Republic of the Philippines

Department of Health

**FOOD AND DRUG ADMINISTRATION**

**Product Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DTN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SELF-ASSESSMENT CHECKLIST FOR INITIAL / VARIATION OF**

**ACTIVE INGREDIENT REGISTRATION APPLICATIONS**

*Note: For variation applications, please check only the applicable requirements.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOCUMENTARY REQUIREMENTS** | **YES** | **NO** | **Remarks** | **FDA’s Use Only** |
| **Part I. Administrative Documents** |  |  |  |  |
| 1. Filled-Out Integrated Application Form with Signatures of Owner/ President/ General Manager and Authorized Representative
 |  |  |  |  |
| 1. Notarized Declaration Annex IV of Integrated Application Form
 |  |  |  |  |
| 1. Copy of Valid License to Operate
 |  |  |  |  |
| 1. For Imported Household Pesticides Only
 |  |  |  |  |
| 1. CFS by a government authority\*
 |  |  |  |  |
| 1. GMP Certificate\*
 |  |  |  |  |
| 1. Manufacturing License or ISO Certificate\*
 |  |  |  |  |
| NOTE: \* - Shall be duly authenticated and notarized by the Philippine embassy |  |  |  |  |
| 1. Payment of fee
 |  |  |  |  |
| **Part II. Technical Documents** |  |  |  |  |
| 1. Chemical Identity
 |  |  |  |  |
| 1. Chemical Abstract Services Number
 |  |  |  |  |
| 1. Name of active ingredient (proposed or accepted by ISO and synonyms)
 |  |  |  |  |
| 1. Structural formula
 |  |  |  |  |
| 1. Chemical name (according to internationally agreed nomenclature, preferably IUPAC)
 |  |  |  |  |
| 1. Empirical formula
 |  |  |  |  |
| 1. Molecular weight
 |  |  |  |  |
| 1. Physical properties of the Active Ingredient
 |  |  |  |  |
| 1. Appearance (physical state, color, odor)
 |  |  |  |  |
| 1. Melting/decomposition/boiling point
 |  |  |  |  |
| 1. Flammability (if liquids- flash point; solids- a statement whether the product is flammable)
 |  |  |  |  |
| 1. pH
 |  |  |  |  |
| 1. Solubility in water and organic solvents
 |  |  |  |  |
| 1. Suspendibility/emulsifying characteristics
 |  |  |  |  |
| 1. Octanol partition coefficient
 |  |  |  |  |
| 1. Density
 |  |  |  |  |
| 1. Hydrolysis
 |  |  |  |  |
| 1. Photolysis
 |  |  |  |  |
| 1. Absorption spectra
 |  |  |  |  |
| 1. Known compatibility/incompatibility with other pesticide active ingredient
 |  |  |  |  |
| 1. The minimum (and maximum) active ingredient content in g/kg
 |  |  |  |  |
| 1. Identity and amount of isomers, impurities and other by-products
 |  |  |  |  |
| 1. Name and address of the manufacturer / source
 |  |  |  |  |
| 1. Process of manufacture
 |  |  |  |  |
| 1. Product Specifications
 |  |  |  |  |
| 1. Certificate of Analysis of the Finished Product

