

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:** |  |