Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Dir97-02

Regulatory Directive

Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals

This Regulatory Directive outlines the requirements for research trials and registration of pest control products containing pheromones and other semiochemicals in Canada at this time.
A pheromone is a semiochemical produced by individuals of a species that affects the behaviour of other individuals of the same species. A semiochemical is a message-bearing substance produced by a plant or an animal, or a synthetic analogue of that substance that evokes a behavioural response in individuals of the same or other species.

The Directive reflects progress made in three important areas:

- the Canadian data requirements are now harmonized with requirements in the U.S.;
- the Guidelines outline for registrants the specific data requirements for these products in order to be considered for registration; and,
- the Guidelines support effective and sustainable pest management and the introduction of new pest management technology.

This document replaces Pro95-03, *Regulatory Guidelines for Pheromones and Other Semiochemicals*, dated September 29, 1995, that invited comments until January 1996 on the registration requirements for pheromones and other semiochemicals proposed by the PMRA. Approximately 25 detailed comments were received, many of which proposed harmonization of data requirements with the U.S. These data requirements may undergo further changes as the result of the international harmonization activities involving countries in the Organisation for Economic Co-operation and Development, currently underway.

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1.0 Introduction

This document outlines the general principles for the regulation of pheromones and other semiochemicals used for the control of arthropod pests. These data requirements may undergo further changes as the result of the international harmonization activities involving countries in the Organisation for Economic Co-operation and Development (OECD), currently underway. For the purposes of this document, pheromones and other semiochemicals are defined in Section 2.0.

Pheromones and other semiochemicals intended for use to mitigate the effects of a pest population are within the definition of a control product in the *Pest Control Products Act* (*PCPA*). Therefore, these products are subject to regulation under the *PCPA* and, in some circumstances, the *Food and Drugs Act* (*FDA*).

In developing a regulatory approach for semiochemicals, the inherent differences between these products and conventional pesticides were taken into consideration. Semiochemicals act by modifying behaviour of the pest species rather than killing it, are more target specific than conventional insecticides, are used at concentrations close to those occurring in nature, and dissipate rapidly. For these reasons it is expected that most semiochemical products will pose low potential risk to human health and the environment compared with conventional pesticides.

The types of semiochemicals which do and do not require registration under the *PCPA* and regulation under the *FDA* are listed below.

Type 1: Registration not required

Semiochemicals that are used in fixed-location lures for the purpose of attracting and monitoring pests are expected to have minimal impact on either the environment or human health. Such products are exempt from registration when used as follows:

(i) Semiochemicals used in pheromone traps in which they are the sole active ingredient.

(ii) Semiochemicals used in lures attached to trap trees.

(iii) Semiochemicals incorporated into pesticide formulations used in fixed location traps (the semiochemical itself does not require registration, but the pesticide formulation does).

Type 2: Registration required

For the following semiochemical-containing products, registration is required for both the technical grade of active ingredient (TGAI) and the end-use product (EP). These products may also require evaluation under the *FDA* if they are used in and/or on food or feed crops offered for sale. The semiochemical alone or in combination with conventional pesticides may be incorporated into the following products:

(i) Semiochemicals contained in solid-matrix dispensers which are placed in large numbers by hand or machine (i.e., not fixed-location traps) for the purpose of pest control. These devices include, but are not limited to, rubber septa dispensers, trilaminate sheets, tapes, tags, wafers, macrocapillary devices such as long tubes or fibres, protected "ropes" and twist-ties. If these products are not in direct contact with a food crop then evaluation under the *FDA* to set a maximum residue limit is not required.

(ii) Semiochemicals to be broadcast or sprayed, alone or formulated into a pesticidal bait. These products include, but are not limited to, liquid flowables, microcapsules, microcapillary straws, granular powders, flakes, confetti formulations, cigarette filters and unprotected "ropes".

Any uses of semiochemicals in pest management not mentioned above will be evaluated on a case-by-case basis with the possibility of enlarging the list of products subject to, or exempt from, registration under the *PCPA* and evaluation under the *FDA*. These guidelines do not pertain to personal insect repellents, which have separate regulatory requirements.

Data Requirements

These guidelines are a general guide to the data requirements for research permits and for registration of pheromones and other semiochemicals that affect the behaviour of arthropods and which are used in pest control products. Additional data may be required if the review of these data suggest that the use of a proposed product could pose a concern to human health or the environment.

There are reduced data requirements for the family of chemicals which comprise the Straight-Chained Lepidopteran Pheromones (SCLPs). Environmental and health studies have demonstrated that these substances pose minimal risk and provide effective pest control at low volumes, similar to naturally occurring concentrations. The SCLPs are defined in Section 2.0.

If applicants are unsure as to the need for research permits or registration, or the precise nature of data requirements to support these requests, they are strongly encouraged to consult with the Pest Management Regulatory Agency (PMRA) **prior to** use of the product and sale of treated crops or submitting an application for a research permit or registration.

Waivers

Requests for waivers for the submission of data required to support applications for research permits or registration will be considered by the PMRA. A scientific rationale must accompany each request for a waiver. For each application, and the situation presented, consideration will be given on a case-by-case basis to the nature of the product and the proposed use pattern.

2.0 Definitions

The following definitions are used for the purpose of these guidelines:

ACTIVE INGREDIENT COMPONENT (AIC):
an individual chemical compound that contributes to the activity of the active ingredient. More than one component or isomer may be combined to form the active ingredient.

ACTIVE INGREDIENT:
the ingredient(s) of a control product to which the effects of the control product are attributed, including a synergist and all AICs, but not including a solvent, diluent, emulsifier or component that by itself is not primarily responsible for the control effect of the control product.

ALLOMONE:
a semiochemical produced by individuals of a species that affects the behaviour of individuals of other species, to the benefit of the species that produces it.

COOPERATOR:
any individual, corporation or institution not engaged in pesticide research that has agreed to use or to allow the use of a pest control product for research on a site owned or operated by that individual, corporation or institution.

END-USE PRODUCT (EP):
a pest control product whose labelling includes directions for direct use or application for its intended pesticidal effect.

KAIROMONE:
a semiochemical produced by individuals of a species that beneficially affects the behaviour of individuals of another species, to the detriment of the emitting species.

PHEROMONE:
a semiochemical produced by individuals of a species that affects the behaviour of other individuals of the same species.

RESEARCH:
tests, trials or experiments carried out to generate new data or to confirm results drawn from other studies, as required by the *Pest Control Products Regulations*, to support registration of a pesticide.

RESEARCHER:
any person who is responsible for using or supervising the use of a pesticide for research purposes. In light of the low potential risk to humans and the environment with

semiochemicals compared with other types of pesticides, a researcher need not necessarily be affiliated with a research establishment.

RESEARCH ESTABLISHMENT:
any public or private corporation or institution or part thereof, engaged in research on pesticides.

SEMIOCHEMICAL:
a message-bearing substance produced by a plant or animal, or a synthetic analogue of that substance, that evokes a behavioural response in individuals of the same or other species. Some examples of semiochemicals are allomones, kairomones, pheromones and synomones. These guidelines pertain only to substances which affect arthropod behaviour.

STRAIGHT-CHAINED LEPIDOPTERAN PHEROMONES (SCLP):
a group of pheromones consisting of unbranched aliphatics having a chain of nine to eighteen carbons, containing up to three double bonds, ending in an alcohol, acetate or aldehyde functional group.

SYNOMONE:
a semiochemical produced by individuals of a species that affects the behaviour of individuals of another species, to the benefit of both species.

TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI):
a manufacturing-use product consisting of an active ingredient that may contain impurities but does not contain added formulants and is produced on a commercial or pilot-plant scale for the manufacture of other pest control products.

3.0 Research Trials

This section applies to research with Type 2 semiochemical end-use products described in Section 1.0, which are subject to registration.

It should be noted that the sale of treated crops is subject to regulation under the *FDA*. Crops harvested from treated research plots or sites must not be sold for food or feed purposes without written authorization from the PMRA, except when used in research where the semiochemical does not actually touch the crop plant (i.e., exemption category 3.1(1) below). This requirement applies to **any** research where the treated crop is to be sold for food and feed and is independent of the size of the research trial. A waiver may be granted by the PMRA depending on the nature of the product and the use pattern. A scientific rationale must accompany each application for a waiver (see Appendix I, Parts 6 and 7, for more information). Each application and the situation presented will be considered on a case-by-case basis.

A two-tiered approach for research trials has been adopted, based on risk assessment, thereby allowing flexibility in regulating semiochemical products. The two tiers of regulation are: (a) Exemption and (b) Research Permit. The researcher should determine in which of these two categories the intended research trial fits. Researchers are invited to consult with the PMRA for clarification regarding regulation of research trials conducted with semiochemicals.

