JABATAN PERTANIAN
(Department of Agriculture)
BAHAGIAN KAWALAN RACUN PEROSAK
(Pesticides Control Division)
TINGKAT 4-6, WISMA TANI,
JALAN SULTAN SALAHUDDIN,
50632 KUALA LUMPUR, MALAYSIA.
Tel: 03-2030 1400 Faks: 03-2691 7551

JABATAN PERTANIAN

Ruj. Kami : JP/KRP/207/12/
(Our Ref.) 656/2 Jld.VI (61)

Tarikh 24 Jun 2015
(Date)

KEPADA YANG BERKENAAN

Tuan/Puan,

AKTA RACUN MAKHLUK PEROSAK 1974
PINDAAN GARIS PANDUAN KEPERLUAN DATA KIMIA BAGI PENDAFTARAN RACUN MAKHLUK PEROSAK (GP1/2015)

Dengan hormatnya perkara diatas adalah dirujuk.

2. Adalah dimaklumkan bahawa Lembaga Racun Makhluk Perosak telah membuat pindaan kepada Garis Panduan Keperluan Data Kimia bagi Pendaftaran Racun Makhluk Perosak (GP1/93). Garis Panduan ini akan digantikan dengan Garis Panduan Keperluan Data Kimia bagi Pendaftaran Racun Makhluk Perosak (GP1/2015).

3. Sehubungan dengan perkara ini, pihak Lembaga ingin memaklumkan bahawa Garis Panduan Keperluan Data Kimia bagi Pendaftaran Racun Makhluk Perosak (GP1/2015) boleh diperolehi dari Portal Rasmi Jabatan Pertanian Malaysia di laman web http://www.doa.gov.my.

4. Sila ambil maklum bahawa Garis Panduan Keperluan Data Kimia bagi Pendaftaran Racun Makhluk Perosak (GP1/2015) adalah berkuatkuasa sepenuhnya pada 1 Januari 2016. Garis Panduan ini digunapakai bagi permohonan pendaftaran baru dan permohonan tambah pembekal racun makhluk perosak sahaja.

Sekian harap maklum.

'BERKHIDMAT UNTUK NEGARA'
'JIHAD MEMERANGI ORANG TENGAH'

Saya yang menurut perintah,

(HALIMI MAHMUD)
Setiausaha,
Lembaga Racun Makhluk Perosak

s.k :
Malaysian Croplife & Public Health Association (MCPA)

GP 1/2015

GUIDELINES ON PRODUCT CHEMISTRY DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

Pesticides Board
Malaysia
2015

Lampiran A

PRODUCT CHEMISTRY DATA REQUIREMENTS
GLOSSARY

ACTIVE INGREDIENT : an ingredient, as listed in the First Schedule, in the Pesticides Act 1974 (Act 149), which has pesticidal properties and gives pesticidal properties to a substance, material, preparation or mixture, of which the ingredient is one of the constituents of substance, material, preparation of mixture.

INERT INGREDIENT also named FORMULANT: any substance other than an active ingredient, which is intentionally included in a pesticide product.

TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) also named TECHNICAL MATERIAL (TC): material containing an active ingredient: together with all impurities from manufacturing process which contains no inert ingredient and which is produced on a commercial or pilot plant production scale (whether or not it is ever held for sale)

TECHNICAL CONCENTRATE (TK) : material consisting in an active ingredient: together with all impurities originating from manufacturing process which contains also additives (not formulants), and or a stabilizer. For example all safety agents and may also contain solvent(s) (including water) and which is produced on a commercial or pilot plant production scale (whether or not it is ever held for sale)

Pure Active Ingredient (PAI) Active Ingredient which have been purified or not with a certified purity higher than 980g/kg.

FORMULATED PRODUCT: pesticide product–whose labeling includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, or desiccating or regulating growth of plant and does not state the product may be used to manufacture of formulate other pesticide products.

STARTING MATERIAL: a substance used to synthesize or purify a technical grade of active ingredient (or the practical equivalent of the technical grade ingredient if the technical grade cannot be isolated) by chemical reaction.

IMPURITY: any substance (or group of structurally similar substances) present in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants and degradation products and pesticide active ingredients other than intended for that product.

SIGNIFICANT IMPURITY: any impurities find in a TC or TK present at a level of 1g/kg or above.

RELEVANT IMPURITY: any impurity of the manufacture or storage of a pesticide which, compared with the active ingredient, is toxicologically significant to health or the environment, is phytotoxic to treated plants, causes taint in food crops, affects the stability of the pesticide, or causes any other adverse effect. An impurity may be non relevant in one pesticide or product and relevant in another, even though it occurs in both, because relevance is determined by impurity hazards relative to those of the active ingredient.

MANUFACTURER: as per the definition given by FAO in the International Code of Conduct, means a corporation or other entity in the public or private sector (including an individual) engaged in the business or function (whether directly or through an agent or entity controlled by or under contract with it) of manufacturing a pesticide active ingredient or preparing its formulation or product. A manufacturer may well have several different manufacturing site legally owned by different legal entities.

MANUFACTURING PLANT: means the place where a pesticide is produced.

