Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Regulatory Decision Document PRDD2004-03

Isomate-P Pheromone for use in Orchards for Mating Disruption of the Peach Tree Borer

The active ingredient Peach Tree Borer Pheromone Technical and the associated end-use product, Isomate-P Pheromone, containing (*Z*,*Z*)-3,13-octadecadien-1-yl acetate and (*E*,*Z*)-3,13-octadecadien-1-yl acetate for mating disruption of peach tree borers (PTB, *Synanthedon exitiosa* [Say]) in peach, nectarine, cherry, prune, plum and apricot orchards are proposed for full registration under Section 13 of the Pest Control Product (PCP) Regulations.

This Proposed Regulatory Decision Document (PRDD) provides a summary of data reviewed and the rationale for the proposed full registration of these products. The Pest Management Regulatory Agency (PMRA) will accept written comment on this proposal up to 45 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address listed below.

(publié aussi en français) **13 July 2004**

This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:

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ISBN: 0-662-37672-2 (0-662-37673-0)
Catalogue number: H113-9/2004-3E (H113-9/2004-3E-PDF)

Foreword

Health Canada's PMRA has reviewed the submissions for the registration of the Peach Tree Borer Pheromone Technical, manufactured by Shin-Etsu Chemical Co., Ltd., of Tokyo, Japan, and its EP Isomate-P Pheromone, manufactured by Pacific Biocontrol Corporation of Vancouver, Washington, for mating disruption of PTBs (*Synanthedon exitiosa* [Say]) in peach, nectarine, cherry, prune, plum and apricot orchards.

Isomate-P Pheromone reduces mating of PTBs by interfering with chemical communication between males and females. The resulting decrease in the number of eggs and larvae reduces the need for conventional insecticides, making this pheromone an important addition to integrated pest management (IPM) strategies in peach, nectarine, cherry, prune, plum and apricot orchards.

Research on the use of pheromones in IPM programs is increasing. Pheromones work by modifying the behaviour of the pests rather than killing them, and are more target-specific than conventional insecticides. Pheromones are used at concentrations close to those occurring in nature and dissipate fairly rapidly. For these reasons, it is expected that pheromone products will pose low potential risk to human health and the environment.

The PMRA has carried out an assessment of available information in accordance with Section 9 of the Pest Control Products (PCP) Regulations and has found it sufficient, pursuant to Section 18(*b*), to allow a determination of the safety, merit and value of Peach Tree Borer Pheromone Technical and the associated EP, Isomate-P Pheromone, containing (*Z,Z*)-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate. The PMRA has concluded that the use of Peach Tree Borer Pheromone Technical and the associated EP, Isomate-P Pheromone, containing (*Z,Z*)-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate, in accordance with their labels has merit and value consistent with Section 18(*c*) of the PCP Regulations and does not entail an unacceptable risk of harm pursuant to Section 18(*d*). Therefore, based on the considerations outlined above, the use of Peach Tree Borer Pheromone Technical and the associated EP, Isomate-P Pheromone, containing (*Z,Z*)-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate for mating disruption of PTBs in peach, nectarine, cherry, prune, plum and apricot orchards are proposed for full registration under Section 13 of the PCP Regulations.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed registration decision for this product.

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1.0 Introduction

Peach Tree Borer Pheromone Technical is manufactured by Shin-Etsu Chemical Co., Ltd., Tokyo, Japan, and its EP, Isomate-P Pheromone, is manufactured by Pacific Biocontrol Corporation of Vancouver, Washington. Both products contain (*Z,Z*)-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate.

Isomate-P Pheromone is for mating disruption of PTBs, *Synanthedon exitiosa* (Say) in peach, nectarine, cherry, prune, plum and apricot orchards.

(*Z,Z)*-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate are straight-chained lepidopteran pheromones (SCLPs). This category of pheromone products is generally considered to pose a low risk to human health and the environment based on available studies.

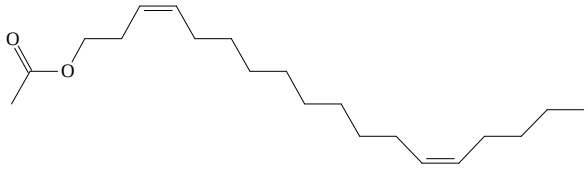
2.0 Product chemistry

2.1 Identity of products

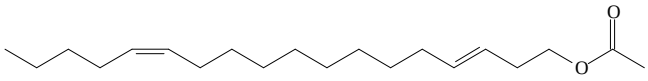
The common name for this product is Peach Tree Borer Pheromone; it functions as an insecticide through the disruption of the mating behaviour of the pest.