It should be noted that certain provinces may require a provincial permit to conduct any research trials, whether conducted under a federal research permit or exemption. **The researcher is responsible for applying to the provincial regulatory officials for such a permit.**

Also note that the research coordinator must ensure the safety of employees and cooperators, and seek guidance from appropriate sources regarding use, handling and disposal procedures. Employees and cooperators should be advised of semiochemical application schedules and be supplied with telephone numbers to access emergency medical information (e.g., product chemistry and antidotal measures).

Whenever possible, research workers should be supplied with a Material Safety Data Sheet (MSDS) that includes appropriate precautions regarding accidental exposure. In the absence of such information, research workers should wear chemical resistant gloves and coveralls during mixing, loading, application, clean-up and repair.

All field research sites should have appropriate warning signs posted at the most likely point of entry. Posting should be installed immediately before the pesticide application and remain in place until the crop has been harvested, or as long as data are being collected.

3.1 Exemption

Under the circumstances regarding small scale research outlined in this section, persons conducting research are exempt from the requirement of obtaining a research permit under the *PCPA* and it is not necessary to report the research trial to the PMRA.

Research which entails any of the following conditions is **not** exempt:

- aquatic applications;
- aerial applications;
- if the semiochemical will be directly applied to food or feed crops and the harvest offered for sale.

Exemptions apply only for the control of arthropod pests on land. Additionally, all of the criteria in one or more of the three exemption categories listed below must be met to qualify for an exemption. The numbers of hectares treated refer to each TGAI, per research establishment, per year**.** The categories are as follows:

(1) Arthropod pheromones contained in affixed solid matrix dispensers or in retrievable sized polymeric matrix dispensers when applied in either food/feed or non-food/feed use areas, providing the treated area does not exceed 100 ha and the maximum use rate does not exceed 375 grams active ingredient/ha/year. Food or feed from such trials can be sold without written authorization from the PMRA providing that the pheromone is not in **direct** contact with the crop.

(2) Arthropod pheromones regardless of formulation, when applied in non-food/non-feed use areas and providing that the treated area does not exceed 100 ha and the maximum use rate does not exceed 375 grams active ingredient/ha/ year. If research is to be conducted on food/feed crops, a research permit is required if the treated produce will be sold.

(3) Semiochemicals regardless of formulation, method of application or application rate. (Note that a research permit will be required if treated produce will be sold.) The following limitations apply:

- **Unregistered** active ingredients: research must involve only the researcher and the treated area must not exceed 5 ha on land owned or operated solely by the research establishment, i.e., no cooperator participation.

- **Registered** active ingredients (research on new sources, new formulations or new uses): the treated area must not exceed 10 ha without restrictions on cooperator participation or land ownership.

3.2 Research Permit

A federal research permit is required before starting trials with pheromones or other semiochemicals if any of the following conditions apply:

(1) Aquatic applications;
(2) Aerial application;
(3) Semiochemicals will be directly applied to food or feed crops and the raw agricultural commodity can be used for human consumption or animal food;
(4) All of the criteria within one or more of the three exemption categories listed in Section 3.1 have not been met.

The general procedures in Regulatory Directive Dir93-22, *Chemical Pesticides Research Permit Guidelines* should be followed where applicable, including:

2.0 Application for Research Permits
5.0 Data Submission and Handling
6.0 Research Records and Data Reporting

7.0 Labels for Research Uses
8.0 Review Procedure for Research Permit Applications
11.0 Provincial Permit
12.0 Importation of Pesticides for Research Purposes
13.0 Disposal
14.0 Sale of Products Under Research
15.0 Sale and Use of Foods Treated Under Research
17.0 Advertising
18.0 Posting of research area
19.0 Audit.

The applicant must submit the following information in advance of the start of the intended research trial, within the time frames indicated in Pro96-01, *Management of Submissions Policy*:

- Research permit application form;
- Specification form for the EP, including a description of the dispenser and, in the case of encapsulated semiochemicals, particle size;
- Basic manufacturer's name and address;
- MSDSs for non-active ingredients and the TGAI, if available;
- Location and/or map of the area to be treated (recognizing that the location of pest infestations in forested areas may be difficult to predict at the time the application for a research permit is made, the location and/or map of the treated forest area should be sent to the PMRA no later than 30 days before the start of the trial);
- Seven copies of the proposed experimental label, including application rate and method of application (these may be typewritten);
- For each AIC:
  - Common name,
  - Chemical name,
  - Chemical Abstracts Service (CAS) registry number (if available),
  - Structural formula,
  - Molecular formula,
  - Molecular weight,
  - Canadian patent status (if available),
  - Manufacturing methods or methods of synthesis, when the proposed product will be used on food and/or feed for sale. Additional information on physical and chemical properties may also be required.

Where a semiochemical product is to be broadcast or sprayed, the applicant is encouraged to submit the following data for the TGAI in order to determine the risk to aquatic systems. In the absence of this information, an untreated buffer zone may be required adjacent to aquatic systems:

- Freshwater invertebrate (e.g., *Daphnia* sp.) acute toxicity,
- Freshwater fish (e.g., salmon or rainbow trout) acute toxicity

Notes:

(i) Following the review of the above data, the applicant may be required to submit additional environmental chemistry and fate, and environmental toxicology data where the proposed use pattern or the potential for exposure is of concern (e.g., large treatment sites or environmentally-sensitive areas).

(ii) Human health safety data may be required in situations where the proposed use pattern or the potential for human dietary, occupational, or bystander exposure is of concern.

(iii) The researcher is encouraged to record any effects on non-target organisms, especially invertebrates, that are observed during a research trial. These records should be submitted with the research data in support of applications for registration of a semiochemical product. (See Appendix 2, Parts 8 and 9 for suggested procedures for monitoring non-target effects.)

4.0 Registration

For general registration procedures, applicants should refer to the PMRAs *Registration Handbook*.

It should be noted that both the TGAI and the EP are subject to registration under the *PCP Act*.

The data requirements for semiochemical TGAIs and EPs are outlined in Appendices 1 and 2, respectively. Data screening tables for pheromones and other semiochemicals can be found in Appendix 4 (Tier One) and Appendix 5 (all requirements).

Potential applicants should consult the Draft Regulatory Proposal *Organizing and Formatting a Complete Submission Package for Pest Control Products* for instructions regarding the formatting of data. Note that incomplete or improperly formatted submissions will be returned.

It should be noted that the numbering system of Parts in the following appendices is intended to facilitate data management by the PMRA, and to form the basis for indices to data submitted by potential applicants. The system follows a standard numbering format pertinent to all applications for the registration of pest control products. If certain Parts or data codes (DACOs) are not identified, these data are not required.

To register a second end-use product containing a TGAI that has already been registered, value (efficacy) and other data may be required depending on the nature of the new end-use product, the proposed use-pattern and the potential for exposure to humans and the environment.

Similarly, if subsequent to the registration of a TGAI, changes to the composition of the technical are proposed (e.g., the addition of other AICs), the need for more data will be assessed on a case-by-case basis.

Data in Support of Registration of a Semiochemical Technical Grade of the Active Ingredient

The Regulatory Proposal: *Organizing and Formatting a Complete Submission for Pest Control Products*, which will be published shortly, should be consulted for specific guidance.

Part 0 - Index

Part 1 - Label

The *Registration Handbook* should be consulted regarding the general labelling requirements for TGAIs.

Part 2 - Product Chemistry

Data for the TGAI and/or each AIC which contributes to its activity should be provided as indicated in the following table. Applicants are encouraged to refer to the documents listed for general guidance and background in developing data to support the registration of semiochemical products from the PMRA, the Environmental Protection Agency of the United States (US EPA) and the OECD. However, when specific requirements differ between the documents, the criteria of this document on requirements for semiochemical products has priority. The submission format should follow the instructions in the Regulatory Proposal: *Organizing and Formatting a Complete Submission Package for Pest Control Products*, which will be published shortly.

