**FINAL EVALUATION OF GENERATED XML: Assessment of Coding of OPP Metabolism Data – Specie (livestock)**

Chemical: **Active substance**

**StudyReference\_activesubstance\_l\_species\_vX.xml**

Importation MDB = Yes/No

Correlation of metabolites in the tree with each treatment group = Yes/No

General overlook on each table = Yes/No

Render = Yes/No

PARAM = Yes/No

MSS composer validated = Yes/No

**Legend:**

*Applicant Updates requested*

Modifications made by RMS

|  |
| --- |
| **Mandatory fields in the MSS/DER composers** |
| Not mandatory fields |
| Mandatory fields |

|  |  |
| --- | --- |
|  | **RMS comments** |
| **I. GENERAL INFORMATION** |  |
| **Reference** |  |
| Author |  |
| Date |  |
| Study title |  |
| Pages |  |
| Reference type |  |
| Testing laboratory |  |
| Company study number |  |
| Identifiers [related to the study reference]: |  |
| - MRID Number |  |
| - PMRA Number |  |
| - Other |  |
| **Test Material** |  |
| **Identifiers** [related to the test material]: |  |
| - PARAM code |  |
| - PC code |  |
| - Other |  |
| **Guidelines** |  |
| **GLP** |  |
| **Acceptability** |  |
| **Evaluators:** |  |
| - Evaluator name |  |
| - Evaluator affiliation |  |
| **Background information** (free text) |  |
| **Executive summary** (free text) |  |
| **II. MATERIALS AND METHODS** |  |
| **A. MATERIALS** |  |
| **1. Test Material** |  |
| Common name |  |
| CAS Chemical Name |  |
| CAS no. |  |
| Company experimental name |  |
| Other synonyms (if applicable) |  |
| Molecular Formula |  |
| Analytical Purity |  |
| Impurities |  |
| Physical State |  |
| Stability Under Test Conditions |  |
| Expiration Date |  |
| Lot/Batch # |  |
| **Radiolabeled test material** |  |
| Radiochemical purity | |  |
| Specific activity as received: | |  |
| Specific activity of dose: | |  |
| Structure | |  |
| **Physicochemical Properties** | |  |
| Melting point/range | |  |
| pH | |  |
| Density | |  |
| Water solubility ( °C) | |  |
| Solvent solubility (mg/L at °C) | |  |
| Vapour pressure at °C | |  |
| Dissociation constant (pKa) | |  |
| Octanol/water partition coefficient Log(Kow) | |  |
| UV/visible absorption spectrum | |  |
| **2. Animals** | |  |
| Species | |  |
| Breed | |  |
| Age | |  |
| Weight at Study Initiation (kg) | |  |
| Health Status | |  |
| Description of Housing/Holding Area | |  |
| **B. STUDY DESIGN** | |  |
| **Dose regime** | |  |
| Number of animals per dose group | |  |
| Rationale for slection of dose group | |  |
| Analysis of feed and water | |  |
| **Test animal dietary regime** | |  |
| Composition of Diet | |  |
| Feed consumption (kg/day) | |  |
| Water | |  |
| Acclimation period | |  |
| Predosing | |  |
| **Test animal dosing regime** | |  |
| Treatment type | |  |
| Treatment level | |  |
| Vehicle | |  |
| Parameters | |  |
| Dosage Rate | |  |
| Timing/duration | |  |
| Timing from final dose to sacrifice | |  |
| **Sampling** | |  |
| [Milk/eggs] collected | |  |
| [Amount of milk/number of eggs] produced during normal production | |  |
| Urine, feces and cage wash collected | |  |
| Interval from last dose to sacrifice | |  |
| Tissues, harvested and analysed | |  |
| **Extraction and Analysis** (free text) | |  |
| **Extraction and Analysis** (flowcharts) | |  |
| **Identification and Characterization** (free text) | |  |
| **III. RESULTS AND DISCUSSION** | |  |
| **A. TOTAL RADIOACTIVE RESIDUES** | |  |
| Recovered equivalents | |  |
| Overall extraction efficiency | |  |
| Defined residue | |  |
| Defined residue extraction efficiency | |  |
| **Quantitation** (free text) | |  |
| **TRR in [milk/eggs], tissue and excreta** | |  |
| Matrix | |  |
| % aministered zone | |  |
| Ppm | |  |
| **TRR in [milk/eggs] as function of time** | |  |
| Interval | |  |
| ppb | |  |
| % of dose | |  |
| Plateauing | |  |
| **General Health of animals** | |  |
| **B. EXTRACTION, CHARACTERIZATION, AND DISTRIBUTION OF RESIDUES** | |  |
| **Distribution of the parent and Metabolites in Ruminant Matrices** | |  |
| **C. STORAGE STABILITY OF RESIDUES** | |  |
| **Storage stability of residues** (free text) | |  |
| **Summary of storage conditions** | |  |
| Matrix (RAC or extract) | |  |
| Storage temperature (°C) | |  |
| Actual storage duration (Days or Months) | |  |
| Interval of Demonstrated storage stability (days/months) | |  |
| **D. IDENTITY OF RESIDUES IN POULTRY/LACTATING RUMINANTS/ OTHER ANIMALS** | |  |
| **Summary of characterization and identification of radioactive residues animal matrices** | |  |
| **E. PROPOSED METABOLIC PATHWAY** | |  |
| **IV. CONCLUSIONS** | |  |
| **Conclusion** (free text) | |  |
| **References** (free text) | |  |
| **V. APPENDIX** | |  |
| **Appendix 1** | |  |
| Test# | |  |
| Sex | |  |
| Number | |  |
| Dose Route | |  |
| Dose (nominal) | |  |
| Dose (measured) | |  |
| Dose Type | |  |
| Test duration | |  |
| Matrix | |  |
| Experimental descriptor | |  |
| Remarks | |  |
| Citation | |  |
| RLTM | |  |
| Species | |  |
| Diet | |  |
| Dosing | |  |
| Samples | |  |
| **Appendix 2** | |  |
| ID | |  |
| Common name/Code | |  |
| Chemical name | |  |
| SMILES | |  |
| Parent(s) | |  |
| Expertise | |  |
| **Appendix 3** | |  |
| **VI. ATTACHMENTS** | |  |