APPENDIX 8

FORMAT FOR COMPILATION OF *TIER II* SUMMARIES - FORMULATED PRODUCT

PART 1

Section 1 **Identity of the plant protection product; Physical, chemical and technical properties; Data on application; Further information on the plant protection product; Proposals including justification of the proposals for the classification and labelling of the plant protection product; Proposals for risk and safety phrases and the proposed label**

The example of a summary and assessment of data which follows is intended to illustrate the approach recommended for the preparation of *Tier II* summaries and assessments. The material included has not been critically assessed for its technical content. The data included in the following summary and evaluation are not based on a real submission.

Applicant should be aware that these guidelines are intended to provide a degree of flexibility. Where in particular cases, it is more appropriate to present the data and information in another format, applicants may do so. In such cases it is recommended that the applicant discuss the format proposed with the Regulatory Authority of the Country to which application is to be made.

1 Identity of the plant protection product

IIIP 1.1 **Applicant**

Contact person:	Dr John Jones
Address:	Pheroco 36 -39 Plant Street Marlborough Wiltshire England
Telephone:	+44 (0) 1345 6789112
Fax:	+44 (0) 1345 4567890

IIIP 1.2.1 **Manufacturer of the preparation**

Contact Person:	Dr A. Wainright
Address:	As above
Telephone:	+44 (0) 1345 6789247
Fax:	+44 (0) 1345 4567990

IIIP 1.2.2 **Manufacturer of the active substance**

Contact Person:	Dr S. Smith
Address:	As above
Telephone:	+44 (0) 1345 6789245
Fax:	+44 (0) 1345 4567990

IIIP 1.2.3 **Statement of purity (and detailed information on impurities) of the active substance**

The information concerned is included with all other confidential information in Document **J**

IIIP 1.3 **Trade name** To be decided - Code OEC PHE_EX - the trade name will be provided prior to the registration of the plant protection product

IIIP 1.4.1 **Contents of active ingredient components, technical active substance and formulants**

Content of active ingredient component 1: 90 g/kg
Content of active ingredient component 2: 45 g/kg
Content of active ingredient component 3: 15 g/kg

Content of technical active substance: 150 g/kg

Information with respect to formulants is included with all other confidential information in Document **J**

IIIP 1.4.1.1 **Certified limits of each component in the technical active substance**

Active ingredient component 1:	600 g/kg +/- 10 g/kg
Active ingredient component 2:	300 g/kg +/- 10 g/kg
Active ingredient component 3:	100 g/kg +/- 10 g/kg

TOTAL active components in technical grade active substance: 985 g/kg +/- 15 g/kg

Formulants: The information concerned is included with all other confidential information in Document J

IIIP 1.4.2.1 **ISO common name proposed or accepted for the active substance**

PHEROMX (proposed ISO name)

IIIP 1.4.3 **Details of components. other than active substance, in the formulation**

chemical name	(IUPAC):	}
	(CAS):	}
structure or structural formula:		} the information concerned is included with all
CAS, CIPAC, EINICS and ELINCS numbers:		} other confidential information in document J
Trade name:		}
Specification:		}

Function: }

IIIP 1.4.4.1 **Description of formulation process**

The information concerned is included with all other confidential information in Document **J**

IIIP 1.4.4.2 **Potential for the formation of impurities of toxicological concern**

The information concerned is included with all other confidential information in Document **J**

IIIP 1.6 **Other/ special studies**

None

2 *Physical, chemical and technical properties of the plant protection product*

Test or Study & Data point	Guideline and method	Test material purity and specification	Findings	Comments	GLP Y/N	Reference
Appearance (IIIP 2.1)	Visual inspection	15% micro-encapsulated concentrate Batch F-9236-6	Amber liquid without discernible odour		Y	Krieke LM 1996
Explosive properties (IIIP 2.2.1)	EU method A.14	15% micro-encapsulated concentrate Batch F-9236-6	OEC_PHE_EX did not react explosively to thermal stress, mechanical stress or to friction	OEC_PHE_EX is not explosive	Y	Krieke LM 1996
Free acidity/ Alkalinity (IIIP 2.4.1)			Not tested	Not relevant since the preparation is neither acidic nor alkaline	-	Waiving statement available
Viscosity (IIIP 2.5.2)			Not tested	Testing not required as formulation is in polyethylene dispensers	-	Waiving statement available
Stability after storage (IIIP.2.7.2)	Modified CIPAC method MT 46		Stable at room temperature for 3 months	The product is sufficiently stable	Y	Krieke LM 1997a
Corrosion characteristics (IIIP 2.13)	-	-	Not tested	container materials known to be resistant to product chemistry and solvents	-	Waiving statement available
Container material (IIIP 2.14)	-	-	-	Laminated film: 48 g polyethylene terphthalate / 1.0 mil oriented high density polyethylene / 3.0 mil liner low density polyethylene	-	Waiving statement available

3 Data on application relevant to the formulated product

IIIP 3.1 **Field of use envisaged:** Forestry

IIIP 3.4 **Application rate:** 200 g of active ingredient per hectare, i.e. 1.000 dispensers of 0.2 g per dispenser.

IIIP 3.6 **Method of application:**

OEC_PHE_EX is to be applied in retrievable polyethylene dispenses at a rate of 1.000 dispensers per ha, equivalent to 13 L of OEC_PHE_EX or 200g of the active substance.

IIIP 3.7.1 **Maximum number of applications and their timing**

and

A single application is recommended, during May/June, depending on local conditions, pest pressure other factors. Duration of control is for one season.

IIIP 3.9 **Proposed instructions for use as printed, or to be printed on labels**

Full details of the proposed instructions for use are included in the draft label provided as part of Document C.

IIIP 3.10 **Other/ special studies**

None

4 Further information on the plant protection product

IIIP 4.1.1 **Description and specification of the packaging and materials used in packaging, size, capacity, size of openings, types of closure and seals**

OEC_PHE_EX is to be packaged in polyethylene dispensers of 13 ml content each. 100 dispensers are sealed in a pressurised, coated plastic bag to ensure a shelf-life over 9 months. Opened containers must be used immediately.

