

**GUIDELINES ON REGISTRATION OF
PESTICIDES**



**Secretariat
Pesticides Board
Department of Agriculture
Ministry of Agriculture and Agro-Based Industry Malaysia**

2005

PREFACE

The Purpose of these of these guidelines is to provide guidance to all potential applicants on the legal requirements to register pesticides before they are allowed to be imported or manufactured for sale and use in the country as provided for under the Pesticides Act 1974.

These Guidelines replace the 'Guidelines on Registration and Labelling of Pesticides' issued by the Pesticides Board in 1991 (4th Edition). The present registration guidelines were revised to accommodate the changes brought about by the amendment to the Pesticides Act 1974 which was passed by the Parliament in 2004. There are a number of new or amended provisions in the Act that affects the registration processes and procedures. These include the requirement for applicants to pay an application fee and a registration fee as well as the extension of the registration period from 3 years to 5 years.

These guidelines provide information on the application procedures to guide the applicants on how submissions for pesticides registration can be made to the Pesticides Board. It also provide an explanation on the requirements to register commodity and proprietary pesticides as well as new registration and re-registration procedures.

It is important to note that, these guidelines should be read together with other guidelines and related circulars produced by the Pesticides Board, in particular guidelines on data requirements namely on physical and chemical properties, toxicology and eco-toxicology, residue, bio-efficacy and environmental fate.

*Pesticides Board
Pesticides Control Division
Department Of Agriculture
Ministry Of Agriculture And Agro-Based Industry Malaysia*

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INTRODUCTION

Sections 7-13 of the Pesticides Act 1974 provides for the control of importation and manufacture of pesticides. The objective of pesticide registration is aimed at ensuring that pesticides offered for sale in the country are of good quality, effective for their intended use and at the same time would not cause unacceptable adverse effects to man and the environment.

Registration of pesticides is implemented through the Pesticides (Registration) Rules 2005 which was gazette on 18 August 2005 to replace the Pesticides (Registration) Rules 1976. These new Rules describe how pesticide registration approval can be obtained from the Pesticides Board.

TERMS AND DEFINITIONS

Pesticide

The term 'pesticide' under the Pesticides Act 1974 is defined as 'any substance that contains an active ingredient' or 'any preparation, mixture or material that contains any one or more of the active ingredients as one of its constituents', while the term 'active ingredient' means an ingredient, as listed in the First Schedule of the Pesticides Act 1974.

Generally pesticides includes, but are not limited to, herbicides, insecticides, fungicides, acaricides, nematocides, rodenticides, molluscicides, bactericides, fumigants, soil fumigants, miticides, preservatives, repellants and termiticides.

Applicants are required to refer to the First Schedule of the Pesticides Act 1974, in order to ascertain whether their product contains any of the listed active ingredients, thus requiring registration. As the First Schedule is updated from time to time to include new active ingredients, it is necessary for the applicant to refer to the Pesticides Board for the updated listing.

Proprietary and Commodity Pesticide

For the purpose of registration, pesticides are divided into 2 categories namely proprietary and commodity.

Commodity pesticides are pesticides containing active ingredients that have been registered in Malaysia for not less than 10 years.

Proprietary pesticides are pesticides that are not commodity pesticides as defined above are classified as proprietary pesticides. In case the of a pesticide mixture containing proprietary and commodity active ingredients, the pesticide shall be considered as a proprietary pesticide.

Manufacture

The term manufacture as defined by the Act means to prepare, compound, formulate, mix, make, pack, re-pack or label a pesticide or otherwise treat the pesticide with a view to its sale.

Registration

Registration is a process of evaluation and approval by the Pesticides Board before a pesticide is allowed to be imported, manufactured, sold and used in the country. Only those pesticides that are of good quality, effective for the intended purposes and do not cause unacceptable adverse effect on human beings, animals, plants, fruits or property would be registered in the country.

In order for the evaluation to be carried out, the Pesticides Board requires the applicant to submit relevant data when applying for the registration. The data requirements for pesticide registration under these rules are adapted from the Food and Agriculture Organisation of the United Nations (FAO) and other international organizations. The details of information required for evaluation are given in the application form.

A separate application is required if the pesticide is different from another pesticide. A pesticide is considered different from another pesticide, if:

- (a) the active ingredient of that pesticide is different from that of the other pesticide;
- (b) the trade name or trade mark of that pesticide is different from that of the other pesticide;
- (c) the ingredients of that pesticide are different from those of the other pesticide in type, number, proportion, concentration, or in other respects; e.g. glyphosate isopropylamine 13.6% w/w soluble concentrate (SL) and glyphosate isopropylamine 41.0% w/w soluble concentrate (SL) must be registered separately under each concentration;
- (d) the pesticide is differently formulated from the other pesticide, e.g. if alpa-cypermethrin is formulated as an emulsifiable concentrate (EC) and also as suspension concentrate (SC), it must be registered separately under each formulation;
- (e) the pesticide is manufactured by a manufacturer other than the manufacturer of the other pesticide; e.g. if benomyl is manufactured by two companies, the products from both companies must be registered separately even if the products are identical; or

(f) that pesticide is different in quality, nature, characteristics or efficacy from the other pesticide; e.g. if one azadirachtin product is different in quality, nature, characteristics or efficacy from another product it must be registered separately from the other.

A separate application is also required if the category of usage is different e.g. insecticide for agriculture use and insecticide for public health.

APPLICATION PROCEDURES

Application For Registration

Application to register and re-register a pesticide must be made using Application Form, Form A [Subrule 2(1)] (Application For Registration/Re-registration Of A Pesticide)] and only locally registered companies may apply. All applications must be submitted to the following address:

Secretary
Pesticides Board
Pesticides Control Division
Department of Agriculture
4th Floor Wisma Tani
Jalan Sultan Salahuddin
50632 Kuala Lumpur.
Tel No: 03-2030 1400
Fax No: 03-2691 7551

Application forms are obtainable from the above-mentioned address. Submissions should be made well in advance of the desired registration date.

