

DATA REQUIREMENTS FOR BIOLOGICAL PESTICIDES FOR AGRICULTURAL USE

1. Description

| | Title | Data Required | Conditions |
|-----|-------------------------------------|---------------|------------|
| 1.1 | Description of Biological 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 biological 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 | Description of active ingredient | R | |
| 3.1.1 | Commercial name | R | |
| 3.1.2 | Chemical name; based on IUPAC; CAS nomenclature | R | |
| 3.1.3 | Common name | R | |
| 3.1.4 | Structural formula | R | |
| 3.1.5 | Empirical Formula | R | |
| 3.1.6 | Chromatogram or atomic absorption spectrum | R | |
| 3.1.7 | Minimum and maximum content of active ingredient; | R | |
| 3.1.8 | Identity and number of isomers, impurities and other by-products | | |
| 3.2 | Identity of active ingredient | R | |
| 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 | |
| 3.2.19 | oxidizing and corrosive properties | R | |
| 3.3 | Active ingredient content of bacterial origin (biopotency) | R | |

4. Formulated biological pesticide

| | Title | Data Required | Conditions |
|-------|--|---------------|------------|
| 4.1 | Identification of the formulated biological pesticide | | |
| 4.1.1 | Commercial name of the formulated biological pesticide | R | |
| 4.1.2 | Class of biological 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 | |
| 4.1.10 | Re0entry period | R | |
| 4.1.11 | Phytoxicity | R | |
| 4.2 | Physical and chemical properties of the formulated biological 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 | |
| 4.2.10 | suspensibility | CR | Dependent on formulation |
| 4.2.11 | humectability | CR | Dependent on formulation |
| 4.2.12 | adhesiveness | CR | Dependent on formulation |
| 4.2.13 | compatibility/non compatibility with other chemical or biological substance | R | |

5. Analytical Methods

| | Title | Data Required | Conditions |
|-----|--|---------------|------------|
| 5.1 | Analytical methods for biological 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 product | R | |
| 11.8 | Emergency procedures | R | |

12. Biological Efficacy Trial

| | Title | Data Required | Conditions |
|------|----------|---------------|------------|
| 12.1 | Efficacy | 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 | |

R: REQUIRED

CR: CONDITIONALLY REQUIRED