

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



FORM HS3

Application for approval to IMPORT OR MANUFACTURE ANY HAZARDOUS SUBSTANCE IN CONTAINMENT

under section 31 of the
 Hazardous Substances and New Organisms Act
 1996

Name of Substance(s): Light brown apple moth (*Epiphyas postvittana*) pheromone mating disruption formulations containing E11-tetradecenyl acetate, E9,E11- tetradecen-1-yl acetate, and inert components

Applicant: Scion (New Zealand Forest Research Institute Limited)

Office use only

Application Code: Date
 received: 5 / 2 / 08

ERMA NZ Contact: _____ Initial Fees Paid: \$

Application Version No: 8

IMPORTANT

1. Before you fill in this application form, you may find it helpful to consult the *User Guide to Hazardous Substance Applications under the HSNO Act 1996*. This User Guide can either be downloaded from our website or purchased from ERMA New Zealand.
2. Part E of the User Guide covers applications under Section 31 of the Act and all of the cross references to this guide that are in this application form relate to Part E.
3. You can also talk to an applications officer at ERMA New Zealand who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process.
4. This application form may be used to seek approvals for more than one hazardous substance where the substances are related, for example a concentrated compound (active ingredient) and its related formulations, or a range of substances for similar purposes to be tested in a field trial.
5. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included in an Appendix to the application form.
6. Commercially sensitive information must be collated in a separate Appendix.
7. Applicants must sign the form and enclose the correct application fee. The initial application fee can be found in our published *Schedule of Fees and Charges*. Make sure that you have an up to date copy of the Schedule. Please check with ERMA New Zealand staff. We are unable to process applications that do not contain the correct fee.
8. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed. Where an applicant is unable to complete the sections marked optional, this information may be derived by ERMA New Zealand and the costs of doing so will be recovered from the applicant as part of the processing costs.

You can get more information at any time by contacting us. One of our staff members will be able to help you.

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NEW ZEALAND
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www.ermanz.govt.nz

Section One – Applicant Details

See comments under “Section One of Application Form” in the User Guide for guidance.

1.1 Name and postal address in New Zealand of the organisation making the application:

Name: Scion (New Zealand Forest Research Institute Limited)

Address: PO Box 29237, Christchurch 8540

Phone: (03) 364 2949

Fax: (03) 364 2812

1.2 The applicant’s location address in New Zealand (if different from above):

Address: Forestry Road, University of Canterbury, Christchurch

1.3 Name of the contact person for the application :

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions on behalf of the applicant that relate to processing the application, or have the ability to go to the appropriate authority.

Name: Dr. Eckehard Brockethoff

Position: Group Leader, Entomology

Address: PO Box 29237, Christchurch 8540

Phone: (03) 364 2949

Fax: (03) 364 2812

Email: eckehard.brockethoff@scionresearch.com

Section Two – Application Type and Related Approvals Required

This form is only to be used for an application to import a hazardous substance into containment or manufacture a hazardous substance in containment.

If you are making the application for some other reason, you will need a different form.

2.1 Is this application to manufacture or import a hazardous substance in containment for any of the following purposes:

Containment applications can only be made for a limited range of purposes. In particular it is not intended for commercial manufacture or sale.
(See comments under “Section 2.1 of Form” in the User Guide)

- Small amounts of any hazardous substance for use as an analytical standard where approval to import or manufacture that substance has been declined? Yes/No
- Research on any hazardous substance to acquire information for use in assessing that substance for a HSNO approval? Yes/No
- Research and development on any hazardous substance? Yes/No
- Use in an emergency? Yes/No
- Other purposes? Yes/No

2.2 If you answered yes to one of the purposes listed above, please provide some supporting detail. If you answered yes to “other purpose”, describe the purpose and explain why this purpose is appropriate to a containment application. (See comments under “Section 2.2 of Form” in the User Guide)

This application is to seek approval for the limited aerial application of “low hazard” (non-toxic) formulations of mating disruption of light brown apple moth (*Epiphyas postvittana*) over a small area (ca. 100 ha) of pine plantation forest in North Canterbury (Eyrewell Forest). In addition, one ground-applied treatment of Isomate “twist-ties” is planned as a further treatment. This is to support an emergency response, the eradication of *E. postvittana* which has recently been detected as an invasive species (native to Australia) and biosecurity threat in California. The United States Department of Agriculture (USDA) urgently needs efficacy data to determine which formulation would be the most successful in their effort to eradicate this insect in California, ahead of the planned treatments in the northern hemisphere spring. The insect is present in New Zealand which allows this research to be conducted now whereas it would not be possible during the current northern hemisphere winter. One of the four the formulations (or equivalents) we plan to test has already received approval for use in the United States by the U.S. Environmental Protection Agency (EPA) which considers all straight-chained lepidopteran pheromones to be “not hazardous”. Two formulations are currently under review by the U.S. EPA, and the USDA will be seeking authority for to use the fourth formulation depending upon the results of this field trial. An initial response from ERMA New Zealand (Beth Dye, e-mail 21 Dec. 2007) recommended that we submit a ‘containment application’ to determine whether ERMA approval is required and to accommodate the urgency of this application.

Note that the research will be observed by MAF-Biosecurity New Zealand because it is likely to be beneficial for future eradication campaigns against similar pests in New Zealand. Because of the possibility of reducing or avoiding pesticides, the use of pheromone formulations, containing naturally occurring active ingredients, is preferred. This information would be invaluable in the likely event that a similar invasive species needs to be eradicated in New Zealand. It would greatly enhance the experience of local biosecurity experts with using this technique which has considerably more environmentally friendly than the use of pesticides.

