

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC # 12): Stored Food and Feed - EP

| Data Code | Title | Data required | Conditions | Volume Number and Pages |
|------------------|---|----------------------|--|--------------------------------|
| 0 | Index | R | | |
| 1 | Label | R | | |
| 3 | Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered technical grade of active ingredients or integrated system products. | | | |
| 3.1 | Product Identification | | | |
| 3.1.1 | Applicant's Name and Office Address | R | | |
| 3.1.2 | Formulating Plant's Name and Address | R | | |
| 3.1.3 | Trade Name | R | | |
| 3.1.4 | Other Names | R | | |
| 3.2 | Formulation Process | | | |
| 3.2.1 | Description of Starting Materials | R | | |
| 3.2.2 | Description of the Formulation Process | R | | |
| 3.2.3 | Discussion of the Formation of Impurities of Toxicological Concern | CR | If applicable | |
| 3.3 | Specifications | | | |
| 3.3.1 | Establishing Certified Limits | R | | |
| 3.3.2 | Control Product Specification Form | R | | |
| 3.4 | Product Analysis | | | |
| 3.4.1 | Enforcement Analytical Method | R | | |
| 3.4.2 | Impurities of Toxicological Concern | CR | If applicable | |
| 3.5 | Chemical and Physical Properties | | | |
| 3.5.1 | Colour | CR | Required for manufacturing concentrates only | |
| 3.5.2 | Physical State | R | | |
| 3.5.3 | Odour | CR | Required for manufacturing concentrates only | |
| 3.5.4 | Formulation Type | R | | |
| 3.5.5 | Container Material and Description | R | | |
| 3.5.6 | Density or Specific Gravity | R | | |
| 3.5.7 | pH | R | | |
| 3.5.8 | Oxidizing or Reducing Action (Chemical Incompatibility) | R | | |
| 3.5.9 | Viscosity | R | | |
| 3.5.10 | Storage Stability Data | R | | |
| 3.5.11 | Flammability | R | | |
| 3.5.12 | Explodability | R | | |
| 3.5.13 | Miscibility | R | | |

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| 3.5.14 | Corrosion Characteristics | R | | |
| 3.5.15 | Dielectric Breakdown Voltage | R | | |
| 3.6 | Sample(s) | CR | If requested by PMRA | |
| 3.7 | Other Studies/Data/Reports | CR | If available | |
| 4 | Toxicology | | | |
| 4.1 | Summaries | R | | |
| 4.6 | Acute Studies — EP | | | |
| 4.6.1 | Acute Oral | R | | |
| 4.6.2 | Acute Dermal | R | | |
| 4.6.3 | Acute Inhalation | R | | |
| 4.6.4 | Primary Eye Irritation | R | | |
| 4.6.5 | Primary Dermal Irritation | R | | |
| 4.6.6 | Dermal Sensitization | R | | |
| 4.6.7 | Potential/Interaction | CR | If available | |
| 4.6.8 | Other Acute Studies | CR | If available | |
| 4.7 | Short-term Studies — EP | CR | Depending on use pattern, required if any component of the EP may increase absorption of the active ingredient(s) or increase toxic or pharmacologic effects | |
| 4.7.1 | Short-term Oral (90-day rodent) | CR | See 4.7 | |
| 4.7.2 | Short-term Oral (90-day and/or 12-month dog) | CR | See 4.7 | |
| 4.7.3 | Short-term Dermal (90-day) | CR | See 4.7 | |
| 4.7.4 | Short-term Dermal (21/28-day) | CR | See 4.7 | |
| 4.7.5 | Short-term Inhalation (21/28-day) | CR | See 4.7 | |
| 4.7.6 | Short-term Inhalation (90-day) | CR | See 4.7 | |
| 4.7.7 | Other Special Studies | CR | See 4.7 | |
| 4.8 | Other Studies/Data/Reports | CR | If available | |
| 5 | Exposure (Occupational and/or Bystander) | | | |
| 5.1 | Summaries | R | | |
| 5.2 | Use Description/Scenario (Application and Post Application) | R | | |
| 5.3 | Pesticides Handlers Exposure Database Assessment (or other database) | R | One of 5.3, 5.4, 5.5 is required | |
| 5.4 | Mixer/Loader/Applicator- Passive Dosimetry Data | R | See 5.3 | |
| 5.5 | Mixer/Loader/Applicator-Biological Monitoring Data | R | See 5.3 | |
| 5.6 | Post Application-Passive Dosimetry Data | CR | 5.6 or 5.7 may be required if there is potential post-application exposure | |
| 5.7 | Post Application-Biological Monitoring Data | CR | See 5.6 | |