Data Code (DACO)	Title	Test Material		Guidance Documents		
		AIC	TGAI	PMRA	U.S. EPA	OECD
2.1	**Applicant's Name and Office Address**[1]		**U**			
2.2	**Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address**	**U** [2]	**U**			
2.3	**Product Trade Name**	**U**	**U**			
2.4	**Common Name (ISO and CAS, if distinct)**	**U**				
2.5	**Chemical Name (CAS and IUPAC)**	**U**				
2.6	**CAS Registry Number**	**U**	**U** [3]			
2.7	**Structural Formula**[4]	**U**				
2.8	**Molecular Formula**	**U**				
2.9	**Molecular Weight**	**U**				
2.10	**Canadian Patent Status** [3]		**U**			

Data Code (DACO)	Title	Test Material		Guidance Documents		
		AIC	TGAI	PMRA	U.S. EPA	OECD
2.11	**Manufacturing Methods** [5]	**U** [2]	**U**			
2.12	**Specifications** [6]		**U**			
2.13	**Preliminary Analysis** [7]		**U**			
2.14	**Chemical and Physical Properties** [8]					
2.14.1	Colour		**U**		830.6302	
2.14.2	Physical state		**U**		830.6303	
2.14.3	Odour		**U**		830.6304	
2.14.4	Melting point / melting range	**U**			830.7200	102
2.14.5	Boiling point / boiling range	**U**			830.7220	103
2.14.6	Density or specific gravity		**U**		830.7300	109
2.14.7	Water solubility (mg/L)	**U**		T-1-255	830.7840 830.7860	105
2.14.8	Solvent solubility (mg/L)	**U**			830.1000	
2.14.9	Vapour pressure	**U**		T-1-255	830.7950	104
2.14.10	Dissociation constant	**U**			830.7370	112
2.14.11	Octanol/water partition coefficient	**U**		T-1-255	830.7550 830.7560 830.7570	107 117
2.14.13	UV/visible absorption spectra	**U**			830.7050	101
2.14.14	Stability (temperature, metals)		**U**		830.6313	113

Footnotes:

[1] The applicant identifies the company that has the ultimate responsibility for certifying the information found on the PMRA *Control Product Specification* form, as distinct from the manufacturing plant which is addressed in Section 2.2.

[2] Required if the AIC is produced by or for the TGAI manufacturer as opposed to being purchased from a commercial supplier. If the AIC is commercially available, and used in the manufacture of the TGAI, the following information is required, in addition to that requested in sections 2.3 to 2.9:(i) the name and address of the company which produces the AIC or, if that information is not known to the applicant, the name and address of the company which supplies it, and (ii) all information concerning the composition of each AIC, including a copy of all specifications or other documents describing it.

[3] If established.

[4] Information is required to show that the synthetic analogue of the semiochemical is structurally and functionally similar to the semiochemical found in nature. Further description of these requirements are found in Part 10.2.1.

[5] A complete description of the manufacturing process may be required including structural formulas, process flow diagrams, details of the starting and intermediate materials, if any. Other parameters, including quantities or ratios, temperature(s), and pH(s) may be required.

[6] Data should be comprised of the precise identification of 1) each of the AICs in the TGAI which contribute to its activity (impurities may be treated collectively if the semiochemical is a natural extract containing many impurities closely related to the active ingredient), and 2) (i) impurities present at or above 0.1% w/w in the TGAI if employed for food or feed uses, (ii) impurities present at or above 1.0% w/w in the TGAI if employed for non-food/feed uses.

[7] Specific methodologies are required for determining the chemical compounds and impurities described under Part 2.12, as identified in Part 2.13. However, batch data requirements found under 2.13.3 are limited to three (3) production batches of representative TGAI.

[8] Chemical and physical properties should be described as fully as possible. Detailed methodology must be provided in the submission. Protocols for developing the above information are not included in this document. Applicants should consult the published literature and the PMRA for further clarification. Potential registrants are referred to the PMRAs Trade Memorandum T-1-255, *Guidelines for Determining Environmental Chemistry and Fate of Pesticides*, the US EPA OPPTS 830 Series, and/or the OECD Test Guidelines, to address the requirements of Part 2.14.

Parts 4, 5, 6 and 7 - Human Health and Safety

Introduction

The purpose of the safety testing is to determine potential risks of semiochemicals to human health. Semiochemicals generally present a very low potential risk to human health, because of their mode of action (i.e., behavioural changes of the pest in response to volatile chemical signals), a rapid rate of dissipation, and the quantities used which often reflect concentrations that occur in nature during an outbreak of the pest.

The following summary lists the tests that are required for registration of the TGAI. Additional testing may be required if results of acute studies indicate any toxicological concern, and/or potential for exposure of food (for semiochemicals used on or around food) and/or humans (see Appendix 5). Applicants may request waivers from testing, where appropriate. Applications for waivers must be supported by sound scientific rationale, and will be considered on a case-by-case basis. Surrogate data may be considered for TGAIs that are similar to those that are already registered.

All acute studies should be conducted using the TGAI. Protocols for studies should be in general accordance with those stated in the OECD guidelines[1]. When validated methodology for equivalent *in vitro* studies becomes available, its use will be considered**.**

Summary of Tier 1 Tests (See Appendix 4)

DACO 4.2: Acute Toxicology Studies:

DACO 4.2.1: Acute Oral Toxicity
DACO 4.2.2: Acute Dermal Toxicity
DACO 4.2.3: Acute Inhalation Toxicity
DACO 4.2.4: Primary Eye Irritation
DACO 4.2.5: Primary Dermal Irritation
DACO 4.2.6: Dermal Sensitization

[1] Principles of Good Laboratory Practice (GLP) should be followed. The GLP principles of the U.S. FDA (Title 21, Part 28, revision of 1 April 1980); U.S. EPA (Volume 48, No. 230, 29 November 1983) and OECD Principles of Good Laboratory Practice (Annex 2 of the Council Decision C(81)30 Final) can serve as guidance.

DACO 4.5: Genotoxicity potential studies:

DACO 4.5.4: Microbial point mutation

DACO 4.5.5: Mammalian (cell) point mutation

DACO 4.5.6: An *in vitro* chromosome aberration assay

Part 6 and Part 7 - Metabolism and Residue Studies

If semiochemicals are applied directly to food, feed or tobacco, the same metabolism and residue studies are required as for other agricultural chemicals. The data required for the registration of proposed products when used on terrestrial or greenhouse food are outlined in Appendices 4 and 5. Proponents should contact the PMRA regarding the data requirements for other use scenarios that would result in direct contact of the semiochemical with food or feed. Guidance is available in the Regulatory Document, *Residue Chemistry Guidelines* regarding the test substance for studies (i.e., the TGAI or the EP).

Waivers from the requirement to submit residue data may be available if a scientific rationale is accepted, indicating, for example, that there will be no detectable residues in or on the consumable portion of the plant, or that the residues are not of concern, or that the residue levels are not significantly different from background levels that would be experienced during an outbreak of the pest. Additional guidance regarding waiver requests can also be found in the Regulatory Document, *Residue Chemistry Guidelines.*

Part 8 - Environmental Chemistry and Fate and

Part 9 - Environmental Toxicology

Environmental chemistry and fate, and environmental toxicology studies are required for semiochemicals which will be used outdoors, for example, in the control of agricultural and forestry pests. No such studies are required for semiochemicals to be used in enclosed buildings (i.e., with walls, floor and ceiling) such as greenhouses, grain storage structures, and residential, commercial and industrial buildings.

With the exception of aquatic toxicology data, sufficient environmental chemistry and fate, and environmental toxicology data have been reviewed for SCLPs to allay concerns regarding their potential environmental impact. Thus, except for aquatic toxicology data, no further data are required in support of applications to register the TGAI of this class of semiochemical. The submission of additional data on SCLPs, however, is encouraged.
For other classes of semiochemicals, the submission of data in addition to the minimum requirements outlined below, if available, is encouraged but not required.

For appropriate methodology in performing environmental chemistry and fate studies, applicants for registration are referred to Trade Memorandum T-1-255.

Tier I

These data will be used for initial evaluation.

Where a semiochemical product, including an SCLP, is to be broadcast or sprayed, the following data are required for the TGAI in order to determine the risk to aquatic systems. In the absence of this information, an untreated buffer zone may be required adjacent to aquatic systems:

DACO 9.3: A freshwater invertebrate acute toxicity study, either
DACO 9.3.2*: Daphnia* sp., or
DACO 9.3.4: Other species.

DACO 9.5.2 A freshwater fish acute toxicity study, one of
DACO 9.5.2.1: Cold water fish (e.g., salmon or rainbow trout) are preferred species,
DACO 9.5.2.2: Warm water fish (e.g., bluegill sunfish), or
DACO 9.5.2.3: Other species.

In addition, for products other than SCLPs, the following data are required for the TGAI:

DACO 9.6: An avian acute oral toxicity study with one of
DACO 9.6.2.1: Bobwhite quail
DACO 9.6.2.2: Mallard duck, or
DACO 9.6.2.3: Other species.
and an avian dietary toxicity study with one of
DACO 9.6.2.4: Bobwhite quail,
DACO 9.6.2.5: Mallard duck, or
DACO 9.6.2.6: Other species.

Tier II

Where data from Tier I demonstrate hazard to biota, one or more of the following data will be required for each AIC of the TGAI. The need for such data will be assessed on a case-by-case basis, and will depend on the properties of the TGAI and the intended use pattern.

