PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC # 3): Empty Food Storage Areas - EP

Data Code	Title	Data required	Conditions	Volume No. 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		
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	

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Data Code	Title	Data required	Conditions	Volume No. and Pages
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	Potentiation/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 or 5.5 is required	
5.4	Mixer/Loader/Applicator- Passive Dosimetry Data	R	See above	
5.5	Mixer/Loader/Applicator-Biological Monitoring Data	R	See above	
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 above	
5.8	Dermal Absorption	CR	Required if margin of safety is inadequate	
5.11	Glove/Clothing Penetration Data	CR	May be required for risk mitigation purposes or if the margin of safety is inadequate	
5.13	Package Integrity Study	CR	Required if packaged in water soluble bags	

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Data Code	Title	Data required	Conditions	Volume No. and Pages
5.14	Other Studies/Data/Reports	CR	If available	
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 the 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**			
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	

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Data Code	Title	Data required	Conditions	Volume No. and Pages
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 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			
10.2.3.2	Efficacy: Laboratory, Growth Chamber Trials			
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)			
10.2.3.4	Efficacy: Operational Trials			
10.3	**Adverse Effects on Use Site**			
10.3.1	Summaries			
10.3.2	Non-Safety Adverse Effects [e.g.: to crop, site of application (discoloration, corrosion), etc.]			
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 TGAIs or ISPs	CR		
12.5.4	Foreign Reviews of Toxicology	CR		
12.5.5	Foreign Reviews of Exposure (Occupational and/or Bystander)	CR		
12.5.8	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		