

Republic of South Africa

 Registrar: Act 36 of 1947

 Private Bag X343

 0001 Pretoria

**FERTILIZER, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT NO 36 OF 1947), AS AMENDED**

**APPLICATION FOR THE REGISTRATION OF AN AGRICULTURAL REMEDY**

**INFORMATION FOR APPLICANTS**

1. The application form must be duly completed in all respects. Where applicable, the requested information can be submitted as separate numbered attachments.
2. The application form and draft label must be submitted in triplicate with an explanatory covering letter.
3. The application must be submitted to the Registrar: Act 36 of 1947, Agriculture Place, 20 Steve Biko Street, Arcadia, Pretoria.0001
4. Every application must be accompanied by the prescribed registration fee.
5. Only one copy is required of supportive studies (e.g., toxicological data, efficacy data, residue data, physical specifications, and any other relevant studies). See Lists I and II as well as all relevant guidelines as listed on the DALRRD website.
6. Lists I and II are supplied as check lists and an index to ensure that the applicant has provided all relevant data.
7. For further information visit our website (Directorate: Agricultural Inputs Control) at www.dalrrd.gov.za

Indicate as appropriate:

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| Agricultural Remedies containing a new active ingredient: |  |
| Agricultural Remedies where source of active ingredient and/or formulation is not identical to that of a registered product: |  |
| Registration transfer: |  |
| Amendments to an existing registration: |  |
| Parallel registration: |  |
| Daughter registration: |  |
| Other:  |  |
| Will product be marketed under own label: | YES: |  | NO: |  |
| Proposed date of marketing: |  |

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| 1. **APPLICANT**
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| Identification: | Name of applicant/corporate name of company, and company registration number: | Name of distributor/agent in country (list of distributors/agents can be attached): |
|  |  |
| Status: (Importer/formulator/distributor) |  |  |
| Physical address:  |  |  |
| Postal address (and postal code) |  |  |
| Telephone: (and area code) |  |  |
| Fax:(and area code) |  |  |
| E-mail address: |  |  |

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| 1. **PRODUCT**
 |
| Designation(description of product): | Tradename: |  |
| Trademark holder: |  |
| Function of product (e.g., insecticide, herbicide, plant growth regulator, etc.): |  |
| Intended use (e.g., public health, industrial, agriculture, forestry): |  |
| Target pest(s) and host(s): |  |
| Method, dosage rates and frequency of application:  |  |
| Type of formulation:  |  | CropLife International / FAO\* code |  |
| Existing reg. no. (if relevant): |  | Customs Tariff Code:(Brussels Tariff Nomenclature) |  |
| Registration in SEARCH\*\* country/ies (please indicate) |  |
| Registration in other country/ies (please indicate) |  |
| Is the product registered in country of manufacture and formulation: | If yes, submit evidence |  | If not, why not?  |  |
| Is this product a parallel or daughter registration? |  |
| Original product registration holder name: |  |
| Original product trade name and registration number: |  |

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| 1. **ACTIVE INGREDIENTS (Technical grade)**
 |
| Active ingredient(s) common name(s): | Manufacturer(Name and physical address of manufacturing site) | Min. a.i. % purity: | Range %: |
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| 1. **FORMULATION**
 |
| Formulator (Name): | Physical address of formulation site: |
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| Composition (where relevant, include the acid and salt content of the a.i.) |
| Ingredients (where relevant, include acid and salt content of a.i.) | Function (e.g., emulsifier) | CAS number | g/L | g/kg  | Range |
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| 1. **TOXICOLOGY AND GHS CLASSIFICATION (formulated product)**
 |
| Final GHS classification of the formulation*(Note: A full classification rationale must accompany the application)* |
| GHS hazard class | GHS hazard category | GHS hazard statement code | Based on calculated or experimental data? |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |
| GHS pictograms |  |
| GHS signal word |  |
| Summary of environmental effects: |
| Toxicity to bees:  |
| Toxicity to birds:  |
| Toxicity to earthworms and soil micro-organims:  |
| Toxicity to other non-target organisms:  |
| Persistence in the environment:  |
| Other effects:  |

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| 1. **PACKAGING**
 |
| Packaging material / container (e.g., plastic jug, glass bottle, etc.) |
| Pack size(s): |
| Disposal of empty container(s): |
| Name of registered Producer Responsibility Organization according to the Regulations Regarding Extended Producer Responsibility: |  |

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| 1. **DECLARATION BY APPLICANT OR THE DULY APPOINTED REPRESENTATIVE**
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| Tradename of product:  |  |
| For and on behalf of ………………………………………………………………………………………I hereby certify that the abovementioned information and data provided in support of this application are, to the best of my knowledge, true, correct and complete. |
| …………………………………..Name in full (printed) | ………………………………..Signature |
| ………………………………..Date | …………………………………Official title and SACNASP registration number |
| Official stamp of applicant / company | FOR OFFICIAL USERegistration is: Recommended Not recommended  |
| Date |

NOTES:

\*CropLife International = Formerly GCPF (Global Crop Protection Federation), formerly GIFAP (International Group of National Association of Manufacturers of Agrochemical products).