Materials: Laminated film; 48 g PET / 1.0 mil MONAX / 3.0 mil LLDPE
PET = Polyethylene terephthalate
Monax = Trade name for oriented High Density Polyethylene
LLDPE = Liner low density polyethylene

Specifications: Total thickness = 4.5 mil

Shape: Flat sachet

Opening: Tear notch 1.5 cm from top, both sides

IIIP 4.1.2 Suitability of the packaging and closures

Test Results:

Seal strength	> 7.5 pound/inch
Tensile - Machine Direction	1100 pound/square inch
Cross Machine Direction	500 pound/square inch
Elongation - (ASTM D-882)	= 40 %
MVTR - (ASTM E-96)	0.015g/100 square inch/day @ 73F & 50% RH 0.12g/100 square inch /day @ 100F & 90% RH
Leak test	Passed according to ASTM (D3078- 84)
Puncture resistance	Dart Impact (ASTM D-883) = 450 g
Vibration and Drop	Inner pouches retained their integrity. Scuffing noted on carton.

IIIP 4.2.1 **Procedures for cleaning application equipment and protective clothing**

Normal procedures, should be followed for the cleaning of protective clothing and equipment. Any contamination on the outside of protective equipment should be removed by washing with clean water. Protective clothing should be washed using clean water followed by soaking in clean water with household ammonia (0.03 %).

IIIP 4.3.1 **Pre-harvest interval (in days) for each relevant crop**

The notifier proposes a pre-harvest interval of 60 days as an additional precautionary measure to exclude any consumer exposure.

Appendix 8 **Format for the compilation of *Tier II* summaries - Formulated Product**

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

IIIA 4.8.1 **Detailed Instructions for safe disposal of the plant protection product and its packaging**

All waste product should be packaged and labelled as waste chemical material. Product and packaging should be disposed of at a suitable waste incineration or disposal plant according to official regulations that apply. For large quantities contact the supplier.

No other methods are currently available.

IIIP 9 **Other /special studies**

None

PART 2

Section 3 Toxicological Studies and Exposure Data and Information

The example of a summary and assessment of data which follows is intended to illustrate the approach recommended for the preparation of *Tier II* summaries and assessments. The material included has not been critically assessed for its technical content. The data presented in the following summary and evaluation, are not based on real studies.

Applicants should be aware that these guidelines are intended to provide a degree of flexibility. Where in particular cases, it is more appropriate to present the data in another format, applicants may do so. In such cases it is recommended that the applicant discuss the format proposed with the Regulatory Authority of the Country to which application is to be made.

IIIP 7.1. **Acute toxicity**

General remark:

OEC_PHE_EX contains PHEROMX as active ingredient, which consists of naturally occurring, straight chain lepidopteran pheromones. Reduced toxicological data requirements have been established for these pheromones, which 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 available in the literature have established that these substances pose no risk. The formulation OEC_PHE_EX is packaged in polyethylene dispensers. No direct contact to the formulation is likely to occur.

Several data requirements were therefore waived.

IIIP 7.1.1 **Acute oral toxicity**

Report: IIIA 7.1.1/01 Crown H 1996, Acute oral toxicity of OEC_PHE_EX in rats, Report Number: CCC-14543

Executive Summary: In an acute oral toxicity study, groups of fasted, young adult Sprague-Dawley rats 5/sex/dose were given a single oral dose (gavage) of OEC_PHE_EX (15%PHEROMX) in corn oil a single dose of 5,000 mg/kg bw and were observed for 14 days

Oral LD_{50} rats = > 5000 mg/kg bw

OEC_PHE_EX was found to be of low acute toxicity following exposure of rats. Clinical signs on the day of dosing or within two days after dosing included faecal staining and soft stools. All animals had gained weight 7 and 14 days following dosing. On the basis of this study, OEC_PHE_EX does not warrant classification as being harmful or toxic

Guidelines: OECD 420

GLP: yes (certified laboratory)

I - MATERIALS AND METHODS

A MATERIALS:

1 Test Material: OEC_PHE_EX

Description: colourless liquid
Lot/Batch #: NPD-9209-4523-T
Purity: 98.5 % as [22]
Stability of test compound: not determined

2 Vehicle and/or positive control: Corn oil

3 Test animals -

Species: Rat
Strain: Crl:CD(SD)BR, albino
Age: Young adult
Weight at dosing: 217 - 286 g males
Source: Charles River Laboratories, Portage, MI
Acclimation period: 7 days
Diet: Chow (#5001), *ad libitum*
Water: Tap water, *ad libitum*
Housing: Animals were individually housed in stainless steel suspended cages

Environmental conditions -
Temperature: Temperature was not specified
Humidity: Relative humidity ranged from 35 to 84 %
Air changes: Not recorded
Photoperiod: Alternating 12-hour light and dark cycles

B STUDY DESIGN AND METHODS:

1 In life dates: 15 January to 5 February 1993

2 Animal assignment and treatment:
A single dose of 5000 mg/kg bw was selected for the sighting study (using one animal) and for the main study (using four animals). One animal was dosed in the sighting study, the other four individuals were exposed to the test substance 24 hours later. Following an overnight fast (17 - 22 hours), rats were given a single dose of PHEROMX (98.5 % pure) by gavage. The test substance was administered in corn oil at a volume of 10 ml/kg bw. Animals were observed for gross toxicity, behavioural changes and/or mortality at approximately 1, 2.5 and 4 hours after dosing and at least once daily for the remainder of the 14-day study. Body weights were recorded at day 0 (prior to dosing), 7 and 14. On day 14, surviving animals were sacrificed and all animals were necropsied and examined for gross pathological changes.

Table IIA 5.2.1-1 Doses, mortality / animals treated

3 Statistics - The data were did not warrant statistical analysis.

II - RESULTS AND DISCUSSION

A Mortality: No mortalities occurred
The oral LD_{50} was > 5,000mg/kg bw

[22] Details with respect to the purity and content of impurities of the test material are provided in Document J

B **Clinical Observations:** Clinical signs on the day of dosing or within two days after dosing included faecal staining and soft stools **.**

C **Body weight:** All animals had gained weight 7 and 14 days following dosing.

D **Necropsy:** No internal abnormalities were observed at necropsy.

E **Deficiencies:** None

III - CONCLUSIONS

The acute oral LD_{50} of OEC_PHE_EX to rats was. was found to be in excess of 5000 mg/kg bw and does not warrant classification as being toxic or harmful on the basis of its acute oral toxicity

(Crown H 1996a)

IIIP 7.1.2 **Acute percutaneous (dermal) toxicity**

The formulation is packaged in polyethylene dispensers. No direct contact to the formulation is likely to occur. In view of the low dermal toxicity of the active substance (see Annex II) dermal testing of the formulation is not necessary. Data requirement waived.

