

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

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

Data Code	Title	Data required	Conditions	Volume No and Pages
0	Index	R		
1	Label	R		
2	Chemistry requirements for the registration of a technical grade of active ingredient or an integrated system product.			
2.1	Applicant's Name and Office Address	R		
2.2	Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address	R		
2.3	Product Trade Name	R		
2.3.1	Other Names	R		
2.4	Common Name	R		
2.5	Chemical Name	R		
2.6	Chemical Abstracts Registry Number	R		
2.7	Structural Formula	R		
2.8	Molecular Formula	R		
2.9	Molecular Weight	R		
2.11	Manufacturing Methods for the TGAI			
2.11.1	Manufacturing Summary	R		
2.11.2	Description of Starting Materials	R		
2.11.3	Detailed Production Process Description	R		
2.11.4	Discussion of Formation of Impurities	R		
2.12	Specifications			
2.12.1	Establishing Certified Limits	R		
2.12.2	Control Product Specification Form	R		
2.13	Preliminary Analysis			
2.13.1	Methodology/Validation	R		
2.13.2	Confirmation of Identity	R		
2.13.3	Batch Data	R		
2.13.4	Impurities of Toxicological Concern	CR	If applicable	
2.14	Chemical and Physical Properties			
2.14.1	Colour	R		
2.14.2	Physical State	R		
2.14.3	Odour	R		
2.14.4	Melting Point / Melting Range	R	Solid at room temperature	
2.14.5	Boiling Point / Boiling Range	R	Liquid at room temperature	
2.14.6	Density or Specific Gravity	R		
2.14.7	Water Solubility (mg/L)	R	See 8.2.1	
2.14.8	Solvent Solubility (mg/L)	R		
2.14.9	Vapour Pressure	R	See 8.2.1	
2.14.10	Dissociation Constant	R	See 8.2.1	
2.14.11	Octanol/Water Partition Coefficient	R	See 8.2.1	
2.14.12	UV/Visible Absorption Spectra	R	See 8.2.1	

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Data Code	Title	Data required	Conditions	Volume No and Pages
2.14.13	Stability (Temperature, Metals)	R		
2.14.14	Storage Stability Data	CR	Required for integrated system products	
2.15	Sample(s) of Analytical Standards and ROC	R		
2.16	Other Studies/Data/Reports	CR	If available	
4	Toxicology			
4.1	Summaries	R		
4.2	Acute Studies — TGAI			
4.2.1	Acute Oral	R		
4.2.2	Acute Dermal	R		
4.2.3	Acute Inhalation	R		
4.2.4	Primary Eye Irritation	R		
4.2.5	Primary Dermal Irritation	R		
4.2.6	Dermal Sensitization	R		
4.2.7	Potential/Interaction	CR	If available	
4.2.8	Antidote	CR	If available	
4.2.9	Other Acute Studies	CR	If available	
4.3	Short-term Studies — TGAI			
4.3.1	Short-term Oral (90-day rodent)	R		
4.3.2	Short-term Oral (90-day and/or 12-month dog)	R		
4.3.3	Short-term Oral (28-day)	CR	If available	
4.3.4	Short-term Dermal (90-day)	CR	If available	
4.3.5	Short-term Dermal (21/28-day)	R		
4.3.6	Short-term Inhalation (90-day)	CR	Required if there is the likelihood of significant repeated inhalation exposure to the product as a gas, vapor or aerosol	
4.3.7	Short-term Inhalation (21/28-day)	CR	If available	
4.3.8	Other Short-term Studies	CR	If available	
4.4	Long-term Studies — TGAI			
4.4.1	Chronic (rodent)	R	4.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4	
4.4.2	Oncogenicity (rodent species 1)	R	4.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4	
4.4.3	Oncogenicity (rodent species 2)	R		
4.4.4	Combined Chronic/Oncogenicity (rodent)	CR	4.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4	
4.4.5	Other Long-term Studies	CR	If available	
4.5	Special Studies — TGAI			
4.5.1	Multigeneration Reproduction (rodent)	R		