Applicants should indicate in the standard cover-letter of the application (see [Annex I](#)) whether the product is a commodity pesticide or a proprietary pesticide. The onus is on the applicant to provide evidence that a product is a commodity pesticide. Some common active ingredients which are considered as commodity pesticides are listed in the latest edition of "Syor-Syor Kawalan Diluluskan Untuk Racun Perosak Komoditi" (GP5). This list serves as a guide only and is subject to review from time to time. For commodity pesticides, some registration requirements have been waived but the Pesticides Board reserves the right to still request for them if necessary.

Applicants are also advised not to proceed with the printing of the final labels until the product has been granted registration.

The period of registration of a pesticide is 5 years, effective from the date of registration unless it is terminated by the registrant or cancelled by the Pesticides Board. Under the Pesticides (Registration) Rules 2005, two types of fee will be imposed on an application to register and re-register a pesticide. The fee for an application is **RM1,500.00 (one thousand five hundred ringgit)** payable at the time the application is submitted. This fee is not refundable. Upon approval, a registration/re-registration fee will be imposed for each product payable prior to the

issuance of the Registration Certificate. The amount¹ imposed for registration varies according to class as follows:-

Class 1a and 1b per approval: RM3,500.00 (three thousand five hundred ringgit)

Class II per approval : RM2,000.00 (two thousand ringgit)

Class III per approval : RM1,000.00 (one thousand ringgit)

Class IV per approval : RM 500.00 (five hundred ringgit only)

New Registration

The following are the requirements for an application for registration of a new pesticide:

a) Five (5) sets of application forms and supporting information.

This must include a set of the original copy. If the information submitted consists of many volumes, a complete dossier with the original set and four (4) sets of summaries may be submitted. Please refer Part E of the Application Form for the information to be submitted.

b) All information must be on A4 size paper, properly filed in A4 size folders and accompanied by a standard cover-letter. (See Annex I).

c) The source(s) of a pesticide must be declared in the cover letter. In addition a letter from the source(s) confirming that they are the suppliers of the pesticide should also be submitted. A maximum of 3 sources will be allowed at any one time provided the composition and percentage of all the ingredients are identical. An outline of the manufacturing process from all the sources must be submitted. Any change of source(s) or manufacturing process during the period of registration must be approved by the Pesticides Board.

d) Letter authorizing the use of data from the owners of the data.

e) Each set of the application should be accompanied by a copy of the draft label. Two additional draft labels are to be attached to the cover-letter.

f) A pesticide sample from each of the sources must be submitted, suitably packed and clearly labeled with the following information i.e trade name, applicant name, active ingredient, concentration, type of formulation and the source name. The quantities required are as follows:

Technical material	-50 g or 50 ml
Formulated material	-100 g or 100 ml
Aerosol	- 4 x 100 ml cans or more
Mosquito coil	- 4 x 10 pieces

Mosquito mat	- 2 x 30 pieces
Others	- refer to Pesticides Board

The registration sample must not be submitted in plastic bags in order to avoid spillage and contamination. Dust/powder or liquid formulations should be placed in either plastic or glass bottles. For dust or powder formulations, wide-mouthed bottles fitted with stoppers or seals should be used. **Samples should be not sent by post** but should be sent either by hand or by courier service. All imported samples must be accompanied with an Import Permit endorsed by the Malaysian Customs.

- g) Analytical standard must be submitted for each active ingredient listed in the application. Analytical standard samples must be accompanied by an Import Permit (endorsed by the Royal Malaysia Customs Department), Certificate of Analysis, and information on the date of expiry of the standard must be provided (date of expiry must not be less than 1 year from date of submission). Some active ingredients are exempted from submission of analytical standard¹. The specifications mentioned above for submission of samples also applies to submission of analytical standards.
- h) Each application must be submitted with a copy of the current Certificate of Registration of the company (ROC/ROB).
- i) Banker's draft/money order/postal order of **RM 1,500.00 (one thousand five hundred ringgit)** per application, made payable to the Director General of Agriculture, as the payment for the application.

¹ as per circular B.81/05.20/Jld. V(25) dated 12 Dis. 2008

² 5 sets as per circular B.81/05.20/Jld. IV(65) dated 6 Dis. 2000

Re-registration

The validity period of a registration is 5 years. Before the end of the validity period, the registrant may make an application to re-register the pesticide, and the application must be submitted not earlier than 1 year **BUT not later than 6 months** before expiry.

Late submissions to re-register may not be accepted and may necessitate the pesticide be submitted as a new application.

The following are the requirements for an application for re- registration:

- a) One (1)* set of application forms.
- b) Four (4) copies of amended draft label.
- c) A copy of the current Registration Certificate.
- d) The source(s) of a pesticide as approved by the Pesticide Board must be declared in the cover-letter. In addition, a recent letter of undertaking (not more than one year from the date of application for re-registration) from the source(s) confirming that they will continue to be the suppliers of the pesticide should also be submitted. A maximum of 3 sources will be allowed at any one time provided the composition and percentage of all the ingredients are identical. An outline of the manufacturing process from all the sources must be submitted (Please Refer Annex II, Chapter 1, Item 1.3 and 1.9). Any change of source(s) or manufacturing process during the period of registration must be approved by the Pesticides Board, and such evidence must be submitted at re-registration.
- e) Data on five batch analysis.
- f) A copy of the current Certificate of Registration of the company (ROC/ROB).
- g) All information must be on A4 size paper and accompanied by a standard cover-letter. (See Annex I).
- h) Banker's draft/money order/postal order of **RM1,500.00 (three thousand ringgit)** per application made payable to the Director General of Agriculture as payment for the application.

How To Complete The Application Form

The Application Form is divided into 7 parts i.e. A, B, C, D, E, F and G and all parts must be completed.

For Part E, however, depending on the general use pattern of the pesticide (whether proprietary or commodity) some studies or information/data may be waived. To assist the applicant in providing the right data/information to support the application to register or re-register a pesticide, Annex II provides a summary of data requirements for different types of pesticides.

In addition to the above, the applicant should also refer to the following guidelines for detailed information on how such data/studies should be generated and compiled:

- i) Guidelines on Product Chemistry Data Requirements For Pesticide Registration (GP 1)
- ii) Guidelines on Toxicological Data Requirements For Pesticide Registration (GP 2)
- iii) Guidelines on Efficacy Data Requirements For Pesticide Registration (GP 3)
- iv) Guidelines on Residue Data Requirements For Pesticide Registration (GP 4)
- v) Syor-Syor Kawalan Diluluskan Untuk Racun Perosak Komoditi (GP 5)

LABELLING REQUIREMENTS

The label represents an important source of information to the user of a pesticide. A label is the written, printed or graphic material firmly attached to a product container.