DACO 8.2.3.2: Hydrolysis,
DACO 8.2.3.3.1: Phototransformation on soil,
DACO 8.2.3.3.2: Phototransformation in water,
DACO 8.2.3.4.2: Biotransformation (aerobic soil),
DACO 8.2.3.5.2: Biotransformation (aerobic aquatic),
DACO 8.2.4.2: Adsorption-desorption.

Tier III

Where data from Tier II demonstrate hazard/risk to the environment or to biota, studies of effects of the TGAI on one or more of the following groups of organisms will be required. The need for such studies will be assessed on a case-by-case basis.

DACO 9.3: Non-target freshwater invertebrates,
DACO 9.4: Non-target marine invertebrates,
DACO 9.7: Terrestrial animals,
DACO 9.8: Non-target

Data in Support of Registration of a Semiochemical End-Use Product

The Regulatory Proposal *Organizing and Formatting a Complete Submission for Pest Control* Products, which will be published shortly, should be consulted for specific guidance. Note that if a proposed product contains semiochemicals in combination with other pesticides (e.g. traditional insecticides), these other pesticides must also be registered. The following information should be provided in support of registration for a semiochemical end-use product:

Part 0 - Index

Part 1 - Label

The *Registration Handbook* should be consulted regarding the general labelling requirements for end-use products.

Part 3 - Product Chemistry

Please refer to the Regulatory Document, *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*, for detailed requirements. The Product Specification Form should include a description of the dispenser, or the particle size in the case of sprayed or broadcast products. Storage stability requirements must be met; however, data need not be generated under ambient conditions, rather one-year stability data may be produced under the recommended storage conditions for the product.

Parts 4, 5, 6 and 7 - Human Health and Safety

DACO 5.2: Use description, use scenario (Application and Post-Application)

Detailed information on potential for exposure, product packaging, application methods and release rates should be provided.

Additional data on the EP may be requested, on a case-by-case basis pending the evaluation of the exposure information and toxicology profile of the TGAI, or if the formulants used in the EP are of potential toxicological concern.

If semiochemicals are applied directly to food, feed or tobacco and residue data are required, the semiochemical metabolites in the plant must be investigated using either the TGAI or the EP. For additional information see the metabolism and residue requirements for TGAIs, Appendix I, Parts 6 and 7.

Part 8 - Environmental Chemistry and Fate and

Part 9 - Environmental Toxicology

Tier I

DACO 9.2.9: Field Studies

To determine whether semiochemicals adversely affect non-target arthropods, field studies are required for EPs intended for use outdoors that contain semiochemicals other than the SCLPs. These data are not required for EPs containing SCLPs only, as sufficient data have been reviewed for these compounds to allay concerns regarding their potential impact on non-target arthropods. Field data should be acquired from areas that have not received conventional pesticide treatments. For example, non-target invertebrates affected by the semiochemical can be identified by comparing semiochemical-baited and unbaited traps placed in environments similar to those of intended use. As the semiochemicals may affect other species beyond the flight period of the intended target, these traps should be monitored until data indicate that the semiochemical is no longer active. Non-target species attracted in large numbers should be identified and recorded. Species investigated should include:

- Beneficial arthropods, including wasps and bees
- Parasites and predators of the pest species
- Organisms that are closely related taxonomically to the pest species (i.e., in the same family or genus).

Tier II

Where data from studies on the TGAI submitted under Tier 1, Parts 8 and 9 demonstrate any hazard to biota, some or all of the following data will be required on a case-by-case basis:

DACO 8.2.4.6: Special studies using the EP:

a) Leaching by water, from dispensers containing the end-use product, of any of the AICs;

b) Volatilization under conditions typical of the proposed use (rate and duration are of particular interest), supported by relevant data from vapour pressure studies. For example**,** release rate characteristics (µg/dispenser/h) of the end-use product could be researched at 20EC, 50% RH and wind speed 5 km/h.

Part 10 - Value (including Efficacy)

Consistent with the requirements of the *PCPA and Regulations*, information is required to demonstrate the value of the proposed product. The purpose of the value assessment is to allow for a balanced decision by considering the benefits from use of the product in addition to any identified risks to human health or the environment. The components of value include efficacy

(including adverse effects to the crop/site), economics, and sustainability. The following information is required to allow for an assessment of value:

DACO 10.1: Value summaries

An overall summary should be provided of the elements submitted in Part 10.

DACO 10.2: Efficacy studies

DACO 10.2.1: Mode of Action

Unlike conventional chemical pesticides, semiochemicals are typically non-lethal to the target pest. The proponent should describe the function of the semiochemical in modifying the behaviour of the target pest, and provide information to support the claim that the active ingredient is a semiochemical. This could include copies of references from refereed journals indicating attraction (or other behavioural modification) of the pest to a semiochemical source as the proposed product in the laboratory or field, or electroantennogram studies. The proponent should also provide a description of the mode of action of the semiochemical in the end-use product (e.g., controls the pest population through mating disruption, acts as an attractant in a pesticidal bait, etc.).

DACO 10.2.2: Description of Pest Problem in Canada

Information should be provided on the biology and life cycle of the pest, and the nature and extent of the damage caused by the pest. This information is useful in the interpretation of results from efficacy trials. Information should also be provided on the crops/sites which are affected by the pest and the geographic distribution of the pest problem in Canada.

DACO 10.2.3: Efficacy Trials

Data from scientifically-conducted efficacy trials are required to demonstrate that the product is effective for its intended purpose when used in accordance with label directions. Information of a testimonial nature without supporting scientific documentation is not acceptable. The proponent should submit study reports for the individual efficacy trials together with a summary assessment of all efficacy results.

As a general guide, proponents should consult Regulatory Directive Dir93-07a, *Guidelines for Efficacy Assessment of Chemicals,* for guidance regarding the principles of efficacy testing and reporting of data. Although this Directive pertains to efficacy assessment of chemical pesticides, the general principles of efficacy testing and reporting are also applicable to semiochemical products. Efficacy data should be generated and reported in accordance with the principles outlined below:

- Studies should be conducted with the EP proposed for registration. Data from studies conducted with similar, but not identical, formulations will be considered provided that an adequate scientific rationale is provided to support equivalence in efficacy to the product proposed for registration.

- Data are required for each of the target pests on the label.

- The EP should be applied in a manner consistent with the proposed label instructions with regards to the rates, timing and methods of application.

- Study reports should clearly state the objective of the trial, the experimental design, evaluation methods, results and conclusions.

- The experimental design of efficacy studies should include untreated check plots as an indication of population pressure. Where possible, plots receiving a commercial standard treatment of known efficacy should be included as a basis for comparison with the semiochemical treatment.

- The criteria for performance assessment should be clearly outlined in the study report. For semiochemicals which act through mating disruption, data should be provided on the effectiveness of the treatment at disrupting the pest from locating a semiochemical source (e.g., through trap catches), together with data on reductions in pest numbers and/or damage.

- At least one of the studies should evaluate a range of rates to demonstrate the lowest effective rate of application.

- For outdoor uses (e.g., agricultural crop protection, forestry), studies should be conducted over more than one season in areas that are representative of the major geographical regions where the product is intended to be used to account for variations in pest population pressures, climate, insect resistance, and/or cultural practices, etc. Studies conducted in adjacent regions of the US are acceptable if climatic and production practices are similar to those found in Canada.

- For indoor uses (e.g., greenhouses) studies from outside of Canada may be considered, provided that the test conditions are similar to those which would be found in Canada.

- As a general rule, a minimum of **three** studies or trials are required for each proposed pest/site combination proposed for registration. Fewer trials may be adequate for some uses if supported by an adequate scientific rationale (e.g., use of bridging data).

DACO 10.3: Adverse effects

Information should be provided on any adverse effects on the crop/site (e.g., phytotoxicity) resulting from use of the EP. This type of information can be generated in conjunction with the efficacy trials.

DACO 10.4: Economic considerations

While it is anticipated that an assessment of economic benefits will not be required for most semiochemical products, if such an assessment is requested, proponents are referred to the Regulatory Directive Dir93-17, *Assessment of the Economic Benefits of Pesticides,* for guidance regarding the type of information to be submitted for review.

DACO 10.5: Sustainability

In addition to efficacy and economics, information on the product's contribution to sustainable pest management is also required in the assessment of value. Sustainability considerations may be important for semiochemical products which may not provide the same level of pest reduction achieved with chemical pesticides, but are of value because of compatibility with integrated pest management (IPM), contribution to risk reduction, reduced reliance on pesticides, or other sustainability considerations. In most cases, qualitative information in the following areas would be adequate in lieu of specific studies. However, specific studies should be submitted, if available.