2.3 Is the information in this application relevant to import, manufacture or both?
(See comments under "Section 2.3 of Form" in the User Guide)

- Import the substance(s) only? Yes/No
- Manufacture the substance(s) only?
Yes/No
- Import and manufacture the substance(s)?
Yes/No
- If import only, indicate whether or not manufacture is likely in New Zealand
Yes/No

2.4 If the information in the application relates to manufacture of the substance(s) in New Zealand, provide information on the proposed manufacturing process and any alternatives.
(See comments under "Section 2.4 of Form" in the User Guide)

NA

2.5 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?
(Optional) (See comments under "Section 2.5 of Form" in the User Guide)

Name of Approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	Yes/No/ <u>NA</u>
Food Act 1981	Yes/No/ <u>NA</u>
Medicines Act 1981	Yes/No/ <u>NA</u>
Chemical Weapons (Prohibition) Act 1996	Yes/No/ <u>NA</u>
Radiation Protection Act 1965	Yes/No/ <u>NA</u>
Biosecurity Act 1993	Yes/No/ <u>NA</u>
Resource Management Act 1991	Yes/No/ <u>NA</u> *
Other (please specify):	Yes/ <u>No</u>
	Yes/No

* **Environment Canterbury** has advised that aerial applications of these products can be done as a "permitted activity" (aerial application of agrichemicals to plantation forest) if ERMA approval will be obtained and if appropriate buffer zones from any water ways can be maintained. We expect to receive confirmation of this in writing.

Note, Maree Zinzley of the **NZ Food Safety Authority** advised (e-mail to Susan O'Toole, USDA, 6 January 2008, with copy to Beth Dye) that pheromone products are exempt from registration for the use over non-food commodities.

The **Department of Conservation** has been informed (letter sent 18/01/2008, Appendix). Several responses were received (forwarded to Noel McCardle, ERMA NZ) and all of these were supportive of the project and did not express any concerns about native species, habitats, or otherwise.

Section Three – Information on the Substance(s)

Note all information that is commercially sensitive must be attached as an Appendix. The application form should be cross-referenced to the Appendix but should be able to be read as a stand-alone document which will be publicly available.

If approval is being sought for more than one hazardous substance, this section must be completed separately for each hazardous substance.

3.1 State the unequivocal identification of the substance(s).

This section should include enough information to unequivocally identify the substance(s) and may include:

Chemical Name (Chemical Abstracts Preferred Index name or IUPAC name)

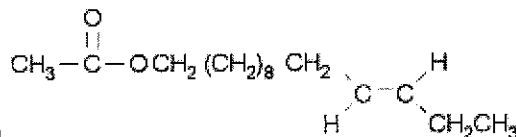
- Common Name: Light brown apple moth (*Epiphyas postvittana*) pheromone containing two substances (see 3.1.a and 3.1.b below), plus inert components as mating disruption formulations (four formulations, see details below, Appendices 1-4). The two active ingredients will be present in the same ratio (20:1) and coming from the same manufacturer (Bedoukian). The four formulations plus a sticker to be used in conjunction with the Hercon Disrupt Bioflake product are identified by the following trade names:

1. CHECKMATE LBAM-F (by Suterra LLC)
2. NoMate LBAM MEC (by Scentry Biologicals, Inc.)
3. Splat LBAM (by ISCA Technologies, Inc.)
4. Disrupt Bioflake LBAM (by Hercon Environmental)
5. X3221 Micro-Tac II Sticker Agent (by Lock N Pop, for use with the Hercon product)

For contact details see below

3.1.a

- Chemical Name (E)-11-Tetradecenyl acetate
- Common Name Light Brown Apple Moth (LBAM) Pheromone
- Synonyms (E)-11-TDA; E-11-TDA
- CAS Registry Number 33189-72-9
- Molecular Formula C₁₆H₃₀O₂



- Structural Formula
- Significant impurities None (Identification of chemical impurities is considered to be Confidential Business Information under U.S. law and so will be submitted separately in a confidential manner by each company in the form of a Confidential Statement of Formula, a standard submission required for all chemical companies by the U.S. Environmental Protection Agency. If further information is required, please let us know.)

3.1.b

- Chemical Name (E,E)-9,11-Tetradecadien-1-yl acetate
- Common Name Light Brown Apple Moth (LBAM) Pheromone
- Synonyms N/A
- Trade Names CHECKMATE LBAM-F
- CAS Registry Number 54664-98-1
- Molecular Formula C₁₆H₂₈O₂
- Structural Formula N/A
- Significant impurities: None (see above)

For mixtures, in addition to the above information being provided on the actual mixture, information is also required on the composition of the mixture ie the chemical name, CAS number, function (eg active ingredient, emulsifier, surfactant, filler) and percentages of ALL components of the mixture (including non-hazardous components and impurities) should be provided. This information may be best expressed in tabular form. If the composition is variable, please ensure to state the limits.

Yes, these products are mixtures, and the relevant information will be submitted confidentially in the form of a Confidential Statement of Formula, as described in the paragraph above

If there are commercial reasons for not providing full information in the main part of the form, alternative approaches must be discussed with and agreed by ERMA New Zealand. These must include the provision of a unique identifier of some kind.

(See comments under "Section 3.1 of Form" in the User Guide)

Contact details

CHECKMATE LBAM-F

Tom Larsen

Suterra LLC

213 SW Columbia Street

Bend, OR 97702 – U.S.A.

e-mail: tlarsen@suterra.com

Cell: +1541-350-4602 (works worldwide)

(or Steven Hartmeier (President) and Jeremiah Wilson (Manager, International Relations))

shartmeier@suterra.com; jwilson@suterra.com; Phone (541) 317 2211; fax(541) 317 2268)

NoMate LBAM MEC

Gerry Bohmfalk (Director - Research and Development)

Scentry Biologicals

Montana Office

gtb123@qwest.net

Tel 520-364-3541 office, 520-220-8672 cell, 1-800-735-5323

Splat LBAM

Agenor Mafra-Neto (CEO & President), Reg Coler (Vice-president), and Michelle Lee (Marketing Coordinator)

ISCA Technologies, Inc.