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| 5.8 | Dermal Absorption (<i>in vivo</i>) | CR | Required if margin of exposure is inadequate | |
| 5.11 | Glove/Clothing Penetration Data | CR | May be required for risk mitigation purposes or for inadequate margin of exposure | |
| 5.13 | Package Integrity Study | CR | Required if packaged in water soluble bags | |
| 5.14 | Other Studies/Data/Reports | CR | If available | |
| 6 | Metabolism/Toxicokinetics Studies (TGAI or EP) | | | |
| 6.1 | Summaries | R | | |
| 6.2 | Livestock | CR | Depends on petitioned use and crops | |
| 6.3 | Plant | R | | |
| 6.4 | Other Studies/Data/Reports | CR | If available | |
| 7 | Food, Feed and Tobacco Residue Studies | | | |
| 7.1 | Summaries | R | | |
| 7.2 | Analytical Methodology (Food Crops & Tobacco) | | | |
| 7.2.1 | Supervised Residue Trial Analytical Methodology | R | | |
| 7.2.2 | Enforcement Analytical Methodology | R | | |
| 7.2.3 | Inter-laboratory Analytical Methodology Validation | R | | |
| 7.2.4 | Multi-residue Analytical Methodology Evaluation | R | | |
| 7.2.5 | Storage Stability of Working Solutions in Analytical Methodology | R | | |
| 7.3 | Freezer Storage Stability Tests | CR | If stored for more than 30 days and/or volatile or labile study required | |
| 7.4 | Crop Residue Data | | | |
| 7.4.1 | Supervised Residue Trial Study | CR | | |
| 7.4.2 | Residue Decline Study | CR | Depends on results of 7.4.1 | |
| 7.4.5 | Processed Food/Feed | CR | Depends on the processed commodities and practices | |
| 7.4.6 | Residue Data for Crops used as Livestock Feed (if needed for forage crops) | CR | Depends on petitioned uses and crops | |
| 7.5 | Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops) | CR | Depends on petitioned uses and crops | |
| 7.6 | Livestock, Poultry, Egg and Milk Residue Data (external application) | | | |
| 7.7 | Tobacco Residue Data (if residues are found on cured tobacco leaves) | CR | Depends on label directions | |
| 7.8 | Other Studies/Data/Reports | CR | If available | |