Trade name	Peach Tree Borer Pheromone Technical
Other names	Isomate-P Technical
Common name	Peach Tree Borer Pheromone
Chemical name	
International Union of Pure and Applied Chemistry	(*Z,Z*)-3,13-octadecadien-1-yl acetate (*E,Z*)-3,13-octadecadien-1-yl acetate
Chemical Abstract Services (CAS)	(*Z,Z*)-3,13-octadecadienyl acetate (*E,Z*)-3,13-octadecadienyl acetate
CAS number	53120-27-7 53120-26-6

Structural formula



(Z,Z)-3,13-Octadecadienyl acetate



(E,Z)-3,13-Octadecadienyl acetate

Molecular formula $C_{20}H_{36}O_2$

Molecular weight 308.5

2.2 Physical and chemical properties of active substance

Technical product: Peach Tree Borer Pheromone

Properties	Value	Comments
Colour	colourless or light yellow transparent	
Physical state	liquid	
Odour	mild waxy and sweet	
Melting point/range	N/A	Product is a liquid.
Boiling point/range	178–180°C at 2 mm Hg	
Specific gravity	0.889 at 20°C	
Water solubility (mg/L)	not soluble in water	
Solvent solubility (mg/L)	soluble in all common organic solvents	
Vapour pressure	1.795×10^{-5} mm Hg at 20°C	
Henry's Law constant at 20°C	Constant cannot be calculated, as value for solubility in water was not reported.	Based on vapour pressure and insolubility in water, this compound will be volatile under field conditions.
Dissociation constant (pK_a)	N/A	Active ingredients do not contain dissociable moiety.

Properties	Value	Comments
n-Octanol/water partition coefficient (K_{ow})	more than 1000	
Ultraviolet/visible absorption spectrum	No absorbance above $\lambda > 400$ nm	
Stability (temperature, metals)	stable against sunlight and hydrolysis when exposed to water	

End-use product: Isomate-P Pheromone

Property	Value	Comment
Colour	colourless or light yellow transparent	
Physical state	liquid	
Odour	mild, waxy and sweet	
Formulation type	slow-release generator	
Container material and description	high-density polyethylene tubes in foil packet (500 tubes in 1 packet)	
Specific gravity	0.889 at 20°C	
pH	3.57	
Oxidizing or reducing action	N/A	Product does not contain redox agents.
Viscosity	8.03 cSt at 20°C	
Storage stability data	Data showed that when stored for 18 months at room temperature and 5°C, losses of 2.7% and 1.0% active ingredient occur, respectively.	
Flammability	flash point, 1348°C	closed cup method
Explodability	N/A	Product is not potentially explosive.

Property	Value	Comment
Miscibility	miscible in all common organic solvents, i.e., *n*-hexane, cyclohexane, benzene, toluene, except DMSO, ethylene, glycol	
Corrosion characteristics	not corrosive	
Dielectric breakdown voltage	N/A	This formulation is not designed for use around electrical equipment.

2.3 Method for analysis of the active substance as manufactured

A single gas chromatographic method was provided for determination of the active ingredients and all major impurities: gas chromatography (GC) with flame ionization detection (FID). The validation data are shown in Table 2.4.

Method validation

Method validation data				
Component	**Method type / ID**	**Retention time (min)**	**Relative standard deviation (%)**	**Method acceptability**
Active ingredients (*Z*,*Z*)-3,13-octadecadien-1-yl acetate (*E*,*Z*)-3,13-octadecadien-1-yl acetate	GC/FID*	35.55 34.04	0.16 1.3	acceptable
(Z,*E*)-3,13-octatecadien-1-yl acetate	GC/FID	33.48	3.5	acceptable
n-octadecyl acetate	GC/FID	30.79	2.3	acceptable
13-octadecen-3-yn-1-ol	GC/FID	46.4		acceptable
(*Z*,*Z*)-5,11-hexadecadiene	GC/FID	8.51	9.3	acceptable
2,13-octadecadien-1-yl acetate	GC/FID	34.54	4.2	acceptable
3,13-octadecadien-1-ol	GC/FID	41.05	3.4	acceptable

