Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Dir98-03

Regulatory Directive

Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products

This Regulatory Directive details the chemistry requirements for registration under the *Pest Control Products Act* (PCPA) and Regulations and the recommended organization of Part 3 of the data submission.

This document replaces Regulatory Directive Dir93-04, *Chemistry Requirements for the Registration of End-Use Products*, February 18, 1993. The revision process sought industry input through Regulatory Proposal Pro97-02, *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated From Registered Technical Grade of Active Ingredients or Integrated System Products*, published in July 1997. Comments received were considered in the final version of the document.

The chemistry requirements have been harmonized with those of the U.S. Environmental Protection Agency (EPA) as described in the *Code of Federal Regulations* (CFR) 40 CFR Š 158, and the *Product Properties Test Guidelines* 830 Series.

A tabular correlation between Pest Management Regulatory Agency (PMRA) and EPA guidance documents is provided in Appendix III to aid applicants in the compilation of a complete product chemistry package.

(publié aussi en français)

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1.0 Introduction

Product chemistry information is developed and submitted for review in order to meet two objectives:

(i) to identify and quantify the active ingredient(s) for purposes of the pest control product's certified limits; and

(ii) to fully characterize the manufacturing concentrate (MA) or end-use product (EP) composition, including technical active ingredient(s) and formulants, in order to:

a) determine the uniqueness of each source with respect to purity and potency; and

b) assess the safety to humans and the environment in relation to the product's proposed uses.

The PMRA has developed a series of data codes (DACOs) to address registration requirements on a use-site category (USC) basis. These are to be used as the basis for the chemistry package submission and will be screened for completeness prior to the review of the chemistry data. Detailed instructions concerning the submission process are found in two Agency publications, Regulatory Proposals Pro96-01, *Management of Submissions Policy*, and Pro98-02, *Organizing and Formatting a Complete Submission for Pest Control Products*, both to be rewritten as Regulatory Directives.

Terminology and acronyms used throughout this document are defined in Appendix V and VI respectively. The use of the term *product* refers to both a MA and an EP. The individual terms are specifically used where warranted.

2.0 Product Chemistry Data Requirements

Appendix I to this document identifies the data requirements for the registration of a MA or an EP prepared from registered technical grade of active ingredients (TGAI) or integrated system products (ISP). A distinct Regulatory Directive, Dir98-04, identifies the requirements for the pest control products from which the MAs and EPs covered by the scope of this Regulatory Directive are formulated.

Guideline Application

Please note that these data requirements may be partially or completely superseded by distinct guidance found in other PMRA publications, e.g., for specific pesticide types including pheromones and microbial pest control agents as per the *Registration Handbook for Pest Control Products Under the Pest Control Products Act* and Regulations, herein, the Registration Handbook. If in doubt, it is recommended that the applicant confirms the relevance of these guidelines for a specific product with the Agency.

Requirements may be waived for some portions of the information requested by Appendix I, on a case-by-case basis, if the applicant can offer an acceptable written rationale based upon scientific reasoning. Such requests should appear in, or be referenced by the corresponding DACO number.

The PMRA may request additional data concerning any requirement found in this Regulatory Directive, also on a case-by-case basis, if deemed necessary for evaluation purposes.

3.0 Submittal of Samples

Pursuant to the Pest Control Products Regulations, 100-g samples of formulated product, or smaller samples of formulants, impurities and/or metabolites, may be required from applicants. If requested, please send samples directly to:

Laboratory Services
Pest Management Regulatory Agency
Health Canada
Laboratory Services Building, No. 22
Central Experimental Farm
Ottawa, Ontario K1A 0C6

NOTES:

(1) Sample packaging must comply with the *Transportation of Dangerous Goods Act* and Regulations. Poorly packed, leaking, or otherwise damaged samples will be destroyed and replacement samples will be requested.

(2) Samples must be properly labelled with concentration, weight and common or chemical names, not trade names or company codes.

(3) Storage instructions and information on the shelf life must be provided. Material Safety Data Sheets (MSDSs) must also be provided, if available.