CONFIDENTIAL BUSINESS INFORMATION (CBI): means any data with commercial value the release of which could harm to the company's business interest leading to unfair competition as provided for under the Pesticides Act 1974 (Act 149).

Product Chemistry Data Requirement for manufacsticide Registration

1. INTRODUCTION

Data requirements on product chemistry include information on the manufacturer, and the manufacturing(s) plants, manufacturing process and manufacturing limits, product composition, chemical and physical properties of the pesticides as well as Method of analysis of the pesticides. These data among other things are required to:

a) support the claims made by the applicant;

b) enable registration authorities to evaluate the pesticide in terms of its quality, potential hazards, decomposition products etc;

c) enable registration authorities to evaluate the pesticide and specify labeling and packaging requirements; and

d) support emergency requests on spillage, fire, poisoning etc.

2. DATA REQUIREMENTS FOR TECHNICAL GRADE OF ACTIVE INGREDIENT (TC/TK)- (CONFIDENTIAL BUSINESS INFORMATION)

2.0 Originator

2.0.1. Manufacturer of the active ingredient.
Name and address of Manufacturer.

2.1. Identity and Composition

2.1.1 Common Name

I. The common name of the active ingredient(s) shall be clearly stated as listed in First Schedule (Section 2) of the Pesticides Act 1974.

II. The ISO common name of the active ingredient(s) shall be stated if any. If no ISO common name is available, then the common name used by Malaysian Standard or other-common name as proposed by other organizations (British Standard Institution (BSI), etc.) may be used. (if not ISO name, must be specified clearly)

III. For products containing biopesticides (microorganism), for example *Bacillus thuringiensis,* the scientific systematic name subspecies and strains of the organism shall be given. Please refer to the relevant guidelines (Guidance For Harmonizing Pesticide Regulatory Management in Southeast Asia, 2012/2013), website: http://www.fao.org/asiapacific and Asean Guidelines On The Regulation, Use and Trade of Biological Control Agent (BCA)

2.1.2 Chemical Name

I. The International Union of Pure and Applied Chemistry (IUPAC) chemical name shall be used.

II. CAS number shall be stated and in addition Collaborative International Pesticides Analytical Council number (CIPAC number) shall also be given if available.

III. CAS number for each isomer or the mixture of isomers shall be stated.

2.1.3 Chemical Formula

I. The molecular formula, molecular mass and structural formula of the active ingredient including its salt or ester wherever applicable shall be provided.

ii. **Proprietary names, synonyms and code names and CIPAC number** to be provided as a guide to identify the products (if applicable).

iii. **Chemical and physical properties** of the technical material shall be provided. (Refer Appendix 1).

iv. The Safety Data Sheet (SDS) of the Technical Grade of Active Ingredient shall be provided. The Safety Data Sheet (SDS) given must according to the Occupational Safety and Health (Classification, labeling and Safety Data Sheet of Hazardous Chemicals Regulation 2013),

- The minimum information in *appendix 2* shall be included on SDS
- Additional information may be required by Pesticide Board.

2.2 Manufacturing Process

The manufacturing activity shall be stated clearly where;

(a) The name and address of the manufacturing plant at which the pesticide will be produced,

(b) For technical materials (TC), the manufacturing process starting from the starting materials, partway, by product and impurities shall be provided. Chemical equations for chemical reactions involved in the manufacturing process shall also be provided. The purity of each starting material used to produce technical material also shall be provided.

(c) A description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produce) shall be provided.

(d) A description of the procedures used to ensure consistent composition of substance produces, e.g., calibration of equipment, sampling regimens, analytical methods or other quality control methods shall be stated clearly.

(e) For each starting material, chemical name, CAS number, or other commercial designation of ingredient;

I. All information that applicant knows concerning the composition (and, if requested by the Pesticide Board), chemical and physical properties of the ingredient, including a copy of technical specifications, Safety Data Sheet (SDS) or other document describing the ingredient.

(f) Flowchart of the process of manufacturing process of the pesticide shall be submitted with the application. Summarizing the conditions and solvent employed also shall be provided.

(g) For technical materials, minimum active ingredient and manufacturing maximum limits for impurities content shall be stated in g/kg.

(h) Information on relevant impurities with explanation of the effects observed (for example, toxicological effects, or effects on the stability of the active ingredient) shall be provided. Limits set by FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) and/or registration authorities shall accompany this information, identifying the authority responsible for setting the limit.

(i) For technical material, manufacturing maximum limits for significant impurities present at or above 1g/kg, supported by batch analysis data (minimum 5 typical batches). The statistical basic for manufacturing limits (confidential data) shall be given. 5 batch studies are required to be Good Laboratory Practices (GLP) studies. Relevant impurities must be identified in the submission. Typically the unidentified and/or unaccountable fraction of TC/TK should not exceed 20g/kg

(j) Manufacturing maximum limits for impurities proposed as relevant at < 1g/kg. Maximum limits for these impurities shall also supported with batch analytical data (minimum 5 typical batches) (all confidential) and proposer shall state the statistical basic for manufacturing limits

(k) The certification statement shall be signed by an authorized representative of the manufacturer.

2.3 Method For Analysis and Testing of Technical Grade Active Ingredient.

I. Validated analytical procedures for determination of the content of active ingredient and content of impurities of toxicological concern in the product shall be provided. Procedures involving use of carcinogenic reagents would not be acceptable. Sources or authorities from which the analytical procedure is extracted shall be mentioned.