2060 Chicago Avenue, Suite C2

Riverside, CA 92507, USA

president@iscatech.com

Tel. +1 (951) 686 5008

Disrupt Bioflake LBAM

Priscilla Maclean (Product Development Manager)

Hercon Environmental

P.O. Box 435

Emigsville, PA 17318, USA

pmaclean@herconenviron.com

Phone direct (717) 779-2018

phone (717) 764-1192 EXT 2262, fax: (717) 767-1016

X3221 Micro-Tac II Sticker Agent (for use with the Hercon product)

Rosanna Cavanaugh and Bob Kostric

Lock N Pop / Key Tech Corporation

rosanna.cavanaugh@locknpop.com

Key Tech Corporation

ISOMATE®-LBAM PLUS “twist-ties”

Kathy Bolan (Registration Agent)

Pacific Biocontrol Corporation, USA (for Shin-Etsu Chemical Co., Japan)

Phone: 707-337-9801, Fax: 707-963-3541

Email: kbolan@pacificbiocontrol.com

3.2 Provide information on the chemical and physical properties of the substance(s).
Provide as much information as possible on the chemical and physical properties of the substance(s) [at 20° C and 1 atmosphere unless otherwise stated] eg

- Appearance Pheromone blend: Yellow liquid with a characteristic waxy, mild odour.
- Formulated in four different formulations (see appendices)
- pH 6.5 – 7.0 for aqueous phase
- Molecular weight (E)-11-Tetradecen-1-yl acetate 254
- (E,E)-9,11-Tetradecadien-1-yl acetate 252
- **Formulations:**
 - Disrupt Bioflake LBAM (by Hercon Environmental)
 - Splat LBAM (by ISCA Technologies, Inc.)
 - CHECKMATE LBAM-F (by Suterra LLC)
 - NoMate LBAM MEC (by Scentry Biologicals, Inc.)
- Density Formulation: 0.98 g/ml
- Vapour density Pheromone blend: > 1
- Boiling/melting point 100 °C for water component; 70 °C for Pheromone blend
- Vapour pressure Pheromone: Not applicable for formulated product
- Solubility in water N/A for Aqueous suspension. Low solubility for the pheromone.
- Water/octanol partitioning co-efficient N/A

For mixtures, information is required on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of EACH hazardous component of the mixture.
(See comments under “Section 3.2 of Form” in the User Guide)

All four formulations are mixtures (of inert components), and detailed information on the composition of each mixture has been (or will be) provided directly to ERMA by the companies (because of the commercially sensitive nature of this information).

**3.3 Provide information on the hazardous properties of the substance(s).
Information should be provided on the hazardous properties of the substance(s) known to the applicant.**

You should consider each of the six hazardous properties below and provide information on those hazardous properties. This information is needed in order to assess risks and determine whether or not and how the substance can be adequately contained.

Hazardous property	Threshold	Classification and Criteria.
Explosive	Not triggered	Refer MSDS - Appendices
Flammability	Not triggered	Refer MSDS – Appendices
Oxidizing agent	Not triggered	Refer MSDS – Appendices
Corrosive substance	Not triggered	Refer MSDS – Appendices
Toxic substance Acute oral Acute dermal Acute inhalation	Not triggered Not triggered Not triggered	Toxicity of pheromone blend based on the similarity of the toxicity of other Straight-Chained Lepidopteran Pheromones (SCLP) (i.e. Codlemone as approved for CheckMate CM-F flowable product HSR007766).
Skin irritation	Triggered	6.3B Classified as moderate skin irritant Refer to study in Appendix “Primary Dermal Irritation Study in Rabbits”
Sensitisation Eye irritation	Not triggered Triggered ?	Do not believe that the effect would put this substance in class 6.4A Refer to study in Appendix 1d)
Mutagenic Carcinogenic Reproductive /developmental Target /organ/systemic	Not triggered Not triggered Not triggered	
Ecotoxicity	Triggered	Cerodaphnia dubia and fathead minnow <i>Pimephales promelas</i> (Pisces) – no effect at up to 24 ppb and 48 ppm, respectively, see appendix “Report-ATL-Pheromone Toxicity Testing[.] pdf” 9.1B (48 hour EC50 Daphnia 8.6 mg/litre- NOEC 3.6 mg/litre – Moderately toxic 96 hour LC50 Rainbow trout 5.87 mg/litre – NOEC < 1.0 mg/litre)

More information on these hazardous properties is given in the text below.

If your substance is a mixture and you cannot provide direct information on its hazardous properties, you can apply mixture rules to the hazardous components of the mixture. If you do this, then you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings.
(See comments under “Section 3.3 of Form” in the User Guide)

Environmental Fate and Toxicity

The substance blend is a concentrated synthetic copy of the Light Brown Apple Moth (LBAM) sex pheromone found naturally in the environment where it is released by the female Light Brown Apple Moth (LBAM) to attract the male moth for mating purposes.

For the purposes of this trial the products will be applied as an aerial spray application once and at a rate of no more than ca. 40 grams active substance per hectare. Some limited aerial application will occur in the same forest area in the days before the treatments for calibration purposes and to determine deposition rates

The active substance is not explosive, oxidizing, flammable and does not hydrolyze in water. The physical and chemical characteristics of this naturally occurring insect pheromone active substance indicate that human or animal intoxication or environmental contamination are not of concern when the preparation is used as recommended.

The technical pheromone blend is not explosive, not flammable (not established for the liquid formulations as the preparations are > 70% water) non-oxidizing (The substance is not expected to react exothermically with combustible materials) and non-corrosive (Still to be determined) and does not hydrolyze in water.

Toxicity of the product is determined by the toxicity of the pheromone active substance blend (none of the ingredients in the substance meet the definition of 'hazardous material' as defined in Council Directive 1999/45/EC (67/548/EEC). The toxicity of this pheromone blend will be similar to the toxicity of other Straight-Chained Lepidopteran Pheromones (SCLP), (e.g. Codlemone as approved for CheckMate CM-F flowable product HSR007766).

Low Toxicity Risk: [none of the ingredients in the substance meet the definition of 'hazardous material' as defined in Council Directive 1999/45/EC (67/548/EEC)].