(4) Samples must be accompanied by correspondence indicating the reason for submission, e.g., requested by the PMRA as a requirement of registration, and include a submission number, if assigned, for ease of reference.

(5) Unless accompanied by an MSDS, the acute oral and dermal toxicity of the sample should be supplied or at least indicated on the sample label.

Data Requirements for Registration (Part 3 of Data Submission)

3.1 Product Identification

3.1.1 Applicant's Name and Office Address

3.1.2 Formulating Plant's Name and Address

3.1.3 Trade Name

3.1.4 Other Names: Include any company development code name/number as well as any equivalent foreign name to which data found in the submission may be referenced.

3.2 Formulation Process

Together, the descriptions of the materials used to formulate the product and the formulation process itself identify the major factors affecting the composition of a MA or an EP. The PMRA reviews this information, along with the EP analytical data requirements showing the absence of formulation interferences, to determine whether the applicant's product will contain the stated ingredients at the certified limits listed on the Control Product Specification form (CPSF).

3.2.1 Description of Starting Materials

The following information is to be provided for each active ingredient present in the MA or EP:

(i) the name and guarantee of the PMRA-registered product; and

(ii) the PMRA registration number of that product.

The following information is to be provided for each formulant present in the MA or EP:

(i) chemical name(s), if it is a specific discrete chemical substance(s);

(ii) brand name, trade name, common name, Chemical Abstracts Service (CAS) Registry number, and other commercial designation of the ingredient;

(iii) all information that the applicant knows (or that is reasonably available) concerning the composition of the ingredient, including a copy of specifications or other documents describing the ingredient; and

(iv) the name and address of the producer of the ingredient or, if that information is not known to the applicant, the name and address of its supplier.

It should be emphasized that an applicant is not required to perform chemical analysis of starting materials to meet the above criteria, but only provide information to which the applicant has, or should have, access.

If multiple suppliers are used for starting materials, specifications for all suppliers should be provided. Changes in suppliers once a product is registered are subject to the requirements of Regulatory Directive Dir94-01, *Notification/Non-Notification*, or subsequent revisions.

3.2.2 Description of the Formulation Process

The following information must be provided:

(i) a general characterization of the process, e.g., whether it is batch or continuous, and the quantity of product produced per batch (or per unit time, if continuous);

(ii) the identities of the reactants, solvents, and catalysts used, as applicable, to formulate the product, including their quantities and the order in which they are added;

(iii) a description of the equipment used that may influence the composition of the MA or EP;

(iv) a description of the conditions, e.g., mixing time, temperature, pressure, pH, humidity, that are controlled during each step of the process to affect the composition of the substance produced, and the limits that are maintained; and

(v) a description of the procedures used to assure consistent composition of the substance produced, e.g., calibration of equipment, sampling regimens and other quality control (QC) measures such as tests used to monitor reaction completion.

3.2.3 Discussion of the Formation of Impurities of Toxicological Concern

The level of detail required for MAs or EPs is typically less stringent than for the registered sources of their active ingredients since the impurities associated with an active ingredient in an MA or EP will almost exclusively reflect those present in the registered material from which they are prepared. Impurities or side reactions rarely occur as a result of the basic blending process typically employed.

However, if the applicant has reason to believe that an impurity the PMRA would consider toxicologically significant[1] may be *introduced* or *enhanced* due to the formulation process, the discussion must include an expanded description of the potential formation of the impurity and the amounts at which it might be present. Analytical methods applicable to such components are to be provided as per Appendix I, clause 3.4.2. In this context, the following potential sources of impurity formation must be considered and identified:

(i) possible reactions occurring during the formulation of the product between any of its active ingredients, between the active and formulants, or between the active ingredient and the production equipment;

(ii) post-production reactions between any of the MA or EP active ingredients and any other component of the product or its packaging;

(iii) the possible migration of packaging materials into the product; and

(iv) the potential carryover of contaminants from earlier use of production equipment to formulate other products.