Among others, the label should contain the identity of the pesticide and instructions on use, precautions to be taken and other relevant information. This is to ensure that the pesticide is used properly and effectively. Under the Pesticides Act 1974, a pesticide shall not be sold unless it is registered and labelled with an approved label. To ensure proper labelling of pesticides sold in the country, the Pesticides (Labelling) Regulations 1984 have been gazetted and should be used. As part of the process of approving an application for registration, the proposed label of a pesticide is evaluated to ensure that it complies with the requirements of these regulations. To comply with the labelling requirement, therefore refer to the Pesticides (Labelling) Regulations 1984. For guidance, the applicant is advised to refer to Annex III which provides two layout examples that meet the requirement of the Pesticides Board.

The applicant should also refer to the latest edition of 'Garis Panduan Untuk Nama Dagangan Racun Perosak' in order to ensure trade name given to the pesticide is acceptable to the Pesticides Board.

MANUFACTURING FOR EXPORT PURPOSES

Registration approval under the Pesticides (Registration) Rules 2005 is only meant for all activities to import and manufacture pesticides intended for local market and sale. However, if the pesticide is solely manufactured for export, registration approval is not required, provided it contains an active ingredient which is at the time registered with the Pesticides Board. It is the duty of the manufacturers to check with the Pesticides Board, to confirm if such an active ingredient is already registered in Malaysia.

IMPORTATION OF AN UNREGISTERED PESTICIDE

An unregistered pesticide may only be imported in a limited quantity for educational or research purposes, or as a registration sample or in the form of analytical standard by means of a import permit as provided for under the Pesticides (Importation for Educational and Research Purposes) Rules 1981. Copies of the "Guidelines on Application for Permit to Import Pesticides for Educational and Research Purposes" are available from the Secretary of the Pesticides Board upon request.

PENALTIES

It is illegal under the Pesticide Act 1974, to import and/or manufacture pesticides without any valid registration approval from the Pesticides Board. Any person, if found guilty of importing or manufacturing any pesticide without valid registration approval, is liable on a first conviction, to imprisonment for 5 years or to a fine of RM50,000 and, on a second or subsequent conviction, to imprisonment for 10 years or to a fine of RM100,000 or both.

**THIS STANDARD COVER LETTER IS TO BE
TYPED ON APPLICANT'S COMPANY LETTERHEAD**

Date :

Secretary
Pesticides Board
Department of Agriculture
4th Floor, Wisma Tani
Jalan Sultan Salahuddin
506320 Kuala Lumpur.

Dear Sir,

APPLICATION TO REGISTER/RE-REGISTER PESTICIDE

Herewith is an application to register/re-register *

 (state trade name)

(please tick whichever is applicable)

<input type="checkbox"/>	Commodity Pesticide		
<input type="checkbox"/>	Proprietary Pesticide		
<input type="checkbox"/>			
<input type="checkbox"/>	<u>New Registration</u>	<input type="checkbox"/>	<u>Re-registration</u>
			LRMP/R1 No. : File No. : JP KRP 207/12/171/.....
<input type="checkbox"/>	5 set of application (Form A)	<input type="checkbox"/>	1 set of application (Form A)
<input type="checkbox"/>	5 sets with 1 original set of data requirements (Part E- Form A)	<input type="checkbox"/>	Data on five batch analysis
<input type="checkbox"/>	1 copy of proposed label in each set	<input type="checkbox"/>	1 Photostat copy of endorsed printed label
<input type="checkbox"/>	2 copies of proposed labels attach with cover letter.	<input type="checkbox"/>	copies of amended draft labels
		<input type="checkbox"/>	Copy of current Registration Certificate

APPLICABLE TO REGISTRATION & RE-REGISTRATION

Sample suitably packed and labeled. (With copy of Import Permit, if necessary)

Sample of analytical standard suitably packed and labeled. (With copy of Import Permit, if necessary)

Letter of certification from source of the pesticide.

Letter of authorization on the use of data.

Copy of company registration (ROC/ROB)

The source(s) (Name and address) of the above pesticide are:

1. _____

2. _____

3. _____

Thank you.
Yours faithfully,

(Name and Signature of
applicant & Company stamp)

**SUMMARY OF DATA REQUIREMENTS FOR PROPRIETARY AND COMMODITY
PESTICIDES ACCORDING TO GENERAL USE PATTERN
(REFER APPLICATION FORM,
PART E: PARTICULARS ON DATA REQUIREMENTS)**

Chapter	General Use Pattern							Notes
	Food Commodity	Non-Food Commodity	Indoor / House hold	Out Door/ Public Health	Forestry	Technical Material (TC)	Technical Concentrate (TK)	
CHAPTER 1: IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES (Refer to GP1/2015)								
Part A : Requirement On Technical Active Ingredient	Data for technical grade of active ingredient (TGAI) is required on cases where TGAI is not registered with Pesticides Board but its formulated product (ready-made) is directly imported and is intended to be registered.							
1.1	Manufacturer name and contact information	√	√	√	√	√	√	
1.2	ISO common name and synonym	√	√	√	√	√	√	
1.3	Chemical name	√	√	√	√	√	√	
1.4	Existing CAS and CIPAC number	√	√	√	√	√	√	
1.5	Identity and composition	√	√	√	√	√	√	
1.6	Specification of purity of active ingredient	√	√	√	√	√	√	
1.7	Molecular formula, molecular mass and molecular structure	√	√	√	√	√	√	
1.8	Method of manufacturing process (starting material, pathway, byproducts and impurities) and quality control.	√	√	√	√	√	√	Endorsed by QA manager
1.9	Identity, content, structural formula of isomer, impurities and additive.	√	√	√	√	√	√	
1.10	Data on five batch analysis including the profile of impurities and chromatogram.	√	√	√	√	√	√	Must comply with the standards of Good Laboratory Practices (GLP).