Acute Toxicity:

Acute Oral LD50 for the rat >5050 mg/kg

Acute Dermal LD50 for the rabbit > 2020 mg/kg

Intratracheal LD50 for the rat > 2.5 ml/kg (Equivalent to LC50 > 5.00 mg /litre of air)

Skin irritation: Rabbit – moderately irritating (refer to Appendices)

Eye irritation: Rabbit – minimal irritation (refer to Appendices)

Skin sensitization: Guinea pig – Negative.

Carcinogen: This requirement has been waived for previous registrations/approvals of Light Brown Apple Moth (LBAM) around the globe. Long term (2 years) oral toxicity and carcinogenicity studies are not necessary to evaluate the hazard of this substance due to the nature of the active ingredient (naturally occurring and volatile pheromone compound), the nature of the end use formulation (micro encapsulated in water) and the negligible risk of exposure of man and the environment to the preparation.

Reproductive Development: Ames mutation assay: Negative (non mutagenic with and without microsomal activation).

Target Organ/Systemic: This requirement has been waived for previous registrations/approvals around the globe. Target organ and systemic studies are not necessary to evaluate the hazard of this substance, due to the nature of the active substance

(naturally occurring and volatile pheromone compound), the nature of the end use formulation (micro encapsulated in water) and the negligible low risk of exposure of man and environment to the substance.

Ecotoxicity: Due to the nature of the active ingredients in the substance (pheromone blend) no effect on soil, water, air, plants or animals is expected. The substance is rapidly degraded by UV-light and oxygen.

Aquatic Toxicity:

48 hour EC50 for the Daphnid *Daphnia magna* is 8.6 mg/litre
 96 hour LC50 for the Rainbow Trout *Oncorhynchus mykiss* is 5.87 mg/litre.

Soil Ecotoxicity: This requirement has been waived for the one formulation (containing a different pheromone for a different, but closely related species) that has previous registrations/approvals around the globe.

Terrestrial Vertebrate Ecotoxicity:

48 hour LD50 for the bird species Northern Bobwhite *Colinus virginianus* > 2050 mg/kg

Terrestrial Invertebrate Ecotoxicity: This requirement has been waived for previous registrations/approvals around the globe.

This data indicates that the substance has a slight risk to the handlers of the substance in terms of what is classified as moderate skin irritation (6.3B) which can be prevented by the use of protective clothing as directed on the label.

Other information

Identification	Classes 6,8,9 controls Regs toxic substances	Description
T1	Regs 11-27	Refers to the setting of an acceptable Daily Exposure Value
T2	Regs 29,30	Refers to the setting of a Workplace Exposure Standard
T4	Reg 7	Refers to spray equipment which must apply the product accurately without leaking
T7	Reg 10	Refers to the carriage of product on passenger service vehicles

Identification	Classes 6,8,9 controls Regs Ecotoxic substances	Description
E1	Regs 32-45	Limiting exposure to ecotoxic substances. The environmental exposure limit (EEL) approach
E2	Regs 46-48	Restrictions on use of substances in application areas
E6	Reg 7	Requirement for equipment used to handle substances

Identification	Identification regulations	Description
I1	Regs 6,7, 32-35, 36 (1)-(7)	Identification requirements, duties of persons

		in charge, accessibility, comprehensibility, clarity and durability
I3	Reg 9	Identifiers for ecotoxic substances
I9	Reg 18	Secondary identifiers for all hazardous substances
I11	Reg 20	Secondary identifiers for ecotoxic substances
I16	Reg 25	Secondary identifiers for toxic substances
I19	Regs 29-31	Additional information requirements, including situations where substances are in multiple packaging.
I21	Regs 37-39, 47-50	General documentation requirements
I23	Reg 41	Documentation for ecotoxic substances (MSDS)
I28	Reg 46	Documentation for ecotoxic substances (MSDS)
I29	Regs 52, 52	Signage requirements

Identification	Packaging regulations	Description
P1	Regs 5, 6, 7(1), 8	General packaging requirements
P3	Reg 9	Criteria that allow substances to be packaged to a standard not meeting Packing Group 1,11,111 criteria
P13	Reg 19	Packaging requirements for toxic substances
P15	Reg 21	Packaging requirements for ecotoxic substances
PS4	Schedule 4	Packaging requirements as per schedule 4
PG3	Schedule 3	Packaging requirements equivalent to UN packing Group 111

Identification	Disposal regulations	Description
D4	Reg 8	Disposal requirements for toxic substances
D5	Reg 9	Disposal requirements for ecotoxic substances
D6	Reg 10	Disposal requirements for packaging
D7	Regs 11, 12	Information requirements for manufacturers, importers, suppliers and persons in charge
D8	Regs 13, 14	Documentation requirements for manufacturers, importers, suppliers and persons in charge

Identification	Emergency management regulations	Description
EM1	Reg 6, 7, 9-118	Level 1 information requirements for suppliers and persons in charge
EM6	Reg 8(e)	Toxic substances: symptoms, first aid, emergency telephone number on the label
EM7	Reg 8(f)	Information requirements for ecotoxic substances
EM8	Reg 12-16, 18-20	Level 2 information requirements for

		suppliers and persons in charge
EM11	Reg 25-34	Level 3 Emergency management requirements: duties of person in charge, emergency response plans
EM12	Reg 35-41	Level 3 Emergency management requirements: secondary containment
EM13	Reg 42	Level 3 Emergency management requirements: signage

3.4 Provide information on what will happen to the substance throughout its whole life from its introduction into New Zealand, its uses, through to disposal.

The information provided needs to reflect the containment character of the application. It will be used in the development of exposure scenarios and the assessment of risks and hence the specification of the containment conditions.
(See comments under "Section 3.4 of Form" in the User Guide)

The four formulations will be imported, aerially applied over a plantation forest in Canterbury (planned for mid-February 2008), pheromones will be released into the atmosphere, and the inerts (all biodegradable) will be decomposed naturally (more information is given on the labels) Containment conditions will be met because treatments will be done such that a **200 m buffer zone** can be maintained along boundaries with neighbouring properties, which will ensure that there will not be any effects outside the treated area. Note, a 200 m buffer zone should be adequate, given the large droplet size and low target wind speeds during the application. Shin-Etsu ISOMATE®-LBAM PLUS "twist-ties" will be ground-applied by tying them around twigs of pine trees at a rate of 600 per ha. LBAM pheromone will evaporate from these devices. Research in Australia indicated that release rates from twist-ties are on average about 20 mg per ha per hour. The release devices will eventually be collected for subsequent disposal (after about 2 months) according to relevant waste disposal regulations.