3.3 Specifications

The nominal concentration and corresponding certified limits must be provided for each MA or EP component[2]. The nominal concentration is defined as the typical amount of an ingredient present in a pest control product at the time of its production. Both the active ingredient nominal concentration and a corresponding nominal equivalence statement, if applicable, e.g., acid salts, are to be provided.

The product guarantee, identified on the CPSF and appearing on the draft product label, is synonymous with the active ingredient(s) nominal concentration. This number most accurately identifies the amount of each active ingredient typically found in the EP or MA and is based upon the nominal concentration of the active ingredient in the registered TGAI, ISP, or MA from which it is formulated. EP or MA active ingredient nominal concentrations are subsequently used to establish corresponding enforceable certified limits, as further discussed in Appendix I, clause 3.3.1.

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1 See Dir98-04, Appendix I, clause 2.13.4 for a more detailed discussion of impurities of toxicological significance. The required level of determination is dictated by the limit of quantitation (LOQ) of the corresponding analytical method, which is sample/chemical dependent, and must also be below any applicable regulatory limit.

2 The Agency requires a nominal approach to active guarantee expression for new technical products and associated EPs. However, currently registered technicals may have minimum active content guarantees and EPs formulated from such products may also express their active ingredient level in terms of a minimum guarantee. Registrants/applicants who wish to convert from a minimum to a nominal guarantee may do so. A target conversion date for all existing registered products will be established only after consultation with registrants.

The following table identifies the required (R) or conditionally required (CR) information:

Table 1: Product Component Identification

EP/MA Component	Common (or Trade[3]) Name	CAS Chemical Name	CAS Registry No.	Component % by Weight	Lower Certified Limit	Upper Certified Limit	Purpose In Product
Source of Active Ingredient(s)[4]	R	R	R	R[5]	R[5]	R[5]	R
Formulants[6]	R	CR[7]	R	R	R	R	R
Impurities of toxicological concern	CR[8]	CR[8]	CR[8]	CR[8]		CR[8]	Identify as an impurity

3.3.1 Establishing Certified Limits

Standard certified limits for active ingredients and formulants are based upon nominal concentration, unless the applicant proposes alternate limits which are deemed acceptable by the PMRA. Where warranted by Appendix I, Section 3.3, the applicant must propose upper certified limits for impurities of toxicological significance as standard certified limits may not be used for such product components.

3 Include only if a common name is unavailable, i.e., certain formulant mixtures.

4 Also include the International Union of Pure and Applied Chemistry (IUPAC) chemical name and the nominal concentration of the active ingredient in the registered source of the active ingredient. For an EP this may be a TGAI, ISP or MA.

5 The component % by weight value reflects the amount of the manufacturing product (TGAI, ISP, MA) used. The associated limits reflect the corresponding amount of the actual active ingredient(s), as it is subject to guarantee and enforcement, rather than the amount of manufacturing product used as the source of the active ingredient. Provide the nominal content (weight % or g/L), as identified in the Registration Handbook, of the active ingredient in the guarantee box of the CPSF, as well as a corresponding equivalence statement, if applicable, e.g., acid salts. Instructions on the proper completion of the form are included with the CPSF.

6 Include a purity statement for each formulant.

7 Required if the formulant is a specific discrete chemical substance(s).

8 Required if the formulation process creates or enhances the presence of an impurity of toxicological concern. Common names and CAS Registry numbers are to be provided if established (also see footnote No. 1).

Standard limits are defined as follows:

Table 2: Standard Certified Limits

Nominal Concentration of Ingredient	Upper Limit	Lower Limit
20.0% < N # 100.0%	N + 3% N	N - 3% N
1.0% < N # 20.0%	N + 5% N	N - 5% N
N # 1.0%	N + 10% N	N - 10% N

An applicant may propose a certified limit for an active ingredient or formulant that differs from the standard limits, but must include an explanation of the basis of the proposed limits, including how they were established, e.g., sample analysis or quantitative estimate based upon the formulation process. Proposed limits should not greatly exceed those actually occurring in the product.