Chapter	General Use Pattern							Notes
	Food Commodity	Non-Food Commodity	Indoor / House hold	Out Door/ Public Health	Forestry	Technical Material (TC)	Technical Concentrate (TK)	
1.11 Physical and chemical properties: i. For solids; its melting point (at stated temperature). ii. For liquids, vapour pressure, boiling point, (at stated temperature), specific gravity and viscosity (at stated temperature) iii. Flash point iv. Solubility in water and other solvents- at least 2 solvent (at stated temperature) v. n-octanol/water partition coefficient vi. Hydrolysis rate, photolysis (under stated conditions) vii. Stability towards oxidizing agents and thermal changes (corrosiveness testing) viii. Dissociation constant (pKa, pKb)	√	√	√	√	√	√	√	Must comply with the standards of Good Laboratory Practices (GLP). Commodity : i, ii & iii. Proprietary : All (i – viii)
Part B : Requirement On The Formulation (if relevant)								
1.12 Manufacturer name and contact information	√	√	√	√	√	-	-	
1.13 Detail qualitative and quantitative information of the composition of preparation	√	√	√	√	√	-	-	Manufacturing Limits (min-max). Endorsed by QA manager
1.14 Method of manufacturing process (material used and condition required)	√	√	√	√	√	-	-	Endorsed by QA manager
1.15 Type of formulation and function	√	√	√	√	√	-	-	

Chapter	General Use Pattern							Notes
	Food Commodity	Non-Food Commodity	Indoor / Household	Out Door/ Public Health	Forestry	Technical Material (TC)	Technical Concentrate (TK)	
1.16 Physical and chemical properties:	√	√	√	√	√	-	-	Comply with the standards of Good Laboratory Practices (GLP) / ISO
i. Appearance								
• Physical state (for all formulation)								
ii. Corrosiveness								
iii. Flammability (if applicable)								
iv. Known compatibility with other chemicals (only to be performed when tank mix is recommended on the label)								
v. Oxidation/reduction : chemical incompatibility (only to be performed when tank mix is recommended on the label)								
vi. Rate of release, or release/retention index, of active ingredient (for slow- release granules (CG), slow-release capsule suspensions (CS), long lasting insecticidal nets (LN).								
vii. “Free” active ingredient (For slow release granules (e.g: encapsulated granules, CG) and slow release capsule suspensions (CS).								
viii. By-products of manufacture or storage (all specifications where relevant impurities may be associated with active ingredient								
ix. Acidity or alkalinity and if necessary pH								
x. Explosivity.								

Chapter	General Use Pattern							Notes
	Food Commodity	Non-Food Commodity	Indoor / Household	Out Door/ Public Health	Forestry	Technical Material (TC)	Technical Concentrate (TK)	
1.17 Specific Properties/ Test Related to Use: <ul style="list-style-type: none"> • Wettability • Persistent foaming • Suspensibility • Wet sieve test • Dry sieve test • Emulsion stability • Dilution stability • Flowability • Pourrability • Dustability • Distribution and - adherence to seed • Others 	√	√	√	√	√	-	-	
1.18 Storage stability test (FAO Accelerated Storage Test Procedures may be employed)	√	√	√	√	√	-	-	Comply with the standards of Good Laboratory Practices (GLP) / ISO
1.19 Specifications of the product (indicate whether it meets any specifications e.g. Malaysian Standard, FAO/WHO specification or others)	√	√	√	√	√	-	-	
1.20 Safety Data Sheet (SDS)	√	√	√	√	√	-	-	
1.21 Packaging (including packaging material and its compliance to any standards or specifications)	√	√	√	√	√	-	-	
1.22 Data on five batch analysis of the active ingredient including chromatogram (if applicable)	√*	√*	√*	√*	√*	-	-	Conditionally required. Required if the product had been registered elsewhere.

Chapter	General Use Pattern							Notes
	Food Commodity	Non-Food Commodity	Indoor / Household	Out Door/ Public Health	Forestry	Technical Material (TC)	Technical Concentrate (TK)	
CHAPTER 2 : METHOD OF ANALYSIS (Refer to GP1/2015)								
2.1 Validated methods of analysis of active ingredient in the technical material	-	-	-	-	-	√	√	
2.2 Validated method of analysis of active ingredient content in the formulation	√	√	√	√	√	-	-	
2.3 Validated methods of analysis of content of impurities in the technical material and formulation.	√	√	√	√	√	√	√	
2.4 Validated methods of analysis for residue of the active ingredient and all important metabolites in all relevant matrix of the crops.	√	-	-	-	-	-	-	
2.5 Validated methods of analysis for residue of the active ingredient and all important metabolites in environmental media.	√	√	-	√	√	-	-	

Chapter	General Use Pattern						Notes
	Food Commodity	Non-Food Commodity	Indoor / House hold	Out Door/ Public health	Forestry	Technical material	
<p>CHAPTER 3 : IMPACT ON HUMAN AND ANIMAL (MAMMALIAN TOXICOLOGICAL DATA) (Refer to GP2/93)</p> <p>To submit requirements of Part A or Part B or both. To submit either Part A or Part B. Submission of both Parts A & B (i.e Data on Technical and Formulation) is also acceptable. However, if any of the a.i(s) in the formulation is proprietary, submission of Part B (if selected) must include data requirements Part A (3.2) to A (3.5). These data may be based on <u>either the technical a.i(s) or formulated product.</u></p> <p><u>PREMIXTURE ACTIVE INGREDIENT</u> - food crop usage (insecticide/fungicide): mandatory toxicology data on MIXTURE - Herbicide: toxicology data on single active ingredient is acceptable.</p> <p><u>SINGLE ACTIVE INGREDIENT</u> - toxicology data on technical grade or finish product is acceptable</p>							
Part A: Requirement On Technical Active Ingredient							Must comply with the standards of Good Laboratory Practices (GLP).
3.1 Acute toxicological data							
3.1.1 Acute oral studies (in rats)	√	√	√	√	√	√	
3.1.2 Acute dermal studies (in rats)	√	√	√	√	√	√	
3.1.3 Acute inhalation studies (in rats)	√	√	√	√	√	√	Not required for commodity pesticide, unless studies indicate significant exposure through this route
3.1.4 Skin irritation studies (in rabbits).	√	√	√	√	√	√	Not required for commodity pesticide, unless studies indicate significant exposure through this route
3.1.5 Eyes irritation studies (in rabbits).	√	√	√	√	√	√	Not required for commodity pesticide, unless studies indicate significant exposure through this route
3.1.6 Dermal sensitisation study (in guinea pigs).	√	√	√	√	√	√	Not required for commodity pesticide, unless studies indicate significant exposure through this route
3.1.7 Acute delayed neurotoxicity in hens (for organophosphates and carbamates)	√	√	√	√	√	√	Not required for commodity pesticide