\*\*SEARCH = Southern and East Africa Regulatory Committee for Harmonization of Pesticide Registrations

**ACTIVE INGREDIENT (TECHNICAL GRADE) LIST I**

The dossier accompanying the application must provide full details (as applicable) of the information requested in the lists, i.e., details on the methods used, summaries of methods and results used in toxicology and ecotoxicology studies, method of analyses, etc. Applicants are advised to use CIPAC methods for physical and chemical properties.

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| **ACTIVE INGREDIENT (a.i.)****Technical grade** | **Official use only** |
| 1. **DESIGNATION**
 |
| 1. Common name (ISO)
 |  |  |
| 1. Manufacturer or development code
 |  |  |
| 1. Chemical name (IUPAC)
 |  |  |
| 1. CAS number
 |  |  |
| 1. Chemical group
 |  |  |
| 1. Structural formula
 |  |  |
| 1. Empirical formula
 |  |  |
| 1. Patent status

Is the a.i. under patent? Who is the patent holder? Expiry date: |  |  |

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| 1. **PHYSICAL AND CHEMICAL PROPERTIES**

**(Active ingredient – technical grade)** |
| 1. Physical state
 |  |  |
| 1. Colour
 |  |  |
| 1. Odour
 |  |  |
| 1. Density at 20 °C
 |  |  |
| 1. Vapour pressure at 20/25 °C
 |  |  |
| 1. Volatility
 |  |  |
| 1. Hydrolysis DT50 … Days … °C … pH
 |  |  |
| 1. Photolysis
 |  |  |
| 1. Solubility in water … °C … pH
 |  |  |
| 1. Solubility in organic solvents
 |  |  |
| 1. N-octanol / water partition coefficient
 |  |  |
| 1. Boiling point °C
 |  |  |
| 1. Melting point °C
 |  |  |
| 1. Decomposition temperature °C
 |  |  |
| 1. Method of analysis and impurities
 |  |  |

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| 1. **TOXICOLOGY**

**(Active ingredient – technical grade)** |
| 1. ADI
 |  |  |
| 1. Acute oral LD50 mg/kg
 |  |  |
| 1. Acute dermal LD50 mg/kg
 |  |  |
| 1. Acute inhalation LC50 mg/L/hour
 |  |  |
| 1. Skin irritation / Skin corrosion
 |  |  |
| 1. Eye irritation / Eye damage
 |  |  |
| 1. Respiratory or Skin Sensitization
 |  |  |
| 1. Germ Cell Mutagenicity
 |  |  |
| 1. Carcinogenicity
 |  |  |
| 1. Reproduction Toxicity
 |  |  |
| 1. Specific Target Organ Toxicity – single exposure
 |  |  |
| 1. Specific Target Organ Toxicity – repeated exposure
 |  |  |
| 1. Aspiration Hazard
 |  |  |
| 1. Sub-chronic toxicity 90-day NOEL mg/kg/day
 |  |  |
| 1. Chronic toxicity NOEL mg/kg/day
 |  |  |
| 1. Metabolism (rat)
 |  |  |
| 1. Other studies
 |  |  |

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| 1. **ECOTOXICOLOGY**

**(Active ingredient – technical grade)** |  |
| 1. Birds (2 species)
 | LD50 mg/kg |  |  |
| NOEL |  |  |
| LD50 mg/kg |  |  |
| NOEL |  |  |
| Reproduction |  |  |
| 1. Fish (2 species)
 | LD50 mg/kg |  |  |
| NOEL |  |  |
| LD50 mg/kg |  |  |
| NOEL |  |  |
| Reproduction |  |  |
| BCF |  |  |
| 1. Daphnia
 | LC50 mg/L |  |  |
| NOEL |  |  |
| 1. Algae
 | LC50 mg/L |  |  |
| NOEL |  |  |
| 1. Bees
 | LD50 μg/bee |  |  |
| 1. Earthworms
 | LC50 mg/kg |  |  |
| 1. Soil micro-organisms
 | EC/LC50 mg/kg |  |  |

