

PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC # 14): Terrestrial Food Crops - 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 (TGAI) 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		
2.14.8	Solvent Solubility (mg/L)	R		
2.14.9	Vapour Pressure	R		
2.14.10	Dissociation Constant	R		
2.14.11	Octanol/Water Partition Coefficient	R		
2.14.12	UV/Visible Absorption Spectra	R		

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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	R		
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	Potentiation/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		
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		

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Data Code	Title	Data required	Conditions	Volume No and Pages
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		
6.2	Livestock	CR	Depends on end use of crop and by-products	
6.3	Plants	R		
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, Solubility in Water, Vapour Pressure, Octanol:Water Partition Coefficient, Dissociation Constant and UV-Visible Absorption (See Part 2) (TGAI)	R	Data submitted under 2.14.7; 2.14.9; 2.14.10; 2.14.11; and 2.14.12	

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Data Code	Title	Data required	Conditions	Volume No and Pages
8.2.2	Analytical Methodology (parent compound and transformation products)			
8.2.2.1	Soil	R		
8.2.2.2	Sediment	R	Can be satisfied by analytical methodology for soil (8.2.2.1)	
8.2.2.3	Water	R		
8.2.2.4	Biota	R	Required for both plant and animal (preferably fish) matrices	
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	R	Not required if application is only by soil injection or soil incorporation	
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	R		
8.2.3.4.4	Anaerobic Soil (Flooded) 20°-30°C	R		
8.2.3.5	Biotransformation in Aquatic Systems			
8.2.3.5.4	Aerobic Water/Sediment 20°-30°C	R		
8.2.3.5.6	Anaerobic Aquatic Sediment 20°-30°C	R		
8.2.4	Laboratory Studies of Mobility			
8.2.4.1	Summary	R		
8.2.4.2	Adsorption/Desorption	R	Adsorption and desorption (8.2.4.2) is preferred, however in some cases, soil column leaching (8.2.4.3) with unaged or aged columns may be necessary to fully characterize the potential mobility of the parent compound and major transformation products	
8.2.4.3	Soil Column Leaching			
8.2.4.5	Volatilization	CR	If volatilization is indicated by vapour pressure or Henry's Law Constant; studies conducted with a typical EP are acceptable and should be submitted under 8.2.4.6	
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	

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Data Code	Title	Data required	Conditions	Volume No and Pages
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		
9.2.3	Earthworms			
9.2.3.1	Acute Toxicity	R		
9.2.4	Bees/Pollinators			
9.2.4.1	Acute Contact	CR	If there is a potential for exposure	
9.2.4.2	Acute Oral	CR	See 9.2.4.1	
9.2.4.3	Hive Study (including Brood)	CR	If there is a potential for exposure, especially for Insect Growth Regulators (IGRs)	
9.2.5	Predators	CR	If there is a potential for exposure	
9.2.6	Parasites	CR	See 9.2.5	
9.2.7	Other Terrestrial Invertebrates	CR	See 9.2.5	
9.3	Non-Target Freshwater Invertebrates			
9.3.1	Summary	R		
9.3.2	<i>Daphnia</i> sp. Acute	R		
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	
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	

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Data Code	Title	Data required	Conditions	Volume No and Pages
9.4.8	Bioconcentration/Depuration (Bivalve or Crustacean)	CR	If there is a potential for exposure and log Kow is greater than or equal to 3	
9.5	Fish			
9.5.1	Summaries	R		
9.5.2	Acute Studies			
9.5.2.1	Cold Water Fish (Rainbow Trout)	R		
9.5.2.2	Warm Water Fish (Bluegill Sunfish)	R		
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 Toxicity 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 Toxicity 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	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)	
9.6.2	Acute Studies			
9.6.2.1	Oral (LD50) Bobwhite Quail	CR	One of 9.6.2.1 or 9.6.2.2 is required (R)	
9.6.2.2	Oral (LD50) Mallard Duck	CR	See 9.6.2.1	
9.6.2.3	Oral (LD50) Other Species	CR	If avian acute oral toxicity is of concern and there is a potential for exposure	
9.6.2.4	Dietary (LC50) Bobwhite Quail	R		
9.6.2.5	Dietary (LC50) Mallard Duck	R		
9.6.2.6	Dietary (LC50) Other Species	CR	If avian acute dietary toxicity is of concern and there is a potential for exposure	

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Data Code	Title	Data required	Conditions	Volume No and Pages
9.6.3	Chronic Studies			
9.6.3.1	Avian Reproduction Bobwhite Quail	R		
9.6.3.2	Avian Reproduction Mallard Duck	R		
9.6.3.3	Avian Reproduction Other Species	CR	If avian reproductive toxicity is of concern and there is a potential for exposure	
9.6.6	Special Studies Related to the Intended Use-Pattern (TGAI and EP)	CR	Based on concerns arising from results of other studies	
9.7	Wild Mammals			
9.7.1	Summary	CR	Based on concerns arising from the results of other studies	
9.8	Non-Target Plants			
9.8.1	Summary	R		
9.8.2	Fresh Water Algae	R		
9.8.3	Marine Algae	CR	If there is a potential for estuarine/marine exposure	
9.8.4	Terrestrial Vascular Plants	R		
9.8.5	Aquatic Vascular Plants	R		
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		
12.5.8	Foreign Reviews of Environmental Chemistry and Fate	CR		
12.5.9	Foreign Reviews of Environmental Toxicology	CR		
12.7	Comprehensive Data Summaries	R		

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