Manufacture and import

The substances will be imported as formulated products in containers large enough to apply to 25 hectares at a rate of approximately 1000 grams active substance per 25 hectares for each formulation. This provides for an application of ca 40 grams of active substance per hectare Additional product (with and without active ingredient) will be imported for calibration and to assess deposition rates (for more information on the amounts imported see below in section 3.5). Shin-Etsu ISOMATE®-LBAM PLUS "twist-ties" will be imported as a ready-to-use product. Each "twist-tie" contains 0.125 g of active ingredient (LBAM pheromone). The trial will require ca. 15,000 twist-ties, and the import will be somewhat over this amount (to allow for losses and release rate determination).

Transport and Storage

The labels include information on the storage of the product. (Labels in Appendix) The products will be transported by road and air to New Zealand and to the applicants and/or the applicator's premises and will remain stored in appropriate warehouses until application. The substances will initially be stored at Scion, Forestry Road, University of Canterbury, Christchurch 8041. The substance will be labelled in New Zealand by Scion in accordance with the ERMA New Zealand requirements for a hazardous substance

The products will be kept at ambient temperature and not be stored in direct sunlight for prolonged periods.

Product Use

The pheromone is a synthetic copy of the natural sex pheromone of the Light Brown Apple Moth (LBAM) *Epiphyas postvittana* and will be applied to the experimental area in Eyrewell Forest in North Canterbury. The purpose of the application of the formulations is to disrupt mating of the Light Brown Apple Moth (LBAM). This process is intended as a form of moth population control eliminating the need to apply toxic pesticides. Moth populations will be monitored using attractant sticky traps containing super lures.

The products are formulated as either water-based spray of micro-encapsulated particle suspensions (CheckMate LBAM-F and NoMate LBAM MEC), amorphous polymer (wax) (Splat LBAM), or as a biodegradable solid flake (Disrupt Bioflake LBAM). Shin-Etsu ISOMATE®-LBAM PLUS “twist-ties” will be ground-applied by tying them around twigs of pine trees, and these devices will be removed after the trial for appropriate disposal.

The precise application rates are given above and methods of application are detailed on the product label in the Appendices and in the Project Plan. Precautions, First Aid advice and advice for spills are also included on the product labels. To our knowledge, all Material Safety Data Sheets (MSDS) have already been provided to ERMA, or, alternatively, all this information is included on labels (also provided), and will be freely available on request for handlers and users of the product to provide further information on safety, disposal and clean up of spills.

Disposal

The labels clearly specify how much product to mix for each usage, therefore if the label directions are followed there should be no left over formulation. There should be no need to dispose of any product in the sales packs as unused product can be safely stored in its original container until required for a later application. If there is a need to dispose of product it will be disposed of via an approved waste contractor.

Empty containers should be triple rinsed and the rinsate added to the spray tank. Empty containers should be crushed and buried in a suitable landfill.

3.5 Provide information on the quantity of the substance proposed to be imported or manufactured.

This information is used in the development of exposure scenarios and the assessment of risks
(See comments under “Section 3.5 of Form” in the User Guide)

All four aerial formulations will be applied at a rate of ca. 37-50 g per ha (up to 75 g per ha) of active ingredient (LBAM pheromone) (15-30 g of active ingredient per acre), over a total area of 100 ha. Hence the total amount applied of each formulation will be approximately 0.9 – 1.8 kg of active ingredient, plus an allowance for calibration and charging / purging the spray equipment, etc

The ISOMATE®-LBAM PLUS “twist-ties” will be imported as a ready-to-use product. Each “twist-tie” contains 0.125 g of active ingredient (LBAM pheromone). The trial will require ca. 15,000 twist-ties amounting to a total of ca. 1.875 kg, and the import will be somewhat over this amount (to allow for losses and release rate determination).

Below we provide more information on how much the companies wish to import of each formulation (please note that these amounts exceed the quantities that will be needed, in case more product is needed for charging of the equipment, etc.):

CHECKMATE LBAM-F (by Suterra LLC)

Suterra will import less than 24 kg of formulation containing ca. 4 kg of active ingredient (possibly only half that, depending on product availability within the time frame of the trial). In addition, up to 25 kg of blank product (without active ingredient) may be imported.

This product is composed of ca. 17% active ingredient (pheromone) and ca. 83% other ingredients. The planned application rate will be ca. **37.5 g of active ingredient per ha** which corresponds to ca. **220 g of formulation per ha**

NoMate LBAM MEC (by Scentry Biologicals, Inc.)

Scentry intends to import ca. 8 kg of formulation containing 1.6 kg of active ingredient. In addition, up to 6 kg of blank product (without active ingredient) will be imported.

This product is composed of 20% active ingredient (pheromone) and 80% other ingredients. The planned application rate will be ca. **40 g of active ingredient per ha** which corresponds to **200 g of formulation per ha**.

Splat LBAM (by ISCA Technologies, Inc.)

ISCA intends to import up to 40 kg of formulation containing 4 kg of active ingredient. In addition, up to 75 kg of blank product (without active ingredient) will be imported.

This product is composed of 10% active ingredient (pheromone) and 90% other ingredients. The planned application rate will be between **37.5 - 75 g of active ingredient per ha** which corresponds to ca. **375 - 750 g of formulation per ha**. The actual application rate (within the range stated) for this product is still being discussed, and the reason for the difference from the other products is that this one can potentially be applied in large droplets that will provide a longer release.

Disrupt Bioflake LBAM (by Hercon Environmental)

Hercon intends to import 30 kg of formulation containing 4.5 kg of active ingredient. In addition, Hercon will import 50 kg of blank product (flakes without active) and about 190 liters of sticker.