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| 1. **BEHAVIOUR IN ENVIRONMENT**

**(Active ingredient – technical grade)** |
| Behaviour, ways of degradation, degradation products in soil |
| 1. Major metabolites
 |  |  |
| 1. DT50 (days)
 |  |  |
| 1. Mobility
 |  |  |
| 1. Absorption
 |  |  |
| 1. Mobility of metabolites
 |  |  |
| Behaviour, ways of degradation, degradation products in water |
| 1. Major metabolites
 |  |  |
| 1. DT50 (days)
 |  |  |
| 1. Surface
 |  |  |
| 1. Ground
 |  |  |

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| **MODE OF ACTION** |
| 1. IRAC code
 |  |  |
| 1. HRAC code
 |  |  |
| 1. FRAC code
 |  |  |
| 1. Description of mode of action
 |  |  |

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| 1. **PLANT RESIDUES**
 |
| 1. Major metabolites
 |  |  |
| 1. Metabolism
 |  |  |
| 1. Behaviour of residues
 |  |  |
| 1. Crop
 |  |  |
| 1. MRL CODEX
 |  |  |
| 1. MRL country
 |  |  |
| 1. PHI and MRL proposed
 |  |  |
| 1. Method of residue analysis
 |  |  |

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| 1. **REGISTRATION STATUS IN OTHER COUNTRIES**
 |
| **Indicate whether substance is registered / restricted / banned. Provide reasoning.**  |
| 1. Japan
 |  |  |
| 1. EU
 |  |  |
| 1. Australia
 |  |  |
| 1. USA
 |  |  |
| 1. Other
 |  |  |

**FORMULATED PRODUCT LIST II**

The dossier accompanying the application must provide full details (as applicable) of the information requested in the lists i.e., details on the methods used, summaries of methods and results used in toxicology and ecotoxicology studies, methods of analysis, etc. Applicants are advised to use CIPAC methods for physical and chemical properties.

|  |  |
| --- | --- |
| **FORMULATED PRODUCT** | **Official use only** |
| 1. **PHYSICAL AND CHEMICAL PROPERTIES**
 |
| 1. Physical state / formulation type
 |  |  |
| 1. Colour
 |  |  |
| 1. Odour
 |  |  |
| 1. Storage stability
 |  |  |
| 1. Shelf life
 |  |  |
| 1. Density
 |  |  |
| 1. Bulk density
 |  |  |
| 1. Flammability
 |  |  |
| 1. Flash point
 |  |  |
| 1. Compatibility with other pesticides
 |  |  |
| 1. pH
 |  |  |
| 1. pH of 1% aqueous dilution
 |  |  |
| 1. Oxidizing properties
 |  |  |
| 1. Corrosiveness
 |  |  |
| 1. Water content
 |  |  |
| 1. Wettability
 |  |  |
| 1. Solubility in water
 |  |  |
| 1. Foaming
 |  |  |
| 1. Particle size
 |  |  |
| 1. Suspensibility / emulsifiability
 |  |  |
| 1. Emulsion stability
 |  |  |
| 1. Volatility
 |  |  |
| 1. Viscosity
 |  |  |
| 1. Other properties (where applicable)
 |  |  |
| 1. Method of analysis
 |  |  |

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| 1. **EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING**
 |
| 1. Symptoms of human poisoning
 |  |  |
| 1. First aid treatment
 |  |  |
| 1. Skin contact
 |  |  |
| 1. Eye contact
 |  |  |
| 1. Inhalation
 |  |  |
| 1. Ingestion
 |  |  |
| 1. Antidote
 |  |  |
| 1. Note to physician
 |  |  |

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| 1. **EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE**
 |
| 1. Fire-fighting measures
 |  |  |
| 1. Procedures in case of spillage
 |  |  |

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| 1. **USES (New label claims with this application)**
 |
| 1. Crop/area of use
 |  |  |
| 1. Target organism
 |  |  |
| 1. Rate
 |  |  |
| 1. Stage of treatment
 |  |  |
| 1. Directions for use
 |  |  |
| 1. Residue data and pre-harvest interval
 |  |  |
| 1. Phytotoxicity
 |  |  |
| 1. Contraindications
 |  |  |

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| 1. **MINIMUM LABEL REQUIREMENTS**
 |
| 1. Product identification
 |  |  |
| 1. Hazard statements (full description)
 |  |  |
| 1. Precautionary statements (full description)
 |  |  |
| 1. First aid/note to physician (as applicable)
 |  |  |
| 1. Pictograms in line with GHS
 |  |  |
| 1. Signal word
 |  |  |
| 1. Directions for use
 |  |  |