IIIP 7.1.3 **Acute inhalation toxicity to rats**

Report: IIIA 7.1.3/01 Crown H 1996, Acute inhalation study of OEC_PHE_EX, Report Number CCC-14545

Executive Summary: In an acute inhalation toxicity study, groups of young adult Sprague-Dawley rats (5/sex) were exposed by the inhalation route to an aerosol of OEC_PHE_EX (79.6 % chemx) for 4 hours to (nose only) at concentrations of 0 and x.x mg/L, the maximum achievable concentration. Animals then were observed for 14 days.

LC_{50}	males =	> x.x mg/L
	females =	> x.x mg/L
	combined =	> x.x mg/L

During the first three days following exposure the following symptoms were observed: rapid respiration, rattling respiratory sounds, red/brown perinasal encrustation, periorbital encrustation and emaciation. All animals appeared normal on days 4 through 14. Weight gain was normal in all animals at the 2, 7 and 14-day measurement intervals. There were no exposure-related abnormalities observed during macroscopic examinations. On the basis of this study, the test material does not warrant classification as being harmful or toxic.

Guidelines: US EPA FIFRA Guideline § 81-3, which is equivalent to OECD 403 and EEC B2

GLP: Yes, but with the exception that the stability of the test material was not determined. However, the dose was prepared freshly prior to dosing. This deviation did not compromise the acceptability of the study.

I - MATERIALS AND METHODS

Appendix 8 **Format for the compilation of *Tier II* summaries - Formulated Product**

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

A MATERIALS:

1 Test Material: OEC_PHE_EX
- **Description:** colourless liquid
- **Lot/Batch #:** NPD-9501-6384-F
- **Purity:** 98.5 % as [23]
- **Stability of test compound:** shown to be stable in an accelerated storage stability test (14 days at 54 _C)

2 Vehicle and/or positive control: OEC_PHE_EX aerosol

3 Test animals -
- **Species:** Rat
- **Strain:** Sprague-Dawley (CD)
- **Age:** Young adult
- **Weight at dosing:** 269 - 295 g males; 236 - 261 females
- **Source:** Charles River Laboratories, Portage, MI
- **Acclimation period:** 8 days
- **Diet:** Chow (#5002), *ad libitum*
- **Water:** Tap water, *ad libitum*
- **Housing:** Animals were individually housed in stainless steel suspended cages

Environmental conditions -
- **Temperature:** Temperature was not specified
- **Humidity:** Relative humidity ranged from 45 to 80 %
- **Air changes:** Not recorded
- **Photoperiod:** Alternating 12-hour light and dark cycles

B STUDY DESIGN AND METHODS:

1 In life dates: 5 February to 27 September 1995

2 Animal assignment and treatment:
Animals were assigned to the test groups listed in Table IIIA 7.1.3-1. Animals were observed approximately hourly during the 4-hour exposure period. Thereafter mortality and moribundity checks were conducted twice daily. Observations for signs of toxicity were conducted immediately following exposure and daily thereafter. Individual body weights were measured and recorded on days 2, 7 and 14. On day 14, surviving animals were sacrificed and all animals were necropsied and examined for gross pathological changes.

Table IIIP 7.1.3-1 Doses, mortality / animals treated

[23] Details with respect to the purity and content of impurities of the test material are provided in Document J

Dose (mg/L) in xx L air / minute	Males	Females	Combined
0	0/5	0/5	0/10
x.x	0/5	0/5	0/10

3 **Generation of the test atmosphere / chamber description:**
An 80-L nose only exposure chamber was used. During exposure (4 hours), individual plastic tubes were positioned in two tiers around the outside of the chamber such that only the nose of test animals was exposed to the interior of the chamber. A JET-O-MIZER- jet mill was used to mill the test material (OEC_PHE_EX) and generate the test aerosol. The test atmosphere was sampled at 20, 80, 140 and 223 minutes into the 240-minute exposure period. The samples were analysed by means of HPLC, using an xxxxxx column, 2 % acetonitrile mobile phase and UV (xx nm) detection. The limit of detection (LOD) for chemx was x _g as/L of air, while the limit of quantification (LOQ) was xx _g as/L of air. The test atmosphere concentration was x.x _ 0.16 mg as/L air.

Two samples were taken for particle size analysis using an Anderson cascade impactor. One of the samples was taken during the first part of the exposure period, the second during the second part of the exposure period:

mass median aerodynamic diameter: 3.6 microns
% particles < 10 microns: 92
% particles < 1 micron: 5

4 **Statistics** - The data were did not warrant statistical analysis.

II - RESULTS AND DISCUSSION

A **Mortality:** Details are provided in Table IIIA 7.1.3-1. No mortalities occurred at x.x mg/L, the only dose level tested.

The 4 hour inhalation LC_{50} for males was > x.x mg / L
for females was > x.x mg / L
combined was > x.x mg / L

B **Clinical Observations:** All animals appeared normal during the exposure period. Nasal and ocular discharges / encrustations were noted immediately following exposure. During the first three days following exposure the following symptoms were observed: rapid respiration, rattling respiratory sounds, red/brown perinasal encrustation, periorbital encrustation and emaciation. All animals appeared normal on day 4 through day 14.

C **Body Weight:** Weight gain was normal in all animals at the 2, 7 and 14-day measurement intervals.

D **Necropsy:** There were no exposure-related abnormalities observed during macroscopic

examinations.

E **Deficiencies:** None.

III - CONCLUSIONS

The four-hour Inhalation LC_{50} of OEC_PHE_EX in rats was greater than x.x mg/l (the maximum achievable concentration). The preparation does not warrant classification as being toxic or harmful on the basis of its acute inhalation toxicity.

(Crown H 1996c)

IIIP 7.1.4 **Skin irritation**

The formulation is packaged in polyethylene dispensers. No direct contact to the formulation is likely to occur. In view of the low irritation of the active substance (see Annex II) dermal testing of the formulation is not necessary.

IIIP 7.1.5 **Eye irritation**

The formulation is packaged in polyethylene dispensers. No direct contact to the formulation is likely to occur. In view of the low irritation of the active substance (see Annex II) testing of the formulation is not necessary.