This product is composed of 15% active ingredient (pheromone) and 85% of a biodegradable flake. The recommended rate of application is ca. **40 g of active ingredient**

per ha which corresponds to 267 g of formulation per ha (equal to 20,000 flakes per hectare).

ISOMATE®-LBAM PLUS “twist-ties” (by Shin-Etsu Chemical Co.)

The import of Isomate twist ties will be somewhat over the required amount of 15,000 twist-tie dispensers, containing total of less than 2 kg of active ingredient.

Section Four – Information on the Proposed Containment System

4.1 Provide information on the proposed containment system.

It is essential that good information is provided on the containment system because the adequacy of containment in conjunction with the hazardous properties of the substance will have a major impact on whether or not approval is given.

You will need to provide a description of the containment proposed AND information on how you intend to address the following issues (proposed controls):

- methods for preventing the escape of the contained hazardous substance and preventing the contamination of the facility.
- methods for excluding unwanted organisms from the facility or to control organisms within the facility
- methods for excluding unauthorised people from the facility
- methods for preventing unintended release of the substance by experimenters
- methods for controlling the effects of any accidental release of the substance
- inspection and monitoring requirements of the containment facility

A management plan may be attached as an appendix. This plan should specify the procedures for implementing the above methods for containing the substance(s), and provide details of the qualifications of the person responsible for implementing those controls.

(See comments under “Section 4.1 of Form” in the User Guide)

The formulations will be imported in appropriate, safe containers. Handling will be done by trained staff who are familiar with the use of agrichemicals and will adhere to all relevant OSH regulations, although the active ingredient and inerts in these formulations are non-toxic (low-hazard). Because the active ingredient occurs naturally as the sex pheromone of the light brown apple moth (present in NZ) whose females release this compound into the atmosphere to attract males of the same species, and because the active ingredient is already being used in New Zealand in pheromone traps and has also had limited use for ground-based mating disruption, the risks associated with unintended release are minimal. However, the material is precious (neat pheromone is very expensive), and any unintended losses and release will be avoided as much as possible. For the experimental aerial application of the four formulations, specialist application equipment for helicopters will be used. The helicopter(s) will be equipped with GPS tools to ensure that only the intended experimental locations will be treated, and applications will only occur when wind speeds are low (mean wind speed less than 12 km/h) to prevent drift. Drift will also be minimised by the fact that most of the applied droplets are ca. 1-3 mm in diameter (i.e., very large). These particle sizes are equivalent to what would be used for a high-risk herbicide application where drift needs to be avoided.

The experimental area is part of a forest that is fenced and can only be accessed by authorised staff. We will work with the forest manager (Alistair Hayward, Rayonier) and their security staff to ensure that no one other than those participating with the experiment will be present. The planned experimental area in Eyrewell Forest (North Canterbury) is

not inhabited, not used for recreation, there are no waterways except for one water race (this area will be avoided, with an generous buffer), and there are no plants or animals present that are used for human consumption.

Monitoring of where the application occurred will be done as part of the experimental plan by several methods including (1) recording flight paths using GPS and wind speeds and direction, (2) monitoring deposition on the ground, (3) monitoring pheromone presence in treated and untreated control areas by operating pheromone traps before, during, and after the application, and (4) by recording mating or a lack thereof in tethered female moths of the target species. All ingredients are biodegradable and will either evaporate or decompose on the ground. More details are reported in the project plan (Appendix).

The pheromone formulations will each be imported as the formulated product in containers large enough to apply to 25 hectares at a rate of ca. 40 g active ingredient per ha (or 1000 grams active substance per 25 hectares, the total treatment area for each product, PLUS additional material for calibration and deposition rate assessments).

The risks involved would be to the individual applying the substance either through direct contact with the concentrated material while filling the spray tank or while the substance is being sprayed. The risk to the environment would be through possible spillage and drift into environmentally sensitive areas. Adequate safety measures will be applied by the applicators who are skilled professionals that are familiar with the use of agrichemicals.

The pheromone blend is not explosive, not flammable (not established for the liquid formulations as the preparations are > 70% water) non-oxidizing (The substance is not expected to react exothermically with combustible materials) and is expected to be non-corrosive (Still to be determined) and does not hydrolyze in water.

The substance is a naturally produced pheromone but is highly concentrated for mating disruption purposes so the environmental risk (9.1B) would be confined to aquatic situations where careful use to prevent spillage and disposal into aquatic situations, would be prevented by following the label guidelines for use and disposal. The only possible risk would be accidental spillage through a transport accident and this would be very short term as the substance is rapidly degraded by UV light and oxygen.

Section Five: Identification and Assessment of Risks

In completing this section, it is important that you take account of the proposed containment system you described in Section 4. We are particularly interested in knowing about risks that may still remain with the containment system in place. You will need to consider the effects on the environment and public health including any social effects. For more details see comments under “Section Five of Application Form” in the User Guide.

You should also take account of the quantity of material involved and the number of different locations that may be involved.

Complete this section as far as you can. If the analysis provided is incomplete, then it will be completed by ERMA New Zealand. However, the costs of doing this will be chargeable.

5.1 Identify all of the risks of the substance(s).

Include information on potentially significant possible risks of the substance and whether or not these risks are likely to be significant. It is important to think about the source of the risk ie the way in which the risk is created (the exposure pathway), and then the consequences of exposure. Risks should be considered in relationship to:

- the sustainability of native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health (including occupational exposure)
- the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga
- the economic and related benefits to be derived from the use of the hazardous substance
- New Zealand’s international obligations.

