DATA REQUIREMENTS FOR

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	CR	If applicable.	
	Concern			
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	рН	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	

DATA REQUIREMENTS FOR

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		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		
5.4	Mixer/Loader/Applicator- Passive Dosimetry Data	R	One of 5.4 or 5.5 is required	
5.5	Mixer/Loader/Applicator-Biological Monitoring Data	R	See 5.4	
5.8	Dermal Absorption	CR	May be required if the margin of safety is inadequate	
5.14	Other Studies/Data/Reports	CR	If available	
8	Environmental Chemistry and Fate			
8.1	Summaries	R		
8.2	Laboratory Studies	1		
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		

DATA REQUIREMENTS FOR

Data Code	Title	Data required	Conditions	Volume No and Pages
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] (EP)			
8.3.1	Summary	CR		
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	R		
9.2	Non-Target Terrestrial Invertebrates			
9.2.1	Summary	R		
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		
9.3.5	Laboratory Studies	CR	If components of the EP are of concern	
9.3.6	Field Studies	CR	Based on concerns arising from results of other studies	
9.5	Fish			
9.5.1	Summaries	CR		
9.5.4	Laboratory Studies	CR	If components of the EP are of concern	
9.5.5	Field Studies	CR	Based on concerns arising from results of other studies	
9.6	Wild Birds			
9.6.1	Summary	R		
9.6.4	Laboratory Studies	CR	If there is a potential for exposure and components of the EP or the EP itself (e.g., granular formulations) are of concern.	
9.6.5	Field Studies	CR	Based on concerns arising from results of other studies	

DATA REQUIREMENTS FOR

Data Code	Title	Data required	Conditions	Volume No and Pages
9.6.6	Special Studies Related to the Intended Use-Pattern (TGAI or EP)	CR	See 9.6.5	
9.7	Wild Mammals			
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		
9.8.6	Laboratory Studies	CR	If components of the EP are of concern	
9.8.7	Field Studies	CR	Based on concerns arising from results of other studies	
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	CR	Once of 10.2.3.2, 10.2.3.3 or 10.2.3.4 are required	
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)	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.]	R		
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		
	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 formaulated from registered TGAIs or ISPs	CR		
12.5.4	Foreign Reviews of Toxicology	CR		
	Foreign Reviews of Exposure	CR		
	(Occupational and/or Bystander)			

DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC #33): Residential Outdoor - EP

Data Code	Title	Data required	Conditions	Volume No and Pages
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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