similar to a registered TNP**:  <insert name of product>  **Proposed use**: | 5 years  [Protected period starts when application is received, ends 5 years after the date the application is granted or refused] |
| **New Provisional Registration** | |
| **Provisional Registration** (innovative - new active ingredient) - Data supplied for a provisional registration of an innovative product.  **Proposed use**: | 5 years – can be extended up to 10 years if it is subject to a new trade name product registration of the same innovative trade name product and no other product containing the same novel active ingredient has been registered.  [Protected period starts when application is received, ends either 5 or 10 years after the date the application is granted or refused] |
| **Provisional Registration** (non-innovative) - Data supplied for a provisional registration of a non-innovative product.  **Proposed use**: | 5 years  [Protected period starts when application is received, ends 5 years after the date the application is granted or refused] |
| **Variations (new uses) to Registration of an Agricultural Chemical** | |
| **Innovative Products**  Data supplied for a new use or method of use for an Innovative product:  **C4:** Extension of use to include an additional situation or target host;  **C5:** Addition of another disease, pest or weed;  **C6:** Change of application rate or timing;  **C7:** Change or addition of a method of application;  **C8:** Change in withholding period.  **Proposed use**: | Protected period starts when application is received. Ends either the longer of the two periods of:  a) End date for the protected period for the 10 years; or b) 5 years from the granting or refusing the variation. |
| **Non-Innovative Products**  Data supplied for a new use or method of use for a non-innovative product:  **C4:** Extension of use to include an additional situation or target host;  **C5:** Addition of another disease, pest or weed;  **C6:** Change of application rate or timing;  **C7:** Change or addition of a method of application;  **C8:** Change in withholding period.  **Proposed use**: | 5 years  [Protected period starts when application is received, ends 5 years after the date the application is granted or refused] |
| **Variations (new uses) to Registration of a Veterinary Medicine** | |
| **Innovative Products**  Data supplied for a new use or method of use for an innovative product:  **C4:** Extension of use to include an additional target species;  **C5:** Addition of another disease/ condition;  **C6:** Change of dose regime;  **C7:** Change to method of administration;  **C8:** Change in withholding period.  **Proposed use**: | Protected period starts when application is received. Ends either the longer of the two periods of:  a) End date for the protected period for the 10 years or b) 5 years from the granting or refusing the variation. |
| **Non-Innovative Products**  Data supplied for a new use or method of use for a non-innovative product:  **C4:** Extension of use to include an additional target species;  **C5:** Addition of another disease/ condition;  **C6:** Change of dose regime;  **C7:** Change to method of administration;  **C8:** Change in withholding period.  **Proposed use:** | 5 years  [Protected period starts when application is received, ends 5 years after the date the application is granted or refused] |
| **Variations (new uses) to Registration of a Vertebrate Toxic Agent** | |
| **Innovative Products**  Data supplied for a new use or method of use for an innovative product:  **C4:** Extension of use to include an additional target species;  **C5:** Addition/ variation to the use situation for an existing target species;  **C6:** Change in application rate regime;  **C7:** Change to or addition of a method of administration;  **C8:** Change to a withholding period.  **Proposed use:** | Protected period starts when application is received. Ends either the longer of the two periods of:  a) End date for the protected period for the 10 years or b) 5 years from the granting or refusing the variation. |
| **Non-Innovative Products**  Data supplied for a new use or method of use for a non-innovative product:  Data supplied for a new use or method of use for an Innovative product:  **C4:** Extension of use to include an additional target species;  **C5:** Addition/ variation to the use situation for an existing target species;  **C6:** Change in application rate regime;  **C7:** Change to or addition of a method of administration;  **C8:** Change to a withholding period.  **Proposed use:** | 5 years  [Protected period starts when application is received, ends 5 years after the date the application is granted or refused] |
| **Reassessment of a Registration** | |
| Reassessment  **Proposed use:** | 5 years  [Protected period starts when data is received, ends 5 years after the date the application is granted or refused] |

**To be completed by the person/company supplying the confidential information. Please note only one of the boxes below (‘Registrant’ OR ‘Other Party’) should be filled out to ensure the supplier of the information is clearly identified.**

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| 4. Registrant Information | | |
| Registrant’s Full Legal Name | | |
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| **Overseas applicants, provide Companies Act reference number** |  | |
| **Street/Physical Address** (for service) | **Postal Address** (for communication) | |
|  |  | |
| **Contact Name** | **Tel** |  |
| **Mobile** |  |
|  | **Email** |  |

**OR**

|  |  |  |
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| 5. Other Party Providing Information | | |
| Organisation’s Full Legal Name | | |
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| **Overseas applicants, provide Companies Act reference number** |  | |
| **Street/Physical Address** (for service) | **Postal Address** (for communication) | |
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| **Contact Name** | **Tel** |  |
| **Mobile** |  |
|  | **Email** |  |

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| 6. Documentation supplied in support of the application | | | | | |
| **Identify confidential information eligible for data protection.**  (List all confidential information[[1]](#footnote-1) provided to support this application where data protection is requested.   Be specific when listing information – include titles, date information was generated, electronic file name from the submission.  Name files according to the ACVM Guideline: E-Files for ACVM applications.  Identify all confidential supporting information supplied (for example, in the footnote of each page of a document). | | | | | |
| **Provider’s Reference** | **Author** | **Title** | **Date** | **Electronic submission file name** | **For ACVM Use** |
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| **7. Statement of Person Providing Information** | | | |
| I confirm that:   * I am authorised to provide this information as the applicant/registrant OR a person with legal authority to act on behalf of the applicant/registrant noted in section 4 OR a person with legal authority to act on behalf of the organisation noted in section 5; and * the information supplied in and with this application is truthful and accurate to the best of my knowledge. | | | |
| **Name** |  | **Tel** |  |
| **Signature** |  | **Email** |  |
| **Date** |  |

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| Collection of Information |
| **Collection of Personal Information**  Pursuant to Principle 3 of the Privacy Act 2020, we advise that:   * This information is being collected for the purpose of registering a trade name product under the ACVM Act; and * The recipient of this information, which is the agency that will collect and hold the information, is the Ministry for Primary Industries, PO Box 2526, Wellington 6140; and * Some of the information being collected will be displayed on a public register; and * The collection of information is authorised under section 10 of the ACVM Act; and * The provision of this information is necessary in order to process this application for registration; and * The supply of this information is voluntary; and * Failure to provide the requested information is likely to result in a return of the application form to the applicant, and in accordance with the ACVM Act, may ultimately result in a refusal to register the product; and * Under Principles 6 and 7 of the Privacy Act 2020, you have the right of access to, and correction of, any personal information which you have provided.   **Collection of Official Information**  All information provided to the Ministry for Primary Industries is official information and may be subject to a request made under the Official Information Act 1982. If a request is made under that Act for information you have provided in this declaration, the Ministry for Primary Industries will consider any such request, taking into account its obligations under the Official Information Act 1982 and any other applicable legislation. |

1. Confidential information means trade secrets and information with commercial value that would, or would be likely to, be diminished by disclosure of the information. [↑](#footnote-ref-1)