All certified limits must:

(i) be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal QC procedures are used;

(ii) allow for all sources of variability likely to be encountered in the formulation process; and

(iii) take into account the stability of the ingredient in the product between production and sale or distribution.

If the PMRA finds any certified limit (either standard or applicant proposed) unacceptable, the Agency will inform the applicant of its determination and will provide supporting reasons. The PMRA may also require, on a case-by-case basis, any or all of the following:

(i) more precise limits;

(ii) a more thorough explanation of how the certified limits were determined; or

(iii) a narrower range between the upper and lower certified limits than that proposed.

3.3.2 Control Product Specification Form

Specification data are to be submitted on a CPSF that includes a signed and dated Declaration of Applicant certifying that the information is true and complete.

Instructions on the proper completion of the form are included with the CPSF.

3.4 Product Analysis

3.4.1 Enforcement Analytical Methods

There is no requirement for the provision of an enforcement analytical method (EAM) for a MA. However, an analytical method suitable for enforcement purposes must be provided for each active ingredient in an EP. This method should reflect that routinely used by the applicant to ensure that batch-to-batch variability does not result in product being released for use that does not meet the criteria identified on the CPSF. A method capable of separating stereoisomers, when applicable, is also required and may result in the need for two methods for the active ingredient(s), one for total isomeric content and a second to confirm any specified ratio.

The recommended reporting format for analytical methodology is outlined in Appendix II.

All methodology must have sufficient precision and accuracy to determine whether the amount of the ingredient found in any sample of the product is within its certified limits.

In addition to validation data including linear range, accuracy and precision; the applicant must provide labelled chromatograms of the EP, the active ingredient analytical standard, the internal standard (if used) and the corresponding blank formulation (containing all formulants without the active) to demonstrate the absence of analytical interference. If the formulation contains two or more active ingredients, chromatograms of the blank formulation individually spiked with each active and another spiked with the internal standard, if used, are to be provided.

EAMs may be validated by the PMRA laboratory at the time the product chemistry data are reviewed. Methods should not be claimed confidential, use commonly available equipment, and be written to include all steps performed even when the author believes that certain steps are *normally* performed in all laboratories.

3.4.2 Impurities of Toxicological Concern

If potential exists for the formulants/formulating process to create or enhance the presence of an impurity of toxicological concern, methodologies, validation data, including spiked sample recovery at the limit of quantitation (LOQ) for expected contaminant(s) or reasonable surrogates, as appropriate, and representative data are required from the analysis of five (5) batches of the MA or EP. For example, data would be required if there exists a potential for N-nitrosamine contamination, above that found in the corresponding source of registered material, due to the introduction of a nitrosating agent in the formulation process.

Since detection and quantitation limits may vary on a case-by-case basis[9], consultation with the PMRA is recommended. If identified, and there is a potential for increased levels over time, the analysis of impurities of toxicological significance must be included in the ambient storage stability study required by Appendix I, clause 3.5.10.

3.5 Chemical and Physical Properties

Protocols for developing property data are not included in this guidance document. Applicants should consult protocols developed and published by various agencies, including those referenced in the comparative table below or listed in Appendix IV. Methodology must be thoroughly described or a copy of the scientific publication describing the protocol must be included with the submission. A reference to internationally established protocols is sufficient, if followed without deviation, and the specific procedure used is clearly identified for those protocols providing multiple options. Study reports should include a complete presentation of the data, sample calculations and an interpretation of the results.

Table 3: Chemical and Physical Properties

Clause	Property	Test Substance	Property Notes	EPA (830 Series)	OECD[10]
3.5.1	Colour	MA, EP	1	830.6302	
3.5.2	Physical state	MA, EP		830.6303	
3.5.3	Odour	MA, EP	1	830.6304	
3.5.4	Formulation type	EP			
3.5.5	Container material and description	MA, EP			
3.5.6	Density or specific gravity	MA, EP	2	830.7300	109
3.5.7	pH	MA, EP	3	830.7000	
3.5.8	Oxidizing or reducing action (chemical incompatibility)	MA, EP	4	830.6314	
3.5.9	Viscosity	MA, EP	5	830.7100	114
3.5.10	Storage stability data	MA, EP	6	830.6317	
3.5.11	Flammability	MA, EP	7	830.6315	
3.5.12	Explodability	MA, EP	8	830.6316	
3.5.13	Miscibility	MA, EP	9	830.6319	
3.5.14	Corrosion characteristics	MA, EP	10	830.6320	
3.5.15	Dielectric breakdown voltage	EP	11	830.6321	

9 The required level of determination is dictated by the LOQ of the corresponding analytical method, which is sample/chemical dependent, and must also be below any applicable regulatory limit.