IIIP 7.1.6 **Skin sensitization**

Report: IIIA 7.1.6/01 Crown H 1996, Guinea pig maximization test with OEC_PHE_EX (Method of Magnusson and Kligman), Report Number CCC-95-194

Executive Summary: In a dermal sensitization study with OEC_PHE_EX (15% PHEROMX) in polypropylene glycol and in Freund's Complete Adjuvant (FCA) emulsion, 20 young adult Dunkin Hartley albino guinea pigs (10/sex) were subjected to testing. The treatment regime involved induction of sensitization by intradermal injection on day 1, induction of sensitization by topical administration on day 8 and challenge by topical administration on day 22

No clinical abnormalities were observed during the study and except for one female which was found dead on day 10, all animals survived and gained weight throughout the study. No abnormalities were observed upon macroscopic post-mortem examination of the dead animal (normal lesions from dosing were seen on the animal's back). The death of this animal does not appear to have been due to administration of the test material. On the basis of this study, the test material does not warrant classification as being a skin sensitizer.

Guidelines: US EPA FIFRA Guideline § 81-6, which is equivalent to OECD 406 and EEC B6

GLP: Fully GLP compliant

I - MATERIALS AND METHODS

A **MATERIALS:**

1 **Test Material:** OEC_PHE_EX

	Description:	colourless liquid
	Lot/Batch #:	NPD-9501-6384-F
	Purity:	98.5 % as [24]
	Stability of test compound:	shown to be stable in an accelerated storage stability test (14 days at 54 _C)
2	**Vehicle and/or positive control:**	polypropylene glycol, Freund's Complete Adjuvant (FCA) emulsion and saline 9 %
3	**Test animals -**	
	Species:	Albino Guinea Pigs
	Strain:	Dunkin Hartley Haz:(DH)FBR
	Age:	5 to 7 weeks at dosing
	Weight at dosing:	345 to 420 g males; 270 to 435 g females
	Source:	GTP, Gainsville, Pa
	Acclimation period:	14 days
	Diet:	Agway Prolab Purina Guinea Pig Diet, *ad libitum*
	Water:	Tap water, *ad libitum*
	Housing:	Animals were individually housed in stainless steel suspended cages with wire mesh bottoms
	Environmental conditions -	
	Temperature:	18 to 24 _C
	Humidity:	Relative humidity ranged from 30 to 60 %
	Air changes:	Not recorded
	Photoperiod:	Alternating 12-hour light and dark cycles

B STUDY DESIGN AND METHODS:

1 In life dates: 11 January to 15 February 1996

2 Animal assignment and treatment:

The treatment regime involved induction of sensitization by intradermal injection on day 1, induction of sensitization by topical administration on day 8 and challenge by topical administration on day 22. The test levels for dermal and intradermal inductions and challenge were selected following preliminary irritancy testing. The sites were pre-treated with 10 % sodium lauryl sulphate to elicit some dermal response, because of the known non-irritancy of the test substance. Propylene glycol was used alone for intradermal induction and mixed with chemx to produce a 5 % w/v mixture for intradermal induction. Freund's Complete Adjuvant (FCA) Emulsion was mixed 50 % v/v in distilled water for intradermal induction and mixed with chemx to produce a 5 % w/v mixture for intradermal induction. 0.9 % saline was used alone for topical induction and challenge and also used to moisten OEC_PHE_EX for topical induction and challenge. The test material was administered at a concentration of 5 % for the intradermal induction and at 100 % for the topical induction to 20 Dunkin Hartley guinea pigs (10 male and 10 female).

II - RESULTS AND DISCUSSION

A FINDINGS: No clinical abnormalities were observed during the study and except for one female which was found dead on day 10, all animals survived and gained weight throughout the study. No abnormalities were observed

[24] Details with respect to the purity and content of impurities of the test material are provided in Document J

upon macroscopic post-mortem examination of the dead animal (normal lesions from dosing were seen on the animal's back). The death of this animal does not appear to have been due to administration of the test material.

Following administration of the topical challenge dose, all 19 test animals and 10 irritation control animals were free of irritation responses at challenge (two animals had scores of 0.5). The severity indices for test animals at 24 and 48 hours were 0.1 and 0.0, respectively, compared with 0.0 at 24 and 48 hours for the irritation control animals. The incidence index of sensitisation to the test material at challenge was 0 %.

III - CONCLUSIONS

On the basis of the test results obtained, the preparation (OEC_PHE_EX) does not warrant classification as being a dermal sensitizer.

(Crown H 1996f)

IIIP 7.3.1 **Estimation of operator exposure**

Report: IIIA 7.3.1/01 Seacombe H 1996, Estimation of operator exposure for OEC_PHE_EX, Report Number CCC-96-4623

Exposure Models: No validated model available for the specific use scenario.

Estimations (protective clothing not worn): The estimated operator exposure values determined using a worst case scenario, assuming protective clothing was not worn are provided in Table IIIP 7.3.1-1. Operator exposure is compared to aerial concentrations of the active substance, which can be expected in situations of high natural infestation with the moth. It is shown that operator exposure remains within a range which can be expected to occur also naturally.

In view of the low toxicity of both, formulated product and active substance, these exposure levels are considered to be acceptable and not to pose any risk to applicators, re-entry workers or bystanders.

Table IIIP 7.3.1-1 Estimations of operator exposure in relation to the AOEL - no protective clothing and equipment used

Situation	Levels in air	Reference
High naturally occurring infestation event:10 mio bugs/ha, each releasing 100 ng SCLP per hour, 1 m air column.	0.1 microgram/l	IIIA 7.3.1/01 Crown H 1996b
Monitoring during field studies at recommended use rate	0.02 microgram/l	IIIA 7.3.1/02 Crown H 1996c
Release from dispensers at 40°C (worst case)1 microgram per hour per dispenser, 1.000 dispensers per ha, 1 m air column	0.1 microgram/l	IIIA 7.3.1/02 Crown H 1996d

It is concluded that exposure levels remain within the range of naturally occurring background levels. No health risk of operators is therefore expected.

IIIP 7.3.3 **Measurement of operator exposure**

During field development monitoring of aerial concentrations of PHEROMX were measured. Results were in the range of 0.2 - 0.4 micrograms per litre, which demonstrated that exposure levels remain within the range of naturally occurring

background levels. On this basis it is concluded that uses of OEC_PHE_EX according to label instructions will not lead to any health risk of operators.

IIIP 7.4.1 **Estimation of bystander exposure, assuming personal protective equipment is not used**

During field development monitoring of aerial concentrations of PHERO were measured (see above). Results show that conditions of usage of OEC_PHE_EX as proposed pose no risk for possible spectators.

