GP1/2019

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)

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 based upon that in which the product is sold.

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 PESTICIDE 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. Data Requirement for Pure and Technical Grade Active Ingredients shall be provided. (Refer Appendix 1).

2.2 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. (Refer to Appendix 2 for details required in the specification).

ii. When such specifications are not available or does not comply with any specifications, the applicant shall state the specification that the pesticide complies with and the reasons for non-compliance must be given with the application.

2.3 Manufacturing Process

i. 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;

(f) 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 or other document describing the ingredient.

(g) 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.

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

(i) Manufacturing maximum limits for significant impurities present at or above 1g/kg or relevant impurities at <1g/kg, must 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) 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.

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

2.4 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. The concentration of active Ingredient and relevant impurities in the Technical Grade Active Ingredient (TGAI) shall be determined using a validated analytical method. Validation data shall be provided to confirm that the analytical procedures used give reliable and accurate results. The type of validation data required is dependent on the analytical technique, but typically includes demonstration of linearity over a suitable concentration range, repeatability, reproducibility, specificity, robustness, precision and accuracy.

v. Analytical methods described in official and recognized publications, such as CIPAC handbooks and the AOAC manual for pesticide products are regarded as validated and do not require revalidation. However, the suitability of these methods should be verified under actual conditions of use; that is, the specificity and accuracy of the method should be demonstrated for the published method when applied to the relevant sample matrix and laboratory conditions.

vi. Validation of methods used to determine physical parameters will not be required, provided that CIPAC or equivalent accepted methods are used.

vii. Analytical standards required for the use of the analytical methods mentioned shall be supplied with the application. (Refer to Appendix 5 Requirement for analytical standard or refer to circular B.81/05.20/Jld.V(23) date 8 July 2008 for exemptions of analytical standard for a few active ingredient.)

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^{o} C for 14 days or at 45 ± 2^{o} C for 6 weeks or at 40 ± 2^{o} C for 8 weeks or at 35 ± 2^{o} C for 12 weeks. Stability test at ambient temperature for 1

year or 2 years (ambient laboratory, or warehouse temperatures) also accepted.

ii. Active Ingredient and relevant impurities according to Manual on Development and Use of FAO and WHO Specifications for Pesticides shall be done at the time zero and after accelerated test. The samples of the test item must comply with specification of the product

iii. Each study must be reported in sufficient detail, whereby the methodology used in each test must be thoroughly described and reference to the method used must be mentioned.

iv. Storage stability studies are required to be performed in laboratory that have Good Laboratory Practices (GLP) certified test facilities or ISO 17025 accredited laboratories.

2.6 Safety Data Sheet (SDS)

The SDS of the Technical Grade of Active Ingredient shall be provided. The 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 4 shall be included on SDS
- Additional information may be required by Pesticide Board.

2.7 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.

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. Composition of the pesticides and physical properties of the formulated product shall be provided. (Refer Appendix 3).

3.2 Specifications

i. Specific properties test for the Formulation formulated 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 should be indicated in the application form. (Refer to Appendix 3 for details required in the specification).

ii. When such specifications are not available or does not comply with any specifications, the applicant shall state the specification that the pesticide complies with and the reasons for non-compliance must be given with the application.

3.3 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/WHO 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 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.

3.4 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. 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.

iii. The concentration of active Ingredient and relevant impurities in the formulated product shall be determined using a validated analytical method. Validation data shall be provided to confirm that the analytical procedures used give reliable and accurate results. The type of validation data required is dependent on the analytical technique, but typically includes demonstration of linearity over a suitable concentration range,

repeatability, reproducibility, specificity, robustness, precision and accuracy.

iv. Analytical methods described in official and recognized publications, such as CIPAC handbooks and the AOAC manual for pesticide products are regarded as validated and do not require revalidation. However, the suitability of these methods should be verified under actual conditions of use; that is, the specificity and accuracy of the method should be demonstrated for the published method when applied to the relevant sample matrix and laboratory conditions.

v. Validation of methods used to determine physical parameters will not be required, provided that CIPAC or equivalent accepted methods are used.

vi. Analytical standards for active ingredient required for the above shall be supplied with the registration application for all products. (Refer to Appendix 5 Requirement for analytical standard or refer to circular B.81/05.20/Jld.V(23) date 8 July 2008 for exemption of analytical standard for a few active ingredient.)

3.5 Evidence of Stability on Storage

3.5.1 Tests To Be Conducted On The Product Will Most Likely Comply With The Shelf Life/Expiry Date Specification Of 2 Years

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 is performed usually at 54 ± 2^{o} C for 14 days or at 45 ± 2^{o} C for 6 weeks or at 40 ± 2^{o} C for 8 weeks or at 35 ± 2^{o} C for 12 weeks.

ii. Two years storage stability (Ambient Testing) also can be accepted to demonstrate the storage stability of a formulation under true storage conditions for two years, the test shall be conducted at ambient temperature or, 20 ^{o} C, 25 ^{o} C or 30 ^{o} C with time interval 0 and 24 months.

iii. Active Ingredient and relevant physical and chemical properties testing based on type of formulation according to Manual on Development and

Use of FAO and WHO Specifications for Pesticides shall be done at the time zero and after accelerated test. The samples of the test item must comply with specification of the product.

