PEST MANAGEMENT REGULATORY AGENCY

DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC # 26): Human Skin, Clothing and Proximal Sites - EP

Data Code	Title	Data required	Conditions	Volume No and Pages
0	**Index**	**R**		
1	**Label**	**R**		
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	R		
3.1.2	Formulating Plant's Name and Address	R		
3.1.3	Trade Name	R		
3.1.4	Other Names	R		
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 applicable.	
3.3	**Specifications**			
3.3.1	Establishing Certified Limits	R		
3.3.2	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	CR	Required for manufacturing concentrates only	
3.5.2	Physical State	R		
3.5.3	Odour	CR	Required for manufacturing concentrates only	
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		
3.5.10	Storage Stability Data	R		
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		

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Data Code	Title	Data required	Conditions	Volume No and Pages
3.6	Sample(s)	CR	If requested by PMRA	
3.7	Other Studies/Data/Reports	CR	If available	
4	**Toxicology**			
4.1	Summaries	R		
4.6	**Acute Studies — EP**			
4.6.1	Acute Oral	R		
4.6.2	Acute Dermal	R		
4.6.3	Acute Inhalation	R		
4.6.4	Primary Eye Irritation	R		
4.6.5	Primary Dermal Irritation	R		
4.6.6	Dermal Sensitization	R		
4.6.7	Potentiation/Interaction	CR	If available	
4.6.8	Other Acute Studies	CR	If available	
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)	CR	See 4.7	
4.7.4	Short-term Dermal (21/28-day)	CR	See 4.7	
4.7.5	Short-term Inhalation (21/28-day)	CR	See 4.7	
4.7.6	Short-term Inhalation (90-day)	CR	See 4.7	
4.7.7	Other Special Studies	CR	See 4.7	
4.8	Other Studies/Data/Reports	CR	If available	
5	**Exposure (Occupational and/or Bystander)**			
5.1	Summaries	R		
5.2	Use Description/Scenario (Application and Post Application)	R		
5.4	Mixer/Loader/Applicator- Passive Dosimetry Data	CR	One of 5.4 or 5.5 is required when clothing or other materials are impregnated with products in an industrial setting	
5.5	Mixer/Loader/Applicator-Biological Monitoring Data	CR	See 5.4	
5.7	Post Application-Biological Monitoring Data	CR	One of 5.7 or 5.8 may be required for products that are directly applied to human skin	
5.8	Dermal Absorption	CR	See 5.7	
5.10	Ambient Air Samples (Indoor - Outdoor)	CR	If there is a potential for post- application inhalation exposure	
5.14	Other Studies/Data/Reports	CR	Leaching and/or migration studies may be required for products impregnated into clothing or other materials	

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DATA REQUIREMENTS FOR

USE SITE CATEGORY (USC # 26): Human Skin, Clothing and Proximal Sites - EP

Data Code	Title	Data required	Conditions	Volume No and Pages
10	**Value (applicable to each pest/site or host combination)**			
10.1	Value Summaries	R		
10.2	**Efficacy Studies**			
10.2.1	Mode of Action	R		
10.2.2	Description of Pest Problem	R		
10.2.3	**Efficacy Trials**			
10.2.3.1	Summaries	R		
10.2.3.2	Efficacy: Laboratory, Growth Chamber Trials	CR		
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)	R	One or both of 10.2.3.3 or 10.2.3.4 may be required	
10.2.3.4	Efficacy: Operational Trials	CR	See 10.2.3.3	
10.3	**Adverse Effects on Use Site**			
10.3.1	Summaries	R		
10.3.2	Non-Safety Adverse Effects [e.g.: to crop, site of application (discoloration, corrosion), etc.]	R		
10.3.3	Damage to Rotational Crops	CR		
10.4	Economics	R		
10.5	**Sustainability**			
10.5.1	Survey of Alternatives (chemical and non-chemical)	CR		
10.5.2	Compatibility with Current Management Practices Including IPM	CR		
10.5.3	Resistance Management	CR		
10.5.4	Contribution to Risk Reduction	CR		
10.6	Other Studies/Data/Reports	CR	If available	
12.5	**Foreign Reviews**			
12.5.3	Foreign Reviews of Chemistry Requirements for MAs and EPs formulated from registered TGAIs or ISPs	CR		
12.5.4	Foreign Reviews of Toxicology	CR		
12.5.5	Foreign Reviews of Exposure (Occupational and/or Bystander)	CR		
12.5.10	Foreign Reviews of Value	CR		
12.7	**Comprehensive Data Summaries**	R		

August 15, 2005