10 OECD: Organisation for Economic Co-operation and Development

Property Notes:

(1) Required for all MAs. Only required for EPs if the property is expected to affect product efficacy.

(2) Bulk density must be defined for solid products. True density or specific gravity is applicable to other test substances.

(3) Required for, (i) 1% solution/suspension as per CIPAC MT 75 for EPs applied as aqueous dilutions and, (ii) liquid products as packaged.

(4) Requirements include an assessment of hazardous reactions that may result from contact with common oxidizing and reducing agents. See the referenced EPA guidance document for a complete description.

(5) Required when the product is a liquid.

(6) Storage stability data must adhere to the following requirements:

(i) A storage stability study of at least one year in duration shall be conducted at either:

(a) a constant ambient temperature of 20 or 25°C and, if the package is permeable, at a relative humidity of 50%; or

(b) under warehouse conditions that reflect the expected storage conditions of the commercial product (this may include the need for freeze-thaw studies). Where possible, the storage environment should approximate any extremes of temperature or climate expected to occur under actual storage conditions.

(ii) The study shall be conducted with the product in its commercial package or in smaller packages of the same construction and materials.

(iii) The study should be carried out with sufficient replicates and sufficient sampling frequency to establish the actual shelf-life if degradation occurs within one year. If a product has a shelf life of less than one year, an expiration date may be required on the product container.

(iv) The analysis is to be conducted using a specific validated method. For EPs, the same method used to determine the level of the active ingredient for establishing certified limits would typically be employed. However, if the methodology differs from that provided in clause 3.4.1, it must be fully described as per Appendix II.

(v) The storage stability report submitted in support of registration shall include the following information:

(a) a description of test procedures and conditions, e.g., study duration, humidity and temperature;

(b) a description of any physical changes, e.g., phase separation or clumping, in the product and any changes to the integrity of the packaging material during the test period and also the consequences, if any, of such changes for safe handling and use of the product; and

(c) quantitative analytical data for the active ingredient at study commencement and following storage periods of 3, 6 and 12 months.

(vi) A surrogate study of a similar formulation may be acceptable in lieu of the storage stability study.

(vii) The stability protocol must contain a test to monitor for the stability of optically pure/enhanced active ingredient(s) towards chiral inversion or other isomerization, if applicable.

(7) The flash point shall be determined for combustible liquid products. For aerosols, the flame extension test method should be conducted. See the referenced EPA guidance document for a complete description.

(8) Required when the product is potentially explosive.

(9) Required when the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

(10) Required unless a reasonable explanation of a lack of corrosivity is provided, e.g., lack of extreme pH, lack of reaction with container material. This study may be performed in combination with the storage stability requirements described in clause 3.5.10 and corresponding Note 6 above.

(11) Required when the EP is a nonconductant liquid and is to be used around electrical equipment.

Analytical Data Reporting Format

This Appendix is included primarily to address the issue of content and to suggest a consistent format for ease of data review; however, it is the content that is of primary significance and a report need not be rewritten to adapt to the format suggested.

Preliminary pages

Title/cover page

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Introduction and Summary

Scope — Identify the analyte(s) for which the method has been validated.

Source of method — Include a reference to a published method, such as sources listed in Appendix IV, if applicable.

Analytical principles — Provide a brief description, including the identification of the chemical species determined, the range over which the analyte(s) has (have) been analysed and, for impurities, the limits of detection and sensitivity.

Materials and Methods

Equipment — List and describe.