II. At least two methods for the identification of the active ingredient shall be provided.

III. Reference test methods for physical properties. Test methods for physical properties may be validated by Collaborative International Pesticides Analytical Council (CIPAC) or American Society for Testing and material (ASTM), or according to the requirements of Organization for Economic Co-

operation and Development (OECD) or European Community (EC), or, where appropriate by pharmaceutical organizations.

IV. Analytical standards required for the use of the analytical methods mentioned shall be supplied with the application. (Refer to Appendix 6 Requirement for analytical standard.)

2.4 Packing

I. The type of packing material used shall be stated.

II. The packaging shall comply with Malaysian Standard (MS 409:2012), Code of Practice for Packaging and Storage of Pesticide, and other international standard.

III. If the packaging does not comply with the Malaysian Standard (MS 409:2012), Code of Practice for Packaging and Storage of Pesticide~~,~~ the results of a quality evaluation test shall be provide.

2.5 Evidence of Stability on Storage of Technical Grade Of Active Ingredient Technical Concentrate (TK)

I. Analytical Test Report as evidence of stability on storage shall be submitted with each application. Stability tests shall be conducted in accordance with the FAO Accelerated Storage Test Procedures usually at 54 ± 2° C for 14 days or at 45 ± 2° C for 6 weeks or at 40 ± 2° C for 8 weeks or at 35 ± 2° C for 12 weeks or at ambient temperature (Malaysian) for 2 years.

II. Samples should be analyzed before and after testing using the same batch.

III. For a critical scientific assessment of these data to be taken, each study must be reported in sufficient detail. The methodology used in each test must be thoroughly described, or if the study has been conducted to an internationally recognized protocol without significant deviations, then a reference to this method will be sufficient.

IV. Storage stability studies are required to be performed in Good Laboratory Practices (GLP) certified-test facilities or in ISO accredited laboratories.

2.6 Specifications

I. Specifications for the Technical Grade Active Ingredient shall be provided. The pesticide shall conform to Malaysian Regulation, FAO or WHO requirements or FAO or WHO specifications whenever such specifications are available. This should be indicated in the application form. When such specifications are not available, the applicant shall state the specification that the pesticide complies with.

II. If the pesticide does not comply with any specifications, the reasons for non-compliance must be given with the application. (Refer to Appendix 3 for details required in the specification)

3. DATA REQUIREMENTS FOR FORMULATED PRODUCTS (CONFIDENTIAL BUSINESS INFORMATION)

Data for Technical Grade of Active Ingredient (TGAI) is required on cases where TGAI is not registered with Pesticide Board but its formulated product (ready-made) is directly imported and is intended to be registered. In this case, the registrant must declare the source of the technical grade active ingredient and provide a letter of undertakings/authorization;

- That it is the sole source
- That if an alternative source is subsequently utilized, prior approval must be obtained from the Board.

3.1 Information on the Active Ingredients

I. Chemical Systematic Name, ISO common name, synonyms and code names to be provided as a guide to identify the products.

II. Chemical and physical properties of the formulated product shall be provided. (Refer Appendix 4).

III. The Safety Data Sheet (SDS) of the proposed formulated product shall be provided. The Safety Data Sheet (SDS) is according to the Occupational Safety and Health (Classification, labeling and Safety Data Sheet of Hazardous Chemicals) Regulation 2013, CLASS Regulations.

- The minimum information in *appendix 2* shall be included on SDS.
- Additional information may be required by Pesticide Board.

3.2 Manufacturing Process on Formulated Product

I. The manufacturing activity shall be stated clearly and the following information must be provided:

a) The name and address of the manufacturing plant who uses the process.

b) A general characterization of the process (e.g., whether it is a batch or continuous process)

c) A description of the procedures used to assure consistent composition of substance produces, e.g., calibration of equipment, sampling regimens, analytical methods or other quality control methods should be stated clearly

d) Flowchart of the process of manufacturing the pesticide shall be submitted with the application. Summarizing the conditions and solvent employed also shall be provided.

e) The following information must be submitted on the material used to produce the product

- The % w/w purity of technical materials used shall be indicated.
- The identity of every ingredient in the formulated product shall be stated and its concentration given in g/kg for solid formulation or g/L for liquid formulation as per recommended by FAO and in %w/w.
- Proposed target limits for the inert ingredients in the product including range of variability for those inert ingredients which vary from batch to batch due to adjustment of the corresponding physical parameter:,

- An upper and lower limit for each active ingredient in line with the Malaysian Regulation and FAO/WHO tolerances.

f) The following information must be submitted on certain inert ingredient:

- Brand name, trade name, common name or other commercial designation of ingredient.

- All information that applicant known (or that is reasonably available to him) concerning the composition (and, if requested by Pesticides Board, chemical and physical properties) of the ingredient, including a copy of technical specifications, Safety Data Sheet (SDS) or other document describing the ingredient.

g) The presence and maximum concentration of any relevant impurities and by-products in the finished product shall be indicated.

