****

**Data Assessment Report for**

**Vertebrate Toxic Agent: Efficacy**

* For new applications, complete this entire form.
* For variation applications, complete the relevant sections.

**Do not use this form if no data is provided to support the claims**.

**If an expert opinion for a particular aspect is required (over and above your own area of expertise), include the expert’s written opinion with your report**.

|  |  |  |
| --- | --- | --- |
| Identity | | |
| **1.1** | **Applicant** |  |
| **1.2** | **Trade name** |  |
| **1.3** | **Registration number (if known)** |  |
| **1.4** | **Active ingredient(s) and concentration** |  |
| **1.5** | **Formulation type** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Proposed use pattern | | | |
|  |  | **Proposed** | **Current (if applicable)** |
| **2.1** | **Target species** |  |  |
| **2.2** | **Use situation** |  |  |
| **2.3** | **Application method(s)** |  |  |
| **2.4** | **Application rate(s)** |  |  |
| **2.5** | **Application timing(s)** |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Risk assessment Guidance as to the content of your assessment is provided in the boxes below. Please replace the guidance with your assessment as you work through the form. | | | |
| **3.1** | **Efficacy** | | *Summarise the data provided. Comment on whether the efficacy information is appropriate and supports the claims.* |
| **3.2** | **Pest resistance** | | *If applicable, indicate appropriateness or otherwise of a pest resistance management strategy for the product. If the label already proposes one, comment on its suitability.* |
| **3.3** | **Method of application** | *Comment on whether the proposed method of application is appropriate.* | |
| **3.4** | **Bait weathering** | *For bait-based products comment on whether sufficient information has been provided on bait weathering and whether this aspect will have impact on the efficacy of the product.* | |
| **3.5** | **Cross references** | *Comment on whether there are products with similar claims that can be cross-referenced to, or comment on the appropriateness of the applicant’s request to cross-reference to other products.* | |

|  |
| --- |
| Conformance |
| *Comment on whether the information provided, including experimental methods, trial design, and statistical analysis, is of a sufficient standard to support the conclusions drawn.*  *Identify and discuss any issues that may have affected the results.*  *Has the applicant addressed any areas of non-conformance? If so, discuss.* |

|  |  |  |
| --- | --- | --- |
| Recommendations of the data assessor | | |
| **5.1** | **Do you believe the data package supplied is sufficient to support the proposed label claims?** | *<yes/no>*  *Outline those areas not supported.*  *In your expert opinion, can those deficient areas be supported? Explain.* |
| **5.2** | **Other comments/issues** | *For example, are there issues the ACVM Group should be aware of that are not identified in the information provided by the applicant?* |
| **5.3** | **Label amendments** | *Does the label contain sufficient information to allow appropriate use? If not, indicated any amendments required.* |
| **5.4** | **Advice to applicant** | *For example, guidance on:*   * *deficiencies that need to be addressed before submitting the application for regulatory appraisal* * *improvements for future submissions.* |

|  |
| --- |
| Conflict of Interest Statement Note: MPI may contact you to request more information if necessary to determine whether the assessment can be considered independent. |
| I do not have any conflicts of interest regarding this application.  <OR>  I have the following associations with this application, which may be regarded or perceived as conflict(s) of interest:  *List any potential conflicts of interest.*  However, I do not consider that these potential conflicts of interest have affected the objectivity of my assessment, for these reasons:  *Explain why they have not influenced your assessment.* |

|  |  |
| --- | --- |
| Assessor's name |  |
| Signature |  |
| Listing status  (delete 2 options) | Listed  Provisionally listed  Not listed |
| If listed, what are your listed areas of expertise? |  |
| Date signed |  |