PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR
USE SITE CATEGORY (USC # 14): Terrestrial Food Crops - 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	
4	**Toxicology**			

PEST MANAGEMENT REGULATORY AGENCY

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USE SITE CATEGORY (USC # 14): Terrestrial Food Crops - EP

Data Code	Title	Data required	Conditions	Volume No and Pages
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	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 *(in vivo)*	CR	Required if margin of exposure is inadequate	
5.9	Dislogeable Residues (Foliar, Soil and Surface)	CR	Required if there is potential for post-application exposure or to establish re-entry times	
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	

PEST MANAGEMENT REGULATORY AGENCY

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Data Code	Title	Data required	Conditions	Volume No and Pages
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 uses and crops	
6.3	Plant	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	R		
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/or 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	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	
7.7	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	
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	R		
8.2.4.6	Special Studies Related to Use-Pattern or Formulation	CR		

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR
USE SITE CATEGORY (USC # 14): Terrestrial Food Crops - EP

Data Code	Title	Data required	Conditions	Volume No and Pages
8.3	**Field Studies of Dissipation/Accumulation [May be Small or Large-Scale]**			
8.3.1	Summary	R		
8.3.2	Terrestrial	R	U.S. field studies are acceptable, if conducted at appropriate sites in relevant ecoregions (see Ecological Regions of North America, Level II)	
8.3.3	Aquatic	CR	Based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, non-target aquatic toxicity or bioaccumulation; U.S. field studies are acceptable, if conducted at appropriate sites in relevant ecoregions (see Ecological Regions of North America, Level II)	
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	Summaries	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	R		
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	
9.4	**Non-Target Marine Invertebrates**			
9.4.1	Summary	CR	If there is a potential for estuarine/marine exposure	
9.4.6	Laboratory Studies	CR	If there is a potential for exposure and components of the EP are of concern	

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR
USE SITE CATEGORY (USC # 14): Terrestrial Food Crops - EP

Data Code	Title	Data required	Conditions	Volume No and Pages
9.4.7	Field Studies	CR	Based on concerns arising from results of other studies	
9.5	**Fish**			
9.5.1	Summaries	R		
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	For granular formulations, the summary should include: (a) granule size (mm) distribution by weight; (b) number granules/kg product; (c) g ai/kg product; (d) kg product/ha; and (e) type of carrier (e.g., type of clay, corn cob, cellulose, etc)	
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	
9.6.6	Special Studies Related to the Intended Use-Pattern (TGAI and EP)	CR	See 9.6.5	
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	
9.8	**Non-Target Plants**			
9.8.1	Summary	R		
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	R		
10.2.3.2	Efficacy: Laboratory, Growth Chamber Trials	CR		

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR
USE SITE CATEGORY (USC # 14): Terrestrial Food Crops - EP

Data Code	Title	Data required	Conditions	Volume No and Pages
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)	R	One or both of 10.2.3.3. or 10.2.3.4	
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	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**			
12.5.2	Foreign Reviews of Chemistry Requirements for TGAIs or Integrated System Products	CR		
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		
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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