3.5.2 Tests To Be Conducted For The Product That Comply The Shelf Life/Expiry Date Less Than 2 Years

i. Analytical Test Report as evidence of stability on storage shall be submitted with each application. Stability tests shall be conducted at "true storage condition (warehouse condition)" to demonstrate the storage stability at real time. Only test that conducted in the region of tropical climate zone (located between latitude 23^0 26' 13.4' N or 23.437050 N and 23^0 26' 13.4'S or 23.437050 S) will be accepted. However, test that conducted at any location that has annual average temperature of 20^oC or above shall be accepted.

ii. Test that conducted in laboratory at temperatures at 30^0C or above over a period of real time will be accepted.

iii. Testing intervals are typically at least every six months or 0, 6, 12, 24 months.

iv. Active Ingredient and relevant physical and chemical properties testing based on type of formulation according to Manual on Development and Use of FAO and WHO Specifications for Pesticides shall be done during the testing interval started for time zero until the end of the true storage stability study. The samples of the test item must comply with specification of the product.

3.5.3 Tests To Be Conducted For The Products That Comply The Shelf Life More Than 2 Years.

i. Analytical Test Report as evidence of stability on storage shall be submitted with each application. Stability tests shall be conducted at "true storage condition" to demonstrate the storage stability at real time. Only test that conducted in the region of tropical climate zone (located between latitude 23^0 26' 13.4' N or 23.437050 N and 23^0 26' 13.4'S or 23.437050

S) will be accepted. However, test that conducted at any location that has annual average temperature of 20^0C or above shall be accepted.

ii. Test that conducted in laboratory at temperatures at 30^0C or above over a period of real time will be accepted.

iii. Testing intervals are typically at least every six months or 0, 6, 12, 24, 36, 48 months.

iv. Active Ingredient and relevant physical and chemical properties testing based on type of formulation according to Manual on Development and Use of FAO and WHO Specifications for Pesticides shall be done during the testing interval started for time zero until the end of the true storage stability study. The samples of the test item must comply with specification of the product.

3.5.4 Accelerated Storage Stability Test And True Storage Stability Test.

3.5.4.1 Both stability tests shall be conducted in accordance with the:

i. Samples shall be analyzed before and after testing using the same batch. The product to be used in the test must be taken from a batch that has passed quality control analysis.

ii. The packaging used in the study shall be based upon that in which the product is sold in the respect of material. 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. For accelerated storage stability test conducted at $54^0 \pm 2^0$C, 2 samples must be prepared. One of the samples is treated in the oven, and the other one is a control sample which must be analyzed concurrently after the test in order to reduce the analytical error.

iv. For accelerated storage stability test conducted at 45 ± 2^{o} C for 6 weeks or at 40 ± 2^{o} C for 8 weeks or at 35 ± 2^{o} C for 12 weeks, only 1 sample must be prepared.

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

vi. 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. Reference to the method used must be mentioned in the report.

vii. Active Ingredient and relevant physical and chemical properties testing for storage stability studies are required to be performed in Good Laboratory Practices (GLP) certified–test facilities or ISO 17025 accredited laboratories.

viii. The acceptable variations in active ingredient content will depend on the nominal concentration of active ingredient content in the formulation.

3.5.5 The active ingredient degradation limits in the product after accelerated and true storage condition.

i. For Chemical Pesticides, the active ingredient degradation limits in the product after accelerated and true storage condition:

% w/w Active ingredient content	Acceptable variation/degradation in active content (%)
< 2.5	±15%
2.5-10	±10%
10-25	If there is a decrease of ≥ 5% in concentration of active ingredient from the test sample at time zero, then additional information will be required. The deviations shall not more than ±10%.
25-50	
>50	

ii. Variations outside those listed in the table above will deem the formulation to have failed the storage stability test.

3.6 Safety Data Sheet (SDS)

The SDS of the proposed formulated product and every single inert use shall be provided. The 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 4 shall be included on SDS.
- Additional information may be required by Pesticide Board.

3.7 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.

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 Report (5 Batch Analysis or Storage Stability Test Studies)

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

iii. Name and address of the sponsor;

iv. Name and address of any test facilities and test sites involved;

v. Name and address of the Study Director;

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

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

viii. Dates

a) Experimental starting and completion dates.

ix. Statement

a) A Quality Assurance 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.

x. Description of Materials and Test Methods

xi. Description of methods and materials used;

xii. Reference to OECD Test Guideline or other test guideline or method.

xiii. Results

xiv. A summary of results;

xv. All information and data required by the study plan;

xvi. A presentation of the results, including calculations and determinations of statistical significance; more detailed explanations regarding the presentation of results.

