DATA REQUIREMENTS FOR

Data Code	Title	Data required	Conditions	Volume No and Pages
0	Index	R		und Tages
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	R		
2.2	Manufacturing Plant's Name and Address	1		
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	See 8.2.1	
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	

DATA REQUIREMENTS FOR

2.14.14 Storage Stability Data	Data Code	Title	Data required	Conditions	Volume No and Pages
2.14.14 Storage Stability Data	2.14.13	Stability (Temperature, Metals)			9
2.15 Sample(s) of Analytical Standards and ROC R	2.14.14		CR	Required for integrated system products	
2.16	2.15		R		
	2.16		CR	If available	
A.1 Summaries	4				
Acute Studies — TGAI	4.1		R		
Acute Oral	4.2	Acute Studies — TGAI			
A.2.2 Acute Dermal R	4.2.1		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 R 4.2.8 Antidote CR If available 4.2.9 Other Acute Studies TGAI 4.3.1 Short-term Studies — TGAI 4.3.2 Short-term Oral (90-day rodent) R 4.3.3 Short-term Oral (90-day and/or 12-month dog) CR If available 4.3.4 Short-term Dermal (90-day) CR If available 4.3.5 Short-term Dermal (90-day) CR If available 4.3.6 Short-term Dermal (21/28-day) R 4.3.7 Short-term Inhalation (90-day) CR If available 4.3.8 Other Short-term Inhalation (21/28-day) R 4.3.9 Short-term Inhalation (21/28-day) CR If available 4.3.1 Chronic (rodent) CR If available 4.3.2 Short-term Inhalation (21/28-day) R 4.3.3 Short-term Inhalation (21/28-day) R 4.3.4 Short-term Inhalation (21/28-day) CR If available 4.3.5 Short-term Inhalation (21/28-day) CR If available 4.3.6 Short-term Inhalation (21/28-day) CR If available 4.3.7 Short-term Inhalation (21/28-day) CR If available 4.3.8 Other Short-term Studies CR If available 4.4.1 Cong-term Studies CR If available 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 4.4.2 Oncogenicity (rodent species 2) R 4.4.3 Oncogenicity (rodent species 2) R 4.4.4 Combined Chronic/Oncogenicity (rodent) CR A.4.1 and A.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 Other Long-term Studies CR If available 4.5.1 Multigeneration Reproduction (rodent) R 4.5.2 Prenatal Developmental Toxicity (rodent) R 4.5.3 Prenatal Developmental Toxicity (rodent) R 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R	4.2.2				
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A.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 A.3.7 Short-term Inhalation (21/28-day) CR If available A.3.8 Other Short-term Studies CR If available A.4.1 Long-term Studies — TGAI A.4.1 Chronic (rodent) Chronic (rodent) R A.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4 A.4.2 Oncogenicity (rodent species 1) CR A.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4 A.4.3 Oncogenicity (rodent species 2) A.4.4 Combined Chronic/Oncogenicity (rodent) CR A.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4 A.5 Other Long-term Studies CR If available A.5 Special Studies — TGAI A.5.1 Multigeneration Reproduction (rodent) R A.5.2 Prenatal Developmental Toxicity (rodent) R A.5.3 Prenatal Developmental Toxicity (non-rodent) R A.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R		` **		ar uvuruuste	
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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 4.4.1 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	1.5.0	phote term innatation (50 day)		*	
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 6.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R				-	
A.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 Genotoxicity: Bacterial Reverse Mutation Assay R	4.3.7	Short-term Inhalation (21/28-day)	CR		
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 4.5.1 Multigeneration Reproduction (rodent) R 4.5.2 Prenatal Developmental Toxicity (rodent) R 4.5.3 Prenatal Developmental Toxicity (non-rodent) R Genotoxicity: Bacterial Reverse Mutation Assay R	4.3.8				
A.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 7 4.5.3 Prenatal Developmental Toxicity (non-rodent) R 8 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R	4.4				
A.4.2 Oncogenicity (rodent species 1) R	4.4.1		R		
4.4.3 Oncogenicity (rodent species 2) 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) 4.5.2 Prenatal Developmental Toxicity (rodent) 4.5.3 Prenatal Developmental Toxicity (non-rodent) 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R	4.4.2	Oncogenicity (rodent species 1)	R	4.4.1 and 4.4.2 could be submitted as a	
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) 4.5.3 Prenatal Developmental Toxicity (non-rodent) R 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R	4.4.3	Oncogenicity (rodent species 2)	R		
4.4.5 Other Long-term Studies 4.5 Special Studies — TGAI 4.5.1 Multigeneration Reproduction (rodent) 4.5.2 Prenatal Developmental Toxicity (rodent) 4.5.3 Prenatal Developmental Toxicity (non-rodent) 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R If available R R	4.4.4		CR		
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	4.4.5	Other Long-term Studies	CR	· ·	
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	4.5				
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	4.5.1	±	R		
4.5.3 Prenatal Developmental Toxicity (non-rodent) R 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R	4.5.2				
4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay R					
	4.5.5	Genotoxicity: In vitro Mammalian Cell Assay	R		

DATA REQUIREMENTS FOR

Data Code	Title	Data required	Conditions	Volume No and Pages
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 in vivo; or iii) causes other types of nervous system involvement at a developmental stage	
4.8	Other Studies/Data/Reports	CR	If available	
8	Environmental Chemistry and Fate	O.I.	ar wywine is	
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.	R	See 2.14.13; 2.14.10; 2.14.7; 2.14.11; 2.14.6 and 2.14.9.	
8.2.2	Analytical Methodology (parent compound and transformation products)			
8.2.2.1	Soil	R		
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		

DATA REQUIREMENTS FOR

Data Code	Title	Data required	Conditions	Volume No and Pages
8.2.3.2	Hydrolysis	R		Ŭ
8.2.3.3	Phototransformation			
8.2.3.3.1	Soil	R		
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 20°-30°C	CR	Can be satisfied by 8.2.3.5.6	
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	R		
8.2.4	Laboratory Studies of Mobility			
8.2.4.1	Summary	R		
8.2.4.2	Adsorption/Desorption	CR	One of 8.2.4.2; 8.2.4.3.1; 8.2.4.3.2; or	
			8.2.4.4 is required (R)	
8.2.4.3	Soil Column Leaching			
8.2.4.3.1	Unaged Soil	CR	See 8.2.4.2	
8.2.4.3.2	Aged Soil	CR	See 8.2.4.2	
8.2.4.4	Soil TLC Leaching	CR	See 8.2.4.2	
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 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 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		
9.2.3	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)	

DATA REQUIREMENTS FOR

Data	Title	Data	Conditions	Volume No
Code	D. 1.	required	70.1	and Pages
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	Daphnia sp. Acute	R		
9.3.3	Daphnia 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 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, 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 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		¥	

DATA REQUIREMENTS FOR

Data	Title	Data	Conditions	Volume No
Code		required		and Pages
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	R		
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	
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	
9.6.3	Chronic Studies			
9.6.3.1	Avian Reproduction Bobwhite Quail	CR	Triggered by acute effects, persistence,	
			bioconcentration potential, mammalian	
			reproductive effects, potential for	
			exposure or frequency of application	
9.6.3.2	Avian Reproduction Mallard Duck	CR	See 9.6.3.1	
9.6.3.3	Avian Reproduction Other Species	CR	See 9.6.3.1	
9.6.6	Special Studies Related to the Intended Use-Pattern	CR	See 9.6.5	
	(TGAI or EP)			
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	

DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC #7): Industrial Oil Seed Crops and Fibre Crops - TGAI

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

August 15, 2005