

NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides

Biopesticides Registration Workshop - Pheromones and Other Semiochemicals

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Marriott Crystal Gateway

Arlington, VA

Regulatory Requirements - Human Health and Safety

◆ Canada

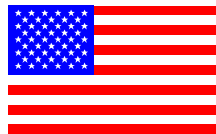
❖ Regulatory Directive DIR97-02

❖ Regulatory Proposal, Pro 2001-XX

◆ United States

❖ 40CFR 158.690





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A. Regulatory Directive

DIR97-02

- 1. Technical Grade Active Ingredient (TGAI)**
- 2. End-Use Product**

1. Technical Grade Active Ingredient (TGAI)

◆ Tier I Tests (required):

❖ Waivers from testing may be requested; must be supported by sound scientific rationale.

◆ a) Acute Toxicity Studies:

- Acute Oral Toxicity
- Acute Dermal Toxicity
- Acute Inhalation Toxicity
- Primary Eye Irritation
- Primary Dermal Irritation
- Dermal Sensitization





◆ Tier I Tests (required) (cont'd):

- ◆ b) Genotoxicity Potential Studies:
 - Microbial Point Mutation
 - Mammalian (Cell) Point Mutation
 - *In Vitro* Chromosome Aberration Assay





◆ **Tier II/Tier III Tests**
(conditionally required):

- ❖ Additional testing may be required if Tier I and/or Tier II studies indicate any toxicological concern and/or potential for exposure of food and/or humans.





◆ **Tier II/Tier III Tests**
(conditionally required) (cont'd):

- ◆ a) Short-Term Toxicity Studies:
 - Oral, rodent
 - Oral, non-rodent
 - Dermal
 - Inhalation, rodent
 - Other Short-Term Studies



◆ Tier II/Tier III Tests (conditionally required) (cont'd):

- ◆ b) Long-Term Studies:
 - Oncogenicity, rodent, 2 species
 - Chronic, rodent, 1 species
- ◆ c) Genotoxicity Potential Studies:
 - *In vivo* Chromosomal Aberration Assay
 - Other Genotoxicity Studies
- ◆ d) Reproduction/Developmental Studies:
 - Reproduction, rat
 - Teratology, rat and/or rabbit



◆ Tier II/Tier III Tests (conditionally required) (cont'd):

- ◆ e) Neurotoxicity Studies
 - Acute and/or 90-day rat
- ◆ f) Metabolism Studies
 - Metabolism: Pharmacokinetic and Metabolite Characterization Studies, rat
- ◆ g) Other Studies/Data/Reports:
 - Special Studies (e.g., Immunotoxicity)



A. Regulatory Directive DIR97-02

2. End-Use Product

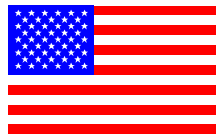
◆ Tier I Tests (conditionally required):

❖ Testing may be required if the formulants used are of toxicological concern.

◆ a) Acute Toxicity Studies:

- Acute Oral Toxicity
- Acute Dermal Toxicity
- Acute Inhalation Toxicity
- Primary Eye Irritation
- Primary Dermal Irritation
- Dermal Sensitization





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B. Regulatory Proposal, Pro 2001-XX

- 1. Technical Grade Active Ingredient (TGAI)**
- 2. End-Use Product**

Regulatory Proposal, Pro 2001-XX

- ◆ Currently being drafted/revised
- ◆ Intended to replace DIR97-02 in the near future
- ◆ Revisions reflect the results of the “OECD Workshop on Common Core Data Requirements for Pheromones and Other Semiochemicals”
- ◆ The aim of this workshop was to work towards harmonization of data requirements for pheromones and other semiochemicals
- ◆ Participants: Canada, United States, Austria, France, Germany, Korea, Luxembourg, Mexico, Netherlands, OECD Secretariat, Commission of the European Union, representatives from industry and representatives from academia



1. Technical Grade Active Ingredient (TGAI)

◆ Tier I Tests (required):

- ❖ Waivers may be requested, if appropriate, for example,
 - ◆ Straight Chained Lepidopteran pheromones (SCLP)
 - ◆ Exposure less than background
- ❖ sound scientific rationale is required
 - ◆ a) Acute Toxicity Studies:
 - Same as DIR97-02



◆ Tier I Tests (required) (cont'd):

- ◆ b) Genotoxicity Potential Studies:
 - Same as DIR97-02
- ◆ c) Short-Term Studies (by appropriate route):
 - Oral, 90-day rodent, **OR**
 - Oral, 21/30 day rodent
- ◆ d) Developmental Studies:
 - Teratology, rat, **OR** rabbit
- ◆ e) Additional Data:
 - Medical data





◆ **Tier II/Tier III Tests**
(conditionally required):

- ❖ Additional testing may be required if Tier I and/or Tier II studies indicate any toxicological concern and/or potential for exposure of food and/or humans.



◆ Tier II/Tier III Tests (conditionally required) (cont'd):

- ◆ a) Short-Term Toxicity Studies:
 - Oral, non-rodent
 - Dermal
 - Inhalation, rodent
 - Other Studies
- ◆ b) Long-Term Studies:
 - Chronic Toxicity, rodent, 1 species
 - Oncogenicity, rodent, 2 species



◆ Tier II/Tier III Tests (conditionally required) (cont'd):

- ◆ c) Reproduction/Developmental Studies:
 - Reproduction, rat
 - Teratology, rat and/or rabbit
- ◆ d) Neurotoxicity Studies
 - Acute and/or 90-day rat
- ◆ e) Metabolism Studies
 - Metabolism: Pharmacokinetic and Metabolite Characterization Studies, rat





◆ Tier II/Tier III Tests (conditionally required) (cont'd):

- ◆ f) Genotoxicity Potential Studies:
 - *In vivo* Chromosomal Aberration Assay
 - Other Genotoxicity Studies
- ◆ g) Other Studies/Data/Reports:
 - Special Studies, e.g., Immunotoxicity



2. End-Use Product

◆ Tier I Tests (conditionally required):

❖ Testing may be required if the formulants used are other than those listed on US EPA's List 4A of Inert Ingredients.

◆ a) MSDSs:

▪ MSDSs must be submitted for all formulant ingredients.

◆ b) Acute Toxicity Studies:

▪ Same as DIR97-02