Method validation data				
Component	**Method type / ID**	**Retention time (min)**	**Relative standard deviation (%)**	**Method acceptability**
Z-9-tetradecen-1-yl bromide	GC/FID	13.12	10.7	acceptable
(*E*,*Z*)-2,13-octadecadien-1-yl acetate	GC/FID	37.02		acceptable
(*E*,*E*)-3,13-octadecadien-1-yl acetate	GC/FID	33.06		acceptable
3,11-tetradecadiyn-1,14-yl diacetate	GC/FID	19.15		acceptable
Z-13-octadecen-1-yl acetate	GC/FID	33.25		acceptable

* see section 2.4 below

2.4 Method for analysis of formulation

The same GC/FID that was used to analyse the technical product was also provided for the analysis of the formulated product. The method was assessed to be specific and precise for use as an enforcement analytical method.

2.5 Product chemistry conclusions

The product chemistry data for Peach Tree Borer Pheromone Technical used in the EP Isomate-P Pheromone are complete. The technical material was fully characterized and the specifications were supported by the analysis of five batches for active ingredients and impurities using specific validated methods of analysis. Based on the starting materials and the manufacturing process used, the technical material does not contain any Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Appendix II of Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. The required physical and chemical properties of the technical material and of the EP were provided. A GC method for the determination of active ingredients in the formulation was submitted.

3.0 Toxicology evaluation

3.1 Human health and safety

Reduced toxicological data requirements have been established for SCLPs. SCLPs are poorly soluble in water and are biodegradable by enzyme systems present in most living organisms; they are products of fatty acid metabolism. Health studies have indicated that these substances pose minimal risks and provide effective pest control at low concentrations, similar to those occurring in nature[1].

The formulated product, Isomate-P Pheromone, is contained within a passive, retrievable dispenser. Therefore, the potential for direct human exposure to the formulation ingredients is considered to be negligible.

A detailed review of the toxicity data base available for Peach Tree Borer Pheromone Technical and its formulation, Isomate-P Pheromone, has been completed. The data submitted satisfactorily addressed the current toxicological requirements for registration of a pheromone TGAI and a pheromone EP.

3.2 Acute toxicity—technical and formulation

Peach Tree Borer Pheromone Technical was considered to be of low acute toxicity by the oral (LD_{50} > 5000 mg/kg bw), dermal (LD_{50} > 2000 mg/kg bw) and inhalation (LC_{50} > 5.32 mg/L) routes to Sprague-Dawley rats. It was mildly irritating when applied to the skin of New Zealand White rabbits and minimally irritating when instilled into the eyes of the same species. Results of skin sensitization testing using albino Hartley guinea pigs were negative.

Isomate-P Pheromone, containing 80.4% (*Z,Z*)-3,13-octadecadienyl acetate and 3.3% (*E,Z*)-3,13-octadecadienyl acetate, was considered to be of low acute toxicity by the oral, dermal and inhalation routes; mildly irritating to the skin; and minimally irritating to the eyes. There is no report of human dermal sensitization resulting from exposure to this product. Since this product is contained within a passive, retrievable dispenser, exposure potential is minimal.

3.3 Mutagenicity—technical

Data provided by the applicant indicated that Peach Tree Borer Pheromone Technical was not a mutagenic agent.

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[1] Refer to *The White Paper – A Review of the Current Bases for the United States Environmental Protection Agency's Policy for the Regulation of Pheromones and Other Semiochemicals, Together with a Review of the Available Relevant Data Which May Impact the Assessment of Risk for These Classes of Chemicals*, Compiled by James E. Touhey, Senior Agricultural Advisor, Field Operations Division, United States Environmental Protection Agency.

3.4 Acceptable daily intake and acute reference dose determination

Based on the chemical, physical, biological and toxicological properties of SCLP compounds, it is considered that they pose little or no risk of eliciting any adverse, toxicological effects. Data indicate that SCLPs pose a minor potential impact on human or animal health due to their inherent safety and use patterns. Adverse human health effects resulting from exposure to pheromone products have never been reported. It is therefore not considered necessary to establish an acceptable daily intake (ADI) or an acute reference dose (ARfD) for Peach Tree Borer Pheromone Technical due to its inherent lack of toxicity and since it does not pose any significant residue concerns.