(See comments under “Section 5.1 of Form” in the User Guide)

Sustainability of native and valued introduced flora and fauna

The area of plantation forest we intend to use for this application is relatively poor in native species and, except for *Pinus radiata* trees, valued introduced flora and fauna. Because of the great species specificity of moth sex pheromones, and because all ingredients are non-toxic, no effects on any other species are expected. Previous trapping in Eyrewell Forest using this and several other pheromones showed that no other moth species were caught with the pheromone of the light brown apple moth (Brockerhoff et al. 2002). Hence, no effects on any non-target species or on the intrinsic value of the ecosystem are expected. This is explained further in a letter to the Department of Conservation (sent on 18 Jan 2008 – see appendix). Several responses from DOC were received (all forwarded to Noel McCardle, ERMA NZ), all supportive of the planned trial and not expressing any concerns

Intrinsic value of ecosystems

No conceivable effect has been identified in the pine forest to be treated.

Public health (including occupational exposure)

Because all the ingredients of the formulations are non-toxic and the treated area is not inhabited or used for the production of anything intended for human consumption, no effects on public health are expected.

Relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga

The land area we plan to use is on a property owned Ngai Tahu, who have been informed in detail about the experiment, and have given us permission to proceed as planned (Edwin Jansen, pers. comm., 8 Jan. 2008, and e-mail received on). No adverse effects on Maori and their cultural and traditional values have been identified. Their support for this trial suggest that a benefit has been identified (such as the control of a pest negatively affecting the pine forest on their land).

Economic and related benefits to be derived from the use of the hazardous substance
The experiment will be immensely valuable for biosecurity research in New Zealand and world-wide because there have been few previous attempts to eradicate invasive species using such non-toxic (low hazard) compounds instead of insecticides. The work will be useful for related research within the Better Border Biosecurity FRST programme, and it will be followed with interest by MAF-Biosecurity New Zealand, who may wish to use this technology for future eradication campaigns in New Zealand.

New Zealand's international obligations

The development of such 'greener' alternatives to pesticides will have benefits for New Zealand's international obligations that discourage the use of pesticides

5.2 Provide an assessment of the potential risks identified in Section 5.1.

An explicit risk assessment only needs to be provided for those risks which might be significant. The assessment should consider whether the identified risks can be adequately managed by the proposed containment system and the substance(s) itself adequately contained.

The assessment should include the nature, probability of occurrence and magnitude of each adverse effect. The uncertainty bounds of the information contained in the assessment should also be discussed.

(Optional) (See comments under "Section 5.2 of Form" in the User Guide).

As outlined above, any non-target effects are highly unlikely to occur. It is conceivable that other moths that use similar pheromones could be affected, but our previous trapping study in the experimental area indicated that no other moths are present that use this particular pheromone (Brockerhoff et al. 2002). Hence, this risk is minimal.

None of the other potential risks are likely to be significant (see above).

Section Six – International Considerations

- 6.1 ERMA New Zealand is interested in whether this substance (or any of its components) has been considered by any other regulatory authority in New Zealand or by any other country. If you are aware of this, please provide details of the results of such consideration.**
(Optional) (See comments under “Section 6.1 of Form” in the User Guide)

Use of the active ingredient is permitted in New Zealand for pheromone trapping and for ground-based mating disruption applications.

The Environmental Protection Agency (EPA), U.S.A., has authorized the United States Department of Agriculture’s Animal and Plant Health Inspection Service (USDA APHIS) to use one of the four formulations (CheckMate LBAM; Suterra LLC) under a Federal Quarantine Exemption in accordance with Section 18 of the U.S. Federal Insecticide Fungicide and Rodenticide Act (FIFRA). This section of FIFRA permits the use of unregistered pesticides in order to address an emergency agricultural situation. The light brown apple moth pheromone has never been registered in the United States due to the fact that there has never been a need for it until now. USDA APHIS is currently seeking approval for the use of the Hercon Product (LBAM Bioflake) and the ISCA Tech Product (SPLAT LBAM) and expects authorization shortly. USDA APHIS will seek authorization to use the Scentry product, depending upon the results of the comparative efficacy trials in New Zealand. Approved labels for the CheckMate product, and the draft labels for the other products are appended. All other products are still considered DRAFT until EPA approves the exemption.

Subsequent to a determination submitted to the NZFSA ACVM Group, the substance is believed to have been classified as not requiring registration under the ACVM Act of 1997.

The substance Light Brown Apple Moth (LBAM) pheromone has been used extensively for mating disruption in all countries that are affected by the Light Brown Apple Moth (LBAM) around the world.

The sprayable formulation CHECKMATE LBAM-F has been registered/approved in the USA during the last year. The need for residue data has been waived in the country where the substance is currently registered.

Section Seven – Miscellaneous

- 7.1 Provide a glossary of scientific and technical terms used in the application.**
(See comments under “Section 7.1 of Form” in the User Guide)

Pheromone – An attractant occurring naturally and most commonly in insects but also in several other taxa.

Sex pheromone – A pheromone used by moths and other species for the attraction of the opposite sex. Note, most moth species are nocturnal and rely primarily on olfactory cues for mate finding. Female moths release such pheromones which are used by males of the same species to find females by means of upwind flight towards the source of the pheromone plume.

Mating disruption – The application of sex pheromone into the habitat of a species that disrupts mate finding and prevents the fertilisation of the females' eggs.

<p>7.2 Provide here any other information you consider relevant to this application not already included. (See comments under “Section 7.2 of Form” in the User Guide)</p>

See appendices for all formulations attached to this application from Scion as well as directly submitted by the companies:

Section Eight – Summary of Public Information

The information provided in this section may be used in the Authority's public register of substances required under Section 20 of the HSNO Act.

This summary information will be used to provide information for those people and agencies (eg Ministry for the Environment, Department of Conservation, Regional Councils, etc), who will be notified of the application, and for potential submitters who request information. This information will also be used to prepare the public notice of the application.

For these reasons, applicants should ensure that this summary information does not contain any commercially sensitive material.

8.1 Name of the substance(s) for the public register:

Please use a maximum of 80 characters.

(See comments under "Section 8.1 of Form" in the User Guide)

Sex pheromone of the light brown apple moth (*Epiphyas postvittana*)

8.2 Purpose of the application for the public register:

This should include (in a maximum of 255 characters) an abstract giving information on the intended use of the substance and why an application is needed based on its hazardous properties.