3.3 Method of Analysis and Testing of Formulated Product.

i. Validated analytical procedure for determination of the content of active ingredient and impurities of toxicological concern in the product shall be provided. Procedure involving use of carcinogenic reagents will not be accepted. Sources or authorities from which the analytical procedure is extracted shall be mentioned.

ii. At least two methods for the identification of the active ingredient shall be provided.

iii. Test methods for physical properties other than Collaborative International Pesticides Analytical Council (CIPAC) can be accepted. However, reference to the test methods shall be stated. Test methods for physical properties may be validated by CIPAC or American Society for Testing and Material (ASTM), or according to the requirements

of Organization for Economic Co-operation and Development (OECD) or European Community (EC), or, where appropriate by pharmaceutical organizations.

iv. Analytical standards for active ingredient required for the above shall be supplied with the registration application for all products. (Refer to Appendix 6 Requirement for analytical standard.)

3.4 Packing

I. The type of packing material used should be stated.

II. The packaging should comply with Malaysian Standard (MS 409:2012), Code of Practice for Packaging and Storage of Pesticide or other international standard.

III. If the packaging does not comply with the Malaysian Standard (MS 409:2012), the results of a quality evaluation report should be provided.

3.5 Evidence of Stability on Storage

I. Analytical Test Report as evidence of stability on storage shall be submitted with each application. Stability tests shall be conducted in accordance with the;

   a. FAO Accelerated Storage Test Procedures is performed usually at 54 ± 2° C for 14 days or at 45 ± 2° C for 6 weeks or at 40 ± 2° C for 8 weeks or at 35 ± 2° C for 12 weeks or at 30 ± 2° C for 18 weeks when applicable or;

   b. Two-Year Storage Stability (Ambient testing) to demonstrate the storage stability of a formulation under "true" storage conditions usually over a period of 2 years. The test shall be conducted at ambient temperature or, 20°C, 25°C or 30°C dependent on the final area of use.

ii. Samples shall be analyzed before and after testing using the same batch. The packaging used in the study shall be based upon that in which the product is sold. If the test product is to be supplied in different packaging material, each type shall be represented in the study or a justification shall be given why the tested packaging material is representative of future packaging materials.

iii. The report must include the observation of the effect on the packaging used.

iv. For a critical scientific assessment of these data to be taken, each study must be reported in sufficient detail. The methodology used in each test must be thoroughly described, or if the study has been conducted to an internationally recognized protocol without significant deviations, then a reference to this method will be sufficient

v. Storage stability studies are required to be performed in Good Laboratory Practices (GLP) certified test facilities or in ISO accredited laboratories.

3.6 Specifications

I. Specifications for the product shall be provided. The pesticide shall conform to Malaysian Regulation, FAO or WHO requirements or FAO or WHO specifications whenever such specifications are available. This shall be indicated in the application form. When such specifications are not available, the applicant should state the specification that the pesticide complies with.

II. If the pesticide does not comply with any specifications, the reasons for non-compliance must be given with the application. (Refer to Appendix 4 for details required in the specification of a product).

4. SATISFYING DATA REQUIREMENT

I. The data and information submitted should be credible and valid.

II. Letter of consent authorizing the applicant to use the data for registration purposes must be provided if another company's data is submitted.

iii. All analytical data obtained from the analysis of samples should be provided, and not just a summary or average figure. It should be clearly stated how the data are calculated and expressed. However, where traceability of raw data is given (archiving of row data), it is sufficient to report the final results and information on the number of replicate analyses shall be given. Trivial calculations and calculations given by the test method do not need to be reported.

5. REPORTING OF STUDY RESULTS

5.1 General

I. A final report should be prepared for each study. In the case of short term studies, a standardized final report accompanied by a study specific extension may be prepared.

II. Reports of Principal Investigators or scientists involved in the study should be signed and dated by them.

III. The final report should be signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these Principles of Good Laboratory Practice should be indicated.

IV. Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and

shall be signed and dated by the Study Director.

V. Reformatting of the final report to comply with the submission requirements of a National registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

5.2 Content of the Final Report

The final report should include, but not be limited to, the following information:

I. Identification of the Study, the Test Item and Reference Item

a) A descriptive title;

b) Identification of the test item by code or name (IUPAC, CAS number, biological Parameters, etc.);

c) Identification of the reference item by name;

d) Characterization of the test item including purity, stability and homogeneity.

II. Information Concerning the Sponsor and the Test Facility

a) Name and address of the sponsor;

b) Name and address of any test facilities and test sites involved;

c) Name and address of the Study Director;

d) Name and address of the Principal Investigator(s) and the phase(s) of the study delegated, if applicable;

e) Name and address of scientists having contributed reports to the final report.

III. *Dates*

Experimental starting and completion dates.

IV. Statement

A Quality Assurance Programme statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

V. *Description of Materials and Test Methods*

a) Description of methods and materials used;

b) Reference to OECD Test Guideline or other test guideline or method.

VI Results

a) A summary of results;

b) All information and data required by the study plan;

c) A presentation of the results, including calculations and determinations of statistical significance; more detailed explanations regarding the presentation of results are given in paragraph 4 iii above.

d) An evaluation and discussion of the results and, where appropriate, conclusions.

VII *Storage*

The location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored.

