Table 2.2[1]
Data Requirement for the Registration and Experimental Uses of All Pesticide Products

Name of data requirement	Use pattern[1] Agricultural	Active ingredient Tech Grade 2	Formulation[2]	EUP[2]	Remarks
1.0 GENERAL					
1.1 Name/address of applicant	R	R	R	A	Required in all cases
1.2 Product Trade/Brand Name	R	R	R	2, 3	-do-
1.3 Manufacturer of Technical Pesticide	R	R	R	A	-do-
1.4 Description of Production Process[3]	R	R	R	X	-do-
2.0 SPECIFICATIONS					
2.1 Common Name of Active Ingredient (Proposed or Accepted ISO name)		R	R	2, 3	-do-
2.2 Chemical Name of Active Ingredient (IUPAC designation)	R	R	R	2, 3	-do-
2.3 Chemical Abstract Service Number	R	R	X	2, 3	-do-
2.4 Formulas (empirical and structural)	R	R	X	2, 3	-do-
2.5 Composition of Technical including impurities (all materials present at or over 0.1%)[4]	R	R	X	2	-do-
2.6 List of ingredients and per cent variations of each[5]	R	R	R	2, 3	-do-
2.7 Appearance, color, state, odor	R	R	R	A	-do-
2.8 Melting point	R	R	X	A	If solid at room temp
2.9 Boiling point	R	R	X	A	If liquid at room temp
2.10 Vapor pressure	R	At 20-25 °C	X	A	Only if $>10^{-3}$ Pascal
2.11 Density or Specific Gravity	R	R	R	A	Required in all cases
2.12 Octanol Partition Coefficient - half-life in soil - K_{oc1} organic carbon partition coefficient	R	R	X	A	Required if Technical A.I. is organic and non-polar
2.13 Formulation Type (GCFP code) [6]	R	X	R	2, 3	
2.14 Storage Stability	R	X	R	2, 3	
2.15 Solubility in water and solvents	R	R	X	2	
2.16 Suspensibility/Emulsifying Characteristics	R	X	R	2	
2.17 Known capability/incompatibility with other pesticide products or Active Ingredients	R	X	R	X	
2.18 Flash point and other indicators of flammability	@	R	R	2, 3	If product contains combustible liquid
2.19 pH	R	R	R	2, 3	
2.20 Methods of destruction or disposal	R	R	R	A	For EUP, includes treated crop disposition

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2.21 Packaging type, sizes and materials	R	R	R	A	
2.22 Assessment of Need of Child-Resistant Packaging	X	X	R	X	For Toxicity Category I and II
2.23 Analytical Methods for Constituents	R	R	R	2	
2.24 Submittal of product samples	R	10g	500ml./0.5kg	X	Analytical Grade A.I, 1g required unless reasons provided by applicant
3.0 BIOEFFICACY (Typical Formulation)					
3.1 Description of mode of action or effect on pest for which control is claimed	R	X	R	X	
3.2 Pests controlled and names of crops, materials or premises to be protected	R	X	R	A	
3.3 Application rate (Kg a.i/Ha or % a.i. spray dilution of each site/pest listed	R	X	R	A	
3.4 Frequency and timing or application for each site/pest listed	R	X	R	A	
3.5 Method of application (ULV, backpack, sprayer, fumigation, etc.)	R	X	R	A	
3.6 Phytotoxicity	R	X	R	2,3	
3.7 Results of laboratory studies, if any	R	X	R	A	
3.8 Complete description and data from local field trials or relevant test performed abroad or request for waiver for each site/pest on label	R	X	R	X	
3.9 Effects on beneficial organisms	@	R	Appropriate pest/predator or parasite complex	X	Technical or formulated material may be used; reflect field use conditions
4.0 TOXICOLOGY					
4.1 Estimation of Acute Oral LD_{50} [7]	R	Study in rat	Study in rat	A	Calculation permissible in some cases from TGAI
4.2 Estimation of Acute Dermal LD_{50} [7]	R	Study in rabbit	Study in rabbit	A	-do-
4.3 Inhalation LC_{50}	@	Study in rat	Study in rat	A	Required only if pesticide has high vapor pressure or if used as gas, fog, smoke, fumigant or contains respirable dust
4.4 Skin Irritation/Corrosivity	R	Unabraded rabbit skin	Unabraded rabbit skin	A	