(See comments under "Section 8.2 of Form" in the User Guide)

To conduct a containment trial with a single aerial application of light brown apple moth sex pheromone in four different formulations for the purpose of evaluating their efficacy for the eradication of this species in California and to experimentally test this technology in general. The trial also includes a treatment of ground-applied "twist-ties" containing the same pheromone.

8.3 Use Categories of the substance(s):

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance(s).

- Main category: There are four main categories - see User Guide for details.
 - Industry category: There are 16 industry categories - see User Guide for details.
 - Function/Use category: There are 55 function/use categories - see User Guide for details.
- (Optional) (See comments under "Section 8.3 of Form" in the User Guide).

Main category: 4

Industry category: 1

Function/Use category: 38

8.4 Executive Summary:

In this section, the applicant should provide a summary of information contained in this application, including:

- the identification of the substance, its hazardous properties, intended uses, and disposal
- an assessment of the adverse effects of the substance
- information on the proposed containment

(See comments under "Section 8.4 of Form" in the User Guide)

This application is to seek approval for the limited aerial and ground-based application of "low hazard" (non-toxic) formulations of mating disruption of light brown apple moth (*Epiphyas postvittana*) over a small area (ca. 100 ha) of pine plantation forest in North Canterbury (Eyrewell Forest). This is to support an emergency response, the eradication of *E. postvittana* which has recently been detected as an invasive species (native to Australia) and biosecurity threat in California. The United States Department of Agriculture (USDA) urgently needs efficacy data to determine which formulation would be the most successful in their effort to eradicate this insect in California, ahead of the planned treatments in the northern hemisphere spring. The insect is present in New Zealand which allows this research to be conducted now whereas it would not be possible during the current northern hemisphere winter. One of the four the formulations (or equivalents) we plan to test by aerial application has already received approval for use in the United States by the U S Environmental Protection Agency (EPA) which considers all straight-chained lepidopteran pheromones to be "not hazardous". Two formulations are currently under review by the U S. EPA, and the USDA will be seeking authority for to use the fourth formulation depending upon the results of this field trial. The ground-applied Isomate "twist-ties" have approval in the United States for use under section 18 FIFRA and, I understand, registration is pending. An initial response from ERMA New Zealand (Beth Dye, e-mail 21 Dec. 2007) recommended that we submit a 'containment application' to determine whether ERMA approval is required and to accommodate the urgency of this application. Note that the research will enhance New Zealand's biosecurity research capability and will also be observed by MAF-Biosecurity New Zealand because it is likely to be beneficial for future eradication campaigns against similar pests in New Zealand. Because of the possibility of reducing or avoiding pesticides, the use of pheromone formulations, containing naturally occurring active ingredients, is preferred. The active ingredient (E11-tetradecenyl acetate and E9,E11-tetradecen-1-yl acetate, the sex pheromone of the light brown apple moth, an Australian species and horticultural pest present in New Zealand) as well as all inert ingredients are non-toxic, not explosive, have no oxidising or corrosive properties, and are biodegradable. The pheromone is highly species specific and not used by any other moths present in the treatment area. This area is not inhabited, fenced, and not used for the production of anything intended for human consumption, so that accidental human exposure is extremely unlikely. There are no water ways in the treatment area, and no valued flora or fauna will be negatively affected. Containment will be ensured because application will only occur during low wind speeds to avoid drift, and application rate and efficacy will be appropriately monitored.

The formulations contain the active substance blend of (E)-11-tetradecenyl acetate and (E,E)-9,11-tetradecadien-1-yl acetate which is a synthetic mating disruptant pheromone for use against the Light Brown Apple Moth (LBAM) *Epiphyas postvittana* in all sites and areas where LBAM has been detected (here we plan a single application within a pine plantation).

Light Brown Apple Moth (LBAM) technical pheromone blend is the synthetic equivalent of the pheromone released by female Light Brown Apple Moths (LBAM) to attract male

moths for mating purposes. Pheromone is sprayed in all sites and areas where LBAM has been detected is slowly released into the atmosphere where it serves to confuse male moths following scent trails to the females. When male moths are prevented from mating females lay sterile eggs and so limit the number of larvae hatching and in turn minimise fruit damage.

The pheromone blend is species specific so does not influence any other Lepidopteran species other than the Light Brown Apple Moth (LBAM). To minimise usage the product label will carry an injunction not to use more than a specific quantity per hectare per season, generally no more than 40 grams active substance per hectare per season.

Technical pheromones in dispensers and flowable preparations have been used extensively in all fruit producing countries around the globe. CHECKMATE LBAM-F is currently registered/approved for use in the USA. The other formulations are pending approval.

It is our estimation that the formulations trigger the following HSNO Classifications:

HSNO Class	Description	Comments
6.3B	Skin Irritation	Wear protective clothing while handling and applying will appear on the label. The active pheromone is enclosed in micro capsules or biodegradable flakes
9.1B	Moderately toxic to fish and aquatic organisms	Mitigated by rapid breakdown due to UV light and oxygen and by the fact that the applications will be made distant (> ca. 200 m) from any open water.

The moderately toxic effect to fish and aquatic organisms will be managed by a label injunction to avoid mixing and loading near water and to avoid spray drift over water.

Mating disruption dispensers have been used extensively and successfully in New Zealand for over 15 years to control Lepidopteran pests including the light brown apple moth and codling moth (CM) in organic apple and pear orchards.

CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	<u>Yes</u>
Initial fee enclosed	No
Application signed and dated	Yes
Electronic copy of application e-mailed to ERMA NZ	Yes

Signed



Date: this draft: 1 February 2008

Senior Scientist, Group Leader Entomology
Scion

Appendix 1. Commercially Sensitive (and other) Information

Several appendices for each of the formulations are attached to this application from Scion. Several other appendices, partly commercially sensitive, will be directly submitted by the companies.

The information provided includes the following:

- Material Safety Data Sheets (MSDS).
- Acute Toxicity and skin irritation tests.
- Product labels and draft labels.
- Other information.