References

1. Food and Agriculture Organization of United Nations and World Health Organization (2013). *International Code of Conduct on the Distribution and Use of Pesticides. Guidelines on data requirements for the registration of pesticides.* (http://www.fao.org./agriculture/crops/corethemes/theme/pests/pm/code/guidelines/en/).

2. World Health Organisation (2012). *Guidelines for Procuring Public Health Pesticide.* (www.who.int/whopes)

3. Food and Agriculture Organization of United Nations and World Health Organization (2006). *Manual on the development and use of FAO and WHO specifications for pesticides. Revision of 1st ed. Rome and Geneva.* *(http://whqlibdoc.who.int/publications/2006/9251048576_eng_update_2006.pdf)*

4. Government of United States of America. *Data Requirements for Pesticides Registration.* *(http://www.epa.gov/opp00001/regulating/data_requirements.htm)*

5. Food and Agriculture Organization of United Nations and World Health Organization (2011). Guideline for Quality Control of pesticides. (www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Specs/qualitycontrol05.pdf)

6. Food and Agriculture Organization of United Nations and World Health Organization (2013). *Guidance for harmonizing pesticide regulatory management in Southeast Asia.* *(http://www.apppc.org/sites/apppc.org/files/1343103031_Guidance_for_pesticide_regul-mgt_0.pdf)*

7. **OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING Document Number 1. OECD Principles on Good Laboratory Practice. (as revised in 1997)** ***http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/mc/chem(98)17&doclanguage]***

Appendix 1

Chemical and Physical Properties of Purified Active Infgredients (PAI) or technical materials (TC) required. (required to be Good Laboratory Practices (GLP) studies;

Data Requirement	Test Substance
1. Minimum and maximum content of active ingredient in g/kg or %w/w	Technical material (TC)
2. Identity and amounts of isomers	Technical material (TC)
3. Absorption spectra (eg.UV, IR, MS or NMR)-	Purified Active Infgredients (PAI)
4. Impurities and other by products and their possible range expressed in g/kg or % w/w	Technical material (TC)
5. For solids; its melting point (at stated temperature)-	Technical material (TC)
6. For liquids, Vapour pressure (at stated temperature)	Purified Active Infgredients (PAI)
7. For liquids; boiling point, , specific gravity and viscosity (at stated temperature)	Technical material (TC)
8. Flash point	Technical material (TC)
9. Solubility in water and other solvents (at stated temperature)	Purified Active Infgredients (PAI)
10. n-octanol/water partition coefficient	Purified Active Infgredients (PAI)
11. Hydrolysis rate, photolysis (under stated conditions),	Technical material (TC)
12. Stability towards oxidizing agents and thermal changes.	Technical material (TC)
13. Dissociation constant (pKa, pKb)	Purified Active Infgredients (PAI)

Note: If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI

Appendix 2

The **Safety Data Sheet** (SDS) of the product shall include minimum information as following:

Section	Title of Section	Minimum Information
1.	**Identification of the hazardous chemical and of the supplier**	(a) Product identifier; (b) Other means of identification; (c) Recommended use of the chemical and restrictions on use; (d) Details of principal suppliers (including name, address, phone number, etc.); (e) Emergency phone number
2.	**Hazard identification**	(a) Classification of the substance/mixture and any nation or regional information; (b) Label elements (hazard pictogram or symbol, signal word, hazard statement and precautionary statements). Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or name of the symbols e.g. 'flame' , ' skull and crossbones'; (c) Other hazards which do not result in classification (e.g. dust explosion hazard) or are not covered by the Regulations.
3.	**Composition and information of the ingredients of the hazardous chemical**	**Substance** (a) Chemical identity; (b) Common name, synonyms, etc; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. **Mixture** The chemical identity and concentration or concentration ranges of all ingredients which are hazardous and are present at or above cut-off value.

4.	**First-aid measures**	(a) Description of necessary measures, subdivided according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion; (b) Most important symptoms/effects, acute and delayed; (c) Indication of immediate medical attention and special treatment needed, if necessary.
5.	**Fire-fighting measures**	(a) Suitable (and unsuitable) extinguishing media; (b) Specific hazards arising from the chemical (e.g. nature of any combustion hazardous products); (c) Special protective equipment and precautions for fire-fighters
6.	**Accidental release measures**	(a) Personal precautions, protective equipment and emergency procedures; (b) Environmental precautions; (c) Methods and material for containment and cleaning.
7.	**Handling and storage**	(a) Precautions for safe handling; (b) Conditions for safe storage, including any incompatibilities.
8.	**Exposure controls and personal protection**	(a) Control parameters e.g. permissible exposure limit and biological limit values; (b) Appropriate engineering controls; (c) Individual protection measures, such as personal protective equipment.
9.	**Physical and chemical properties**	(a) Appearance (physical state, colour, etc.); (b) Odour; (c) Odour threshold; (d) pH; (e) Melting point/freezing point; (f) Initial boiling point and boiling range;