DACO 10.5.1: Survey of Alternatives

The proponent should provide a list of currently available control options (chemical and non-chemical) for the target pest together with a brief description of their effectiveness in comparison with the proposed EP.

DACO 10.5.2: Compatibility with Current Management Practices Including IPM

Information should be provided on the compatibility of the proposed EP with established or developing pest management strategies for the crop. This should include any positive features of the semiochemical (e.g., low toxicity to pest predators or parasites) or negative features (e.g., flair-up of secondary pest species which were previously held in check by broad spectrum chemicals used for control of the target pest) which could impact on pest management strategies. Documented studies to support these claims should be provided, if available.

DACO 10.5.3: Resistance Management

Resistance to chemical pesticides is a problem in the control of many pests. Semiochemicals have a different mode of action than chemical pesticides. The proponent should indicate

whether resistance to conventional chemical pesticides is a problem with the target pest and explain how the EP may fit in with strategies to manage resistance.

DACO 10.5.4: Contribution to Risk Reduction

The proponent should discuss how the proposed EP may contribute to risk reduction (e.g., may provide an alternative to highly toxic, broad spectrum chemical pesticides; reduced reliance on chemicals; reduced pesticide residues on food, etc.).

List of Relevant Publications:

Regulatory Authority

Pest Control Products Act (PCPA)
Pest Control Products Regulations
Food and Drugs Act (FDA)

Submission formatting:

Draft Regulatory Proposal, *Organizing and Formatting a Complete Submission for Pest Control Products*, Contact Roy Lidstone at (613) 736-3585.

Guidelines for General Guidance and Background

Registration Handbook for Pest Control Products Under the Pest Control Products Act and Regulations

Dir93-07a - *Guidelines for Efficacy Assessment of Chemical Pesticides*
Dir93-17 - *Assessment of the Economic Benefits of Pesticides*
Dir93-22 - *Chemical Pesticides Research Permit Guidelines*
T-1-255 - *Guidelines for Determining Environmental Chemistry and Fate of Pesticides*
Pro96-01 - *Management of Submissions Policy*
Pro97-01 - *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*
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*
Pro97-03 - *Residue Chemistry Guidelines*

Note: It should be noted that the above documents may be revised in the future. When a revised or final document is issued, the title may be slightly modified and there will be a new reference number. The applicant should contact the PMRA to determine whether any of the listed references have been superseded by more recent or final versions.

PEST MANAGEMENT REGULATORY AGENCY DATA SCREEN
PHEROMONES AND OTHER SEMIOCHEMICALS -TIER I

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Conditions KEY: R = required; CR = conditionally required
0	**Index**	**R**	**R**	
1	**Label**	**R**	**R**	
2	**Chemistry for registration of a Technical Grade of Active Ingredient (TGAI)**			
2.1	**Applicant's Name and Office Address**	R	R	
2.2	**Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address**	R	R	
2.3	**Product Trade Name**	R	R	
2.3.1	Other Names	R	R	
2.4	**Common Name**	R	R	
2.5	**Chemical Name**	R	R	
2.6	**Chemical Abstracts Registry Number**	R	R	
2.7	**Structural Formula**	R	R	
2.8	**Molecular Formula**	R	R	
2.9	**Molecular Weight**	R	R	
2.1	**Canadian Patent Status**	R	R	
2.11	**Manufacturing Methods**			
2.11.1	Manufacturing Summary	R	R	
2.11.2	Description of Starting Materials	R	R	
2.11.3	Detailed Process Description	R	R	
2.11.4	Discussion of Formation of Impurities	R	R	
2.12	**Specifications**			
2.12.1	Establishing Certified Limits	CR	CR	A justification must be provided if standard limits are not met
2.12.2	Control Product Specification Form	R	R	
2.13	**Preliminary Analysis**			
2.13.1	Methodology/Validation	R	R	
2.13.2	Confirmation of Identify	R	R	
2.13.3	Batch Data	R	R	
2.13.4	Impurities of Toxicological Concern	CR	CR	If a review of the manufacturing methods and materials indicates that a potential for presence of such impurities exists
2.14	**Chemical and Physical Properties for each AIC**			
2.14.4	Melting Point or Range	CR	CR	If solid at room temperature
2.14.5	Boiling Point or Range	CR	CR	If liquid at room temperature
2.14.7	Water Solubility (mg/L)	R	R	
2.14.8	Solvent Solubility (mg/L)	R	R	
2.14.9	Vapour Pressure	R	R	
2.14.10	Dissociation Constant	CR	CR	Required when the test substance contains an acid or base functionality and either when used on food crops and residue data are required or possibly when Tier I environmental toxicity tests demonstrate hazard to biota

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Conditions KEY: R = required; CR = conditionally required
2.14.11	Octanol/Water Partition Coefficient	CR	CR	If the chemical is organic, unless it hydrolyses in water or is soluble in water in all proportions
2.14.13	UV-Visible Absorption Spectra	CR	R	If used on food crops and residue data are required. If Tier I environmental toxicity tests demonstrate hazard to biota, these data will be required or on a case-by-case basis
	Properties for the TGAI			
2.14.1	Colour	R	R	
2.14.2	Physical State	R	R	
2.14.3	Odour	R	R	
2.14.6	Density or Specific Gravity	R	R	
2.14.14	Stability (temperature, metals)	R	R	
2.15	Other Studies/Data/Reports			
3	**Specifications and Analytical Methodology Required for Registration of an EP**			
3.1	**Product Identification**	R	R	
3.1.1	Applicant's Name and Office Address	R	R	
3.1.2	Formulating Plant's Name and Address	R	R	
3.1.3	Trade Name	R	R	
3.1.4	Other Names	R	R	
3.2	**Formulation Process**			
3.2.1	Description of Starting Materials	R	R	
3.2.2	Description of the Formulation Process	R	R	
3.2.3	Discussion of the Formation of Impurities of Toxicological Concern	CR	CR	If a review of the manufacturing methods and materials indicates that a potential for presence of such impurities exists
3.3	**Specifications**			
3.3.1	Establishing Certified Limits	CR	CR	A justification must be provided if standard limits are not met
3.3.2	Additional Product Specific Requirements	CR	CR	If applicable
3.3.3	Control Product Specification Form	R	R	
3.4	**Product Analysis**			
3.4.1	Enforcement Analytical Method	R	R	
3.4.2	Impurities of Toxicological Concern	CR	CR	If a review of the manufacturing methods and materials indicates that a potential for presence of such impurities exists
3.5	**Chemical and Physical Properties**			
3.5.1	Colour	R	R	
3.5.2	Physical State	R	R	
3.5.3	Odour	R	R	
3.5.4	Formulation Type	R	R	
3.5.5	Container Material and Description	R	R	
3.5.6	Density or Specific Gravity	R	R	
3.5.7	pH	R	R	
3.5.9	Viscosity	CR	CR	Required if a liquid
3.5.10	Storage Stability Data	R	R	

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Conditions KEY: R = required; CR = conditionally required
3.6	Other Studies/Data/Reports			
4	**Toxicology**			
4.1	Summaries - Toxicology Profile			
4.2	**Acute Studies - TGAI**			
4.2.1	Acute Oral	R	R	
4.2.2	Acute Dermal	R	R	
4.2.3	Acute Inhalation	R	R	
4.2.4	Primary Eye Irritation	R	R	
4.2.5	Primary Dermal Irritation	R	R	
4.2.6	Dermal Sensitization	R	R	
4.5	**Special Studies TGAI**			
4.5.4	Genotoxicity: Microbial Point Mutation	R	R	
4.5.5	Genotoxicity: Mammalian (cell) Point Mutation	R	R	
4.5.6	Genotoxicity: *In vitro* Chromosomal Aberrations	R	R	
4.6	**Acute Studies (EP)**			
4.6.1	Acute Oral	CR	CR	If the formulants are of potential toxicological concern
4.6.2	Acute Dermal	CR	CR	If the formulants are of potential toxicological concern
4.6.3	Acute Inhalation	CR	CR	If the formulants are of potential toxicological concern
4.6.4	Primary Eye Irritation	CR	CR	If the formulants are of potential toxicological concern
4.6.5	Primary Dermal Irritation	CR	CR	If the formulants are of potential toxicological concern
4.6.6	Dermal Sensitization	CR	CR	If the formulants are of potential toxicological concern
4.8	Other Studies/Data/Reports			
5	**Exposure (Occupational and/or Bystander)**			
5.1	Summaries	R	R	
5.2	Use Description/Scenario (Application and Post Application)	R	R	
5.14	Other Studies/Data/Reports			
6	**Metabolism/Toxicokinetics Studies for Direct Application of Semiochemicals to Greenhouse or Terrestrial Food or Feed Crops (Contact the PMRA for requirements pertaining to other use/site categories) (TGAI or EP)**			
6.1	Summaries	R	R	
6.2	Livestock	CR	CR	Depends on end use of crop and by-products
6.3	Plants	R	R	
6.4	Other Studies/Data/Reports			

