****

**Data Assessment Report for**

**Vertebrate Toxic Agents:   
Chemistry and Manufacturing**

* For new applications, complete this entire form.
* For variation applications, complete the relevant sections.
* Assess data for conformance with the VTA Chemistry and Manufacturing Information Requirements, including the Annexes.

|  |  |  |
| --- | --- | --- |
| Identity | | |
| **1.1** | **Registrant** |  |
| **1.2** | **Trade name** |  |
| **1.3** | **Registration number (if known)** |  |
| **1.4** | **Application type** |  |

|  |  |  |
| --- | --- | --- |
| Chemistry Guidance as to the content of your assessment is provided in many of the boxes below. Please replace the guidance with your assessment as you work through the form. | | |
| **2.1** | **Formulation type** |  |
| **2.2** | **Formulation of the trade name product** | *For a new formulation, list all ingredients (active ingredient[s] and non-active ingredients) by their CAS number and chemical/common name with their concentrations and functions in the first table on page 2.*    *For variations, specify existing and proposed formulations in the second table on page 2.*  *Delete the table you have not used.* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Details for a New Formulation (see 2.2) | | | | |
| **Ingredient Name (Common or Chemical)** | | **CAS Number** | **Quantity (g/kg or g/L)** | **Function** |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
| **TOTAL** | |  | | |
| **Specific Gravity** | |  | | |
|  | | | | |
| **2.3** | **Discuss the formulation** | *Is the formulation appropriate?*  *Does the specific gravity for liquid formulations equal the g/L calculated from ingredient amounts in the formulation table; or total 1000 g/kg for solid formulations.*  *Have the formulations of all proprietary ingredients been supplied?* | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Details for a Change in Formulation (see 2.2) | | | | | | |
| **Ingredient Name (Common or Chemical)** | | **CAS Number** | | **Current**  **(g/kg or g/L)** | **Proposed**  **(g/kg or g/L)** | **Function** |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
|  | |  | |  |  |  |
| **TOTAL** | | |  | | | |
| **Specific Gravity** | | |  | | | |
|  | | | | | | |
| **2.3** | **Discuss the formulation** | | *Is the formulation appropriate?*  *Does the specific gravity for liquid formulations equal the g/L calculated from ingredient amounts in the formulation table; or total 1000 g/kg for solid formulations.*  *Have the formulations of all proprietary ingredients been supplied?* | | | |

|  |  |  |
| --- | --- | --- |
| Active ingredient | | |
| **3.1** | **Manufacturer of active ingredient(s) provided?** | <yes/no>  Active ingredient:  Manufacturer details: |
| **3.2** | **Minimum purity** | Minimum purity: |
| **3.3** | **Impurities associated with active ingredient(s) stated?** | <yes/no>  *List significant impurities and state if they are within prescribed limits. The EPA may identify impurities.* |
| **3.4** | **Are any additives (e.g. stabilisers) added to the active ingredient?** | <yes/no>  *State details if present.* |
| **3.5** | **Number of batches tested** | *State.* |
| **3.6** | **Batch analysis of active ingredient provided for each manufacturer?** | <yes/no>  *Does it meet the stated specifications?*  *Does it include all the parameters listed in the Information Requirements (date of manufacture, batch size etc)?*  *Is it a commercial batch? If not, has the registrant explained why?* |
| **3.7** | **Active ingredient analytical method supplied?** | *Identify the method.*  *This may be the same method as that used for the formulated product however it should be clear the method can be used to test the active ingredient as a raw material, not just in formulation.* |
| **3.8** | **Other Issues** | *Discuss any other issues relating to the active specifications (e.g. FAO specs)* |

