Product Name: _____ **DTN:** _____

SELF-ASSESSMENT CHECKLIST FOR INITIAL APPLICATION OF HOUSEHOLD/URBAN PESTICIDE REGISTRATION

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				
2. Notarized Declaration Annex IV of Integrated Application Form				
3. Copy of Valid License to Operate				
4. For Imported Household Pesticides Only				
a. CFS by a government authority*				
b. GMP Certificate*				
c. Manufacturing License or ISO Certificate*				
NOTE: * - Shall be duly authenticated and notarized by the Philippine embassy				
5. Copy of Previous CPR				
Part II. Technical Documents				
6. Product Identity				
a. Formulator's name and address				
b. Proprietary name				
c. Use category				
d. Type of formulation				
7. Quantitative and Qualitative Composition of product				
a. Content of technical grade active ingredient(s)				
b. Content and nature of other components in the formulation				
8. Technical specifications of the formulated product				
a. Appearance (physical state, color, odor)				
b. Density				
c. Flammability (if liquids- flash point; solids- a statement whether the product is flammable)				
d. pH				
e. Wettability				
f. Persistent foam				
g. Suspendibility				
h. Wet sieve test				
i. Dry sieve test				
j. Emulsion stability				
k. Corrosiveness (when necessary)				
l. Known incompatibilities with other products				
m. Shelf life/ Stability Data				

9. Product Specifications - Tolerance for the Active Ingredient/s				
10. Certificate of Analysis of the Finished Product (with manufacturing date, batch/lot number, name and signature of the lab analyst and manager)				
11. Test procedures/methods conducted on the formulated product				
12. Safety Data Sheet (SDS) of the formulated product				
a. Identification				
b. Hazard identification				
c. Composition and information of ingredients				
d. First-aid measures				
e. Fire-fighting measures				
f. Accidental release measures				
g. Handling and storage				
h. Exposure controls and personal protection				
i. Physical and chemical properties				
j. Stability and reactivity				
k. Toxicological information				
l. Ecological information				
m. Disposal considerations				
n. Transport information				
o. Regulatory information				
p. Other information				
13. Labeling Materials				
a. Brand Name and Product Name				
b. Product or user category				
c. Type of formulation				
d. Intended use				
e. Active ingredients including percentage concentration in %w/w or %w/v				
f. Net content				
g. Batch/Lot number				
h. Manufacturing date				
i. Expiry date				
j. Registration number				
k. GHS pictogram, signal word and hazard statement				
l. Precautionary statement or warnings				
m. Color band based on GHS Acute Toxicity				
n. Signs/symptoms of poisoning				
o. First aid treatment/ Antidote information				
p. Medical advice/ Note to physician				
q. Accidental spills advice				
r. Directions for use (field of use, dilution and application rate, re-entry period and frequency of re-application)				
s. Storage and Disposal				

t. Name, complete address and contact information of the marketing authorization holder (MAH)				
u. Contact information of the national/regional poison center				
14. Packaging Materials				
a. Specification of primary package				
b. Specification of secondary packaging				
c. Specification of bulk package for transport				
d. Assessment of need of child resistant packaging				
15. Specimen of actual sample and reference standard				
16. Toxicity Study				
a. Acute oral toxicity				
b. Acute dermal toxicity				
c. Acute inhalational toxicity				
d. Primary skin corrosion/irritation				
e. Serious eye damage/irritation				
f. Allergy/sensitization test				
g. Sub-chronic toxicity				
h. Reproduction effects studies				
i. Teratogenicity studies				
j. Neurotoxicity studies				
k. Mutagenicity studies				
l. Carcinogenicity test				
m. Chronic (long term) toxicity in rats				
17. Bio-efficacy Study*				
a. Abstract				
b. Introduction				
c. Methodology				
d. Presentation, Analysis and Interpretation of Data				
e. Summary of Findings, Conclusions and Recommendations				
f. Bibliography				
g. Annexes, if any				
*Bio-efficacy test protocol pre-approval (if the study is conducted on 01 Oct 2023 onwards)				
18. Human Exposure and Safety Data				
a. Operators exposure data				
b. Bystanders exposure data				
c. Medical data/Poisoning symptoms/Antidote				
d. Permissible exposure level				
e. Personal protective equipment				
f. Other precautions				
19. Environmental Data				
a. Data on translocation of pesticides in soil and water				

b. Primary data on potential hazards (infectivity) to mammals (including humans)				
c. Data on aquatic toxicity				
d. Data on phytotoxicity effects				
e. Data on treatment of effluents and methods of destruction or disposal				
20. Product Stewardship Program				
21. Substantiation to support special product claims				

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