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Data Code	Title	Data required	Conditions	Volume No and Pages
4.5.2	Prenatal Developmental Toxicity (rodent)	R		
4.5.3	Prenatal Developmental Toxicity (non-rodent)	R		
4.5.4	Genotoxicity: Bacterial Reverse Mutation Assay	R		
4.5.5	Genotoxicity: In vitro Mammalian Cell Assay	R		
4.5.6	Genotoxicity: In vitro Mammalian Clastogenicity	CR	Required if not addressed in study submitted for 4.5.5	
4.5.7	Genotoxicity: In vivo Cytogenetics	R		
4.5.8	Other Genotoxicity Studies	CR	If available	
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animals)	R		
4.5.10	Acute Delayed Neurotoxicity (hen)	CR	Required if the test substance is an organophosphorus substance or is structurally related to other substances that may cause delayed neurotoxicity	
4.5.11	28-day Delayed Neurotoxicity (hen)	CR	Required if results of acute delayed neurotoxicity study indicates effects, or if other available data indicate the potential for this type of delayed neurotoxicity	
4.5.12	Acute Neurotoxicity (rat)	CR	Required if there is neurotoxic potential	
4.5.13	90-day Neurotoxicity (rat)	CR	Required if there is neurotoxic potential	
4.5.14	Developmental Neurotoxicity	CR	Required if neurological effects are observed in other studies Should be considered if test substance: i) causes neuropathology or neurotoxicity in adults; ii) is hormonally active <i>in vivo</i> ; or iii) causes other types of nervous system involvement at a developmental stage	
4.8	Other Studies/Data/Reports	CR	If available	
6	Metabolism/Toxicokinetics Studies (TGAI or EP)			
6.1	Summaries	R		

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Data Code	Title	Data required	Conditions	Volume No and Pages
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	
8	Environmental Chemistry and Fate			
8.1	Summaries	R		
8.2	Laboratory Studies			
8.2.1	Summary of Physicochemical Properties to include: Density or Specific Gravity, Solubility in Water, Vapour Pressure, Dissociation Constant, Octanol/Water Partition Coefficient, UV-Visible Absorption (See Part 2)	R	Data submitted under 2.14.6; 2.14.7; 2.14.9; 2.14.10; 2.14.11; and 2.14.12	
8.2.2	Analytical Methodology (parent compound and transformation products)			
8.2.2.1	Soil	CR	If there is a potential for soil exposure	
8.2.2.2	Sediment	R		
8.2.2.3	Water	R		
8.2.2.4	Biota	R		
8.2.3	Laboratory Studies of Transformation			
8.2.3.1	Summary	R		
8.2.3.2	Hydrolysis	R		
8.2.3.3	Phototransformation			
8.2.3.3.1	Soil	CR	If there is a potential for soil exposure	
8.2.3.3.2	Water	R		
8.2.3.3.3	Air	CR	If volatilization is indicated by vapour pressure or Henry's Law Constant	
8.2.3.4	Biotransformation in Soil			
8.2.3.4.2	Aerobic Soil 20°-30°C	CR	If there is a potential for soil exposure	
8.2.3.5	Biotransformation in Aquatic Systems			
8.2.3.5.2	Aerobic Water 20°-30°C	R	Preferred over 8.2.3.5.4	
8.2.3.5.4	Aerobic Water/Sediment 20°-30°C	CR	If partitioning into sediment is expected.	
8.2.3.5.6	Anaerobic Sediment/Water 20°-30°C	CR	See 8.2.3.5.4	
8.2.4	Laboratory Studies of Mobility			

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Data Code	Title	Data required	Conditions	Volume No and Pages
8.2.4.1	Summary	R		
8.2.4.2	Adsorption/Desorption	R	With aquatic sediment rather than soil for marine sediment, the requirement is CR, based on solubility, persistence in seawater, and log Kow	
8.2.4.3	Soil Column Leaching			
8.2.4.3.1	Unaged Soil	CR	One of 8.2.4.3.1; 8.2.4.3.2; or 8.2.4.4, if there is a potential for soil exposure	
8.2.4.3.2	Aged Soil	CR	See 8.2.4.3.1	
8.2.4.4	Soil TLC Leaching	CR	See 8.2.4.3.1	
8.2.4.5	Volatilization	CR	If volatilization is indicated by vapour pressure or Henry's Law Constant	
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			
9.3.1	Summary	CR	If there is a potential for freshwater exposure	
9.3.2	<i>Daphnia</i> sp. Acute	CR	See 9.3.1	
9.3.3	<i>Daphnia</i> sp. Chronic (Life-Cycle)	CR	Most sensitive (i.e., one of) daphnid (9.3.3); marine crustacean or estuarine/marine mollusk (9.4.5); or fish (9.5.3.1), where there is concern based on acute effects, persistence, potential for exposure or frequency of application	
9.3.4	Laboratory Studies with Other Species	CR	If there is a potential for exposure	
9.4	Non-Target Marine Invertebrates			
9.4.1	Summary	CR	If there is a potential for estuarine/marine exposure	
9.4.2	Acute (Crustacean)	CR	See 9.4.1	