Chapter	General Use Pattern						Notes
	Food Commodity	Non-Food Commodity	Indoor / House hold	Out Door/ Public health	Forestry	Technical material	
3.2 Sub-acute toxicological data							Not required for commodity pesticide, unless acute toxicity profile indicates that there is a strong possibility that sub-acute exposure can result in significant negative effects.
3.2.1 Repeated dose 21 or 28 days dermal toxicity (in rats)	√	√	√	√	√	√	
3.2.2 Repeated dose 28 days oral delayed neurotoxicity in hens (organophosphates and carbamates if triggered by findings of acute delayed neurotoxicity).	√	√	√	√	√	√	
3.2.3 Sub-acute 90 days dietary feeding study (in rats)	√	√	√	√	√	√	
3.3 Chronic toxicological data							Not required for commodity pesticide, unless acute and sub-chronic toxicity profile indicates that there is a strong possibility that chronic exposure can result in significant negative effects.
3.3.1 Chronic dietary feeding study (24 months in rats, 18 months in mouse and 1 year in dogs).	√	√	√	√	√	√	
3.3.2 Oncogenicity study (not less than 24 months for rats and 18 months for mouse. This study can be combined with chronic feeding study, if appropriate).	√	√	√	√	√	√	
3.4 Supplemental toxicological studies							Not required for commodity, unless its toxicity profile/ use recommendations indicates that there is a strong possibility that exposure can result in long-term significant negative effects in relation to the aspects as stated below.
3.5 Teratogenicity study (2 species, one rodent and one non-rodent)	√	√	√	√	√	√	

Chapter	General Use Pattern						Notes
	Food Commodity	Non-Food Commodity	Indoor / House hold	Out Door	Forestry	Technical material	
3.6 Reproductive study (2 generations of rodents and one litter).	✓	✓	✓	✓	✓	✓	Not required for commodity
3.7 Mutagenicity study (at least in 3 battery of tests to detect gene mutation, chromosomal aberration and genotoxic effects)	✓	✓	✓	✓	✓	✓	Not required for commodity
3.8 Metabolic study (at least one species)	✓	✓	✓	✓	✓	✓	Not required for commodity
3.9 Human toxicology data (such as industrial exposure data, accidental data or volunteer data).	✓*	✓	✓	✓	✓	✓	Not required for commodity Optional unless requested
3.10 Toxicological information of every ingredient, synergist, and major or important impurity of the pesticides.	✓	✓	✓	✓	✓	✓	Not required for commodity pesticide
Part B : Requirement On The Formulation (if applicable)							Must comply with the standards of Good Laboratory Practices (GLP).
3.7 Acute oral toxicity study in rats.	✓	✓	✓	✓	✓	-	Preferred studies, in additions to studies on technical material (Refer 3.1.1.)
3.8 Acute dermal toxicity study in rates.	✓	✓	✓	✓	✓	-	Preferred studies, in additions to studies on technical material (Refer 3.1.2.)
3.9 Skin irritation study in rabbits	✓	✓	✓	✓	✓	-	Not required for commodity pesticide, unless studies indicate significant exposure through this route.
3.10 Eye irritation study in rabbits	✓	✓	✓	✓	✓	-	Not required for commodity pesticide, unless studies indicate significant exposure through this route.
3.11 Skin sensitisation study in guinea pigs.	✓	✓	✓	✓	✓	-	Not required for commodity pesticide, unless studies indicate significant exposure through this route.
3.12 Acute inhalation study in rats (if applicable)	✓	✓	✓	✓	✓	-	Not required for commodity, unless studies indicate significant exposure through this route.

Chapter	General Use Pattern						Notes	
	Food Commodity	Non-Food Commodity	Indoor / House hold	Out Door	Forestry	Technical material		
CHAPTER 4 : RESIDUE (Refer to GP4/2012) & (16th Schedule (Regulation 41))							No required if it is recommended on 16 th Schedule (Regulation 41)	
4.1	Definitions of the residue to Maximmm Residue Limits (MRLs)	√	-	-	-	-	-	
4.2	Detailed reports on supervised residue trial on recommended crops based on accepted protocols (e.g. FAO Manual on the Submission and Evaluation of Pesticide Residue Data for the Estimation of MRL in Food and Feed, FAO, UN 2002). Studies conducted under similar climatic conditions may be submitted.	√	-	-	-	-	-	At least three field experiments done at different sites must be submitted. For a major crop, which is oil palm, cocoa, paddy and black pepper, at least one field experiment must be generated under local conditions.
4.3	Residue analytical method with chromatograms for standard, control, sample and recovery test.	√	-	-	-	-	-	Analytical method by crop
4.4	Information on metabolism or degradation of the active ingredient in crops or plants	√	-	-	-	-	-	Mandatory for proprietary a.i.
4.5	Acceptable Daily Intake (ADI) of the pesticide in mg/kg body weight.	√	-	-	-	-	-	ADI by a.i
4.6	Proposed Pre-harvest interval (PHI) or Pre-Slaughter Interval (PSI)	√	-	-	-	-	-	PHI by crop
4.7	Proposed Maximum Residue Limits (MRLs) calculated based on Dietary Risk Assessment of the pesticide.	√	-	-	-	-	-	Proposed MRL by crop
4.8	Maximum Residue Limits (MRLs) from other countries that have registered the pesticide	√	-	-	-	-	-	MRL by crop