		(g) Flash point; (h) Evaporation rate; (i) Flammability (solid, gas); (j) Upper/lower flammability or explosive limits; (k) Vapour pressure; (l) Vapour density; (m) Relative density; (n) Solubility(ies); (o) Partition coefficient : n-octanol/water; (p) Auto-ignition temperature; (q) Decomposition temperature; (r) Viscosity.
10.	**Stability and reactivity**	(a) Reactivity; (b) Chemical stability; (c) Possibility of hazardous reactions; (d) Condition to avoid (e.g. static discharge, shock or vibration); (e) Incompatible materials; (f) Hazardous decomposition products.
11.	**Toxicological information**	Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including (a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); (b) Symptoms related to the physical, chemical and toxicological characteristics; (c) Delayed and immediate effects and also chronic affects from short and long term exposure; (d) Numerical measures of toxicity (such as acute toxicity estimates).
12.	**Ecological information**	(a) Ecotoxicity (aquatic and terrestrial, where available); (b) Persistence and degradability; (c) Bioaccumulative potential; (d) Mobility in soil; (e) Other adverse effects.

13.	**Disposal information**	Description of waste residues and information on their safe handling and method of disposal, including the disposal of any contaminated packaging.
14.	**Transportation information**	(a) UN number; (b) UN proper shipping name; (c) Transport hazard class(es); (d) Packing group, if applicable; (e) Environmental hazards (e.g. marine pollutant (Yes/No); (f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code); (g) Special precautions which a user needs to be aware of, or needs to comply with, in connection either within or outside their premise.
15.	**Regulatory information**	Safety, health and environmental regulations specific for the product in question.
16.	**Other information**	(a) Date of preparation of the SDS; (b) Date of revision of the SDS; (c) Key literature references and sources for data used to compile the SDS; (d) Key/legend to the abbreviations and acronyms used in the SDS; (e) Other information deems necessary by a supplier.

Appendix 2

Maklumat minimum bagi SDS adalah seperti yang di dalam jadual di bawah;

Seksyen	Tajuk seksyen	Maklumat minimum
1.	**Pengenalan bahan kimia dan pembekal**	(a) Pengecam produk; (b) Kaedah pengenalan lain; (c) Kegunaan yang disarankan bagi bahan kimia dan kekangan kegunaan; (d) Rincian pembekal (termasuk nama, alamat, nombor telefon dan sebagainya.); (e) Nombor telefon kecemasan.
2.	**Pengenalan bahaya**	(a) Pengelasan bagi bahan/campuran dan apaapa maklumat negara atau serantau; (b) Unsur label (piktogram bahaya atau simbol, kata isyarat, pernyataan bahaya dan pernyataan berjaga-jaga). Simbol bahaya boleh diberikan sebagai salinan grafik bagi simbol dalam warna hitam dan putih atau nama simbol tersebut seperti 'nyalaan', 'tengkorak dan tulang bersilang'; (c) Bahaya lain yang tidak termasuk dalam pengelasan (misalnya, bahaya letupan habuk) atau tidak diliputi dalam Peraturan ini.
3.	Komposisi dan maklumat mengenai ramuan bahan kimia berbahaya	**Bahan** (a) Identiti bahan kimia; (b) Nama biasa, sinonim, dan sebagainya; (c) Nombor CAS dan pengecam unik lain; (d) Bendasing dan bahan tambah penstabil yang telah dikelaskan dan menyumbang kepada pengelasan bahan. **Campuran** Identiti bahan kimia dan kepekatan atau julat kepekatan bagi semua ramuan yang berbahaya dan hadir melebihi aras nilai pemisah bagi kepekatan.
4.	**Langkah-langkah pertolongan cemas**	(a) Perihalan langkah yang perlu diambil, disubbahagikan menurut laluan pendedahan yang berbeza; iaitu, penyedutan, sentuhan kulit dan mata, serta pengingesan; (b) Gejala/kesan akut dan tertangguh yang paling penting;

		(c) Petunjuk bagi keperluan perhatian perubatan segera dan rawatan khas, jika ada.
5.	**Langkah-langkah pemadaman kebakaran**	(a) Bahan memadamkan api yang sesuai (dan tidak sesuai); (b) Bahaya khusus daripada bahan kimia (misalnya ciri produk pembakaran berbahaya); (c) Kelengkapan pelindung khas dan langkah berjaga-jaga bagi petugas pemadam
6.	**Langkah-langkah pelepasan tidak sengaja**	(a) Tatacara perlindungan diri, kelengkapan pelindung, dan kecemasan. (b) Langkah melindungi alam sekitar. (c) Kaedah dan bahan untuk pembendungan dan pembersihan.
7.	**Pengendalian dan penyimpanan**	(a) Langkah berjaga-jaga untuk pengendalian selamat. (b) Keadaan penyimpanan selamat, termasuk apa-apa ketakserasian.
8.	**Kawalan pendedahan dan perlindungan diri**	(a) Parameter kawalan, misalnya had pendedahan dibenarkan atau nilai had biologi. (b) Kawalan kejuruteraan yang sesuai. (c) Langkah perlindungan individu, seperti kelengkapan perlindungan diri.
9.	**Sifat fizikal dan kimia**	(a) Rupa (keadaan fizikal, warnadan sebagainya). (b) Bau. (c) Ambang bau. (d) pH. (e) Takat lebur/takat beku. (f) Takat didih awal dan julat didih. (g) Takat kilat. (h) Kadar penyejatan. (i) Kemudahbakaran (pepejal, gas). (j) Had kemudahbakaran atau boleh letup atas/bawah. (k) Tekanan wap. (l) Ketumpatan wap. (m) Ketumpatan bandingan. (n) Keterlarutan. (o) Pekali petakan: n-oktanol/air. (p) Suhu pengautocucuhan. (q) Suhu penguraian.

