

DATA REQUIREMENTS FOR BOTANICAL PESTICIDES IN AGRICULTURE USE

1. Description

	Title	Data Required	Conditions
1.1	Description of Botanical Pesticide	R	

2. General Information

	Title	Data Required	Conditions
2.1	Name and address of registrant	R	
2.2	Dated request	R	
2.3	Certificate of origin for the formulated Botanical pesticide issued by a competent legal entity.	R	
2.4	Certificate of origin and/or free sale in the country of origin and issued a legal, official entity	R	
2.5	Certificated of composition, issued by the company laboratory, and signed by the person in charge of said laboratory	R	

3. Active Ingredient(s)

	Title	Data Required	Conditions
3.1	Identity and composition		
3.1.1	Commercial name	R	
3.1.2	Chemical name; based on IUPAC; CAS nomenclature	R	
3.1.3	Common name	R	
3.1.3	Structural formula	R	
3.1.4	Empirical Formula	R	
3.1.5	Chromatogram or atomic absorption spectrum	R	
3.1.6	Minimum and maximum content of active ingredient	R	
3.1.7	Identity and number of isomers, impurities, and other by-products	R	
3.2	Physical and chemical properties		
3.2.1	Molecular weight	R	
3.2.2	Physical state	R	
3.2.3	Colour	R	
3.2.4	Odour	R	
3.2.5	pH	R	
3.2.6	point of fusion	CR	Dependent on physical state

3.2.7	boiling point	CR	Dependent on physical state
3.2.8	point of decomposition	CR	Dependent on physical state
3.2.9	vapour pressure	CR	Dependent on physical state
3.2.10	solubility in water	CR	Dependent on physical state
3.2.11	solubility in organic solvents	CR	Dependent on physical state
3.2.12	partition coefficient n-octanol/water	CR	Dependent on physical state
3.2.13	density; in the case of liquids	CR	Dependent on physical state
3.2.14	specific weight; in the case of solids	CR	Dependent on physical state
3.2.15	flammability	R	
3.2.16	explosivity	R	
3.2.17	reactivity	R	
3.2.18	oxidizing and corrosive properties	R	

4. Formulated product

	Title	Data Required	Conditions
4.1	Identification of the formulated Botanical pesticide		
4.1.1	Commercial name of the formulated Botanical pesticide	R	
4.1.2	Class of Botanical pesticide (insecticide, fungicide, etc.)	R	
4.1.3	Species of pest control	R	
4.1.4	Crops on which use is recommended	R	
4.1.5	Mode of action	R	
4.1.6	Recommended dosage	R	
4.1.7	Optimum phytosanitary and environmental conditions for its application	R	
4.1.8	Methods of application	R	
4.1.9	Application intervals	R	

4.1.1 0	Re-entry period	R	
4.1.1 1	Phytoxicity	R	
4.2	Physical and chemical properties of the formulated Botanical pesticide		
4.2.1	pH	R	
4.2.2	colour	R	
4.2.3	odour	R	
4.2.4	physical state	R	
4.2.5	particle size	R	
4.2.6	name and proportion of additives and solvents	R	
4.2.7	type of formulation and characteristics	R	
4.2.8	stability in storage	R	
4.2.9	pH and optimum water quality for application	R	
4.2.1 0	suspensibility	CR	Dependent on formulation
4.2.1 1	humectability	CR	Dependent on formulation
4.2.1 2	adhesiveness	CR	Dependent on formulation
4.2.1 3	compatibility/non compatibility with other chemical or Botanical substance	R	

5. Analytical methods

	Title	Data Required	Conditions
5.1	Analytical methods for Botanical pesticides	R	

6. Primary toxicological data

	Title	Data Required	Conditions
6.1	Acute oral toxicity	R	
6.2	Acute dermal toxicity	R	
6.3	Acute respiratory toxicity	R	
6.4	Primary dermal irritation	R	
6.5	Primary eye irritation	R	

7. Toxicological data

	Title	Data Required	Conditions
7.1	Short term toxicity of active ingredient and formulated product	R	
7.2	Chronic toxicity of the active ingredient and the formulated product	R	
7.2.1	Chronic toxicity: long term oral toxicity and carcinogenicity	R	
7.2.2	Mutagenicity	R	
7.3	Toxicity and reproduction		
7.3.1	Teratogenicity testing	R	
7.4	Metabolic testing in mammals		
7.4.1	Absorption, distribution and excretion tests following oral and dermal exposure	R	
7.4.2	Explanation of metabolic pathways	R	
7.5	Neurotoxicity testing	R	
7.6	Additional testing		
7.6.1	Toxic effect of metabolites	CR	
7.6.2	Immunotoxicity	CR	

8. Other requirements

	Title	Data Required	Conditions
8.1	Medical Data	R	
8.2	Residue data when product is applied	R	
8.3	Ecotoxicity data		
8.3.1	Oral toxicity in birds	R	
8.3.2	Toxicity in fresh water and marine fish	R	
8.3.3	Toxicity in earthworms	R	
8.3.4	Toxicity in freshwater invertebrates (Daphnia spp.)	R	
8.3.5	Testing with non-target insects	R	
8.3.6	Testing with non-target plants	R	
8.3.7	Toxicity in bees	R	

9. First Aid

	Title	Data Required	Conditions
9.1	Symptoms of intoxication and first aid	R	

10. Residues

	Title	Data Required	Conditions
10.1	Data on residues	R	

11. Data relevant to accidents, contamination, and occupational health

	Title	Data Required	Conditions
11.1	Procedures for destruction	R	
11.2	Elimination of residues	R	
11.3	Decontamination of waters	R	
11.4	Recommended methods and safety measures for handling product	R	
11.5	Information on personal protective equipment	R	
11.6	Cleansing and decontamination of application equipment and contaminated areas	R	
11.7	Conditions of storage, transport, and use of all products	R	
11.8	Emergency procedures	R	

12. Botanical Efficacy Trial

	Title	Data Required	Conditions
12.1	Efficacy Trial	R	

13. Packaging, labelling and pamphlet

	Title	Data Required	Conditions
13.1	Packaging	R	
13.1.1	Type of packaging or container	R	
13.1.2	Material	R	
13.1.3	Capacity	R	
13.1.4	Resistance	R	
13.2	Label/ pamphlet	R	