PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE-SITE CATEGORY (USC # 1): Aquaculture -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 and for EPs which expect to affect product efficacy	
3.5.2	Physical State	R		
3.5.3	Odour	CR	Required for manufacturing concentrates and for EPs which expect to affect product efficacy	
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		

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE-SITE CATEGORY (USC # 1): Aquaculture -EP

Data Code	Title	Data required	Conditions	Volume No and Pages
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**			
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		
5.4	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 above	
5.6	Post Application - Passive Dosimetry Data	CR	5.6 or 5.7 may be required if there is potential for post application exposure	

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE-SITE CATEGORY (USC # 1): Aquaculture -EP

Data Code	Title	Data required	Conditions	Volume No and Pages
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	
5.11	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		
6	**Metabolism/Toxicokinetics Studies (TGAI or EP)**			
6.1	Summaries	R		
6.2	Livestock - Fish/Shellfish	CR	Depending on aquatic system involved and if water/irrigated crops are fed to livestock; and if fish may be exposed to the pesticide or its degradation products	
6.3	Plants	CR	Depending on aquatic system and irrigated crop involved	
6.4	Other Studies/Data/Reports	CR	If available	
7	**Food, Feed and Tobacco Residue Studies**			
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	R		
7.4.4	Field Crop Rotation Trial Study	R		
7.4.5	Processed Food/Feed	R		
7.8	Other Studies/Data/Reports	CR	If available	
8	**Environmental Chemistry and Fate**			
8.1	Summaries	R		

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE-SITE CATEGORY (USC # 1): Aquaculture -EP

Data Code	Title	Data required	Conditions	Volume No and Pages
8.2	Laboratory Studies			
8.2.1	Summary of Physicochemical Properties to Include: Density or Specific Gravity (see Part 3 - EP)	R	Data submitted under 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	Rate of release from treated surfaces is required for antifouling products	
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	CR	If there is a potential for soil exposure	
8.3.2.2	Northern U.S.	CR	Can substitute for some Canadian studies	
8.3.2.3	Other			
8.3.3	**Aquatic**			
8.3.3.1	Canada	CR	Based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, non-target aquatic toxicity or bioaccumulation	
8.3.3.2	Northern U.S.	CR	Can augment Canadian studies	
8.3.3.3	Other			
8.3.4	Special Studies Related to Intended Use Pattern	CR	See 8.2.4.6 for rate of release from treated surfaces is required for antifouling products	
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		
9.3	**Non-Target Freshwater Invertebrates**			

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE-SITE CATEGORY (USC # 1): Aquaculture -EP

Data Code	Title	Data required	Conditions	Volume No and Pages
9.3.1	Summary	CR	If there is a potential for freshwater exposure	
9.3.5	Laboratory Studies	CR	If there is a potential for exposure and 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	
9.4.7	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 there is a potential for exposure and 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	CR		
9.6.4	Laboratory Studies	CR	If there is a potential for exposure and components of the EP 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 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	

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE-SITE CATEGORY (USC # 1): Aquaculture -EP

Data Code	Title	Data required	Conditions	Volume No and Pages
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 - TGAI	R		
10.2.2	**Description of Pest Problem**			
	Identity of Pest	R		
	Benefits/Need for Control of Pest	CR	Required if a new site-pest combination	
	Any Biological Aspect of Pest That Affect Application Rates/Timing	CR	Required if a new site-pest combination	
10.2.3	**Efficacy Trials**			
10.2.3.1	Summaries	R		
10.2.3.2	Laboratory Trials (includes minimal effective dose) including test protocol(s)	R	One or both of 10.2.3.3 or 10.2.3.4 are required	
10.2.3.3	Small-scale Trials including test protocol(s)	R	See 10.2.3.2	
10.2.3.4	Operational Trials	CR	Large scale, often unreplicated operation use trials for which a research permit is usually required. Requirement to be determined at review.	
10.3	**Adverse Effects on Use Site**			
10.3.1	Summaries	R		
10.3.2	Non-Safety Adverse Effects	R	Observation during efficacy trials that there are no known adverse effects is acceptable; Includes discoloration, corrosion, deposits, etc.	
10.4	Economics	CR	Requirement determined at preliminary review	
10.5	**Sustainability**			
10.5.1	Survey of Alternatives (chemical and non-chemical)	CR	Requirement determined at preliminary review; Includes chemical or non-chemical alternatives	
10.5.2	Compatibility with Current Management Practices Including IPM	CR	Requirement determined at preliminary review	
10.5.3	Resistance Management	CR	Requirement determined at preliminary review	
10.5.4	Contribution to Risk Reduction	CR	Requirement determined at preliminary review	

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE-SITE CATEGORY (USC # 1): Aquaculture -EP

Data Code	Title	Data required	Conditions	Volume No and Pages
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		
12.5.6	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		

August 15, 2005