3.5 *Food Quality Protection Act* considerations and endocrine disruptor potential

Based on all of the available data for SCLPs, there is no evidence of increased susceptibility of infants and children in comparison to adults that may result from exposure to SCLPs. Furthermore, there is no evidence that SCLPs have a potential to disrupt endocrine activity in humans.

4.0 Occupational and bystander exposure assessment

4.1 Exposure assessment

The proposed end product is formulated as retrievably sized twist-tie rope dispensers to be attached to orchard tree branches in spring prior to moth emergence. The active ingredient (a.i.) is impregnated into a polyethylene tube that slowly releases into the atmosphere at a rate of 9.45–23.63 g a.i./ha. A repeat application may be made during the season.

Based on the toxicological profile of the active ingredient, a quantitative estimate of exposure was not required for this product. Exposure is anticipated to be primarily dermal and could occur during handling and placement of the dispensers. Bystander and re-entry exposure is considered negligible.

4.2 Risk assessment

Based on the toxicological profile of the active ingredient, it is concluded that the use of the proposed product is not likely to present a risk to workers when it is used according to label directions.

5.0 Food residue exposure

With respect to Isomate-P Pheromone, neither the TGAI nor the EP are considered to pose any significant residue concern. Furthermore, no ADI or ARfD were established for Peach Tree Borer Pheromone Technical due to inherent lack of toxicity of this compound.

Therefore, it is unlikely that this pheromone will pose any dietary concern to any segment of the population.

6.0 Environmental assessment

The method of application of Isomate-P Pheromone is described under Value assessment in Section 7.1.1, Intended Uses. The active ingredients in the subject product are SCLPs.

Exposure of the environment to the EP will be very limited because the dispensers containing Isomate-P Pheromone are to be manually attached to fruit trees for control of the pest.

7.0 Value assessment

7.1 Effectiveness

7.1.1 Intended uses

Pacific Biocontrol Corporation has applied for full registration of an EP, Isomate-P Pheromone, for the control of PTBs (*Synanthedon exitiosa* [Say]) in peach, almond, nectarine, cherry, prune, plum and apricot orchards. The product is formulated as discrete hand-applied dispensers, each containing 37.8 mg of the active ingredients (80.4% (*Z,Z*)-3,13-octadecadien-1-yl acetate and 3.3% (*E,Z*)-3,13-octadecadien-1-yl acetate). The application rate is a minimum of 250 dispensers/ha and a maximum of 625 dispensers/hectare. Dispensers are to be attached to trees prior to moth emergence in the spring.

7.1.2 Mode of action

Isomate-P Pheromone acts through mating disruption (i.e., through disruption of pheromone communication between male and female moths for mating activities) rather than by killing the pest. This non-toxic mode of action differs from that of conventional insecticides.

(*Z,Z*)-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate have been identified as sex pheromone components of PTBs. In nature, sex pheromones are produced and released into the air by the female moth to attract a mate. “Mating disruption” refers to the process of releasing a synthetic pheromone into the air at concentrations that disrupt communication between female and male moths. Although the exact mechanisms by which mating disruption occur are not known, the end result is that normal mating behaviour between male and female moths is disrupted, resulting in a reduction of pest populations. To be effective in reducing insect damage, the product must be applied prior to the beginning of the adult moth flight season. In addition, an ambient level of pheromone sufficient to disrupt communication must remain throughout the entire mating period of the insect.

7.1.3 Nature of the pest problem

The PTB (*Synanthedon exitiosa* [Say]) is an significant pest of peach trees in Ontario and British Columbia. Plum, cherry and apricot trees are also occasionally attacked by this insect. The larvae tunnel into the bark and outer wood to feed. The main roots near the ground surface may also be attacked. Gum oozing from injured areas usually contains sawdust and borer excrement. Trees older than eight years are more resistant to injury. Younger trees, especially those under three years, may be seriously damaged or killed.

The adult PTB, unlike most other moths, is active in the daytime. The moths emerge from mid-June to early September, with peak emergence occurring around the first of August. The females lay their eggs on the trunk or foliage, or in the soil close to the peach tree. These eggs hatch in about 12 days, and the young larvae bore into the bark of the trunk near ground level. In the spring, after wintering in their feeding tunnels or in the soil, larvae resume feeding, in either their old tunnels or in new ones. The larvae mature in June or July and pupate in their tunnels or near the surface of the soil within 8 cm (3 inches) of the trunk before emerging as moths. Some borers complete their life cycle in one year; others require two. Regardless of the life cycle, all borers overwinter in the larval stage.