IIIP 7.5.2 **Estimation of re-entry worker exposure, assuming personal protective equipment is not used**

During field development monitoring of aerial concentrations of PHERO were measured (see above). Results demonstrate that exposure levels remain within the range of naturally occurring background levels. On this basis it is concluded that uses of OEC_PHE_EX according to label instructions will not lead to any health risk of workers in the treated area.

IIIP 7.6 **Dermal absorption**

The formulation is packaged in polyethylene dispensers. No direct contact to the formulation is likely to occur. In view of the low dermal toxicity of the active substance (see Annex II) a dermal exposure study is not considered necessary. Data requirement is therefore waived.

IIIP 7.8 **Epidemiology**

Since OEC_PHE_EX is a new plant protection product containing the new active substance PHEROMX, epidemiological data does not yet exist.

IIIP 7.9.1 **Material safety data sheet for each formulant**

Copies have been provided (Document H).

IIIP 7.9.2 **Available toxicological data for each formulant**

Additional data is not currently available to the applicant.

IIIP 7.10 **Domestic animal / livestock safety**

Since residues in feedingstuffs or in pet food will not exceed natural background levels, dietary exposure will be insignificant.

IIIP 7.11 **Other / special studies**

None were deemed necessary.

PART 3

Section 6 Ecotoxicological Studies

The example of a summary and assessment of data which follows is intended to illustrate the approach recommended for the preparation of *Tier II* summaries and assessments. The material included has been critically assessed for its technical content. The data presented in the following summary and evaluation are not based on a real substance.

Applicants should be aware that these guidelines are intended to provide a degree of flexibility. Where in particular cases, it is more appropriate to present data in another format, applicants can seek to do so. In such cases it is recommended that the applicant discuss the format proposed with the Regulatory Authority of the Country to which application is to be made.

For the purposes of calculating toxicity exposure ratios (TER values), distances and scenarios used as a basis for estimation of predicted environmental concentrations (PEC values) should reflect the results of risk assessments carried out *i.e.* where a calculation based on overspray is provided to illustrate the worst case likely to arise, it should be followed by a calculation reflecting risk mitigation measures proposed, such as use of buffer zones

IIIP 10.1 **Birds**

OEC_PHE_EX is an insecticide intended for use as a mating disruption agent. The recommended application rate is 1.000 dispensers per ha, equivalent to 13L of OEC_PHE_EX or 200 g of the active substance. One application per season is proposed.

OEC_PHE_EX is to be applied in retrievable polyethylene dispensers. No avian exposure will arise as a result of contact with the product or treated foliage and soil and as a result of ingestion of avian food sources contained therein.

All data requirements are therefore waived.

IIIP 10.2.1.11 **TER_{LT} for algae**

OEC_PHE_EX is to be applied in retrievable polyethylene dispensers on land. Exposure is unlikely to exceed natural background levels. 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.

IIIP 10.2.2.1 **Acute toxicity (aquatic/fish) of the preparation**

OEC_PHE_EX is to be applied in retrievable polyethylene dispensers on land. Exposure is unlikely to exceed natural background levels. 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.

IIIP 10.3 **Effects on terrestrial vertebrates other than birds**

Toxicity data for human safety are sufficient to assess potential effects to wild mammals, so no further wild mammal testing is required. Exposure is unlikely to exceed natural background levels.

Table IIIP 10.3.1-1 Toxicity of PHEROMX to terrestrial vertebrates

Species	**Exposure**	**Toxicity Value (mg as/kg bw)**	**Reference**
Rat	Acute - Oral LD_{50}	> 5000	Smith H, 1993

IIIP 10.4 **Bees**

OEC_PHE_EX is to be applied in retrievable polyethylene dispensers on land. Exposure is unlikely to exceed natural background levels. 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.

Therefore it is unlikely that the behaviour or reproduction of bees would be affected.

IIIP 10.5 **Effects on arthropods other than bees**

For potential effects of nontarget insects one report and 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 further nontarget testing has been indicated.

IIIP 10.5.1 **Effects on sensitive species already tested, using artificial substrates**

Testing for effects on arthropod species other than bees was carried out using the formulated product OEC_PHE_EX rather than the active substance. Laboratory study was conducted to assess effects on the carabid beetle, *Bembidion tetracolum*.

Report: IIIP 10.5.1/01 Burke H 1994, An evaluation of the side-effects of the insecticide OEC_PHE_EX on adults of the carabid beetle, *Bembidion tetracolum*, Report Number CCC-15234

Guidelines

BBA Guideline VI, 23-2.1.8 which is equivalent to the that contained in the SETAC Guidance document on regulatory testing procedures for pesticides with non-target arthropods

GLP

Fully GLP compliant - laboratory certified by the UK Department of Health and Social Security.

Executive Summary

In an acute toxicity laboratory study, two to three week old, laboratory-bred adult *Bembidion tetracolum* (*Coleoptera* : *Carabidae*) were exposed to OEC_PHE_EX, when placed in groups of six in arenas containing moist sand. Five replicate arenas were treated with OEC_PHE_EX at a rate equivalent to the maximum recommended rate of 13L g product/ha and five with water as a control. An additional two arenas were treated with a toxic reference product (*Afugan* 1L product/ha).

After treatment, the condition of the beetles was monitored for two weeks and their feeding activity was assessed by the provision of fruit fly pupae at regular intervals.

All of the beetles treated with the toxic standard died within 1 day. No beetles died in either the OEC_PHE_EX treatment or the control throughout the study. There was no indication of a reduction in the feeding activity of beetles in the OEC_PHE_EX treatment, when compared with beetles in the control.