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Conditions KEY: R = required; CR = conditionally required
7	**Food, Feed and Tobacco Residue Studies for Direct Application of Semiochemicals to Greenhouse or Terestrial Food or Feed Crops (Contact the PMRA for requirements pertaining to other use/site categories)**			
7.1	Summaries	R	R	
7.2	Analytical Methodology (Food Crops & Tobacco)			
7.2.1	Supervised Residue Trial Analytical Methodology	R	R	
7.3	Freezer Storage Stability Tests	CR	CR	Depends on length of storage
7.4	Crop Residue Data			
7.4.1	Supervised Residue Trial Study	R	R	
7.4.2	Temporal Residue Trial Study	CR	CR	Depends on acerage of crop
7.4.3	Confined Crop Rotation Trial Study	CR	CR	Depends on cropping practice
7.4.4	Field Crop Rotation Trial Study	CR	CR	Depends on cropping practice
7.4.5	Processed Food/Feed	CR	CR	If commodity will be processed
7.4.6	Residue Data for Crops used as Livestock Feed	CR	CR	If treated crop will be used as livestock feed
7.5	Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops)	CR	CR	If treated crop will be fed to animals
7.6	Livestock, Poultry, Egg and Milk Residue Data (external application)	CR	CR	If pheromone will be directly applied to animals
7.7	Tobacco Residue Data	CR	CR	If applied directly to tobacco
7.8	Other Studies/Data/Reports	CR	CR	If available
9	**Environmental Toxicology**			
9.1	Summary	R	R	
9.2	**Non-Target Terrestrial Invertebrates**			
9.2.9	Field Studies (EP) (i.e., beneficial arthropods including bees and wasps, parasites and predators of the pest species, and taxonomically related organisms of the pest)	-	R	
9.3	**Non-Target Freshwater Invertebrates (TGAI)**			Where broadcast or sprayed, these data are required for each TGAI in order to determine the risk to aquatic systems. In the absence of this information, an untreated buffer zone may be required adjacent to aquatic systems.
9.3.2	*Daphnia* sp. Acute	CR	CR	See 9.3 above. One of 9.3.2 or 9.3.4 is required
9.3.4	Laboratory Studies with Other Species	CR	CR	See 9.3 above. One of 9.3.2 or 9.3.4 is required
9.5	**Fish (TGAI)**			
9.5.2	**Acute Studies**			
9.5.2.1	Cold Water Fish (e.g., salmon or rainbow trout)	CR	CR	See 9.3 above. One of 9.5.2.1, 9.5.2.2 or 9.5.2.3 is required; 9.5.2.1 is preferred.
9.5.2.2	Warm Water Fish (e.g., bluegill sunfish)	CR	CR	See 9.3 above. One of 9.5.2.1, 9.5.2.2 or 9.5.2.3 is required; 9.5.2.1 is preferred.
9.5.2.3	Other Freshwater Fish Species	CR	CR	See 9.3 above. One of 9.5.2.1, 9.5.2.2 or 9.5.2.3 is required; 9.5.2.1 is preferred.
9.6	**Wild Birds (TGAI)**			

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Conditions KEY: R = required; CR = conditionally required
9.6.2	**Acute Studies**			
9.6.2.1	Oral (LD_{50}) Bobwhite Quail	-	CR	One of 9.6.2.1, 9.6.2.2 or 9.6.2.3 is required
9.6.2.2	Oral (LD_{50}) Mallard Duck	-	CR	One of 9.6.2.1, 9.6.2.2 or 9.6.2.3 is required
9.6.2.3	Oral (LD_{50}) Other Species	-	CR	One of 9.6.2.1, 9.6.2.2 or 9.6.2.3 is required
9.6.2.4	Dietary (LC_{50}) Bobwhite Quail	-	CR	One of 9.6.2.4, 9.6.2.5 or 9.6.2.6 is required
9.6.2.5	Dietary (LC_{50}) Oral Mallard Duck	-	CR	One of 9.6.2.4, 9.6.2.5 or 9.6.2.6 is required
9.6.2.6	Dietary (LC_{50}) Oral Other Species	-	CR	One of 9.6.2.4, 9.6.2.5 or 9.6.2.6 is required
9.9	Other Studies/Data/Reports			
10	**Value (applicable to each pest/site or host combination) (EP)**			
10.1	Value Summaries	R	R	
10.2	**Efficacy Studies**			
10.2.1	Mode of Action - TGAI	R	R	
10.2.2	Description of Pest Problem	R	R	
10.2.3	**Efficacy Trials (EP)**			
10.2.3.1	Small Scale Trials Lab, Greenhouse	CR	CR	May be submitted in support of 10.2.1
10.2.3.2	Field Trials/Operational Use Trials	R	R	
10.3	**Adverse Effects on Use Site (EP)**			
10.3.1	Adverse Effects to Crop (phytotoxicity), Host Animals, Note of Application	R	R	
10.4	Economics	-	CR	Required if health or environmental concerns have been identified that cannot be easily mitigated by use restrictions or limitations
10.5	**Sustainability**			
10.5.1	Survey of Alternatives (chemical and non-chemical)	R	R	
10.5.2	Compatibility with Current Management Practices Including IPM	R	R	
10.5.3	Resistance Management	R	R	
10.5.4	Contribution to Risk Reduction	R	R	
10.6	Other Studies/Data/Reports			
12	**Summaries**			
12.5	Foreign reviews			Please code 12.5 . _ and incude at end of applicable Part, (e.g., a foreign review of Value would be coded 12.5.10 and submitted under Part 10.6).
12.7	Comprehensive summaries	R	R	Required for new active ingredients and major new uses of registered actives

PEST MANAGEMENT REGULATORY AGENCY DATA SCREEN
PHEROMONES AND OTHER SEMIOCHEMICALS - ALL TIERS

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Tier	Conditions KEY: R = required; CR = conditionally required
0	**Index**	**R**	**R**		
1	**Label**	**R**	**R**		
2	**Chemistry for registration of a Technical Grade of Active Ingredient (TGAI)**				
2.1	**Applicant's Name and Office Address**	R	R		
2.2	**Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address**	R	R		
2.3	**Product Trade Name**	R	R		
2.3.1	Other Names	R	R		
2.4	**Common Name**	R	R		
2.5	**Chemical Name**	R	R		
2.6	**Chemical Abstracts Registry Number**	R	R		
2.7	**Structural Formula**	R	R		
2.8	**Molecular Formula**	R	R		
2.9	**Molecular Weight**	R	R		
2.1	**Canadian Patent Status**	R	R		
2.11	**Manufacturing Methods**				
2.11.1	Manufacturing Summary	R	R		
2.11.2	Description of Starting Materials	R	R		
2.11.3	Detailed Process Description	R	R		
2.11.4	Discussion of Formation of Impurities	R	R		
2.12	**Specifications**				
2.12.1	Establishing Certified Limits	CR	CR		A justification must be provided if standard limits are not met
2.12.2	Control Product Specification Form	R	R		
2.13	**Preliminary Analysis**				
2.13.1	Methodology/Validation	R	R		
2.13.2	Confirmation of Identify	R	R		
2.13.3	Batch Data	R	R		
2.13.4	Impurities of Toxicological Concern	CR	CR	II	If a review of the manufacturing methods and materials indicates that a potential for presence of such impurities exists
2.14	**Chemical and Physical Properties**				
	Properties for each AIC				
2.14.4	Melting Point or Range	CR	CR		If solid at room temperature
2.14.5	Boiling Point or Range	CR	CR		If liquid at room temperature
2.14.7	Water Solubility (mg/L)	R	R		
2.14.8	Solvent Solubility (mg/L)	R	R		
2.14.9	Vapour Pressure	R	R		
2.14.10	Dissociation Constant	CR	CR		Required when the test substance contains an acid or base functionality and if the chemical is organic, unless it hydrolyses in water or is soluble in water in all proportions