		(r) Kelikatan. 10. Kestabilan dan kereaktifan
10.	**Kestabilan dan kereaktifan**	(a) Kereaktifan. (b) Kestabilan kimia. (c) Kemungkinan tindak balas berbahaya. (d) Keadaan yang perlu dielakkan (misalnya, nyahcas statik, kejutan atau getaran). (e) Bahan tak serasi. (f) Produk penguraian berbahaya.
11.	**Maklumat toksikologi**	Perihalan yang padat tetapi lengkap dan boleh difahami bagi pelbagai kesan toksikologi (kesihatan) dan data tersedia yang digunakan untuk mengenal pasti kesan tersebut, termasuk: (a) Maklumat tentang laluan pendedahan yang mungkin (penyedutan, pengingesan, sentuhan kulit dan mata); (b) Gejala berkaitan dengan ciri fizikal, kimia, dan toksikologi. (c) Kesan tertangguh dan serta-merta dan juga kesan kronik daripada pendedahan jangka pendek dan jangka panjang. (d) Ukuran berangka bagi ketoksikan (seperti anggaran ketoksikan akut).
12.	**Maklumat ekologi**	(a) Keekotoksikan (akuatik dan daratan, sekiranya boleh didapatkan) (b) Keselanjaran dan keterdegradan. (c) Potensi bioterkumpul. (d) Kebolehgerakan di dalam tanah. (e) Kesan mudarat yang lain.
13.	**Maklumat pelupusan**	Perihalan baki sisa dan maklumat tentang pengendalian yang selamat dan kaedah pelupusan, termasuk pelupusan apa-apa pembungkusan tercemar.
14.	**Maklumat pengangkutan**	(a) Nombor UN. (b) Nama penghantaran sah PBB. (c) Kelas bahaya pengangkutan. (d) Kumpulan pembungkusan, jika berkenaan. (e) Bahaya alam sekitar (contoh: Bahan cemar marin (Ya/Tidak)). (f) Pengangkutan secara pukal (menurut

		Tambahan II bagi MARPOL 73/78 dan Kod IBC) (g) Langkah berjaga-jaga khas yang pengguna perlu ketahui atau patuhi berhubung dengan pengangkutan atau penghantaran sama ada di dalam atau di luar premis mereka.
15.	**Maklumat pengawalseliaan**	Peraturan keselamatan, kesihatan, dan alam sekitar yang khusus untuk produk yang berkenaan.
16.	**Maklumat lain**	(a) Tarikh penyediaan SDS; (b) Tarikh semakan SDS; (c) Rujukan utama dan sumber data yang digunakan untuk menyusun SDS; (d) Kekunci/petunjuk kepada singkatan dan akronim yang digunakan dalam SDS; (e) Apa-apa maklumat yang dirasakan perlu oleh pembekal.

Appendix 3

Specification of Pesticides - Technical Grade of Active Ingredient (TC/TK)

The specifications of a pesticide shall conform to the either Malaysian Regulations, FAO or WHO requirements or FAO or WHO specifications wherever such specifications are available and shall include the following, where appropriate:

1. Composition of the pesticide (including impurities, by-products, related products, stating their concentrations)

    - Minimum content of active ingredient, state in g/kg or % w/w
    - Maximum content of significant and relevant impurities, state in g/kg or % w/w
    - Necessary method of analysis

2. Specific Properties/ Test Related to Use

    a) Appearance
        - physical state, colour, (for all formulation)
    b) Relevant impurities
    c) Water content (if applicable) and insoluble (if applicable)
    d) Acidity and/or alkalinity or pH range – (for any material where adverse reaction would accrued in the presence of excessive acid or alkali)

Appendix 4

Specification of Pesticides (Formulated Product)

The specifications of a pesticide shall conform to the either-Malaysian Regulations, FAO or WHO requirements or FAO or WHO specifications wherever such specifications are available and shall include the following, where appropriate:

1. Composition of the pesticide (including inerts ingredients stating their concentrations)

    a. State in g/kg or g/L or % w/w or %w/v.
    b. Maximum content of relevant impurities, state in g/kg or % w/w
    c. By products of manufacture (if applicable)
    d. Specific properties/Test related to use
    e. Necessary method of analysis.