These results indicated that OEC_PHE_EX exposure was not harmful to adult Bembidion tetracolum when the beetles were treated topically with the product at its maximum recommended application rate.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: OEC_PHE_EX

- **Description:** pale brown liquid (dispenser)
- **Lot/Batch #:** NPD-9402-5737-F
- **Purity:** 90 % as
- **Stability of test compound:** shown to be stable in an accelerated storage stability test (14 days at 54 °°C)

2. Vehicle and/or positive control: tap water; *Afugan* in tap water

3. Test animals -

- **Species:** *Bembidion tetracolum (Coleoptera : Carabidae)*
- **Age:** Less than 3 weeks
- **Source:** Bio-Test Labor GmbH, Sagerheide, Germany
- **Acclimation period:** 3 days
- **Environmental conditions -**
- **Temperature:** 20 °°C
- **Photoperiod:** 16-hour photoperiod of low intensity light (< 300 lux)

B. STUDY DESIGN AND METHODS:

1. In life dates: 5 to 22 May 1994

2. Experimental treatments

Adult beetles (*Bembidion tetracolum*), 2 to 3 weeks old at treatment, were acclimatised to the test conditions without food for 3 days prior to treatment, in groups of 6 (3 males and 3 females), at *circa* 20 °C with 16 hour photoperiod of low intensity light (< 300 lux). The test arenas consisted of pots (diameter 9 cm, height 4 cm) containing sand at 70 % of water holding capacity. Just prior to application, a group of beetles was transferred to a test arena and provided with 2 *Drosophila melanogaster* pupae per beetle. OEC_PHE_EX was sprayed onto the sand, beetles, and food in the test arena at an application rate equivalent to 37.5 g/ha. *Afugan*, a reference standard, was applied to separate test arenas at a

rate of 1 L/ha. Five replicate chambers were used for the control treatments and a further five were used for the OEC_PHE_EX treatments, while 2 replicate chambers were used for *Afugan* treatment. Immediately following treatment ventilated lids were placed on the test arenas. The treated pots were maintained at 18 - 22 °C with a 16-hr photoperiod (< 300 lux) for 14 days. Beetles were fed and the moisture content of the sand was adjusted at day 2, 4, 7 and 10.

3. Observations

Beetles were observed at 2 and 4 hours and 1, 2, 4, 7, 10 and 14-day intervals after treatment.

II. RESULTS AND DISCUSSION

A. FINDINGS

All of the beetles treated with the toxic standard died within 1 day. No beetles died in either the OEC_PHE_EX treatment or the control throughout the study. There was no indication of a reduction in the feeding activity of beetles in the OEC_PHE_EX treatment, when compared with beetles in the control.

III. CONCLUSIONS

OEC_PHE_EX was found not to be toxic to carabid beetles at an application rate higher than the maximum field application rate.

Table IIIP 10.5.1-1 **Direct effect of OEC_PHE_EX on the carabid beetle (*Bembidion tetracolum)***

Time after Treatment	Control* (n=30)				OEC_PHE_EX * (n=30)				*Afugan** (n=12)			
	L	A	M	D	L	A	M	D	L	A	M	D
2 h	28	1	1	0	29	0	1	0	0	0	12	0
4 h	28	1	1	0	30	0	0	0	0	0	8	4
1 d	30	0	0	0	30	0	0	0	0	0	0	12
2 d	30	0	0	0	30	0	0	0				
4 d	30	0	0	0	30	0	0	0				
7 d	30	0	0	0	30	0	0	0				
10 d	30	0	0	0	30	0	0	0				
14 d	30	0	0	0	30	0	0	0				

* Beetles categorised as alive (L), affected (A), moribund (M), or dead (D)

Table IIIP 10.5.1-2 **Effect of OEC_PHE_EX on the food consumption of carabid beetles**

	Mean Number of *Drosophila* pupae eaten / surviving beetle		
Days after Treatment	Control	OEC 2222	*Afugan*
0-2	1.97	2.00	0
2-4	1.73	1.67	
4-7	1.53	1.43	
7-10	1.30	1.67	
10-14	1.07	1.30	

(Burke H 1994)

IIIP 10.6 **Earthworms and other soil macro-organisms**

OEC_PHE_EX is to be applied in retrievable polyethylene dispensers on land. Exposure is unlikely to exceed natural background levels. 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.

All data requirements are therefore waived.

IIIP 10.7 **Soil microbial activity**

OEC_PHE_EX is to be applied in retrievable polyethylene dispensers on land. Exposure is unlikely to exceed natural background levels. 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.

All data requirements are therefore waived.

IIIP 10.8 **Effects on non-target terrestrial plants**

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

IIIP 10.10.2 **Other / special studies - field studies**

In the context of .....*(in the interest of brevity and to avoid the inference that particular justifications have universal application, the remainder of the text is omitted)*

IIIP 10.11 **Summary and evaluation of points IIIA 9 and IIIA 10.1 to 10.10, together with a detailed and critical assessment of the data**

A summary and assessment of points IIIP 9 and IIIP 10.1 to 10.10, is included in the *Tier III* overall summary and assessment (active substance and formulated product dossiers), provided (Document N).

PART 4

Section 7 Efficacy Data and Information

The summary and assessment of efficacy data prepared for individual plant protection products, should take the form of a ***biological dossier*** which should allow a comprehensive understanding of the application and facilitate evaluation and decision making having regard to the evaluative and decision making criteria which are relevant in the country to which application is made, notwithstanding the clear need for reference to some or all of the individual study reports during the course of evaluating the data base concerned.

The example of a summary and assessment of data which follows is intended to illustrate the approach recommended for the preparation of *Tier II* summaries and assessments. The material included has not been critically assessed for its technical content. The data included in the following summary and evaluation are not based on a real submission.

Applicants should be aware that these guidelines are intended to provide a degree of flexibility. Where in particular cases, it is more appropriate to present the data and information in another format, applicants may do so. In such cases it is recommended that the applicant discuss the format proposed with the Regulatory Authority of the Country to which application is to be made.

Introduction

I **PHEROMX**

PHEROMX is a pheromone, consisting of three components, which all belong to the class of straight chain lepiodteran pheromones. The substances, in the composition provided in PHEROMX, effectively disrupts mating by disorienting the females so they can not locate their mating partners.

ii **OEC_PHE_EX**

OEC_PHE_EX is to be applied in retrievable polyethylene dispensers at a rate of 1.000 dispensers per ha, equivalent to 13L of OEC_PHE_EX or 200 g of the active substance.

(a) **Efficacy of the plant protection product**

A single application is recommended, during May/June, depending on local conditions, pest pressure and other factors. Duration of control is for one season.

Following application the active substance evaporates slowly from its microcapsule. Overall, the aerial concentrations reached in the treated area are comparable to high natural infestation events.

(b) **Adjuvants**

Only water has been used to dilute the product.

©) **Pests in forestry**

Insect anonymia is a pest of pines. *Insect anonymia* overwinters as a pupae on the ground. Moths emerge in the spring with peak adult activity occurring from late April to mid-May. Male moths locate females through pheromone communication. The adult flight season generally lasts four to five weeks. Eggs are laid either on the bark, needles, needle sheaths or buds of new shoots and generally hatch within two to four weeks. First instar larvae bore directly into the pith region and tunnel toward the base of the shoot. The insect passes through five larval stages, each of which feeds in a tunnel within the shoot. At the end of feeding, the mature larvae chews an exit hole in the shoot, drops to the ground and pupates within a cocoon in the soil. There is a single generation per year.

