PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC # 11): Seed Treatments Non-Food - 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	See 8.2.1	
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		

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Data Code	Title	Data required	Conditions	Volume No and Pages
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	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 5.3	
5.5	Mixer/Loader/Applicator-Biological Monitoring Data	R	See 5.3	
5.6	Post Application-Passive Dosimetry Data	R	One of 5.6 or 5.7 is required	
5.7	Post Application-Biological Monitoring Data	R	See 5.6	
5.8	Dermal Absorption *(in vivo)*	CR	Required if margin of safety is not adequate	
5.11	Glove/Clothing Penetration Data	CR	May be rquired for risk mitigation purposes or for inadequate margin of safety	
5.13	Package Integrity Study	CR	Required if packaged in water soluble bags	

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DATA REQUIREMENTS FOR

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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 of Physicochemical Properties**			
8.2.1	Summary of Physicochemical Properties to Include, Solubility in Water, Vapour Pressure, Octanol:Water Partition Coefficient, Dissociation Constant, UV-Visible Absorption, Density or Specific Gravity (See parts 2 and 3)	R	See 3.5.6	
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	R		
8.3.2	**Terrestrial**			
8.3.2.1	Canada	R		
8.3.2.2	Northern U.S.	CR	Can substitute for some Canadian studies	
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 or EP)**			
8.4.1	Summary	R		
8.5	**Other Environmental Fate Studies (TGAI or 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	R		
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 (i.e., treated seed) are of concern	
9.6.5	Field Studies	CR	Based on concerns arising from results of other studies	
9.6.6	Special Studies Related to the Intended Use-Pattern (TGAI or EP)	CR	See 9.6.5	

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Data Code	Title	Data required	Conditions	Volume No and Pages
9.7	**Wild Mammals**			
9.7.1	Summary	CR	Based on concerns arising from the results of other studies	
9.7.2	Field Studies	CR	See 9.7.1	
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	One or both of 10.2.3.2 or 10.2.3.4 may be required	
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)	R		
10.2.3.4	Efficacy: Operational Trials	CR	See 10.2.3.2	
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	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 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		

August 15, 2005