

Republic of the Philippines

Department of Health

**FOOD AND DRUG ADMINISTRATION**

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

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

**HOUSEHOLD/URBAN PESTICIDE APPLICATIONS**

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

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| --- | --- | --- | --- | --- |
| **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. Copy of Previous CPR |  |  |  |  |
| 1. Payment of fee |  |  |  |  |
| **Part II. Technical Documents** |  |  |  |  |
| 1. Product Identity |  |  |  |  |
| 1. Formulator’s name and address |  |  |  |  |
| 1. Proprietary name |  |  |  |  |
| 1. Use category |  |  |  |  |
| 1. Type of formulation |  |  |  |  |
| 1. Quantitative and Qualitative Composition of product |  |  |  |  |
| 1. Content of technical grade active ingredient(s) |  |  |  |  |
| 1. Content and nature of other components in the formulation |  |  |  |  |
| 1. Technical specifications of the formulated product |  |  |  |  |
| 1. Appearance (physical state, color, odor) |  |  |  |  |
| 1. Density |  |  |  |  |
| 1. Flammability (if liquids- flash point; solids- a statement whether the product is flammable) |  |  |  |  |
| 1. pH |  |  |  |  |
| 1. Wettability |  |  |  |  |
| 1. Persistent foam |  |  |  |  |
| 1. Suspendibility |  |  |  |  |
| 1. Wet sieve test |  |  |  |  |
| 1. Dry sieve test |  |  |  |  |
| 1. Emulsion stability |  |  |  |  |
| 1. Corrosiveness (when necessary) |  |  |  |  |
| 1. Known incompatibilities with other products |  |  |  |  |
| 1. Shelf life/ Stability Data |  |  |  |  |
| 1. Product Specifications - Tolerance for the Active Ingredient/s |  |  |  |  |
| 1. Certificate of Analysis of the Finished Product (with manufacturing date, batch/lot number, name and signature of the lab analyst and manager) |  |  |  |  |
| 1. Test procedures/methods conducted on the formulated product |  |  |  |  |
| 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. Labeling Materials |  |  |  |  |
| 1. Brand Name and Product Name |  |  |  |  |
| 1. Product or user category |  |  |  |  |
| 1. Type of formulation |  |  |  |  |
| 1. Intended use |  |  |  |  |
| 1. Active ingredients including percentage concentration in %w/w or %w/v |  |  |  |  |
| 1. Net content |  |  |  |  |
| 1. Batch/Lot number |  |  |  |  |
| 1. Manufacturing date |  |  |  |  |
| 1. Expiry date |  |  |  |  |
| 1. Registration number |  |  |  |  |
| 1. GHS pictogram, signal word and hazard statement |  |  |  |  |
| 1. Precautionary statement or warnings |  |  |  |  |
| 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, dilution and application rate, re-entry period and frequency of re-application) |  |  |  |  |
| 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. Assessment of need of child resistant packaging |  |  |  |  |
| 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. Bio-efficacy Study |  |  |  |  |
| 1. Abstract |  |  |  |  |
| 1. Introduction |  |  |  |  |
| 1. Methodology |  |  |  |  |
| 1. Presentation, Analysis and Interpretation of Data |  |  |  |  |
| 1. Summary of Findings, Conclusions and Recommendations |  |  |  |  |
| 1. Bibliography |  |  |  |  |
| 1. Annexes, if any |  |  |  |  |
| 1. Human Exposure and Safety Data |  |  |  |  |
| 1. Operators exposure data |  |  |  |  |
| 1. Bystanders exposure data |  |  |  |  |
| 1. Medical data/Poisoning symptoms/Antidote |  |  |  |  |
| 1. Permissible exposure level |  |  |  |  |
| 1. Personal protective equipment |  |  |  |  |
| 1. Other precautions |  |  |  |  |
| 1. Environmental Data |  |  |  |  |
| 1. Data on translocation of pesticides in soil and water |  |  |  |  |
| 1. Primary data on potential hazards (infectivity) to mammals (including humans) |  |  |  |  |
| 1. Data on aquatic toxicity |  |  |  |  |
| 1. Data on phytotoxicity effects |  |  |  |  |
| 1. Data on treatment of effluents and methods of destruction or disposal |  |  |  |  |
| 1. Product Stewardship Program |  |  |  |  |
| 1. Substantiation to support special product claims |  |  |  |  |

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