Both lateral shoots and the terminal leader may be attacked by eastern pine shoot borer. Early symptoms of feeding damage include slow growth of needles. Feeding by late-instar larvae causes loss of turgidity and internal structural support of the shoot, which may result in drooping of the terminal portion of the shoot. Killed shoots eventually bend over and are broken off leaving a short distinctive stub.
Insect anonymia rarely kills the host tree; however, repeated attack of shoots in the upper canopy can result in malformation of the tree crown. Attack of the terminal leader result in forking and a reduction in height growth.

(d) **Supporting information from earlier formulations of the active substance or similar active substances**

No other formulations containing PHEROMX have been developed to-date. Data concerning plant protection products containing similar active substances are not available to the applicant.

(e) **Further relevant data on the active substance and formulation**

Details of intended use: *Insect anonymia* in forestry.

Details of harmful organisms against which protection is afforded

Insects controlled
Insect anonymia

Application rate: 1.000 dispensers (200 g of active ingredient) per hectare

Concentration of active substance in material used The active substance consists of three active components with a total concentration of 150 g/kg.

Method of application OEC_PHE_EX is to be applied in dispensers.

Maximum number of applications and their timing A single application is recommended during May/June.

For each application, growth stages of the crop or plants to be protected Not applicable.

For each application, development stage of the harmful organisms concerned Application in the spring peak during the adult flight season.

Duration of protection afforded by each application A single application is recommended.

Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops A period of 60 days is recommended.

Limitations on choice of succeeding crops There are no limitations on choice of succeeding crops.

Description of damage to rotational crops No damage was observed to rotational crops.

(f) **Proposed label text**

CROP	forestry
VARIETIES	pines
APPLICATION TIMING A single application is recommended, during May/June, depending on local conditions, pest pressure and other factors. Duration of control is for one season	
PRODUCT	OEC_PHE_EX

Dose Rate **PLUS** Additional recommended surfactant	1.000 dispensers (200 g of active ingredient) per hectare n.a.

INSECT SPECIES CONTROLLED		
insects: *Insect anonymia*	**Susceptibility** S	**Growth stage controlled** disrupts mating by disorienting the females so they can not locate their mating partners
SUSCEPTIBILITY RATINGS S = Susceptible MS = Moderately susceptible Suppression = Reduction in plant biomass but incomplete control		

IIIP 6.1.3 **Efficacy trials - operational, large scale**

Testing facility or organization

Data to support the label claims and which are summarized in this biological dossier were generated in a total of 36 trials, carried out in the UK, Ireland and Germany during the period 1994 to 1997. All trials were carried out by officially recognized organisations in accordance with the Principles of *Good Experimental Practice* (GEP). Further details of the individual trials conducted are provided in Table IIIP 6.1.3-1.

Appendix 8 **Format for the compilation of *Tier II* summaries - Formulated Product**

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

Table IIIP 6.1.3-1 Format for presentation of information concerning trials sites and application details in summary form

Type of trials: effectiveness / phytotoxicity / other	:	effectiveness
Identity of the product under test (commercial name (s), active substance (s), content, formulation type (s)	:	OEC_PHE_EX
Crop	:	Forestry
Harmful organism (common name, scientific name, Bayer Code) or intended use	:	*Insect anonymia*
Responsible body for reporting trial (name, address and telephone number)	:	Chemco, 36 – 39 Plant Street, Marlborough, Wiltshire, England, +.44.1345 6789112
Date of submission	:	September 1998

Company name

Test Report (1)	Testing Unit (2)	Trial Location (3)	Test Method Plot Size (4) Sample Size (5)	Application details			Remarks
				Method (6)	Equipment (7)	GS Harmful organism incidence (8)	
94-267-000	Agronomy Department, University College	Clonalvey, Meath, Ireland	EPPO 93, 152 & 181 6.0m x 10m (60m^2) 4 x 0.1m quadrants	fixed dispensers	dispenser	*Insect anonymia* 93 % infestation	
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Notes: (1) Indicate the test report number including the year of establishing the trial (*e.g.* PM 96/1)

2. Indicate the name, address and telephone number of the test unit
3. Indicate the precise location of the trial and the country in which it was conducted (*e.g.* Rheims, France)
4. Indicate the plot size
5. Indicate the sample size per plot
6. Indicate the method of application
7. Indicate the type of equipment used
8. Indicate the growth stage (s) (GS) of the crop and where relevant weeds, in accordance with the BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), at each application and the corresponding severity of incidence of harmful organism

MATERIALS AND METHODS

Sites

Sites were selected on the basis of a history of infestation, in areas representative of those where the crop is grown commercially.

Experimental details

Trials were carried out to evaluate the efficacy and crop safety of OEC_PHE_EX when applied in the spring peak during the adult flight. Trial plot size ranged from 1-2 ha.

Formulations applied and application rates

Details of the formulations tested follow (Table IIIP 6.1.3-2), while details of application rates and timings are provided in Table IIIP 6.1.3-3.

Table IIIP 6.1.3-2 Formulations included in efficacy trials

Product	Authorisation Number(s)	Active substance	Active substance content	Formulation type
OEC_PHE_EX	Not available	PHEROMX	150 g/kg	dispenser
CHEMX	MAFF 04932 PCS 91585	Chemx	800 g/kg	WG

Application methods

Treatments were applied to all trials using dispensers (PHEROMX) and a foliar plot sprayer, calibrated to apply a spray volume of 200 – 250 L/ha for CHEMX. Further details of the method of application used in individual trials are summarized in the individual trial reports.

Assessment methods - insect control

Efficacy was assessed by placing pheromone baited traps in the treated and untreated plots and recording trap catches of male moths following application.