Current control strategies involve applying chemical insecticides to tree trunks from ground level to lower scaffold limbs when the first moths are captured in pheromone traps. The treatment threshold is an average of one moth captured per trap per week in a block of young trees and two moths per trap per week in a mature block. For effective control, it is essential to treat for two or more consecutive years.

7.1.4 Effectiveness against the pest

Five field trials using the proposed PTB sex pheromone (3,13-octadecadien-1-yl acetate) to disrupt the mating of PTBs were reviewed. Efficacy was assessed by comparing the number of male PTB caught in traps placed in orchards treated with the pheromone to the number caught in traps placed into orchards treated with a conventional insecticide. One study also assessed the effect of pheromone disruption on female reproductive output. The following is a summary of the efficacy trial results.

Biglerville, Pennsylvania, 1998
A field trial was conducted in four orchards (all blocks were 2–3 ha in size). Insecticide was applied to all blocks before the trial started and only to the conventionally treated blocks (i.e., blocks not treated with the pheromone) afterwards. Pheromone-treated blocks received 247 dispensers/ha of Isomate-P Pheromone. The dispensers were placed on trees by hand in early June before the flight of PTB. The conventionally treated blocks were either adjacent to or within 400 m of the pheromone-treated blocks. Limited detailed information was available on the experimental protocol and statistical analysis in this trial.

Efficacy was assessed by monitoring male moth catches in pheromone-treated and conventionally treated blocks. Trap catches in the blocks treated with Isomate-P Pheromone were zero throughout the trial, while substantially more male moths (cumulative moth catch over the growing season was 53 adult PTBs) were captured in the blocks that were not treated with the pheromone. These results indicated that treatment with the pheromone disrupted communication between male and female PTBs.

Cream Ridge, New Jersey, 1996
This field trial was conducted in four orchards, and protocols and results are similar to those for the trial conducted in Pennsylvania. Pheromone-treated blocks received 247 dispensers/ha of Isomate-P Pheromone. Information on details of experimental protocol and statistical analysis was limited. Efficacy was assessed by monitoring male moth catches in pheromone-treated and conventionally treated blocks. Trap catches in the blocks treated with Isomate-P Pheromone were zero throughout the trial, while substantially more male moths (cumulative trap catch over the growing season was 59 male PTBs) were caught in the untreated blocks. However, neither direct nor indirect assessment of mating disruption were carried out (e.g., measuring percentage of mated females, larval population, level of tree damage). The submitted data did not indicate the period of time for which the dispensers would be effective.

Byron, Georgia, 1984 and 1985
Field trials were carried out over two years (1984 and 1985) in several blocks of peach orchards. Some wild host trees around the orchards were also treated with dispensers. Both pheromone-trap catches and the percentage of mated females were assessed in the field trials. Trap catches in four blocks treated with Isomate-P Pheromone showed a significant reduction in the number of males caught per pheromone trap (compared to blocks not treated with the pheromone). Only one percent of 200 females captured in pheromone-treated blocks and later dissected were found to be mated, compared to 84% of 42 females captured in blocks that were not treated with the pheromone.

In this trial, there was a difference in the amount of pheromone in tested dispensers (68 mg/dispenser) and in the proposed EP (37.8 mg/dispenser). The pheromone blend used to assess mating status of females was 100% (*Z*,*Z*)-3,13-octadecadien-1-yl acetate, which is different from the blend of the proposed product of 80.4% (*Z*,*Z*)-3,13-octadecadien-1-yl acetate and 3.3% (*E*,*Z*)-3,13-octadecadien-1-yl acetate.

Kelowna, British Columbia, 2002
The efficacy trial conducted in British Columbia was replicated three times, and pheromone-treated plots were treated with 400–500 dispensers/ha of Isomate-P Pheromone. Pheromone-treated plots were located in a commercial nursery (two replicates) and a commercial peach orchard (one replicate). All sites had a history of damage by PTBs. In the commercial nursery, all plots were treated with an insecticide (endosulfan) to target PTBs (including pheromone-treated plots), but in the commercial orchard, insecticides were not applied to target PTBs in any plots.

Results were assessed using pheromone-baited traps. In the commercial nursery, tree damage from PTBs was assessed during October and November. Nursery trees were mechanically harvested and manually graded by nursery personnel. The grading procedure included a visual inspection of each tree trunk for PTB damage and occasionally opening a tree to verify the presence of PTB larvae.

