

**PEST MANAGEMENT REGULATORY AGENCY**

**DATA REQUIREMENTS FOR**

**USE SITE CATEGORY (USC # 24): Companion Animals - TGAI**

<b>Data Code</b>	<b>Title</b>	<b>Data required</b>	<b>Conditions</b>	<b>Volume No and Pages</b>
<b>0</b>	<b>Index</b>	<b>R</b>		
<b>1</b>	<b>Label</b>	<b>R</b>		
<b>2</b>	<b>Chemistry requirements for the registration of a technical grade of active ingredient (TGAI) or an integrated system product.</b>			
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		
<b>2.11</b>	<b>Manufacturing Methods for the TGAI</b>			
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		
<b>2.12</b>	<b>Specifications</b>			
2.12.1	Establishing Certified Limits	R		
2.12.2	Control Product Specification Form	R		
<b>2.13</b>	<b>Preliminary Analysis</b>			
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	
<b>2.14</b>	<b>Chemical and Physical Properties</b>			
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		

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2.14.12	UV/Visible Absorption Spectra	R		
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	
<b>4</b>	<b>Toxicology</b>			
4.1	Summaries	R		
<b>4.2</b>	<b>Acute Studies — TGAI</b>			
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	
<b>4.3</b>	<b>Short-term Studies — TGAI</b>			
4.3.1	Short-term Oral (90-day rodent)	R		
4.3.2	Short-term Oral (90-day and/or 12-month dog)	CR	If available	
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	
<b>4.4</b>	<b>Long-term Studies — TGAI</b>			
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	
<b>4.5</b>	<b>Special Studies — TGAI</b>			
4.5.1	Multigeneration Reproduction (rodent)	R		
4.5.2	Prenatal Developmental Toxicity (rodent)	R		
4.5.3	Prenatal Developmental Toxicity (non-rodent)	R		

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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	
<b>12.5</b>	<b>Foreign Reviews</b>			
12.5.2	Foreign Reviews of Chemistry Requirements for TGAIs or Integrated System Products			
12.5.4	Foreign Reviews of Toxicology			
<b>12.7</b>	<b>Comprehensive Data Summaries</b>			

August 15, 2005