Reagents and standards — List and describe source and preparation.

Analytical procedure — Detail in a stepwise fashion, with special emphasis on reagents or procedural steps requiring special precautions to avoid safety or health hazards:

(i) preparation of sample;
(ii) extraction (if any);
(iii) clean-up (if any);
(iv) derivatization (if any); and
(v) instrumental analysis, including:

a) description - make/model, type/specificity of detectors, columns, packing materials, carrier gases, mobile phase, etc.;
b) operating conditions - flow rates, detector wavelength, temperatures, voltage, etc.; and

c) calibration procedures.

Methods of calculation Describe in a stepwise fashion

Other Identify any and all relevant information the applicant considers appropriate to provide a complete and thorough description of the analytical methodology and the means of calculating the results, i.e., critical control points.

Results and discussion

Describe the established performance criteria for the method

Accuracy

Precision Identify the number of replicates used.

Limit of Detection (LOD)/LOQ Provide definition.

Selectivity/specificity Describe tests used to establish the lack of interferences from other product components or from solvents and materials used in the methodology.

Ruggedness testing If performed.

Limitations

Linear range

Tables and figures

These are to be fully referenced to the body of the report and included where appropriate.

References

Appendices

Representative chromatograms, spectra, etc. As applicable and in accordance with Appendix I, Section 3.4.

Other Any relevant material not fitting into any other sections of this report.

Table 4: Correlation of Corresponding PMRA/EPA Guidance Documents

	PMRA Regulatory Directive Dir98-03		Corresponding EPA Documentation	
Section	**Section Title**	**EPA No.**	**EPA Title[11]**	**40 CFR 158**
1.0	Introduction	830.1000	Background for Product Properties Test Guidelines	
2.0	Product Chemistry Data Requirements	830.1000	Background for Product Properties Test Guidelines	
3.0	Submittal of Samples	830.1900	Submittal of Samples	158.190
Appendix I	Data Requirements for Registration (Part 3 of Data Submission)			
3.1	Product Identification			
	3.1.1 Applicant's Name and Office Address			
	3.1.2 Formulating Plant's Name and Address			
	3.1.3 Trade Name	830.1000	Background for Product Properties Test Guidelines	
	3.1.4 Other Names	830.1000	Background for Product Properties Test Guidelines	
3.2	Formulation Process			
	3.2.1 Description of Starting Materials	830.1600	Description of Materials used to Produce the Product	158.160
	3.2.2 Description of the Formulation Process	830.1650	Description of Formulation Process	158.165
	3.2.3 Discussion of the Formation of Impurities of Toxicological Concern	830.1670	Discussion of Formation of Impurities	158.167
3.3	Specifications	830.1550	Product Identity and Composition	158.155
	3.3.1 Establishing Certified Limits	830.1750	Certified Limits	158.175
	3.3.2 Control Product Specification Form	830.1550	Product Identity and Composition (Confidential Statement of Formula, EPA Form 8570-4)	158.155
3.4	Product Analysis			
	3.4.1 Enforcement Analytical Methods	830.1800	Enforcement Analytical Method	158.180
	3.4.2 Impurities of Toxicological Concern	830.1800	Enforcement Analytical Method	158.180
3.5	Chemical and Physical Properties	Various	See Correlation in Appendix I, Section 3.5	158.190

[11] The EPA 830 Series of requirements supersede the 1982 *Pesticide Assessment Guidelines Subdivision D, Product Chemistry*.

References for Developing Chemistry Data

Applicants should ensure that they have the latest editions of the following documents.

1. Agriculture Canada, *Guidelines for Determining Environmental Chemistry and Fate of Pesticides*, Trade Memorandum T-1-255, 1987.

2. American Society for Testing and Materials, *Annual Book of ASTM Standards*; ASTM, Philadelphia, PA, U.S.

3. Association of Official Analytical Chemists, *Official Methods of Analysis of AOAC- International*; AOAC-International, Arlington, VA, U.S.