In all replicates, no PTB adults were captured in pheromone-baited traps in pheromone-treated plots. This was significantly lower than the number of PTB adults captured in plots which were not treated with pheromone. In pheromone-treated blocks, there was no observed PTB damage to host trees (i.e., peach trees and chokecherry). In previous years, trunk damage from PTB would typically range between 2 to 5% of graded peach trees.

Utah, 2000–2002

This study (Alston et al. 2003) provides support for the proposed label claims of Isomate-P Pheromone. The trial was conducted in Utah from 2000–2002. In mid-late June of each year (2000–2002) Isomate-P Pheromone dispensers were applied in 0.4 ha (1 acre) orchards at a density of 387–437 dispensers/ha. The same two orchards were treated in all three years, and a third orchard was added to the study in 2001 and 2002. Dispensers were applied within four days of the first capture of a PTB. The same sized insecticide-treated comparison block (0.6 ha)was used in all three years. This block was treated for PTBs with a single application of chlorpyrifos to lower trunks in early July of each year. PTBs were also monitored in another reference block that was not treated with the pheromone, but was treated with chlorpyrifos for control of PTBs.

Each year, treatments were evaluated by placing a pheromone-baited trap in each block and recording the number of PTBs captured from late June to late August or mid-September. Every tree trunk in each block was evaluated for PTB injury in late September or early October of each year. This was done by visual inspection of the lower trunk and removal of approximately 2.5 cm (1 inch) of soil around the base of each tree.

No PTBs were captured in pheromone-treated blocks after Isomate-P Pheromone dispensers were placed in the peach trees. Low to moderate densities of PTBs (0.5–2 moths per trap per day) were captured in the insecticide-treated comparison peach orchards. No PTB injury was detected in any block in any year.

7.2 Phytotoxicity to target plants (including different cultivars) or to target plant products

No adverse effect to the treated crop was reported in the efficacy field trials conducted with Isomate-P Pheromone.

7.3 Observations on undesirable or unintended side effects

Due to its non-toxic mode of action, Isomate-P Pheromone is not expected to negatively impact beneficial and other nontarget organisms.

7.3.1 Impact on succeeding crops

Isomate-P Pheromone is not expected to impact on succeeding crops.

7.3.2 Impact on adjacent crops

Isomate-P Pheromone is not expected to impact on adjacent crops.

7.4 Economics

Economics were not assessed.

7.5 Sustainability

7.5.1 Survey of alternatives

The major alternative insecticide active ingredients currently registered for control of the PTB include, but are not necessarily limited to, endosulfan, deltamethrin, azinphos-methyl, diazinon and carbaryl.

7.5.2 Compatibility with current management practices including IPM

Pheromone products are generally more target specific than conventional pesticides. The mode of action of these products is through disruption of pheromonal communication rather than directly killing the target pest. Isomate-P Pheromone has potential as a tool in the management of resistance of PTB to conventional chemical insecticides, and as an integral part of an IPM strategy to control this pest. Due to the specificity and the non-toxic nature of its mode of action, Isomate-P Pheromone is compatible with current orchard management practices, particularly with those of organic orchard producers.

7.5.3 Contribution to risk reduction

Due to the non-toxic mode of action of Isomate-P Pheromone, the use of this product would contribute to risk reduction.

7.5.4 Information on the occurrence or possible occurrence of the development of resistance

No clear evidence of the development of resistance to pheromone products has been established.

7.6 Conclusions from value assessment

Results from evaluated studies show that Isomate-P Pheromone can reduce damage from PTBs to a commercially acceptable level when used under low pest population densities

or when used in a program combining pheromone and insecticide treatments to target PTBs. Although trap catch data for pheromone-baited traps suggest that Isomate-P Pheromone is effective in disrupting pheromone communication, these data do not unequivocally demonstrate that mating has been disrupted. In the trial carried out in Byron, Georgia, data did show that successful mating disruption was achieved using Isomate-P Pheromone. However, in that study, the pheromone blend and the amount of pheromone loaded into dispensers were different from that of the proposed EP. The tested material consisted of the major pheromone component alone and did not include the E/Z isomer.

Sufficient efficacy data have been evaluated to support full registration of Isomate-P Pheromone. A value summary of Isomate-P Pheromone is shown in Table 7.1.