Chapter	General Use Pattern						Notes
	Food Commodity	Non-Food Commodity	Indoor / House hold	Out Door	Forestry	Technical material	
CHAPTER 5 : FATE AND BEHAVIOUR IN THE ENVIRONMENT (Refer to GP2/93)							
5.1 Definition of the residue relevant to the environment	√	√	-	√	√	-	
5.2 Degradation and dissipation studies (hydrolysis, photolysis in water and soil)	√	√	-	√	√	-	
5.3 Metabolism studies (in water and soil for both aerobic and anaerobic conditions).	√	√	-	√	√	-	
5.4 Mobility studies (leaching and adsorption or desorption studies, volatility in laboratory and field).	√	√	-	√	√	-	
5.5 Fate and behavior in air.	√	√	-	√	√	-	
5.6 Bioaccumulation study in fish	√	√	-	√	√	-	
CHAPTER 6 : EFFECTS ON NON TARGET SPECIES (Refer to GP2/93)							
6.1 Effects on terrestrial vertebrates (including acute oral toxicity to avian species e.g. pigeon, quail, pheasant, or duck).	√	√	-	√	√	-	
6.2 Effects on aquatic species							
6.2.1. Acute LC ₅₀ , 96 hours exposure on the suitable fish species.	√	√	-	√	√	-	
6.2.2. Acute LC ₅₀ , 48 hours exposure on one suitable fish-food species e.g. daphnia	√	√	-	√	√		
6.3 Effects on bees and other arthropod species (including acute oral LD ₅₀ and contact toxicity on honey bees)	√	√	-	√	√		
6.4 Effects on earthworms and other soil macro-organisms (including acute toxicity on earthworms).	√	√	-	√	√		

6.5 Effects on other non-target organisms (flora and fauna)	√	√	-	√	√		
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Chapter	General Use Pattern						Notes
	Food Commodity	Non-Food Commodity	Indoor / House hold	Out Door	Forestry	Technical material	

CHAPTER 7 :

EFFICACY DATA AND INFORMATION (Refer to GP3/93)

- All reports submitted must be very recent and shall **not be more than 15 years** from the date of submission.
 - Not required for HERBICIDE if the active ingredient and its formulation is listed in GP5. *Please refer latest secular dated 26 Feb 2013. - Journal data on bio-efficacy trial is acceptable.

7.1 Local Bio-efficacy trials on the recommended crops based on the accepted protocols (e.g. FAO Harmonized Bio-efficacy Protocols). Trials conducted under similar climatic regime and cultural practices may be used for minor crops)	√*	√	-	-	√		* Not required for veterinary products. - Must submit bio-efficacy trial data <u>for each crop</u> . - For a major crop, which is oil palm, cocoa, paddy and black pepper, one field experiment (with multiple replicates) must submit bio-efficacy trial generated under local conditions. - For Non major crop, bio-efficacy trial from overseas is acceptable.
7.2 Phytotoxicity assessment on crops based on accepted protocols (e.g. FAO Guidelines for Phytotoxicity Assessment)	√*	√	-	-	√	-	* Not required for veterinary products.
7.3 Effects on natural Enemies	√*	√	-	-	√	-	* Not required for veterinary products.
7.4 Information on potential occurrence to resistance	√	√	-	-	√		
7.5 Comparative study using Malaysian Standard or other internationality accepted protocols for all non-agriculture pesticides	√*	-	√	√	-	-	* Not required for agricultural products.
7.6 Information on mode of action and its grouping.	√	√	√*	-	√	-	* Not required for household pesticides.
7.7 Propose use(s) and Recommendation in tabulated form - tabulated format - statement format	√	√	√*	√	√	-	*depending on the type of usage Refer to “Garis Panduan (Pelabelan)”

[KEY : (√) = Required; (√*) = Conditionally required and (-) = Not required]

EXAMPLES OF GENERAL USE PATTERNS

<p><u>Food commodity</u></p> <ul style="list-style-type: none">▪ Agricultural crops for human consumption▪ Veterinary	<p><u>Indoor / Household</u></p> <ul style="list-style-type: none">▪ Household Pesticides▪ Rodenticides for household use▪ Pet animals pesticides	<p><u>Forestry</u></p> <ul style="list-style-type: none">▪ Forest trees including dead trees, logs and stumps▪ Forest tree nurseries▪ Non-ornamental trees including rubber trees
<p><u>Non-food commodity</u></p> <ul style="list-style-type: none">▪ Crop for smoking▪ Ornamental plants▪ Lawn and turf grasses▪ General soil treatments▪ Recreational areas▪ Roads, tracks and paved areas	<p><u>Outdoor</u></p> <ul style="list-style-type: none">▪ Wood treatments▪ Antifouling treatments▪ Public health▪ Preservative	<p><u>Technical material</u></p> <ul style="list-style-type: none">▪ Technical material for manufacturing purposes

a) **CONTOH DRAF LABEL- Gred Teknikal Untuk Tujuan Perkilangan**

TRADE NAME

RACUN MAKHLUK PEROSAK BAHAN TEKNIKAL (TC)

GRED TEKNIKAL UNTUK TUJUAN PERKILANGAN SAHAJA

(TECHNICAL GRADE FOR MANUFACTURING PURPOSES ONLY)

Perawis Aktif: xxxxxxxxxxx xx.xx% w/w
Perawis Lengai: x.x% w/w

Didaftarkan oleh:

NAMA SYARIKAT. (XXXXX-X)

Alamat 1,

Alamat 2,

Poskod, Negeri.

Tel.: xx-xxxxxxx Faks: xx-xxxxxxx

Email:xxxxxxx@xxxx.xxx

No. Pendaftaran: LRMP. R1/

Tarikh Mengilang:

Kandungan Bersih: x kg

Jika berlaku **KERACUNAN**, sila hubungi:

PUSAT RACUN NEGARA - 1-800-88-8099 (waktu pejabat)

- 012-4309499 (lepas waktu pejabat)

BACA LABEL SEBELUM GUNA

**BERBAHAYA
JAUHKAN DARIPADA
MAKANAN DAN
KANAK-KANAK**

KELAS III

**HARMFUL
KEEP AWAY FROM
FOODSTUFF AND
CHILDREN**

AWAS:

a) Bahaya Kepada Manusia: Berbahaya jika tertelan. Elakkan daripada terhidu wasap. Elakkan daripada terkena pada kulit dan mata. Ketika mengendalikan produk ini, **JANGAN** makan, minum atau merokok. Selepas mengendalikan produk ini, pastikan basuh badan sebersih-bersihnya dengan sabun dan air. Tutup bekas racun dengan rapat dan simpan di tempat berkunci yang mempunyai peredaran udara yang baik, kering dan dingin.