Table IIIP 6.1.3-3 Rates of application and timing of applications

Trial reference numbers	Product	Application timing	Application rate	
			g as / ha	product / ha
94-267-000	Untreated	-	-	-
94-267-007	OEC_PHE_EX	May	200	1.000 dispensers
	OEC_PHE_EX	May	150	1.000 dispensers
	OEC_PHE_EX	May	250	1.500 dispensers
	OEC_PHE_EX	June	200	1.000 dispensers
	OEC_PHE_EX	June	150	1.000 dispensers
	OEC_PHE_EX	June	250	1.500 dispensers
	OEC_PHE_EX	May	100	500 dispensers
	OEC_PHE_EX	June	100	500 dispensers
	OEC_PHE_EX	May	50	250 dispensers
	OEC_PHE_EX	June	50	250 dispensers
96-152-001	Untreated	-	-	-
96-152-005 96-259-004	CHEMX	May	800	1250 g
	OEC_PHE_EX	May	200	1.000 dispensers
96-152-006	Untreated	-	-	-
96-152-022 96-259-001	OEC_PHE_EX	May	200	1.000 dispensers
	OEC_PHE_EX	June	250	1.000 dispensers
	OEC_PHE_EX	May	200	1.000 dispensers

In trial XX, 3 x 1ha^2 quadrants/plot were assessed and in trials YY, YY and ZZ, 5 x 1ha^2 quadrants/plot were assessed and from the data generated, the mean percentage trap catches of male moths per treatment was calculated.

Assessment methods – crop yield

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.

Assessment methods – crop safety

Crop safety was assessed on an overall plot basis, as the mean % leaf area affected by chlorosis and necrosis.

Assessment methods – safety in following crop

Phytotoxicity in the following crops was assessed, 1 and 2 years after application. Crops were examined for effects such as stand reduction, growth reduction. The mean % leaf area affected by either chlorosis or necrosis was recorded.

Details of assessment dates, the assessment types and crop growth stages are provided in Table IIIP 6.1.3-4. The

information included in the table is that used to support the proposed label claims. Further assessments were carried out in individual trials, which are fully described in the individual trial reports.

Statistical analysis

Data were analysed using two-way analysis of variance (ANOVA) on untransformed and transformed data. The probability of no significant differences occurring between treatment means was calculated as the F probability value (pF). Significant differences reported where the pF value was greater than 0.05 should be interpreted with caution as these are derived at correspondingly lower levels of confidence than the generally accepted 95 % confidence limit.

Duncan's Multiple Range (DMR) test was then applied to assess any treatment differences identified on the basis of the ANOVA TEST. Results obtained are indicated by a letter - treatment means with no letters in common are significantly different in accordance with a DMR conducted at a 95% confidence level.

Where data have been transformed, treatment means in the trial report are presented in their untransformed state, with the appropriate letter test derived from the transformed ANOVA. Plot mean data, analysis details of untransformed data, and analysis details of any data subjected to transformation/detransformation are included in the individual trial reports.

The tabulated data presented in this ***biological dossier*** only represents the means of selected treatments, within an assessment. However, the statistics presented in conjunction with these data are derived from all data points from all treatments within the assessment. Tables of data comprising all treatment means are presented in the individual trial reports.

Where appropriate, treatment effects are reported in terms of a percentage of the untreated control. The values for the untreated control are indicated in individual table keys.

Table IIIP 6.1.3-4 Details of assessments carried out in efficacy tests with OEC_PHE_EX

Trial no	Assessment date		Assessment type
94-267-000	11.07.94	-	% Chlorosis
	12.09.94	-	% Insect control (visual)
94-267-003	29.07.94	-	% Insect control (visual)
	20.07.95	-	% Insect control (count)
94-267-005	01.08.94	-	% Insect control (visual)
94-267-006	27.07.94	-	% Insect control (visual)
	27.07.95	-	% Insect control (count)
	27.08.94	-	Yield
94-267-007	21.06.94	-	% Chlorosis
	27.07.94	-	% Insect control
94-267-008	02.08.94	-	% Insect control (visual)
	02.05.95	-	Phytotoxicity in following crop
94-267-009	02.08.94	-	% Insect control (visual)
	07.07.95	-	% Insect control (count)
	02.05.95	-	Phytotoxicity in following crop
94-267-010	02.08.94	-	% Insect control (visual)
	19.05.95	-	Phytotoxicity in following crop

94-267-015	09.06.94	-	% Insect control (visual)
94-267-018	22.07.94	-	% Insect control (visual)
	24.07.95	-	% Insect control (visual)
	06.09.94	-	Yield
94-267-022	29.06.94	-	% Insect control (visual)
94-298-146	11.05.94	-	% Chlorosis
	08.08.94	-	Yield (INSECT FREE)
	31.10.94	-	Phytotoxicity in following crop
	05.12.94	-	Phytotoxicity in following crop
	19.05.95	-	Phytotoxicity in following crop
	09.08.95	-	Phytotoxicity in following crop
94-298-147	10.05.94	-	% Insect control (visual)% Chlorosis
	20.06.94	-	% Chlorosis
	14.08.94	-	Yield
	01.11.94	-	Phytotoxicity in following crop
	02.12.94	-	Phytotoxicity in following crop
	25.04.95	-	Phytotoxicity in following crop

IIIP 6.2.1 **Phytotoxicity to target plants (including different cultivars) or to target plant products**

Assessments for the phytotoxic effects of OEC_PHE_EX were made in a total of 24 trials. There were no necrotic effects or crop vigour effects in any of the trials at any time of assessment.

IIIP 6.2.3 **Adverse effects on site of application (discolouration, corrosion, *etc.*)**

The occurrence of chlorosis was noted in none of the conducted trials.

IIIP 6.2.4 **Adverse effects on beneficial and other non-target organisms**

There were no adverse affects on beneficial and other non-target organisms observed in any of the effectiveness and phytotoxicity trials conducted. Further testing of OEC_PHE_EX is also not required because exposure is not likely to exceed natural background levels.

IIIA 6.2.7 **Impact on other plants including adjacent crops**

Because OEC_PHE_EX is to be applied in retrievable polyethylene dispensers no crop damage associated with the use of OEC_PHE_EX is likely to occur. Also observations from efficacy trials and literature indicate no potential adverse effects.

IIIP 6.4.2 **Compatibility with current management practices including IPM**

There are no chemical insecticides registered for control of *Insect anonymia*. Control with chemical insecticides is considered to be difficult as the larvae are internal feeders. High application of a systemic insecticide as soil treatment

have been reported to provide good control of larvae. However, such treatment is considered impractical except for individual high-value trees.

A number of species of hymenopterous parasites are known to attack *Insect anonymia*. There are no known attempts of rearing and release of predators or parasites for control of *Insect anonymia*.

Pruning and removal of infested shoots may reduce population levels in the following year. However, this activity is very labour intensive and is practical only in small, high-value plantations of small trees.

IIIP 6.4.3 **Contribution to risk reduction**

See IIIP 6.4.2.

IIIP 6.6 **Summary and evaluation of data presented**

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.