• Analytical test report of impurity profile and AI content• Analytical test report of other specifications |  |  |  |  |
| 1. Safety Data Sheet (SDS) of the formulated product
 |  |  |  |  |
| 1. Identification
 |  |  |  |  |
| 1. Hazard identification
 |  |  |  |  |
| 1. Composition and information of ingredients
 |  |  |  |  |
| 1. First-aid measures
 |  |  |  |  |
| 1. Fire-fighting measures
 |  |  |  |  |
| 1. Accidental release measures
 |  |  |  |  |
| 1. Handling and storage
 |  |  |  |  |
| 1. Exposure controls and personal protection
 |  |  |  |  |
| 1. Physical and chemical properties
 |  |  |  |  |
| 1. Stability and reactivity
 |  |  |  |  |
| 1. Toxicological information
 |  |  |  |  |
| 1. Ecological information
 |  |  |  |  |
| 1. Disposal considerations
 |  |  |  |  |
| 1. Transport information
 |  |  |  |  |
| 1. Regulatory information
 |  |  |  |  |
| 1. Other information
 |  |  |  |  |
| 1. Proof of Manufacturer’s Compliance to Good Manufacturing Practices (GMP)
 |  |  |  |  |
| 1. Labeling Materials
 |  |  |  |  |
| 1. Chemical Name
 |  |  |  |  |
| 1. Trade Name
 |  |  |  |  |
| 1. Net content
 |  |  |  |  |
| 1. Batch/Lot number
 |  |  |  |  |
| 1. Manufacturing date
 |  |  |  |  |
| 1. Registration number
 |  |  |  |  |
| 1. Batch/Lot number
 |  |  |  |  |
| 1. GHS pictogram, signal word, hazard statement
 |  |  |  |  |
| 1. Color band based on GHS Acute Toxicity
 |  |  |  |  |
| 1. Signs/symptoms of poisoning
 |  |  |  |  |
| 1. First aid treatment / Antidote information
 |  |  |  |  |
| 1. Medical advice/Note to physician
 |  |  |  |  |
| 1. Accidental spills advice
 |  |  |  |  |
| 1. Directions for Use (Field of use, if applicable)
 |  |  |  |  |
| 1. Storage and disposal
 |  |  |  |  |
| 1. Name, complete address and contact information of the marketing authorization holder (MAH)
 |  |  |  |  |
| 1. Contact information of the national/regional poison center
 |  |  |  |  |
| 1. Packaging Materials
 |  |  |  |  |
| 1. Specification of primary package
 |  |  |  |  |
| 1. Specification of secondary packaging
 |  |  |  |  |
| 1. Specification of bulk package for transport
 |  |  |  |  |
| 1. Specimen of actual sample and reference standard
 |  |  |  |  |
| 1. Toxicity Study
 |  |  |  |  |
| 1. Acute oral toxicity
 |  |  |  |  |
| 1. Acute dermal toxicity
 |  |  |  |  |
| 1. Acute inhalational toxicity
 |  |  |  |  |
| 1. Primary skin corrosion/irritation
 |  |  |  |  |
| 1. Serious eye damage/irritation
 |  |  |  |  |
| 1. Allergy/sensitization test
 |  |  |  |  |
| 1. Sub-chronic toxicity
 |  |  |  |  |
| 1. Reproduction effects studies
 |  |  |  |  |
| 1. Teratogenicity studies
 |  |  |  |  |
| 1. Neurotoxicity studies
 |  |  |  |  |
| 1. Mutagenicity studies
 |  |  |  |  |
| 1. Carcinogenicity test
 |  |  |  |  |
| 1. Chronic (long term) toxicity in rats
 |  |  |  |  |
| 1. Human Exposure and Safety Data
 |  |  |  |  |
| 1. Medical data/Poisoning symptoms/Antidote
 |  |  |  |  |
| 1. Personal protective equipment
 |  |  |  |  |
| 1. Other precautions
 |  |  |  |  |
| 1. Environmental Data
 |  |  |  |  |
| 1. Volatility
 |  |  |  |  |
| 1. Data on translocation of pesticides in soil and water
 |  |  |  |  |
| 1. Primary data on potential hazards (infectivity) to mammals (including humans)
 |  |  |  |  |
| 1. Primary data on potential toxicity to birds and non-targeted beneficial organisms
 |  |  |  |  |
| 1. Primary data on aquatic toxicity
 |  |  |  |  |
| 1. Primary data on phytotoxicity effects
 |  |  |  |  |
| 1. Primary data on treatment of effluents and methods of destruction or disposal
 |  |  |  |  |

|  |
| --- |
| *--- To be filled out by CCRR Personnel ---* |
| **Evaluator:** |  | **Signature:** |  |
| **Position:** |  | **Date:** |  |
| **Decision:** |  Acceptance Non-acceptance | **Remarks:** |  |