Pakaian dan Alat Perlindungan: Ketika mengendalikan produk ini, pastikan pakai pakaian pelindung diri (PPE) berpiawaian termasuk sarung tangan, goggles, penutup muka dan alat pernafasan (respirator).

b) Bahaya Pada Alam Sekitar: Produk ini adalah berbahaya pada organisma akuatik dan ikan. **JANGAN** cemarkan kolam, sungai atau saluran air dengan tumpahan, sisa-sisa bahan atau larutan pencuci.

TANDA KERACUNAN:

Gatal-gatal pada mata atau kulit.

RAWATAN KECEMASAN:

Tanggalkan pakaian yang terkena racun. Jika terkena pada kulit, basuh dengan menggunakan sabun dan air. Jika terkena pada mata, bersihkan dengan menggunakan air bersih yang banyak selama sekurang-kurangnya 15 minit. Jika tertelan, ikhtiarkan supaya pesakit itu muntah dengan menjolok jari ke dalam kerongkong selepas diberi minum air. Jangan beri apa-apa melalui mulut dan jangan ikhtiarkan pesakit itu muntah jika dia tidak sedar. Dapatkan rawatan perubatan dengan segera.

RAWATAN PERUBATAN:

Rawatan hendaklah mengikut tanda sakit.

MEDICAL TREATMENT:

Treatment is symptomatic.

BILAS BEKAS KOSONG TIGA (3) KALI SEBELUM MELUPUSKANNYA. JANGAN

GUNAKAN BEKAS RACUN UNTUK MENYIMPAN MAKANAN.

VERSI CINA**KELAS III****VERSI TAMIL**

b) CONTOH DRAF LABEL- Formulated product

TRADE NAME
RACUN KULAT

SERBUK BANCUH (xx)
Kandungan Bersih:xx kg

Perawis Aktif:	xxxxxxxxx	x.x% w/w
	xxxxxxxxx	xx.xx% w/w
Perawis Lengai:	xx.xx% w/w

No. Pendaftaran: LRMP. R1/

Tarikh Mengilang:

Didaftarkan oleh:

NAMA SYARIKAT. (xxxxxxx-x)

Alamat 1,

Alamat 2,

Poskod, negeri.

Tel.: xx-xxxxxxxx Faks: xx-xxxxxxxx

Email: xxxxxx@xxxxx.xxx

Jika berlaku **KERACUNAN**, sila hubungi:

PUSAT RACUN NEGARA: 1-800-88-8099 (waktu pejabat)

012-4309499 (lepas waktu pejabat)

BACA LABEL SEBELUM GUNA

KELAS IV

**KEEP AWAY
FROM FOODSTUFF
AND CHILDREN**

**JAUHKAN
DARIPADA
MAKANAN DAN
KANAK-KANAK**

VERSI TAMIL

VERSI CINA

ATURAN PENGGUNAAN: TRADE NAME ialah racun xxxxxxxxxxxx pracampuran daripada kumpulan xxxxxxxxxxxxxxxx dan xxxxxxxxxxxxxxxx yang bertindak memberi perlindungan kepada tanaman. Racun xxxxxxxx ini berkesan untuk kawalan xxxxxxxxxxxxxxxx seperti yang tercetak pada label.

Penggunaan tidak mengikut label adalah satu kesalahan.

TANAMAN	JENIS xxxxxxxxxx	KADAR RACUN		ISI PADU SEMBURAN SEHEKTAR	BILANGAN SEMBURAN MAKSIMUM
		10 liter air	Sehektar		
xxxxxxxxxx	xxxxxxxxxxxx (xxxxxxxxxxxxxxx)	xx g	xx kg	xx liter	x kali semusim

Jangan kutip hasil tanaman yang disyorkan sekurang-kurangnya xx hari selepas semburan terakhir.

Tidak boleh digunakan pada peringkat mengutip hasil bagi tanaman xxxxx.

Panduan Membancuh: Disyor menggunakan alat penyembur gelas. Isikan tangki setengah penuh dengan air bersih. Campurkan **TRADE NAME** secukupnya mengikut syor yang ditetapkan dalam jadual sukatan dan bancuh. Seterusnya tambah baki air bersih yang diperlukan dan kacau. Jangan guna pada kadar yang lebih tinggi dari yang disyorkan.

Panduan Menyembur: Lakukan semburan apabila tanda-tanda penyakit mulai kelihatan. Untuk kawalan yang baik, sembur secara menyeluruh ke atas daun. Ulangi semburan selang **x hari** sekali apabila serangan masih berkekalan. Jika rawatan perlu diulangi, gunakan **TRADE NAME** berselang-seli dengan racun kulat yang mempunyai cara tindakan yang berbeza.

Tempoh Dilarang Masuk Semula Kawasan Rawatan (REI): xx jam

AWAS: a) Bahaya Kepada Manusia: Berbahaya jika termakan. Elakkan daripada terhidu debu atau kabus semburan. Elakkan daripada terkena pada kulit atau mata. Ketika mengendalikan produk ini, **JANGAN** makan, minum atau merokok. Selepas mengendalikan racun ini, pastikan basuh badan sebersih-bersihnya dengan sabun dan air. Tutup bekas racun dengan rapat dan simpan di tempat berkunci yang mempunyai peredaran udara yang baik, kering dan dingin. Cuci tangan dan alat penyembur sebersih-bersihnya selepas menggunakannya.

Pakaian dan Alat Perlindungan: Ketika mengendalikan produk ini, pastikan pakai pakaian pelindung diri (PPE) berpiawai termasuk sarung tangan, gogal, penutup muka dan alat pernafasan (respirator) supaya tidak terhidu kabus semburan.

b) Bahaya Pada Alam Sekitar: Produk ini adalah berbahaya pada organisma akuatik dan ikan. **JANGAN** cemarkan kolam, sungai atau saluran air.

TANDA KERACUNAN: Pendedahan yang berlebihan menyebabkan mual, muntah dan gatal-gatal kerongkong dan kulit.

