****

**Data Assessment Report for**

**Agricultural Chemicals: Residues**

* 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** | **Active ingredient (common name)** |  |
| **1.3** | **Trade name** |  |
| **1.4** | **Registration number (if known)** |  |
| **1.5** | **Application type** |  |
| **1.6** | **Brief statement on scope and purpose (new ai, additional use, revised use, history)** |  |

|  |  |  |
| --- | --- | --- |
| Proposed use pattern | | |
| **2.1** | **Crop** |  |
| **2.2** | **Pest(s) treated** |  |
| **2.3** | **Use directions** | *Application concentration/rate/timing/frequency/growth stages/PHI etc.* |
| **2.4** | **Proposed withholding period** | *Days before harvest/grazing and/or growth stage of last application* |

|  |  |  |
| --- | --- | --- |
| 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** | **Identity and properties** | |
| *Comment on the key properties of the active ingredient that impact on the residue behaviour of the compound in plant and animal tissues, soil and water (e.g. volatility, solubility, partition coefficient, hydrolysis, photolysis).* | | |
| **3.2** | **Good agricultural practice** | |
| Comment on the appropriateness of the proposed use pattern, particularly on rates/dosages, number and timing of treatments likely to result in the highest level of residues.  Comment on the proposed withholding period, including an indication of the minimum, maximum and mean pre harvest intervals (in days) for proposed uses that involve withholding periods associated with specific crop growth milestones. Include comparisons with use patterns established for similar active ingredients and provide comments on any specific aspects of proposed use that are novel or at variance with similar compounds or current practices.  Statements about meeting ‘nil residues’ or compliance with overseas MRLs are not sufficient to justify the proposed use as GAP. You could include equivalent authorisations in other countries and references to existing New Zealand label claims for other pesticides against the pests of interest. | | |
| **3.3** | **Metabolism** | |
| **Plant metabolism** | | Provide a brief overview of these studies, including %TRRs, extraction efficiency, characterised and identified metabolites. Highlight the major terminal residues (above 10% TRR or 0.01 mg/kg), their concentrations and distribution. |
| **Rotational crop metabolism** | | Provide a brief overview of these studies, including %TRRs, extraction efficiency, characterised and identified metabolites. Highlight the major terminal residues (above 10% TRR or 0.01 mg/kg), their concentrations and distribution. |
| **Animal metabolism** | | Provide a brief overview of these studies, including %TRRs, extraction efficiency, characterised and identified metabolites. Include identity and concentrations of major metabolites (above 10% TRR or 0.01 mg/kg). |
| **3.4** | **Method of analysis and residue definition** | |
| **Analytical methods** | | Comment on the suitability and robustness of the available methods of analysis, particularly with respect to the limits of detection, limit of quantification and recovery rates, for both trial purposes and for compliance. Indicate whether the methods have been independently validated and whether they are suitable for detecting residues of significant metabolites and/or indicator compounds. |
| **Residue definition** | | Use plant, rotational crop, animal metabolism and processing (hydrolysis) studies to propose and justify residue definitions for plant and animal commodities, both for dietary intake estimation and GAP/MRL compliance. Consider definitions proposed by JMPR, EU, Australia, USA etc. |
| **Residue stability in stored sample** | | Note whether the available studies on the stability of residues in frozen analytical samples include representative commodities with high acid, high water, high oil, protein and high starch content. Summarise acceptable maximum storage intervals (more than 70% of spiked residues remaining). Comment on whether the stability of residues in stored analytical samples is likely to affect the validity of residue trial results or to influence the risk assessment. |
| **3.5** | **Supervised residue trials** | |
| Provide a summary of the NZ residue trial protocols, including information on plot sizes, treatment replication, crop stages, application techniques, sampling methodology (e.g. field sample size, preparation, transport and storage). Describe laboratory sample handling, storage intervals and preparation procedures. Residue results should be summarised in the Data Summary table included at the end of this report. | | |
| **3.6** | **Fate of residues during processing** | |
| Comment on the residue stability under simulated processing conditions (hydrolysis) and the significance of any metabolites present. Report the processing factors calculated from the processing studies, highlighting those commodities where residues concentrate as a result of processing. | | |
| **3.7** | **Environmental fate** | |
| Summarise **soil** mobility, degradation rates, pathways and degradates (laboratory and field studies), reporting both DT50s and DT90s. Summarise the degradation pathways (e.g. adsorption, photolysis), persistence and nature of residues in **water** and **water/sediment** systems.  Summarise (if relevant) **rotational crop** field studies (e.g. trial design, application rates, plant-back intervals) and report detectable residues in succeeding crops (both food and feed commodities).  Provide an overall assessment of the potential for residues to occur in food and animal feeds from soil ingestion, from rotational crops and on the potential for residues to migrate/remain in ground water or water systems, at levels that could result in residues in drinking water, food and animal feeds. | | |
| **3.8** | **Animal transfer studies** | |
| Provide an overview of the available studies (generally dairy cows and poultry), commenting on the relevance of the dose rates (ppm in the diet), sampling and analysis methodology.  Report residues of interest in matrices and when residues plateau (eggs, milk). | | |