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|------------------|--|----------------------|---|--------------------------------|
| 7.8.1 | Other Studies/Pyrolysis Study | R | Pyrolysis studies on cigarettes manufactured from treated leaves are required if tobacco residues > 0.1 ppm | |
| 8 | Environmental Chemistry and Fate | | | |
| 8.1 | Summaries | R | | |
| 8.2 | Laboratory Studies | | | |
| 8.2.3 | Laboratory Studies of Transformation | | | |
| 8.2.3.1 | Summary | R | | |
| 8.2.3.6 | Special Studies Related to Use-Pattern or Formulation | CR | | |
| 8.2.4 | Laboratory Studies of Mobility | | | |
| 8.2.4.1 | Summary | CR | If there is a potential for soil exposure | |
| 8.2.4.6 | Special Studies Related to Use-Pattern or Formulation | CR | | |
| 8.3 | Field Studies of Dissipation/Accumulation [May be Small or Large-Scale] | | | |
| 8.3.1 | Summary | CR | | |
| 8.3.2 | Terrestrial | | | |
| 8.3.2.1 | Canada | CR | | |
| 8.3.2.2 | Northern U.S. | CR | Can substitute for Canadian studies, if they are required | |
| 8.3.4 | Special Studies Related to Intended Use Pattern | CR | Based on concerns arising from results of other studies | |
| 8.4 | Storage, Disposal and Decontamination (TGAI and EP) | | | |
| 8.4.1 | Summary | R | | |
| 8.5 | Other Environmental Fate Studies (TGAI and EP) | | | |
| 8.5.1 | Summary | CR | Based on concerns arising from results of other studies | |
| 8.6 | Other Studies/Data/Reports | CR | If available | |
| 9 | Environmental Toxicology | | | |
| 9.1 | Summary | CR | | |
| 9.2 | Non-target Terrestrial Invertebrates | | | |
| 9.2.1 | Summaries | CR | | |
| 9.3 | Non-Target Freshwater Invertebrates | | | |
| 9.3.1 | Summary | CR | If there is a potential for freshwater exposure | |
| 9.4 | Non-Target Marine Invertebrates | | | |
| 9.4.1 | Summary | CR | If there is a potential for estuarine/marine exposure | |
| 9.5 | Fish | | | |

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| 9.5.1 | Summaries | CR | If there is a potential for exposure | |
| 9.6 | Wild Birds | | | |
| 9.6.1 | Summary | CR | If there is a potential for exposure | |
| 9.6.6 | Special Studies Related to the Intended Use-Pattern (TGAI and EP) | CR | Acute inhalation (LD ₅₀) with bobwhite quail or mallard duck, if there is a potential for avian exposure | |
| 9.8 | Non-Target Plants | | | |
| 9.8.1 | Summary | CR | | |
| 9.9 | Other Studies/Data/Reports | CR | If available | |
| 10 | Value (applicable to each pest/site or host combination) | | | |
| 10.1 | Value Summaries | R | | |
| 10.2 | Efficacy Studies | | | |
| 10.2.1 | Mode of Action | R | | |
| 10.2.2 | Description of Pest Problem | R | | |
| 10.2.3 | Efficacy Trials | | | |
| 10.2.3.1 | Summaries | R | | |
| 10.2.3.2 | Efficacy: Laboratory | CR | | |
| 10.2.3.3 | Efficacy: Small-scale Trials (storage facility) | CR | | |
| 10.2.3.4 | Efficacy: Operational Trials | CR | | |
| 10.3 | Adverse Effects on Use Site | | | |
| 10.3.1 | Summaries | R | | |
| 10.3.2 | Non-Safety Adverse Effects [e.g.: to crop, site of application (discoloration, corrosion), etc.] | CR | | |
| 10.4 | Economics | CR | | |
| 10.5 | Sustainability | | | |
| 10.5.1 | Survey of Alternatives (chemical and non-chemical) | CR | | |
| 10.5.2 | Compatibility with Current Management Practices | CR | | |
| 10.5.3 | Resistance Management | R | | |
| 10.5.4 | Contribution to Risk Reduction | CR | | |
| 10.6 | Other Studies/Data/Reports | CR | If available | |
| 12.5 | Foreign Reviews | | | |
| 12.5.3 | Foreign Reviews of Chemistry Requirements for MAs and EPs formulated from registered TGAIs or ISPs | CR | | |
| 12.5.4 | Foreign Reviews of Toxicology | CR | | |
| 12.5.5 | Foreign Reviews of Exposure (Occupational and/or Bystander) | CR | | |
| 12.5.6 | Foreign Reviews of Metabolism / Toxicokinetics Studies | CR | | |

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| 12.5.7 | Foreign Reviews of Food, Feed and Tobacco Residue Studies | CR | | |
| 12.5.8 | Foreign Reviews of Environmental Chemistry and Fate | CR | | |
| 12.5.9 | Foreign Reviews of Environmental Toxicology | CR | | |
| 12.5.10 | Foreign Reviews of Value | CR | | |
| 12.7 | Comprehensive Data Summaries | R | | |

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