PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR IMPORT MRLs ON USE SITE CATEGORY

(USC # 12): Stored Food and Feed

Data Code	Title	Data required	Conditions	Present/ Absent
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		
2.10	Canadian Patent Status	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	CR	A justification must be provided if standard limits are not met.	
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	Vapor Pressure	R		
2.14.10	Dissociation Constant	R		

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Data Code	Title	Data required	Conditions	Present/ Absent
2.14.11	Octanol/Water Partition Coefficient	R		
2.14.12	pH	R		
2.14.13	UV/Visible Absorption Spectra	R		
2.14.14	Stability (Sunlight, Temperature, Metals)	R		
2.14.15	Storage Stability Data	R	Ambient 1 year may be submitted later but short term data is required	
2.15	Other Studies/Data/Reports/Foreign Reviews			
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			
3.1.2	Formulating Plant's Name and Address			
3.1.3	Trade Name			
3.1.4	Other Names			
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 aplicable.	
3.3	Specifications			
3.3.1	Establishing Certified Limits	CR	A justification must be provided if standard limits are not met.	
3.3.2	Additional Product Specific Requirements			
3.3.2.1	Granules and Baits	CR	If applicable.	
3.3.2.2	Seed Coatings	CR	If applicable.	
3.3.3	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	R		
3.5.2	Physical State	R		
3.5.3	Odour	R		
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		

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Data Code	Title	Data required	Conditions	Present/ Absent
3.5.10	Storage Stability Data	R	Ambient 1 year may be submitted later but short term data is required	
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	Other Studies/Data/Reports/Foreign Reviews			
4	**Toxicology**			
4.1	Summaries	R		
4.2	**Acute Studies — TGAI**			
4.2.1	Acute Oral	R		
4.2.2	Acute Dermal	NR		
4.2.3	Acute Inhalation	NR		
4.2.4	Primary Eye Irritation	NR		
4.2.5	Primary Dermal Irritation	NR		
4.2.6	Dermal Sensitization	NR		
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)	NR		
4.3.5	Short-term Dermal (21/28-day)	NR		
4.3.6	Short-term Inhalation (90-day)	NR		
4.3.7	Short-term Inhalation (21/28-day)	NR		
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		

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Data Code	Title	Data required	Conditions	Present/ Absent
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 *in vivo*; or iii) causes other types of nervous system involvement at a developmental stage	
4.6	**Acute Studies — EP**			
4.6.1	Acute Oral	CR	If available	
4.6.2	Acute Dermal	NR		
4.6.3	Acute Inhalation	NR		
4.6.4	Primary Eye Irritation	NR		
4.6.5	Primary Dermal Irritation	NR		
4.6.6	Dermal Sensitization	NR		
4.6.7	Potentiation/Interaction	CR	If available	
4.6.8	Other Acute Studies	CR	If available	

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DATA REQUIREMENTS FOR IMPORT MRLs ON USE SITE CATEGORY

(USC # 12): Stored Food and Feed

Data Code	Title	Data required	Conditions	Present/ Absent
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)	NR		
4.7.4	Short-term Dermal (21/28-day)	NR		
4.7.5	Short-term Inhalation (21/28-day)	NR		
4.7.6	Short-term Inhalation (90-day)	NR		
4.7.7	Other Special Studies	CR	See 4.7	
4.8	Other Studies/Data/Reports	CR	If available	
6	**Metabolism/Toxicokinetics Studies (TGAI or EP)**			
6.1	Summaries	R	Input to assessment of toxicity to wildlife	
6.2	Livestock	CR	If fed	
6.4	Other Studies/Data/Reports/Foreign Reviews	CR	Reference reached commodity	
7	**Food, Feed and Tobacco Residue Studies**			
7.1	Summaries	R	Input to assessment of wildlife exposure	
7.2	**Analytical Methodology (Food Crops & Tobacco)**			
7.2.1	Supervised Residue Trial Analytical Methodology	R		
7.3	Freezer Storage Stability Tests	CR	Depends on length of storage	
7.4	**Crop Residue Data**			
7.4.1	Supervised Residue Trial Study	R		
7.4.2	Temporal Residue Trial Study	CR		
7.4.5	Processed Food/Feed	CR		
7.4.6	Residue Data for Crops used as Livestock Feed	CR	See 7.5	
7.5	Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops)	CR	If fed	
7.7	Tobacco Residue Data	CR		
7.8	Other Studies/Data/Reports/Foreign Reviews	CR		

August 15, 2005