|  |  |  |
| --- | --- | --- |
| Manufacturing | | |
| **4.1** | **Manufacturer(s) of the formulated product** | *State each manufacturing site and indicate purpose (e.g. formulator or repacking/relabelling only)* |
| **4.2** | **Manufacturer(s) approved by ACVM (GMP)** | <yes/no>  *List approved class of products. Indicate if the manufacturer is approved by authorities in other countries.* |
| **4.3** | **Batch analysis of product provided from each manufacturer?** | <yes/no>  *<N/A> Taken from the initial readings of the stability trial. Please state if this is the case.*  *Can all batches be identified as originating from the manufacturer? State size of batches used.*  *Can it be confirmed to be a commercial batch?*  *Comment on the date of manufacture – is it within the last few years?*  *Summarise results.* |
| **4.4** | **Release specifications of product** | *List specifications including analytical methods*  *Are these appropriate for quality control?*  *Do they include all parameters recommended in the Chemistry Information Requirements? If not, comment on the justification provided by the applicant.* |
| **4.5** | **Active ingredient analytical method supplied?** | *Identify the method.*  *If it is not an internationally recognised method (e.g. pharmacopoeial, ISO), is a method validation provided?*  *Does validation confirm that the method is appropriate?* |
| **4.6** | **Manufacturing process and quality control steps described?** | <yes/no>  *Describe process and note any issues.*  *Are quality control steps carried out at appropriate times?* |
| **4.7** | **Packaging specifications provided?** | <yes/no>  Immediate commercial pack sizes:  Packaging material and composition:  Pack size range: |

|  |  |  |
| --- | --- | --- |
| Stability | | |
| **5.1** | **Proposed shelf life** | *State the proposed shelf life in months.* |
| **5.2** | **Was the stability study performed on the proposed formulation?** | <yes/no>  *If not, state the differences and why it was not performed on the proposed formulation.* |
| **5.2.1** | **Temperature and duration** | *State the stability study temperature and duration (e.g. 540C for 14 days, 250C for 2 years).*  *Note: Accelerated stability data may only be used to* ***support*** *real time stability data.* |
| **5.2.2** | **Number of batches tested** | *State.*  *Note: VTAs require a minimum of 3 batches to be tested.* |
| **5.2.3** | **Type of batch (laboratory, pilot, commercial)** | *Has any argument been provided for use of a laboratory or pilot batch?* |
| **5.2.4** | **Packaging used in stability trial** | *State size and type.*  *Is it the smallest proposed pack size?*  *Does it reflect all proposed commercial packaging types?* |
| **5.3** | **Expiry specifications** | *List.*  *Are these appropriate for quality control?*  *Do they include all parameters recommended in the Chemistry Information Requirements? If not, comment on the justification provided by the applicant.* |
| **5.4** | **Stability assessment** | *Summarise results.*  *Have all the required parameters from the Chemistry Information Requirements been included in the stability study?*  *Discuss changes/trends seen in the parameters measured in the stability trial.*  *Does the stability data indicate the product will remain within its expiry specifications over the requested shelf life?*  *Are the release and expiry specifications appropriate based on the stability study results?*  *Discuss the impact of any differences noted above.* |
| **5.5** | **Overage** | *Is an overage of active used in the formulation?*  *Discuss whether this is justified by the stability of the active.* |
| **5.6** | **Shelf life** | *State the shelf life you believe is supported by the data.* |
| **5.7** | **Label storage statement** | *Copy from the label.*  *Is this appropriate?* |

|  |
| --- |
| Conformance and deficiencies |
| *List the main data on which the assessment was made - PDS, draft label, chemistry and manufacture data volume etc*  *Identify and discuss any issues relating to lack of conformance with the Chemistry and Manufacturing Information Requirements.*  *Do you believe the applicant has adequately addressed these areas of non-conformance or is further information/justification required?*  *(Note: if there is a large data gap, that data should be requested from the applicant and assessed before completion of the data assessment report.)*  *List any other deficiencies that need to be addressed by the applicant before the application is submitted for regulatory appraisal.* |

|  |  |  |
| --- | --- | --- |
| Recommendations of the data assessor | | |
| **7.1** | **Do you believe the data package supplied is sufficient to identify the product and give an assurance of quality?** | <yes/no> |
| **7.2** | **Label amendments and/or conditions** | *State any label content amendments and/or additional conditions that you recommend based on the Chemistry and Manufacturing data assessment.* |
| **7.3** | **Advice to applicant** | *If appropriate, indicate any areas of improvement (e.g. data, layout, arguments) you believe the applicant may want to address prior to data assessment of future applications.* |
| **7.4** | **Any other issues?** | *Comment on any issues that have not been addressed elsewhere.* |

|  |
| --- |
| 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** |  |