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Tier	Conditions KEY: R = required; CR = conditionally required
2.14.11	Octanol/Water Partition Coefficient	CR	CR		If the chemical is organic, unless it hydrolyses in water or is soluble in water in all proportions
2.14.13	UV-Visible Absorption Spectra	CR	R		If used on food crops and residue data are required. If tier I environmental toxicity tests demonstrate hazard to biota, these data will be required or on a case-by-case basis
	Properties for the TGAI				
2.14.1	Colour	R	R		
2.14.2	Physical State	R	R		
2.14.3	Odour	R	R		
2.14.6	Density or Specific Gravity	R	R		
2.14.14	Stability (temperature, metals)	R	R		
2.15	Other Studies/Data/Reports				
3	**Specifications and Analytical Methodology Required for Registration of an EP**				
3.1	**Product Identification**	R	R		
3.1.1	Applicant's Name and Office Address	R	R		
3.1.2	Formulating Plant's Name and Address	R	R		
3.1.3	Trade Name	R	R		
3.1.4	Other Names	R	R		
3.2	**Formulation Process**				
3.2.1	Description of Starting Materials	R	R		
3.2.2	Description of the Formulation Process	R	R		
3.2.3	Discussion of the Formation of Impurities of Toxicological Concern	CR	CR	II	If a review of the manufacturing methods and materials indicates that a potential for presence of such impurities exists
3.3	**Specifications**				
3.3.1	Establishing Certified Limits	CR	CR		A justification must be provided if standard limits are not met
3.3.2	Additional Product Specific Requirements	CR	CR		If applicable
3.3.3	Control Product Specification Form	R	R		
3.4	**Product Analysis**				
3.4.1	Enforcement Analytical Method	R	R		
3.4.2	Impurities of Toxicological Concern	CR	CR	II	If a review of the manufacturing methods and materials indicates that a potential for presence of such impurities exists
3.5	**Chemical and Physical Properties**				
3.5.1	Colour	R	R		
3.5.2	Physical State	R	R		
3.5.3	Odour	R	R		
3.5.4	Formulation Type	R	R		
3.5.5	Container Material and Description	R	R		
3.5.6	Density or Specific Gravity	R	R		
3.5.7	pH	R	R		
3.5.9	Viscosity	CR	CR		Required if a liquid
3.5.10	Storage Stability Data	R	R		
3.6	Other Studies/Data/Reports				

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Tier	Conditions KEY: R = required; CR = conditionally required
4	**Toxicology**				
4.1	Summaries - Toxicology Profile				
4.2	**Acute Studies - TGAI**				
4.2.1	Acute Oral	R	R		
4.2.2	Acute Dermal	R	R		
4.2.3	Acute Inhalation	R	R		
4.2.4	Primary Eye Irritation	R	R		
4.2.5	Primary Dermal Irritation	R	R		
4.2.6	Dermal Sensitization	R	R		
4.3	**Short-Term Studies (TGAI)**				
4.3.1	Short-Term Oral (90 day) (rodent)	CR	CR	II	If Tier I toxicity tests indicate a need
4.3.2	Short-Term Oral (6-12 month) (Non-rodent, e.g. dog)	CR	CR	II	If Tier I toxicity tests indicate a need
4.3.3	Short-Term Oral (21 day, 30 day)	CR	CR	II	If Tier I toxicity tests indicate a need
4.3.4	Short-Term Dermal (90 day)	CR	CR	II	If Tier I toxicity tests indicate a need
4.3.5	Short-Term Dermal (21 day, 30 day)	CR	CR	II	If Tier I toxicity tests indicate a need
4.3.6	Short-Term Inhalation (90 day)	CR	CR	II	If Tier I toxicity tests indicate a need
4.3.7	Short-Term Inhalation (21 day, 30 day)	CR	CR	II	If Tier I toxicity tests indicate a need
4.3.8	Other Short-Term Studies	CR	CR	II	If Tier I toxicity tests indicate a need
4.4	**Long-Term Studies (TGAI)**				
4.4.2	Oncogenicity (rodent species 1)	CR	CR	II, III	If Tier I toxicity tests indicate a need
4.4.3	Oncogenicity (rodent species 2)	CR	CR	II, III	If Tier I toxicity tests indicate a need
4.4.4	Combined Chronic/Oncogenicity (rodent)	CR	CR	II, III	If Tier I toxicity tests indicate a need
4.5	**Special Studies TGAI**				
4.5.4	Genotoxicity: Microbial Point Mutation	R	R	I	
4.5.5	Genotoxicity: Mammalian (cell) Point Mutation	R	R	I	
4.5.6	Genotoxicity: *In vitro* Chromosomal Aberrations	R	R	I	
4.5.7	Genotoxicity: *In vivo* Chromosomal Aberrations	CR	CR	II, III	If Tier I toxicity tests indicate a need
4.5.8	Other Genotoxicity Studies	CR	CR	II, III	If Tier I toxicity tests indicate a need
4.5.12	Other Special Studies (e.g., reproduction, teratoloty, metabolism)	CR	CR	II, III	If Tier I toxicity tests indicate a need
4.6	**Acute Studies (EP)**				
4.6.1	Acute Oral	CR	CR	I	If the formulants are of potential toxicological concern
4.6.2	Acute Dermal	CR	CR	I	If the formulants are of potential toxicological concern
4.6.3	Acute Inhalation	CR	CR	I	If the formulants are of potential toxicological concern
4.6.4	Primary Eye Irritation	CR	CR	I	If the formulants are of potential toxicological concern
4.6.5	Primary Dermal Irritation	CR	CR	I	If the formulants are of potential toxicological concern
4.6.6	Dermal Sensitization	CR	CR	I	If the formulants are of potential toxicological concern
4.8	Other Studies/Data/Reports				

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Tier	Conditions KEY: R = required; CR = conditionally required
5	**Exposure (Occupational and/or Bystander)**				
5.1	Summaries	R	R		
5.2	Use Description/Scenario (Application and Post Application)	R	R	I	
5.4	Mixer/Loader/Applicator- Passive Dosimetry Data	CR	CR	II	If Tier I toxicity tests indicate a need and product use involves human exposure
5.5	Mixer/Loader/Applicator-Biological Monitoring Data	CR	CR	II, III	If Tier I toxicity tests indicate a need and product use involves human exposure
5.6	Post Application-Passive Dosimetry Data	CR	CR	II	If Tier I toxicity tests indicate a need and product use involves human exposure
5.7	Post Application-Biological Monitoring Data	CR	CR	II, III	If Tier I toxicity tests indicate a need and product use involves human exposure
5.8	Dermal Absorption	CR	CR	II, III	If Tier I toxicity tests indicate a need and product use involves human exposure
5.9	Dislodgable Residues (Foliar, Soil and Surface)	CR	CR	II	If Tier I toxicity tests indicate a need and product use involves human exposure
5.1	Ambient Air Samples (Indoor - Outdoor)	CR	CR	II	If Tier I toxicity tests indicate a need and product use involves human exposure
5.11	Glove/Clothing Penetration Data	CR	CR	II, III	If Tier I toxicity tests indicate a need and product use involves human exposure
5.12	Epidemiology	CR	CR	II, III	If Tier I toxicity tests indicate a need and product use involves human exposure
5.13	Package Integrity Study	CR	CR	II, III	If Tier I toxicity tests indicate a need and product use involves human exposure
5.14	Other Studies/Data/Reports				
6	**Metabolism/Toxicokinetics Studies for Direct Application of Semiochemicals to Greenhouse or Terrestrial Food or Feed Crops (Contact the PMRA for requirements pertaining to other use/site categories) (TGAI or EP)**				
6.1	Summaries	R	R	I	
6.2	Livestock	CR	CR	I	Depends on end use of crop and by-products
6.3	Plants	R	R	I	
6.4	Other Studies/Data/Reports				
7	**Food, Feed and Tobacco Residue Studies for Direct Application of Semiochemicals to Greenhouse or Terestrial Food or Feed Crops (Contact the PMRA for requirements pertaining to other use/site categories)**				
7.1	Summaries	R	R	I	
7.2	Analytical Methodology (Food Crops & Tobacco)				
7.2.1	Supervised Residue Trial Analytical Methodology	R	R	I	
7.3	Freezer Storage Stability Tests	CR	CR	I	Depends on length of storage
7.4	Crop Residue Data				
7.4.1	Supervised Residue Trial Study	R	R	I	
7.4.2	Temporal Residue Trial Study	CR	CR	I	Depends on acerage of crop
7.4.3	Confined Crop Rotation Trial Study	CR	CR	I	Depends on cropping practice
7.4.4	Field Crop Rotation Trial Study	CR	CR	I	Depends on cropping practice
7.4.5	Processed Food/Feed	CR	CR	I	If commodity will be processed
7.4.6	Residue Data for Crops used as Livestock Feed	CR	CR	I	If treated crop will be used as livestock feed
7.5	Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops)	CR	CR	I	If treated crop will be fed to animals
7.6	Livestock, Poultry, Egg and Milk Residue Data (external application)	CR	CR	I	If pheromone will be directly applied to animals