4. Collaborative International Pesticide Analytical Council, *CIPAC Handbooks*, CIPAC, Hatching Green, Harpenden, Hertfordshire, England, 1970 - 1995.

5. Organisation for Economic Co-operation and Development, *Guidelines for Testing of Chemicals*, OECD 101 - 117; OECD, Paris, France, 1981 - 1995.

6. United States Environmental Protection Agency, *Product Properties Test Guidelines* (830 Series); U.S. Government Printing Office, Washington, DC, U.S., 1996.

7. United States Environmental Protection Agency, *EPA Manual of Chemical Methods for Pesticides and Devices*, 2nd edition; AOAC, Arlington, VA, U.S., 1992.

Definition of Terminology

Note: Italicized text found in a definition identifies that the term is also defined in this appendix.

Active ingredient: the ingredient(s) of a control product to which the effects of the pest control product are attributed, including a synergist, but does not include a solvent, diluent, emulsifier or component that by itself is not primarily responsible for the control effect of the product.

Diastereomer: *stereoisomers* not related as mirror images.

Enantiomer: one of a pair of molecular species that are non-superimposable mirror images of each other.

End-use product: a product containing *active ingredient(s)* and usually *formulant(s)* that is labelled with instructions for direct pest control use or application.

Formulant: any substance or group of substances other than an *active ingredient* that is intentionally added to a pest control product to improve its physical characteristics, e.g., sprayability, solubility, spreadability, and stability.

Formulation: the process of mixing, blending, or diluting one or more *active ingredients* with one or more *formulants*, typically without an intended chemical reaction, to obtain a distinct *manufacturing-use product* or an *end-use product*.

Formulation type: the physical form of the pest control product. These are listed in the Registration Handbook.

Guarantee: the typical or *nominal concentration* of an ingredient that is expected to be present in a representative sample of a pest control product at the time of its production.

Impurity: any substance in a control product other than an *active ingredient* or a *formulant*, e.g., contaminants, residual starting materials, reaction products, degradation products or products added for purposes of extraction or purification.

Integrated system product: may be used in manufacture of an *end-use product* or may itself be an *end-use product*; formed in a manufacturing process in which the ISP:

(a) contains an *active ingredient* that is not isolated due to physical limitations or uncertainty as to the specific active component(s); or

(b) is purposely left as a mixture of components due to manufacturing or integrity considerations.

Manufacturing concentrate: a product containing a registered *technical grade of active ingredient(s)* and *formulant(s)* intended for further reformulating and/or repackaging into *end-use products.*

Manufacturing-use product: products for manufacturing use only which include *technical grade of active ingredients* and *manufacturing concentrates*. It may also include *integrated system products* when they are used for reformulating or repackaging.

Nominal concentration: the typical amount, or *guarantee*, of an ingredient that is expected to be present in a representative sample of a pest control product at the time of its production.

Starting material: any substance, including reactants, solvents and catalysts, used to manufacture or purify a pest control product.

Stereoisomers: *isomers* with identical atomic connectivities and differing only by the spatial arrangements of their atoms or groups. Subclasses are *enantiomers* and *diastereomers*.

Technical active ingredient: see *technical grade of active ingredient*.

Technical grade of active ingredient: contains the *active ingredient* and normally contains *impurities* that are by-products of the manufacturing process.

Acronym List

CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council
CPSF	Control Product Specification Form
CR	Conditionally Required
CV	Coefficient of Variation
DACO	Data Code
EAM	Enforcement Analytical Method
EPA	Environmental Protection Agency (United States)
EP	End-Use Product
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (EPA)
ID	Identify
ISP	Integrated System Product
IUPAC	International Union of Pure and Applied Chemistry
LOD	Limit of Detection
LOQ	Limit of Quantitation
MA	Manufacturing Concentrate
MP	Manufacturing-Use Product
MSDS	Material Safety Data Sheet
OECD	Organisation for Economic Co-operation and Development
PCPA	Pest Control Product Act
PMRA	Pest Management Regulatory Agency
QC	Quality Control
R	Required
TGAI	Technical Grade of Active Ingredient
USC	Use-Site Category