APPENDIX 10

FORMAT FOR COMPILATION OF *TIER III* OVERALL SUMMARIES AND ASSESSMENTS FOR PHEROMONES AND SEMIOCHEMICALS

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

1.1 Identity of the Active Substance and preparations containing it

OEC_PHE_EX is a microencapsulated formulation containing 15% of the active substance PHEROMX. The end-use product is proposed for control of insect (*Insect anonymia*) in forests and woodlands through mating disruption. The product is proposed for application at a rate of 200 g a.i./ha by ground equipment (dispensers). The proposed timing of application is one week before the adult moth flight begins.

PHEROMX is a "straight-chained lepidopteran pheromone" (SCLP). This category of pheromones product is generally regarded to pose a low risk to human health and the environment based on available studies.

Product analysis information submitted is sufficient to identify the active ingredient and formulants. Impurities of toxicological concern are not expected to be present in the raw materials, nor are they expected to be generated during the manufacturing process. Identity data prove that the active ingredient is substantially similar to the naturally occurring substance.

A description of starting materials and manufacturing process has been provided with upper and lower concentrations (certified limits).

1.2 Physical and Chemical Properties

Physical and Chemical Properties of the Active Substance

property	result
colour and physical state	colourless liquid
odour	mild
melting point	not applicable
boiling point	110°C at 0.5 mm Hg
density	0.772 g/cm^3 at 25 °C
vapour pressure	1.26 x 10^{-2} mm Hg at 20 °C
UV/visible spectrum	Not expected to absorb UV at wavelength above 300 nm
solubility in water	1.4 x 10^{-5} mol/L
solubility in organic solvents	completely soluble in hexane, acetone and methanol
n-Octanol/water partition coefficient	K_{ow} = 1.7 x 10^5
dissociation constant	not applicable

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Company name	Month and year	Active Substance (Name)	page of

Physical, Chemical and Technical Properties of the Plant Protection Product

property	result
colour	pale brown
odour	paraffinic
physical state	liquid
formulation type	microencapsulated formulation
container material and description	high density polyethylene
Ph	8.6
storage stability	stable for 30 days at 50°C. A one-year ambient temperature testing is under way

1.3 Details of uses and further handling

PHEROMX has been identified as the sex pheromone for insect (*Insect anonymia).* In nature, the sex pheromone is produced and released into air by the female moth and it is used to attract a mate.
"Mating disruption" refers to the process of releasing synthetic pheromone into the air in concentrations above background levels produced by female moths, thus disrupting communication between male and female moths. Although the exact mechanism by which mating disruption occurs is not known, the end result is that the male moth does not locate a female and mating does not occur, resulting in subsequent reductions in the pest population. To be effective in reducing insect damage, the product must be applied prior to the beginning of the adult moth flight season, and an ambient level of pheromone sufficient to disrupt communication must last throughout the moth mating period.

The end-use product is proposed for control of insect (*Insect anonymia*) in forests and woodlands through mating disruption. The product is proposed for application at a rate of 200 g a.i./ha by ground equipment (dispensers). The proposed timing of application is one week before the adult moth flight begins.

The container consists of a high density polyethylene material.

1.4 Classification and labelling

No classification is needed.

Chapter 2: Methods of Analysis

A gas chromatography (GC) method with flame ionization detector was used for the determination of the active substance and significant impurities (content $\geq$ 1%) in the technical product. The method fulfills the requirements for specificity and limit of determination. Validation data for linearity and repeatability of the method were waived, as there are no cleanup procedures involved in the sample preparation, and the flame ionization detector usually has a wider linear range.

The formulation process introduces or enhances the presence of impurities of toxicological concern. An enforcement analytical method with upper limits has been provided to identify these impurities.

A gas chromatography (GC) method with flame ionization detector was used for the determination of active substance in the formulation. The method has been validated for specificity, linearity, repeatability and limit of determination.

Analytical standards have been submitted.

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Chapter 3: Impact on Human and Animal Health

Reduced toxicological data requirements have been established for SCLPs. Straight-chained lepidopteran pheromones contain only carbon, hydrogen and oxygen and are poorly soluble in water. They are products of fatty acid metabolism and are biodegradable by enzyme systems present in most living organisms. Health studies have indicated that these substances pose minimal risk and provide effective pest control at low concentrations, similar to those occurring in nature.

The following is a summary of the toxicity data submitted by the registrant to support the registration of PHEROMX. These studies were not analysed for compliance with guideline requirements; however, the toxicity levels and categories were found to be comparable to similar pheromone pesticide products:

Acute Toxicity Study	
Oral (single oral gavage/10 rats/14 day study)	LD50 > 15 g/kg
Dermal (single 24 hr exposure/4 rabbits/14 day study)	LD50 > 3 g/kg
Inhalation (single 1 hr exposure/10 rats/14 day study)	LC50 not determined; no animals died but dose level not clearly reported (4 g/hr).
Eye Irritation (single 0.1 mL exposure in 1 eye/6 rabbits)	Irritation in 2 animals; cleared within 72 hours.
Skin Irritation (single 24 hr. Exposure/6 rabbits)	Minimal edema in 1 rabbit with abraded skin; cleared within 24 hours.

It is important to note that the dermal sensitization study, which is expected to be negative, relied upon surrogate data with 2 similar compounds (2-hexenyl acetate, 10-undecenyl acetate). This was acceptable because there is a requirement for the reporting of hypersensitivity incidents, if they are known prior to or arise during the use of the product. If such incidents are reported, this information would override the expectation that the pheromone product would be negative in a dermal sensitization study (the basis for waiver of this study), and appropriate precautionary label language would be required.