|  |
| --- |
| Estimated residue levels in food and feed |
| Report the residue results from the independent field trials that reflect the proposed GAP or can be proportionally adjusted to the proposed GAP. Indicate the degree of substitution and extrapolation and the relevance of the studies to the proposed use. Comment on the validity of combining NZ and overseas trial results (e.g. similarity of production practices and growing conditions). Estimate residue levels expected in food or feed (STMRs and HRs) for MRL-estimation and dietary intake estimation.  Estimate livestock dietary burdens and use livestock feeding study results to report expected maximum and mean residues in animal products. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Residue Definition** | **MRL-compliance**: Definitions for plant and animal commodities **Dietary intake assessment**: Definitions for plant and animal commodities | | | |
| Commodity | WHPD | STMR (mg/kg) | Highest Residue (mg/kg) | Comments |
| Commodity-1 | x days | nn.nn | nn.nn | If needed |
|  |  |  |  |  |

|  |
| --- |
| Conformance |
| Comment on whether the information provided 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.  If residues are expected to be below the LOQ and the number of residue trials has been reduced as a consequence, has the applicant sufficiently explained why no quantifiable residues are anticipated, as described in the Residue Guidance Section 7.4(5) (eg discussion on the properties of the active ingredient). |

|  |  |  |
| --- | --- | --- |
| Risk assessor conclusions | | |
| **5.1** | **Use pattern & Good Agricultural Practice** | Recommend whether or not the proposed use pattern (and withholding period) can be accepted as Good Agricultural Practice. |
| **5.2** | **Expected residues in food and feed commodities** | Identify (or confirm) residue definitions for dietary intake assessment and MRL-compliance and recommend whether or not the supporting data are sufficient to conclude what residues could be expected in food and feed commodities at harvest following treatment in accordance with GAP.  Propose STMRs and HRs for each food commodity or commodity group, using the residue definition proposed for dietary intake assessment, together with a brief comment on the basis for these proposals (NZ and overseas trials, proportionality, extrapolation etc.).  Estimate potential mean and maximum livestock dietary burdens (for primary feeds and processed feed commodities) and indicate whether an assessment is needed on the potential transfer of residues into animal products (including milk and eggs).  Propose STMR-Ps and HR-Ps for processed food and feed commodities, using the residue definition proposed for dietary intake assessment. |

|  |
| --- |
| 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 |  |

## **Data Summary**

## **Chemistry (active ingredient)**

|  |  |
| --- | --- |
| Vapour pressure (25°C) |  |
| Partition coefficient |  |
| Solubility (water @ 25°C) |  |
| Solubility (solvent @ 20°C) |  |
| Specific gravity |  |
| Hydrolysis |  |
| Photolysis |  |