Appendix 5

Physical and Chemical Properties For Formulated Product

i) Appearance

- physical state, colour, (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) Specific Properties/ Test Related to Use

a. Density Properties
    i. Bulk (pour and tap) density (for powders and granulated materials)
    ii. Relative density (for all liquid formulations)

b. Surface Properties
    i. Wettability (for all solid formulation to be dispersed or dissolved in water)
    ii. Persistent foam (for all formulations intended for dilution with water before use)

c. Volatilization Properties

i. Volatility (for Ultra –low volume liquids (UL))

ii. Flammability

d. Particulate, fragmentation properties

i. Wet sieve test (applicability for Wettable powders (WP), Suspension concentrate including those for seed treatment and oil based (SC, FS and OD), Water dispersible powders foe slurry seed treatment (WS), water dispersible granules (WG), aqueous capsule suspensions (CS), dispersible concentrates (DC), suspo-emulsions (SE), water-soluble and dispersible tablets (ST and WT) and emulsifiable granules and powder (EG and EP)

ii. Dry sieve test – (for powders and granules intended for direct application)

iii. Nominal size range – (for granules (GR) formulation)

iv. Dustiness – (For Granules (GR), water dispersible granules (WG), emulsifiable granules (EG) and water soluble granules (SG)

v. Attrition resistance or degree of attrition – (for Granular formulation (GR,WG,SG and EG) and tablet formulation (DT, WT, ST, depending upon their intended mode of use)

vi. Tablet intergrity –(Tablet (DT, ST and WT)

vii. Adhesion to seeds – (for all seed treatment)

viii. Particle size range – (for multiple phase formulation, if appropriate)

e. Dispersion Properties

i. Dispersibility and spontaneity of dispersion – (for suspension concentrate (SC), aqueous capsule suspensions (CS) and water dispersible granules (WG)

ii. Suspensibility – (for wettable powder (WP), suspension concentrate (SC), capsule suspension (CS) and water dispersible granules (WG)

iii. Dispersion stability – (for suspo-emulsion (SE), emulsifiable granules (EG), emulsifiable powders (EP), dispersible concentrate

concentrates (DC) , oil based suspension concentrate (OD), mixed formulations of CS and SE (ZC), mixed formulation of CS and EW (ZW)

iv. Emulsion stability and re-emulsification – (for emulsifiable concentrates (EC), emulsions, oil in water (EW) and microemulsion (ME)

f. Flow properties

i. Flowability – (for water dispersible granules (WG), water soluble granules (SG), granules (GR)

ii. Pourability – (for Suspension concentrates (SC,FS and OD), aqueous capsule suspension (CS), suspo- emulsions (SE), and similarity viscous formulations, but may also be applied to formulations in solution, such as soluble concentrate (SL) and emulsifiable concentrate (EC)

iii. Viscosity - (for Ultra –low volume liquids (UL))

g. Solution and dissolution properties

i. Acidity and/or alkalinity or pH – (for any material where adverse reaction would occurred in the presence of excessive acid or alkali)

ii. Miscibility with hydrocarbon oil – (for any specification for a formulation intended to be diluted with oil before use (e.g. OL)

iii. Dissolution of water soluble bags – (for all formulations packaged in water soluble bags)

iv. Solution stability – (specification for all water soluble formulations)

h. Others

i. Burning time (for mosquito coil)

ii. Breaking load (for mosquito coil)

iii. Strength of coil (for mosquito coil)

iv. Separation of 'twin' coil (for mosquito coil)

v. Separation test (for mosquito coil)

vi. Discharge rate (for aerosol)

vii. Internal pressure (for aerosol)

viii. Particle size

ix. Vaporization rate (liquid vaporizer)

x. Minimum effective rate (liquid vaporizer)

xi. Evaporation rate (Vaporizing mats)

2. All test methods must be specified and supported by references.

Appendix 6

GARIS PANDUAN PENGHANTARAN PIAWAI ANALISIS UNTUK TUJUAN PENDAFTARAN RACUN PEROSAK

1. Piawai Racun Perosak

1.1 Bekas Piawai
- Botol kaca.
- Saiz botol : diameter atas (mulut) : ~ 1.5cm, tinggi ~ 4.0cm.
- Warna botol : amber atau gelap.
- Penutup botol : jenis yang mudah buka dan tutup.

1.2 Maklumat pada label bekas piawai (sekurang-kurangnya);
- Nama kimia atau nama biasa (nama ISO atau nama yang disahkan).
- Nombor lot atau *batch.*
- Berat.
- Ketulinan (*purity*).
- Tarikh luput.
- Label dilekat pada bekas yang mengandungi piawai.

1.3 Berat 100mg, 250mg atau 1g.
(berat yang kurang daripada 100mg tidak diterima).

1.4 Ketulinan minima yang boleh diterima iailah 95%
(Pengecualian adalah diberi kepada piawai analisis dari kumpulan *natural products* seperti pyrethrins, CMIT, MIT, BIT, Azadiracthin, Karanjin dsb.).

1.5 Tarikh luput minima satu tahun.

2. Sijil Analisis Piawai (COA)

2.1 Maklumat yang terdapat pada beaks piawai mestilah juga terdapat dan sepadan dengan COA.

2.2 COA adalah yang asal dengan tandatangan pegawai bertanggungjawab (*chemist or authorized signatory*) atau salinan yang diakui sah oleh pegawai yang diberi kuasa dengan nama dan jawatan.

2.3 Maklumat pada COA sekurang-kurangnya;
- Nama kimia atau nama biasa (nama ISO atau nama yang disahkan)
- Nombor lot atau *batch*
- Ketulinan (*purity*)
- Tarikh luput
- Pernyataan *measurement of uncertainty* (*m.u*) atau *tolerance limit.* (Pernyataan ini boleh disertakan sebagai lampiran).
- Cara penyimpanan (suhu penyimpanan).