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Name of data requirement	Use pattern[1]	Active ingredient Tech Grade 2	Formulation[2]	EUP[2]	Remarks
	Agricultural				
4.5 Eye Irritation	@	X	Study in rabbit	2, 3	Not required if pH is less than 3 or greater than 11.5; or if corrosive to skin
4.5.1 Dermal Sensitization	R	X	Study in guinea pig	2, 3	
4.6 Allergic Sensitization	@	X	R	2	If positive in 4.5.1
4.7 Subchronic toxicity (21 day, dermal)	X				
4.7.1 Subchronic toxicity (90 days, oral)	R	Studies in rodent (oral)	X	2	Two species for food crop, one for non-food; required for household if significant exposure
4.7.2 Subchronic toxicity (90 days, dermal)	@	Study in rodent (dermal)	X	2	Rarely required; Special exposure cases
4.8 Teratology	R	Studies in rabbit and rat	X	2, 3	
4.9 Reproduction	R	Study in rabbit or rat (preferred)	X	2, 3	Two generations adequate
4.10 Chronic toxicity	R	Lifetime in rat	X	X	Not required for EUP but submit if available
4.11 Oncogenicity	R	Lifetime in rat and mouse	X	X	-do-
4.12 Mutagenicity	R	Multi-test battery	X	2, 3	Battery should include point mutation, chromosomal aberration and in vivo mammalian tests
4.13 Acute delayed neurotoxicity	@	Study in hen	X	2, 3	When cholinesterase depression expected
4.13.1 Subchronic neurotoxicity	@	Hens or mammals	X	2, 3	If effects noted in 4.13 or mammalian acute studies
4.14 Pharmacokinetics (absorption, storage, metabolism and elimination)	R	Appropriate spec.	X	2, 3	For EUP only if crop is to be used
4.15 Observations on Man, if any	R	R	R	A	
5.0 HUMAN EXPOSURE AND SAFETY					
5.1 Assessment of applicator exposure	@	X	Monitoring or calculation	2, 3	Required when potential exposure is close to an effect level
5.2 Assessment of farm worker exposure	@	X	Monitoring or calculation	2, 3	Required for Toxicity Category 1 when hand labor in dense foliage is concern; and toxic compounds
5.3 Signs and symptoms of acute human poisoning	R	Observations or judgements	Observations or judgments	A	

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Name of data requirement	Use pattern[1] Agricultural	Active ingredient Tech Grade 2	Formulation[2]	EUP[2]	Remarks
5.4 Recommend first aid procedures	R	R	R	A	
5.5 Recommend medical treatment for poisoning, include antidote, if any	R	R	R	A	
5.6 Proposed Acceptable Daily Intake	R	Calculated	X	2,3	Food uses only; For EUP if not crop destruct basis
5.7 Protective equipment	@	R	R	A	If needed; Required for Toxicity Category I and II
5.8 Other precautions	@	R	R	A	If needed
6.0 ENVIRONMENTAL EFFECTS					
6.1 Avian acute oral toxicity	R	X	Test in one species for each typical formulation	2, 3	Suitable species, pigeon, quail, pheasant, duck, or a Bengalese finch; hen not suitable
6.2 Avian dietary acute toxicity	@	X	Test in one species needed to assess potential effects	X	If indicated by acute test results and type of formulation and use
6.3 Fish acute toxicity	R	96-hour test in two species one of which is a local species	X	2, 3	Suitable specifies include rainbow trout, zebra fish, fat head minnow, tilapia fingerlings
6.4 Sub-acute fish toxicity	@	Prolonged exposure test, one or more species	X	X	Where prolonged exposure likely; Test period up to 30 days
6.5 Aquatic acute toxicity	R	48-hour acute test suitable species	X	X	Suitable fish food species, e.g., Daphnia
6.6 Accumulation in fish	@	Test in one species	X	X	Where indicated by use pattern, formulation type and partition coefficient
6.7 Avian reproduction	@	Test in one species	X	X	If need is indicated by feeding study results
6.8 Fish reproduction	@	Test in Daphnia and one fish species	X	X	Test to be performed if persistent exposure indicated by use pattern and chemical persistence
6.9 Acute toxicity to honeybees	@	R	X	X	Test to be performed if use involves crop where bees are present during or just after treatment
6.10 Contact toxicity to honeybees	@	X	Typical formulation	X	Test needed for uses involving exposure and acute test shows high bee toxicity