RAWATAN KECEMASAN: Tanggalkan pakaian yang terkena racun. Jika terkena pada kulit, basuh dengan menggunakan sabun dan air. Jika terkena pada mata, bersihkan dengan menggunakan air bersih yang banyak selama sekurang-kurangnya 15 minit. Jika tertelan, ikhtiarkan supaya pesakit itu muntah dengan menjolok jari ke dalam kerongkong selepas diberi minum air. Jangan beri apa-apa melalui mulut dan jangan ikhtiarkan pesakit itu muntah jika dia tidak sedar. Dapatkan rawatan perubatan dengan segera.

RAWATAN PERUBATAN: Rawatan hendaklah mengikut tanda sakit.

MEDICAL TREATMENT: Treatment is symptomatic.

BILAS BEKAS KOSONG TIGA (3) KALI SEBELUM MELUPUSKAN. JANGAN GUNAKAN BEKAS RACUN UNTUK MENYIMPAN MAKANAN.

c) CONTOH DRAF LABEL- Formulated product- Highly Toxic Pesticides (HTP)

PENGENDALIAN DAN PENGGUNAAN PRODUK INI ADALAH TERTAKLUK KEPADA PERATURAN-PERATURAN RACUN MAKHLUK PEROSAK (RACUN MAKHLUK PEROSAK AMAT BERBISA) 1996

TRADE NAMA
RACUN SERANGGA

PEKATAN LARUT AIR (SL)
Kandungan Bersih: **x kg**

Perawis Aktif:	xxxxxxxxxxxxxxxxx	xx.0% w/w
Perawis Lengai:	xx.0% w/w

No. Pendaftaran: LRMP. R1/

Tarikh Mengilang:

Didaftarkan oleh:

NAMA SYARIKAT. (xxxxxxx-x)

Alamat 1,

Alamat 2,

Poskod, Negeri .

Tel.: xx-xxxxxxx

Faks: xx-xxxxxxx

Email: xxxxxx@xxx.xx

Jika berlaku **KERACUNAN**, sila hubungi:

PUSAT RACUN NEGARA: 1-800-88-8099 (waktu pejabat)

012-4309499 (lepas waktu pejabat)

BACA LABEL SEBELUM GUNA

KELAS Ia or Ib (SKULL)

VERY HIGHLY POISONOUS
KEEP AWAY
FROM FOODSTUFF
AND CHILDREN

BERACUN-AMAT BISA
JAUHKAN
DARIPADA
MAKANAN DAN
KANAK-KANAK

VERSI TAMIL

VERSI CINA

TRADE NAMA ialah racun xxxxxxxxxxxxxx jenis 'xxxxxxx' sistemik yang bertindak secara sentuhan dan keracunan perut. **ATURAN PENGGUNAAN: Penggunaan tidak mengikut label adalah satu kesalahan.**

TANAMAN	SERANGGA	KADAR RACUN SEPOKOK	CARA RAWATAN
xxxxx	xxxxx (xxxxxxxxxxx) xxxxx(xxxxxxxxxxxx)	xx ml	Lakukan suntikan apabila terdapat serangan melebihi tahap ambang tindakan (ATL). Tebuk lubang pada sudut xx° sedalam xxxxx cm dengan lebar xxxx cm pada batang pokok. Jarak lubang dari tanah adalah lebih kurang x kaki. Suntikkan xxx ml TRADE NAME dan tutup lubang dengan tanah dan plastisin.
xxxx	Xxxxxxxxxx (xxxxxxxxxxx)		

Jangan kutip hasil tanaman xxxxxxx sekurang-kurangnya x hari selepas rawatan suntikan batang dan xx hari bagi tanaman xxxxxxxxxxx.

Tempoh Dilarang Masuk Semula Kawasan Rawatan (REI): xx jam

AWAS: a) Bahaya Kepada Manusia: Berbahaya jika terminum. Elakkan daripada terhidu wasap. Elakkan daripada terkena pada kulit atau mata. Ketika mengendalikan produk ini, **JANGAN** makan, minum atau merokok. Selepas mengendalikan produk ini, pastikan basuh badan sebersih-bersihnya dengan sabun dan air. Tutup bekas racun dengan rapat dan simpan di tempat berkunci yang mempunyai peredaran udara yang baik, kering dan dingin. Cuci tangan dan alat penyuntik sebersih-bersihnya selepas menggunakannya.

Pakaian dan Alat Perlindungan: Ketika mengendalikan produk ini, pastikan pakai pakaian pelindung diri (PPE) berpiawai termasuk sarung tangan, gogal, penutup muka dan alat pernafasan (respirator) supaya tidak terhidu kabus semburan.

b) Bahaya Pada Alam Sekitar: Produk ini adalah berbahaya pada organisma akuatik dan ikan. **JANGAN** cemarkan kolam, sungai atau saluran air.

TANDA KERACUNAN: Berpeluh, sakit kepala, pening, pandangan kabur, kjang otot, mual, muntah, sesak nafas, cirit-birit dan besar ludah.

RAWATAN KECEMASAN: Tanggalkan pakaian yang terkena racun. Jika terkena pada kulit, basuh dengan menggunakan sabun dan air. Jika terkena pada mata, bersihkan dengan menggunakan air bersih yang banyak selama sekurang-kurangnya 15 minit. Jika tertelan, ikhtiarkan supaya pesakit itu muntah dengan menjolok jari ke dalam kerongkong selepas diberi minum air. Ulangkan sehingga air muntah menjadi jernih. Jangan beri apa-apa melalui mulut dan jangan ikhtiarkan pesakit itu muntah jika dia tidak sedar. Dapatkan rawatan perubatan dengan segera.

RAWATAN PERUBATAN: Suntikkan Atropina Sulfat (2-4 mg) secara intravena atau intraotot. Ulang setiap 30 minit sehingga pesakit itu pulih dengan sepenuhnya. Kemudian suntikkan pralidoksim (1 g) secara intravena, jika perlu.

MEDICAL TREATMENT: Inject Atropine Sulphate (2-4 mg) intravenously or intramuscularly. Repeat every 30 minutes until the patient is fully atropinised. Then, administer pralidoxime (1 g) intravenously, if necessary.

BILAS BEKAS KOSONG TIGA (3) KALI SEBELUM MELUPUSKAN. JANGAN GUNAKAN BEKAS RACUN UNTUK MENYIMPAN MAKANAN.