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

xviii. Storage

a) 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 Organization (2012). *Guidelines for Procuring Public Health Pesticide.*
(www.who.int/whopes)

3. Food and Agriculture Organization of United Nations and World Health Organization (2016). Manual on the development and use of FAO and WHO specifications for pesticides. 3rd Revision of 1st ed. Rome and Geneva.
(http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Specs/JMPS_Manual_2016/3rd_Amendment_JMPS_Manual.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]*

8. Crop-life International, “Guidelines for Specifying the Shelf Life of Plant Protection Products” Technical Monograph n°17, 2nd Edition, June 2009

9. OECD Guidance Document For Storage Stability Testing, First Draft, 21 May 2014.

10. Australian Pesticides and Veterinary Medicines – Generation of Storage Stability Data for Agricultural Products.

Appendix 1

Data Requirement for Pure and Technical Grade Active Ingredients (TC/TK).

1. Identity of the active ingredient

a. ISO common name
b. Chemical name (IUPAC)
c. CAS No.
d. CIPAC No.
e. Molecular formula and structure
f. Molecular weight
g. Isomeric composition, if applicable

2. Physical and Chemical Properties

a. Appearance
   - physical state, color or odor
b. Melting point
c. Boiling point
d. Specific gravity/ density
e. pH
f. Volatile point
g. Vapour pressure
h. Flash point
i. Solubility in water
j. Solubility in organic solvents
k. n-octanol/water partition coefficient (log K_{ow})
l. Hydrolysis rate, photolysis (under stated conditions)
m. Dissociation constant (pKa, pKb)

Appendix 2

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)

    a. Minimum content of active ingredient, state in g/kg or % w/w
    b. Maximum content of significant and relevant impurities, state in g/kg or % w/w
        - By-products of manufacture or storage, if required
        - Water, if required
        - Insolubles, if required

3. Specific Properties/ Test Related to Use and CIPAC Method

    a) Acidity and/or alkalinity or pH range, if required – MT 31 or MT 191 or pH range (MT 75.3)
    b) Any other clause – Such as a sieve test, kinematic viscosity range, specific gravity, etc.

Appendix 3

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. Rate of release, or release/retention index, of active ingredient (if applicable)
    d. "Free" active ingredient (if applicable)
    e. By-products of manufacture or storage (all specifications where relevant impurities may be associated with active ingredient. (if applicable)

2. Physical Properties
    a. Appearance
    b. Physical state, color or odor (for all formulated product)
    c. Flammability (if applicable)

3. Specific properties/Test related to use and CIPAC method

    a. Density Properties
        i. Bulk (pour and tap) density - MT 186

    b. Surface Properties
        i. Wettability – MT 53.3
        ii. Persistent foam – MT 47.3

    c. Volatilization Properties
        i. Volatility – No CIPAC method

    d. Particulate, fragmentation properties
        i. Wet sieve test – MT 185
        ii. Dry sieve test – MT 170
        iii. Nominal size range – MT 170 or MT 187
        iv. Dustiness – MT 171.1
        v. Attrition resistance or degree of attrition – MT 178 or MT 178.2

vi. Tablet integrity – Visual observation
vii. Adhesion to seeds – MT 194
viii. Particle size range – MT 187
ix. Tablet hardness – No CIPAC method

e. Dispersion Properties

i. Spontaneity of dispersion – MT 160 or MT 174
ii. Suspensibility – MT 184
iii. Dispersion stability – MT 180
iv. Emulsion stability and re-emulsification – MT 36.3

f. Flow properties

i. Flowability – MT 172.1
ii. Pourability – MT 148.1
iii. Viscosity – MT 22 or MT 114

g. Solution and dissolution properties

i.
ii. Acidity and/or alkalinity or pH – MT 31 or MT 191 or pH range (MT 75.3)
iii. Miscibility with hydrocarbon oil – MT 23
iv. Dissolution of water soluble bags – MT 176
v. Degree of dissolution and solution stability – MT 179.1 or MT 41.1

a. Others

i. Burning time – No CIPAC method
ii. Average weight of coils – No CIPAC method
iii. Strength of coil – No CIPAC method
iv. Separation of 'twin' coil – No CIPAC method
v. Discharge rate – No CIPAC method
vi. Internal pressure – No CIPAC method
vii. Vaporization rate – No CIPAC method
viii. Minimum effective rate – No CIPAC method
ix. Evaporation rate – No CIPAC method

4. All specific properties test methods must be specified and supported by references.

Appendix 4

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; Product trade name (b) Other means of identification; (c) Recommended use of the chemical and restrictions on use; (d) Details of principal suppliers and local registrant (including name, address, phone number, etc.); (e) Emergency phone number (local)
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) Inerts or 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 5

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) : ~ 1.5 cm , tinggi ~ 4.0 cm
- 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 ialah 95 %
(pengecualian adalah diberi kepada piawai analisis dari kumpulan *natural products* seperti pyrethrins, CMIT, MIT, Bit. , Azadirachtin, Karanjin dsb.)

1.5 Tarikh luput minima satu tahun.

2. Sijil Analisis Piawai (COA)

2.1 Maklumat yang terdapat pada bekas 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 diberikuasa 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
- Tarikh luput
- Pernyataan measurement of uncertainty *(m.u)* atau *tolerance limit* (pernyataan ini boleh disertakan sebagai lampiran)
- Cara penyimpanan (suhu penyimpanan)