## **Supervised residue trials data**

| Crop name | | | | | |
| --- | --- | --- | --- | --- | --- |
| Application Details Rate, Timing, GS, Variety | DAT | Residues (mg/kg) (uncorrected) | | | Trial Ref & Comments |
| Country |  | Analyte1 | | Analyte2 |  |
| Example (flat crops)  4 X 60 g ai/ha, 400 L water/ha 6-7d intervals (9, 16, 23, 30 March 2000) BBCH 81 – BBCH 93  var: Moonlight  knapsack & 3-nozzle miniboom | 1 3 7 10 (H) 14 21 | 0.92 0.43 0.15 0.04 0.06 <0.01 | | 0.14 0.06 0.01 <0.01 ND ND | Trial ref  Treatment ref  Site  Sample size  Analysis Method  LOQ, LOD |
|  |  | Analyte | mean |  |  |
| Example (tree crops)  4 X 10 g ai/hL, 1000 L water/ha (9, 16, 23, 30 March 2000)  6-7d intervals BBCH 81 – BBCH 93  var: Moonlight  motorised 2-nozzle handgun | 1 3 7 10 (H) 14 | 1.5, 1.3 0.95, 0.86 0.73, 0.65 0.51, 0.49 0.28, 0.22 0.13, 0.08 | 1.4 0.91 0.69 0.5 0.25 0.11 |  | Trial ref  Treatment ref  Site  Sample size  Analysis Method  LOQ, LOD |

Values matching GAP and used to estimate STMRs, HRs, MRLs are underlined.  
(H) = sample taken at commercial harvest  
ND = residues below the LOD

# \*\* Study Reference List \*\*

| Reference | Author(s) | Year | Title |  | Edition No |
| --- | --- | --- | --- | --- | --- |
| JMPR 2010 E | Anon | 2010 | Pesticide residues in food – 2010 Evaluations. Part I. Residues. Compound X (124), pp 1415-1701. FAO Plant Production and Protection Paper 206, 2011. Published. |  |  |
| 08-2034 | Cavaille, C. | 2010 | Determination of the residues of AB 1234 in/on bean, kidney after spraying of compound X SC 500 in the field in France (North). Registrant, Address. Report includes Trial Nos: 08-2034-01, 08-2034-02. Date: 2010-03-15. GLP/GEP: yes, unpublished. |  | M-365530-01-1 |

## **ADDITIONAL NOTES**

## One report to be completed for each active ingredient and significant residue component in the trade name product. Each report should include reference to the full studies and trial reports included in the applicant’s data package and summarised in their Overview document.

## Where full evaluation reports from an OECD member country regulatory authority have been included in the applicant’s data package instead of the full study reports, this should be noted in the relevant sections of the Data Assessment Report. Note that OECD member country public release summaries of their evaluation reports, while helpful, are not sufficient to allow a deviation from the requirement to provide full study reports in the data package.

## Where the formulated end-use product contains more than one active ingredient, the Risk Assessor Recommendations should include any extrapolations needed to link the individual active ingredient reports to the proposed product use pattern/label claim.

## Assessors should refer to recent JMPR Appraisals for guidance on the scope and level of detail to be provided in their Data Assessment Reports. It is expected that the overview documents provided by the applicants will contain all the necessary information to allow the Data Assessment Report to be completed. Recent JMPR Evaluations and/or OECD Guidelines provide guidance on the scope and levels of detail that should be included in the Overview documents.

## Where an assessment is for an additional clearance, most of the core data sets may have already been assessed. In such cases, where the assessor has access to the previous assessments they should address the question of whether the previously assessed data are still sufficient to support the additional clearance. Where the assessor does not have access to the previous assessments, then they should make a comment in the relevant sections that they have no information on this. However, should the information in the previous assessments be critical to complete the current assessment then they should seek advice from the applicant in the first instance.