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Name of data requirement	Use pattern[1] Agricultural	Active ingredient Tech Grade 2	Formulation[2]	EUP[2]	Remarks
6.11 Soil non-target microorganisms	@	X	Typical formulation	X	Required if high soil concentrations expected from use; Test maybe conducted with TGAI or formulation
6.12 Soil non-target macroorganisms	@	X	Earthworms	X	Same as above; also collect residue data if high avian toxicity
Note: Special pen and field studies may be required depending upon uses, formulation and results of above studies					
7.0 RESIDUE IN FOODS					
For food use only					
7.1 Identity of principal residues, metabolites and degradation products in edible crops, foods or feeds	R	Each crop	X	2, 3	Food/feed uses only
7.2 Residue decay curves for residues on crops to be treated	R	Each crop	X	2, 3	Food/feed uses only
7.3 Residues of active ingredient and principal metabolite in animals fed treated feeds or grazed on treated fields or pastures	R	Each crop	X	2, 3	Feed or pasture/range-land use only
7.4 Effects of food processing or home preparation on residues	@	Each crop	X	2, 3	For foods which are processed or cooked before eating
7.5 Analytical method for detection of principal residues, metabolites on treated commodities	@	Each crop	X	2, 3	Food/feed uses only when finite residue expected
7.6 Proposed maximum residue level for each crops, food, feed or animal expected to contain residues	R	Each crop	X	2, 3	Food/feed uses only. Residue definition also required for enforcement
Note: Residue data may also be required for inerts which are not provided a general exception or generally regarded as safe. Above residue data not required for EUP on a crop-destruct basis					
8.0 ENVIRONMENTAL FATE AND TRANSPORT					
8.1 Volatility	R	R	X	X	
8.2 Adsorption/desorption	@	Test in two soil types	X	X	If pesticide likely to reach soil or water; radio-labelled test material best
8.3 Leaching	R	Test in several soil types	Sometimes	X	Field leaching tests may also be required
8.4 Degradation in soil	@	Test in agricultural soil; sandy loam	Sometimes	A	Required for pesticides reaching the soil. Simulate field conditions. Field study may be required

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Name of data requirement	Use pattern[1] Agricultural	Active ingredient Tech Grade 2	Formulation[2]	EUP[2]	Remarks
8.5 Biodegradation	@	Approximate field conditions	X	X	If applied directly to water or likely to enter due to formulation or use. Field tests may be required
8.6 Hydrolysis	@	R	X	A	Same as above
8.7 Aqueous photolysis	@	R	X	A	Same as above
8.8 Analytical method – residues in soil	R	R	X	X	
8.9 Analytical method – residues in water	@	R	X	X	When used directly or expected to reach water
9.0 LABELLING					
9.1 Proposed toxicity category	R	R	R	A	
9.2 Draft label (3 copies)	R	X	R	A	See note for EUP's. A.I. must meet shipping label requirements.
Note: EUP labels may be typewritten and need to contain product identification warnings and precautions for storage, use and disposal, symptoms and signs of poisoning, first aid procedures and medical treatment					

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