

Product Name: _____

DTN: _____

**SELF-ASSESSMENT CHECKLIST FOR INITIAL APPLICATION
OF ACTIVE INGREDIENT 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				
Part II. Technical Documents				
5. Chemical Identity				
a. Chemical Abstract Services Number				
b. Name of active ingredient (proposed or accepted by ISO and synonyms)				
c. Structural formula				
d. Chemical name (according to internationally agreed nomenclature, preferably IUPAC)				
e. Empirical formula				
f. Molecular weight				
6. Physical properties of the Active Ingredient				
a. Appearance (physical state, color, odor)				
b. Melting/decomposition/boiling point				
c. Flammability (if liquids- flash point; solids- a statement whether the product is flammable)				
d. pH				
e. Solubility in water and organic solvents				
f. Suspendibility/emulsifying characteristics				
g. Octanol partition coefficient				
h. Density				
i. Hydrolysis				
j. Photolysis				
k. Absorption spectra				
l. Known compatibility/incompatibility with other pesticide active ingredient				
m. The minimum (and maximum) active ingredient content in g/kg				

n. Identity and amount of isomers, impurities and other by-products				
o. Name and address of the manufacturer / source				
p. Process of manufacture				
7. Product Specifications				
8. Certificate of Analysis of the Finished Product <ul style="list-style-type: none"> Analytical test report of impurity profile and AI content Analytical test report of other specifications 				
9. 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				
11. Proof of Manufacturer's Compliance to Good Manufacturing Practices (GMP)				
12. Labeling Materials				
a. Chemical Name				
b. Trade Name				
c. Net content				
d. Batch/Lot number				
e. Manufacturing date				
f. Registration number				
g. Batch/Lot number				
h. GHS pictogram, signal word, hazard statement				
i. Color band based on GHS Acute Toxicity				
j. Signs/symptoms of poisoning				
k. First aid treatment / Antidote information				
l. Medical advice/Note to physician				
m. Accidental spills advice				
n. Directions for Use (Field of use, if applicable)				
o. Storage and disposal				
p. Name, complete address and contact information of the marketing authorization holder (MAH)				

q. Contact information of the national/regional poison center				
13. Packaging Materials				
a. Specification of primary package				
b. Specification of secondary packaging				
c. Specification of bulk package for transport				
14. Specimen of actual sample and reference standard				
15. 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				
16. Human Exposure and Safety Data				
a. Medical data/Poisoning symptoms/Antidote				
b. Personal protective equipment				
c. Other precautions				
17. Environmental Data				
a. Volatility				
b. Data on translocation of pesticides in soil and water				
c. Primary data on potential hazards (infectivity) to mammals (including humans)				
d. Primary data on potential toxicity to birds and non-targeted beneficial organisms				
e. Primary data on aquatic toxicity				
f. Primary data on phytotoxicity effects				
g. Primary data on treatment of effluents and methods of destruction or disposal				

--- To be filled out by CCHUHSRR Personnel ---

Evaluator:		Signature:	
Position:		Date:	
Decision:	<input type="checkbox"/> Acceptance <input type="checkbox"/> Non-acceptance	Remarks:	