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Tier	Conditions KEY: R = required; CR = conditionally required
7.7	Tobacco Residue Data	CR	CR	I	If applied directly to tobacco
7.8	Other Studies/Data/Reports				
8	**Environmental Chemistry and Fate**				
8.1	**Summary**				
8.2	**Laboratory Studies of Physicochemical Properties**				
8.2.3	**Laboratory Studies of Transformation (TGAI)**				Analysis must be conducted for each AIC. Where data from Tier I (TGAI) demonstrate hazard to biota, these data will be required on a case-by-case basis
8.2.3.2	Hydrolysis	-	CR	II	See 8.2.3, above
8.2.3.3	**Phototransformation (TGAI)**				
8.2.3.3.1	Soil	-	CR	II	See 8.2.3, above
8.2.3.3.2	Water	-	CR	II	See 8.2.3, above
8.2.3.4	**Biotransformation in Soil (TGAI)**				
8.2.3.4.2	Aerobic Soil 20E-30EC	-	CR	II	See 8.2.3, above
8.2.3.5	**Biotransformation in Aquatic Systems (TGAI)**				
8.2.3.5.2	Aerobic Water 20E-30EC	-	CR	II	See 8.2.3, above
8.2.4	**Laboratory Studies of Mobility**				
8.2.4.2	Adsorption/Desorption (TGAI)	-	CR	II	See 8.2.3, above
8.2.4.6	Special Studies: a) leaching by water from dispenser (EP)	-	CR	II	See 8.2.3, above
	b) volatization under conditions typical of use (EP)	-	CR	II	Where data from Tier I (TGAI) demonstrate hazard to biota, these data will be required on a case-by-case basis.
8.6	Other Studies/Data/Reports				
9	**Environmental Toxicology**				
9.1	Summary	R	R		
9.2	**Non-Target Terrestrial Invertebrates**				
9.2.9	Field Studies (EP)(i.e., beneficial arthropods including bees and wasps, parasites and predators of the pest species, and taxonomically related organisms of the pest)	-	R	I	
9.3	**Non-Target Freshwater Invertebrates (TGAI)**				Where broadcast or sprayed, these data are required for each TGAI in order to determine the risk to aquatic systems. In the absence of this information, an untreated buffer zone may be required adjacent to aquatic systems
9.3.2	*Daphnia* sp. Acute	CR	CR	I	See 9.3 above. One of 9.3.2 or 9.3.4 is required
9.3.3	*Daphnia* sp. Chronic (Life-Cycle)	-	CR	III	Where data from Tier II demonstrate hazard to biota, these data will be required on a case-by-case basis
9.3.4	Laboratory Studies with Other Species	CR	CR	I	See 9.3 above. One of 9.3.2 or 9.3.4 is required
9.3.5	Laboratory Studies with EP	-	CR	III	See 9.3.3 above
9.3.6	Field Studies (EP)	-	CR	III	See 9.3.3 above
9.4	**Non-Target Marine Invertebrates (TGAI)**				Where data from Tier II (TGAI) demonstrate hazard to biota, these data will be required on a case-by-case basis
9.4.2	Acute (Crustacean)	-	CR	III	See 9.4 above

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Tier	Conditions KEY: R = required; CR = conditionally required
9.4.3	Mollusk embryo larvae	-	CR	III	See 9.4 above
9.4.4	Mollusk shell deposition	-	CR	III	See 9.4 above
9.4.5	Chronic (Mollusk or Crustacean)	-	CR	III	See 9.4 above
9.4.6	Laboratory Studies with EP	-	CR	III	See 9.4 above
9.4.7	Field Studies (EP)	-	CR	III	See 9.4 above
9.4.8	Bioconcentration/Depuration (bivalve or Crustacean)	-	CR	III	See 9.4 above
9.5	**Fish (TGAI)**				
9.5.2	**Acute Studies**				
9.5.2.1	Cold Water Fish (e.g., salmon or rainbow trout)	CR	CR	I	See 9.3 above. One of 9.5.2.1, 9.5.2.2 or 9.5.2.3 is required; 9.5.2.1 is preferred
9.5.2.2	Warm Water Fish (e.g., bluegill sunfish)	CR	CR	I	See 9.3 above. One of 9.5.2.1, 9.5.2.2 or 9.5.2.3 is required; 9.5.2.1 is preferred
9.5.2.3	Other Freshwater Fish Species	CR	CR	I	See 9.3 above. One of 9.5.2.1, 9.5.2.2 or 9.5.2.3 is required; 9.5.2.1 is preferred
9.6	**Wild Birds (TGAI)**				
9.6.2	**Acute Studies**				
9.6.2.1	Oral (LD_{50}) Bobwhite Quail	-	CR	I	One of 9.6.2.1, 9.6.2.2 or 9.6.2.3 is required
9.6.2.2	Oral (LD_{50}) Mallard Duck	-	CR	I	One of 9.6.2.1, 9.6.2.2 or 9.6.2.3 is required
9.6.2.3	Oral (LD_{50}) Other Species	-	CR	I	One of 9.6.2.1, 9.6.2.2 or 9.6.2.3 is required
9.6.2.4	Dietary (LC_{50}) Bobwhite Quail	-	CR	I	One of 9.6.2.4, 9.6.2.5 or 9.6.2.6 is required
9.6.2.5	Dietary (LC_{50}) Oral Mallard Duck	-	CR	I	One of 9.6.2.4, 9.6.2.5 or 9.6.2.6 is required
9.6.2.6	Dietary (LC_{50}) Oral Other Species	-	CR	I	One of 9.6.2.4, 9.6.2.5 or 9.6.2.6 is required
9.7	**Wild Mammals (TGAI)**				
9.7.2	Field Studies (EP) (i.e., terrestrial animals)	-	CR	III	Where data from Tier II (TGAI) demonstrate hazard to biota, these data will be required on a case-by-case basis
9.8	**Non-Target Plants (TGAI)**				Where data from Tier II (TGAI) demonstrate hazard to biota, these data will be required on a case-by-case basis
9.8.2	Fresh Water Algae	-	CR	III	See 9.8 above
9.8.3	Marine Algae	-	CR	III	See 9.8 above
9.8.4	Terrestrial Vascular Plants	-	CR	III	See 9.8 above
9.8.5	Aquatic Vascular Plants	-	CR	III	See 9.8 above
9.8.6	Laboratory Studies with EP	-	CR	III	See 9.8 above
9.8.7	Field Studies (EP)	-	CR	III	See 9.8 above
9.9	Other Studies/Data/Reports				
10	**Value (applicable to each pest/site or host combination) (EP)**				
10.1	Value Summaries	R	R		
10.2	**Efficacy Studies**				
10.2.1	Mode of Action - TGAI	R	R		
10.2.2	Description of Pest Problem	R	R		
10.2.3	**Efficacy Trials (EP)**				
10.2.3.1	Small Scale Trials Lab, Greenhouse	CR	CR		May be submitted in support of 10.2.1
10.2.3.2	Field Trials/Operational Use Trials	R	R		
10.3	**Adverse Effects on Use Site (EP)**				
10.3.1	Adverse Effects to Crop (phytotoxicity), Host Animals, Note of Application	R	R		

Data Code	Title	Data required for SCLPs	Data required for non-SCLPs	Tier	Conditions KEY: R = required; CR = conditionally required
10.4	Economics	-	CR		Required if health or environmental concerns have been identified that cannot be easily mitigated by use restrictions or limitations
10.5	**Sustainability**				
10.5.1	Survey of Alternatives (chemical and non-chemical)	R	R		
10.5.2	Compatibility with Current Management Practices Including IPM	R	R		
10.5.3	Resistance Management	R	R		
10.5.4	Contribution to Risk Reduction	R	R		
10.6	Other Studies/Data/Reports				
12	**Summaries**				
12.5	Foreign reviews				Please code 12.5 . _ and incude at end of applicable Part, (e.g., a foreign review of Value would be coded 12.5.10 and submitted under Part 10.6)
12.7	Comprehensive summaries	R	R	I	Required for new active ingredients and major new uses of registered actives

ACRONYMS

AIC	Active Ingredient Component
CAS	Chemical Abstracts Service
CR	Conditionally Required
DACO	Data Code
EP	End-Use Product
FDA	Food and Drugs Act
GLP	Good Laboratory Practice
IPM	Integrated Pest Management
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
MSDS	Material Safety Data Sheet
OECD	Organisation for Economic Co-operation and Development
PCPA	Pest Control Products Act
PMRA	Pest Management Regulatory Agency
R	Required
SCLP	Straight-Chained Lepidopteran Pheromones
TGAI	Technical Grade of Active Ingredient
U.S. EPA	United States Environmental Protection Agency
U.S. FDA	United States Federal Department of Agriculture
UV	Ultraviolet