

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC # 8): Livestock for Food - 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	Explosibility	R		
3.5.13	Miscibility	R		
3.5.14	Corrosion Characteristics	R		
3.5.15	Dielectric Breakdown Voltage	R		
3.6	Sample(s)	CR	If requested by PMRA	

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Data Code	Title	Data required	Conditions	Volume Number and Pages
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	
4.9	Safety to Treated Animals	R		
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 or 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 for post application exposure	
5.7	Post Application-Biological Monitoring Data	CR	See 5.6	
5.8	Dermal Absorption	CR	Required if margin of exposure is inadequate	

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Data Code	Title	Data required	Conditions	Volume Number and Pages
5.11	Glove/Clothing Penetration Data	CR	May be required for risk mitigation purposes or if there is an 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	R		
6.4	Other Studies/Data/Reports	CR	If available	
7	Food, Feed and Tobacco Residue Studies EP			
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	R		
7.4.2	Residue Decline Study	CR		
7.4.3	Confined Crop Rotation Trial Study	CR	Depends on petitioned uses and cropping practices	
7.4.4	Field Crop Rotation Trial Study	CR	Depends on cropping practices and results from 7.4.3	
7.4.5	Processed Food/Feed	CR	Depends on 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)	R	For direct treatment of livestock used for food	
7.8	Other Studies/Data/Reports	CR	If available	
8	Environmental Chemistry and Fate			

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Data Code	Title	Data required	Conditions	Volume Number and Pages
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	R		
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		
9.2.8	Laboratory Studies	CR	If there is a potential for exposure and components of the EP are of concern	
9.2.9	Field Studies	CR	Based on concerns arising from results of other studies	
9.3	Non-Target Freshwater Invertebrates			
9.3.1	Summary	CR	If there is a potential for freshwater exposure	
9.5	Fish			
9.5.1	Summaries	CR	If there is a potential for exposure	
9.7	Wild Mammals			

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Data Code	Title	Data required	Conditions	Volume Number and Pages
9.7.1	Summary	CR	Based on concerns arising from results of other studies	
9.7.2	Field Studies	CR	See 9.7.1	
9.8	Non-Target Plants			
9.8.1	Summary	CR	If there is a potential for exposure	
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, Growth Chamber Trials	CR		
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)	R	One or both of 10.2.3.3 and 10.2.3.4 are required	
10.2.3.4	Efficacy: Operational Trials	CR	see 10.2.3.3	
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.]	R		
10.3.3	Damage to Rotational Crops			
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 Including IPM	CR		
10.5.3	Resistance Management	CR		
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 TGAI's 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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Data Code	Title	Data required	Conditions	Volume Number and Pages
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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