Other toxicology studies that are required or conditionally required for food uses of biochemical pesticides include: genotoxicity and immunotoxicity (required), and subchronic (90-day) oral, dermal or inhalation and developmental toxicity in one species (conditionally
required), and the reporting of any adverse effects (including hypersensitivity incidents as mentioned above). Because [this pheromone] is a SCLP these studies can be waived.

The formulated product is encapsulated and is not for use on food. Hence, the potential for direct human exposure is considered to be negligible. In addition, since capsule size is ~25 microns, it is not considered to pose and hazard via the inhalation route to applicators.

The results of the acute toxicity testing indicate low acute oral, dermal and inhalation toxicity, slightly irritating to the skin and eyes, and not expected to be a dermal sensitizer.

Based on the toxicological profile of the active ingredient, a quantitative estimate of exposure was not required for this product. Exposure to the applicator could occur during mixing, loading and application. Exposure would be predominantly dermal.

Re-entry exposure is considered to be negligible due to the rapid dissipation of the product.

Based on the toxicological profile of the active ingredient, it is concluded that use of the proposed product is not likely to present a risk to workers provided the label specifies appropriate protective equipment.

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Chapter 4: Residues

For semiochemical PHEROMX no residue data are required because it is determined that detectable residues on the consumable commodity are unlikely to occur.

For semiochemical PHEROMX no residue data are required because residue levels are unlikely to exceed natural background levels during outbreaks of the pest and any residues are not toxic. The product is used in retrievably-sized polymeric dispensers used at a rate no more than 375 g ai/ha/yr (150 g ai/acre/yr).

Residue data for tomatoes and leaf lettuce were submitted, but due to the exemption from the requirement of a tolerance on food commodities for lepidopteran pheromones, these data are not required and thus were not reviewed.

Chapter 5: Fate and Behaviour in the Environment

Data on the persistence of a semiochemical and its transport from the site of application to another site or medium are not required because ecotoxicity data and public literature indicate no hazard to biota. These data indicate that no significant persistence and transport of these agents in any part of the environment occurs.

The environmental fate of the semiochemical PHEROMX (e.g. stability in air and water) has been assessed, based on available information. Test data on the compound PHEROMX are not required because its use will not result in environmental contamination exceeding natural background levels.

Chapter 6: Effects on Non-target Species

Experience to date indicates that SCLPs are not acutely toxic to birds. Toxicity data for human safety are sufficient to assess potential effects to wild mammals, so no further wild mammal testing is required. Aquatic testing is not required for fixed point dispensers applied over land.
For potential effects of nontarget insects literature is provided by the registrant on specificity to target insects. The registrant has reported any adverse effects on nontarget insects noted during efficacy testing, particularly effects on insect predators or parasites of the target organism, species closely related to the target pest, and pollinators. The range of invertebrates likely to be affected by a semiochemical has been established by comparing baited and unbaited traps in environments similar to those of intended use. Because no such effects are noted during efficacy testing, and in the absence of any other data indicating potential for adverse effects, no nontarget testing has been indicated.

The registrant submitted a request for waiver of non-target data (terrestrial and aquatic invertebrates, and fish) based upon the following rationale.

- Application rates of up to 375 g SCLP/ha/yr are generally understood to result in exposure levels which are comparable to natural emissions and safe for nontarget species.
- No adverse effects were noted on non-target terrestrial invertebrates during efficacy trials.
- The values obtained for an "identical blend of pheromone" published in the CRC Handbook of Natural Pesticides were as follows:

Study	Findings
8-day dietary/Mallard duck	LC50 > 5000 ppm
single oral dose/Mallard duck	LD50 > 2 g/kg
96 hr. Static Bluegill Sunfish	LC50 > 300 ppm
48 hr. Static Daphnia magna	LC50 = 1.3 ppm

- A worst-case scenario exposure of aquatic animals to the technical active ingredient was submitted that estimated if all of the active ingredient were released at one time from microcapsules, the resultant total concentration would be 40 times less than the currently published LC50 for Daphnia and 10,000 times less than the published LC50 for Bluegill Sunfish.
- An overspray onto water of 50 g ai/ha would result in only 0.044 in^2 of water surface being covered.
- The microcapsules exhibit poor film formation properties, thus an overspray onto water surfaces is be expected to significantly reduce the transmission of oxygen.
- A literature search yielded no information that microcapsules of the size intended for use with this product would interfere with Daphnia or fish respiration.

No nontarget terrestrial plant studies (seedling emergence, vegetative vigor) are required because there is no reason to suspect possible effects.

Chapter 7: Efficacy data and information

Results from 36 scientifically-conducted efficacy trials were assessed. Products were applied by fixed dispensers at rates from 200 g a.i./ha.
The treatments were timed to coincide with the beginning of the moth flight period. Efficacy was assessed by placing pheromone baited traps in the treated and untreated plots and recording trap catches of male moths following application. The treatment is assumed to be effective if few or no male moths are caught in the traps in the treated plots and many male moths are caught in the untreated plots. A reduction in trap catches in the treated plots reflects disruption of pheromone communication by male and female moths.

In all trials, trap catches of male moths in treated plots were reduced by > 90% during the moth flight period compared with the untreated plots. This suggests that the treatments were effective in disrupting pheromone communication.

Also information has been submitted on the compatibility of PHEROMX with Integrated Pest Management programs and its contribution to risk reduction.