REQUIREMENTS FOR REGISTRATION OF PESTICIDES

Sample requirements

1. Two (2) commercial samples of the product(s)
2. Two (2) coloured artwork/Label of the product and leaflet insert of the product (where applicable).

Data requirements for registration

A. Administrative requirement

1. Dated and signed cover letter
2. Application form
3. Contract Manufacturing Agreement (where applicable)
4. Manufacturing license
5. A valid GMP or other applicable internationally recognized Management System certification
6. Appointment letter of the local technical representative with original copy of Power of attorney from the product manufacturer (if imported)
7. Proof of payment of non-refundable registration application fee
8. Commitment letters (Ongoing stability studies) where applicable

B. Technical requirements

Section A: Data on raw data

B.1 chemical analytical data of raw materials

1. Name for each ingredients
2. Name and address of manufacturer for each ingredients
3. Certificate of Analysis(COA) for each ingredient
4. Safety Data Sheets (SDS) for each ingredient

Section B: Data on final product

B.2 Manufacturing process

1. Flow chart and narrative of manufacturing process.
2. References used
3. Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated

B.3 Product efficacy

1. Type of formulation (e.g. soluble concentrate, wettable powder, emulsifiable concentrate)
2. Function of the product (e.g. insecticide, insect repellent, rodenticide, …) and target pest species
3. Application rate per unit treated and concentration of active ingredient in the material as applied (for example, if the product is diluted before application)
4. Comprehensive Certificate of Analysis.
5. Method of analysis
6. Application and mixing instructions, including method of application, type of equipment used, application techniques and rates for each use site, and type and volume of diluent per unit of area or volume
7. Number, frequency and timing of applications (e.g. per year, per month) and duration of protection expected

B.4 Human health assessment

1. Re-entry periods (e.g. after space spray for mosquito control), waiting periods and other precautions to protect people, livestock and the environment.
2. Study data for adverse and chronic toxicity due to exposure
3. A statement about any risk arising from the recommended methods and precautions and handling procedures, in order to minimize those risks (e.g. precautionary statements of the Globally harmonized system of classification and labelling of chemicals)
4. Information on antidotes, if any, and medical treatment in the case of accidental exposure; names of co-formulants that may influence the toxicity of the product

B.5 General safety information

1. Procedures for cleaning application equipment, if relevant to the proposed use
2. Proposed hazard classification (according to WHO classification), labelling and safety phrases and symbols

B.6 Packaging and Labelling information

B.7 Others

1. Stability studies data
2. Other available study reports to support safety and efficacy