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USE SITE CATEGORY (USC # 1): Aquaculture - TGA1

Data Code	Title	Data required	Conditions	Volume No and Pages
9.4.3	Mollusk embryo larvae	CR	One of 9.4.3 or 9.4.4 is required, if there is a potential for estuarine/marine exposure	
9.4.4	Mollusk shell deposition	CR	See 9.4.3	
9.4.5	Chronic (Mollusk or Crustacean)	CR	Most sensitive (i.e., one of) daphnid (9.3.3); marine crustacean or estuarine/marine mollusk (9.4.5); or fish (9.5.3.1), where there is concern based on acute effects, persistence, potential for exposure or frequency of application	
9.4.8	Bioconcentration/Depuration (bivalve or Crustacean)	CR	If log Kow is greater than or equal to 3	
9.5	Fish			
9.5.1	Summaries	CR		
9.5.2	Acute Studies			
9.5.2.1	Cold Water Fish (rainbow trout)	CR	If there is a potential for freshwater exposure	
9.5.2.2	Warm Water Fish (bluegill sunfish)	CR	See 9.5.2.1	
9.5.2.3	Other Freshwater Fish Species	CR	If there is a potential for exposure	
9.5.2.4	Marine/Estuarine Fish	CR	If there is a potential for estuarine/marine exposure	
9.5.2.4.1	Salinity Challenge	CR	For estuarine fish; to follow 9.5.2.4 (if there is a potential for exposure)	
9.5.3	Sublethal and Chronic Studies			
9.5.3.1	Fish, Early Life Cycle Tox. Test	CR	Most sensitive (i.e., one of) daphnid (9.3.3); marine crustacean or estuarine/marine mollusk (9.4.5); or fish (9.5.3.1), where there is concern based on acute effects, persistence, potential for exposure or frequency of application	
9.5.3.2	Fish, Life Cycle Tox. Test	CR	Where there is concern based on acute effects, persistence, potential for exposure or frequency of application	
9.5.6	Bioaccumulation	CR	If log Kow is greater than or equal to 3	
9.6	Wild Birds			
9.6.1	Summary	CR		
9.6.2	Acute Studies			

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

Data Code	Title	Data required	Conditions	Volume No and Pages
9.6.2.2	Oral (LD50) Mallard Duck	CR	If there is a potential for freshwater exposure	
9.6.2.3	Oral (LD50) Other Species	CR	If avian acute oral toxicity is of concern and there is a potential for exposure	
9.6.2.5	Dietary (LC50) Mallard Duck	CR	If there is a potential for freshwater exposure.	
9.6.2.6	Dietary (LC50) Other Species	CR	If avian acute dietary toxicity is of concern and there is a potential for exposure.	
9.6.3	Chronic Studies			
9.6.3.2	Avian Reproduction Mallard Duck	CR	Triggered by acute effects, persistence, bioconcentration potential, mammalian reproductive effects, potential for exposure or frequency of application	
9.6.3.3	Avian Reproduction Other Species	CR	See 9.6.3.2	
9.6.6	Special Studies Related to the Intended Use-Pattern (TGAI and EP)	CR	Based on concerns arising from the results of other studies	
9.7	Wild Mammals			
9.7.1	Summary	CR	Based on concerns arising from results of other studies	
9.7.3	Other Studies	CR	See 9.7.1	
9.8	Non-Target Plants			
9.8.1	Summary	CR		
9.8.2	Fresh Water Algae	CR	If there is potential for freshwater exposure	
9.8.3	Marine Algae	CR	If there is a potential for estuarine/marine exposure	
9.8.5	Aquatic Vascular Plants	CR	If there is a potential for freshwater exposure	
9.9	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		
12.5.4	Foreign Reviews of Toxicology	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		

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Data Code	Title	Data required	Conditions	Volume No and Pages
12.5.9	Foreign Reviews of Environmental Toxicology	CR		
12.7	Comprehensive Data Summaries	R		

August 15, 2005