Table 7.1 Value summary for Isomate-P Pheromone

Site	peaches, nectarines, apricots, cherries, prunes and plum
Product	Isomate-P Pheromone containing (*Z*,*Z*)-3,13 octadecadien-1-yl acetate (80.4%) and (*E*,*Z*)-3,13 octadecadien-1-yl acetate (3.3%); Registration Number 26141
Rate of application	250–625 dispensers/ha (each dispenser contains 37.8 mg of pheromone) Attach one dispenser per tree.
Number of applications	One application per year.
Application methods	Attach dispensers to branches about the mid point of the tree.
Application timing	Apply prior to moth emergence in the spring. A single application can provide season long control. Consult your local pest control advisor for proper timing.

Note	It is critical that ISOMATE-P PHEROMONE be applied as directed. Growers using this product must maintain careful records of damage within their orchard. Careful monitoring of adult populations is essential since the use of ISOMATE-P PHEROMONE is dramatically different from traditional broad-spectrum insecticides registered for peach tree borer control. Designing successful programs with ISOMATE-P PHEROMONE depends on ongoing discussion with IPM specialists, extension horticulturists, and company representatives. ISOMATE-P PHEROMONE reduces mating of peach tree borer. However, if a major source of mated female moths of this species is present adjacent to the treated field, migration of these moths may significantly reduce the level of control achieved. Sources are likely to be untreated host trees within 300 m of treated field. This can be overcome by: a. Treatment of entire blocks and not just sections of large conventionally treated fields, which frequently serve as sources of mated females. b. Treatment of infestation sources with ISOMATE-P PHEROMONE c. Treatment of infestation sources with a registered insecticide. d. Treatment of edges of field with timely application of registered insecticide. Supplementary applications of a registered insecticide are advised when ISOMATE-P PHEROMONE is used to control very high populations of peach tree borer. All pests must be monitored so that timely intervention with conventional registered insecticides is possible.
Pests managed	peach tree borer, *Synanthedon exitiosa*

8.0 Overall conclusions

The PMRA has assessed the safety, merit and value of Peach Tree Borer Pheromone Technical and its associated, EP Isomate-P Pheromone. In terms of human exposure, bystander and re-entry exposure to workers is considered negligible. Further, it is unlikely that this pheromone will pose any dietary concern to any segment of the population. Exposure to the environment will be very limited because the product is contained in dispensers. No TSMP issue is associated with this product. Sufficient efficacy data have been evaluated to support the full registration of Peach Tree Borer Pheromone Technical and its associated EP, Isomate-P Pheromone.

9.0 Regulatory decision

The PMRA has carried out an assessment of available information in accordance with Section 9 of the Pest Control Products (PCP) Regulations and has found it sufficient,

pursuant to Section 18(*b*), to allow a determination of the safety, merit and value of Peach Tree Borer Pheromone Technical and the associated EP, Isomate-P Pheromone, containing (*Z,Z*)-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate. The PMRA has concluded that the use of Peach Tree Borer Pheromone Technical and the associated EP, Isomate-P Pheromone, containing (*Z,Z*)-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate in accordance with their labels have merit and value consistent with Section 18(*c*) of the PCP Regulations and do not entail an unacceptable risk of harm pursuant to Section 18(*d*). Therefore, based on the considerations outlined above, the use of Peach Tree Borer Pheromone Technical and the associated EP, Isomate-P Pheromone, containing (*Z,Z*)-3,13-octadecadien-1-yl acetate and (*E,Z*)-3,13-octadecadien-1-yl acetate, for mating disruption of the PTB (*Synanthedon exitiosa* [Say]) in peach, nectarine, cherry, prune, plum and apricot orchards are proposed for full registration under Section 13 of the PCP Regulations.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed regulatory decision for this product.

List of abbreviations

a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstract Service
cSt	centistokes
FID	flame ionization detector
GC	gas chromatography
Hg	mercury
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol/water partitioning coefficient
L	litre
LD_{50}	median lethal dose
mm	millimetre(s)
mg	milligram(s)
MSDS	Material Safety Data Sheet
PCP	Pest Control Products
PTB	peach tree borer
PMRA	Pest Management Regulatory Agency
SCLP	straight-chained lepidopteran pheromone
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Reference

Alston, D.G., M.E. Reding and C.A. Miller. 2003. Proceedings of the 77th Annual Western Orchard Pest and Disease Management Conference, Portland, Oregon, 15–17 January 2003