



Proposed Regulatory Decision Document PRDD2003-06

Isomate-M 100 Oriental Fruit Moth Pheromone for use in Orchards to Disrupt Oriental Fruit Moth Mating

The active ingredient Oriental Fruit Moth Pheromone Technical and associated end-use product Isomate-M 100 Oriental Fruit Moth Pheromone, containing Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol, for mating disruption of Oriental fruit moth in peach, nectarine, apricot, apple, and pear orchards are proposed for full registration under Section 13 of the Pest Control Products (PCP) Regulations.

This proposed regulatory decision document (PRDD) provides a summary of data received 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 below.

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Foreword

The submissions for registration of the Oriental Fruit Moth Pheromone Technical, manufactured by Shin-Etsu Chemical Co., Ltd., Tokyo, Japan, and its end-use product Isomate-M 100 Oriental Fruit Moth Pheromone, manufactured by Pacific Biocontrol Corporation of Vancouver, Washington, for use against the Oriental fruit moth in peach, nectarine, apricot, apple, and pear orchards have been reviewed by Health Canada's Pest Management Regulatory Agency (PMRA).

The product reduces mating of Oriental fruit moth 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 the pheromone an important addition to integrated pest management (IPM) strategies in peach, nectarine, apricot, apple, and pear orchards.

Pheromones are increasingly being investigated for use as alternatives to conventional pesticides. They control pests by modifying the mating behaviour of the pests rather than killing them. They are more target-specific than conventional insecticides, 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 compared with conventional pesticides.

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 Oriental Fruit Moth Pheromone Technical and associated end-use product Isomate-M 100 Oriental Fruit Moth Pheromone, containing Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol. The PMRA has concluded that the use of Oriental Fruit Moth Pheromone Technical and associated end-use product Isomate-M 100 Oriental Fruit Moth Pheromone, containing Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol 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 Oriental Fruit Moth Pheromone Technical and associated end-use product Isomate-M 100 Oriental Fruit Moth Pheromone, containing Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol, for mating disruption of Oriental fruit moth in peach, nectarine, apricot, apple, and pear 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

Oriental Fruit Moth Pheromone Technical is manufactured by Shin-Etsu Chemical Co., Ltd., Tokyo, Japan, and its end-use product Isomate-M 100 Oriental Fruit Moth Pheromone is manufactured by Pacific Biocontrol Corporation of Vancouver, Washington. Both products contain Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol.

The pheromone for the Oriental fruit moth (OFM) has not been registered previously for pest control in Canada. Isomate-M 100 Oriental Fruit Moth Pheromone has been proposed for mating disruption of the Oriental fruit moth in peach, nectarine, apricot, apple, and pear orchards.

Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol are “straight chain 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.

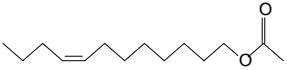
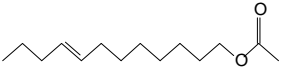
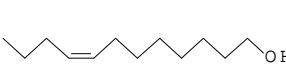
2.0 Product chemistry

2.1 Identity of products

The common name for this product is Oriental Fruit Moth Pheromone and it functions as an insecticide.

Table 2.1 Identity of the active substance and preparation containing it

Component	Z-8-Dodecen-1-yl acetate	E-8-Dodecen-1-yl acetate	Z-8-Dodecen-1-ol
Chemical name			
1. International Union of Pure and Applied Chemistry (IUPAC)	(Z)-dodec-8-en-1-yl acetate	(E)-dodec-8-en-1-yl acetate	(Z)-8-dodecenyl alcohol
2. Chemical Abstracts Service (CAS)	(Z)-8-dodecen-1-ol acetate	(E)-8-dodecen-1-ol acetate	(Z)-8-dodecen-1-ol
CAS number	9561767	38363-29-0	40642-40-8
Molecular formula	C ₁₄ H ₂₆ O ₂	C ₁₄ H ₂₆ O ₂	C ₁₂ H ₂₄ O

Component	Z-8-Dodecen-1-yl acetate	E-8-Dodecen-1-yl acetate	Z-8-Dodecen-1-ol
Molecular weight	226.36	226.36	184.32
Structural formula			
Nominal purity of active ingredient	92.0%	5.9%	1.0%

Identity of relevant impurities of toxicological, environmental, and other significance: Based on the starting materials and the manufacturing process used, impurities of toxicological concern as identified in Section 2.13.4 of Regulatory Directive DIR98-04 or Toxic Substances Management Policy (TSMP) Track-1 materials as identified in Appendix II of Regulatory Directive DIR99-03 are not expected to be present or formed in the product.

2.2 Physical and chemical properties of active substance

Table 2.2 Technical product: Oriental Fruit Moth Pheromone

Property	Result	Comment
Colour and physical state	Colourless or light yellow transparent liquid	
Odour	Mild and fruity	
Melting point range	N/A	
Boiling point range	115–123°C at 3 mm Hg	
Specific gravity	0.879 at 20°C	
Vapour pressure	5.3×10^{-3} mm Hg at 20°C	
Henry's Law constant at 20°C	Cannot be calculated, as value for solubility in water not reported	Based on vapour pressure and insolubility in water, this compound will be volatile under field conditions
Ultraviolet (UV)–visible spectrum	λ_{\max} for all three actives is <300 nm	
Solubility in water	Not soluble in water	

Property	Result	Comment
Solubility in organic solvents	Soluble in all common organic solvents; insoluble in DMSO, ethylene, and glycol	
<i>n</i> -Octanol–water partition coefficient, K_{ow}	>1000	
Dissociation constant	There are no dissociable moieties	
Stability (temperature, metal)	Stable against sunlight and hydrolysis when exposed to water	

Table 2.3 End-use product: Isomate-M 100 Oriental Fruit Moth Pheromone

Property	Result
Colour	Colourless or light yellow transparent
Odour	Mild waxy and sweet
Physical state	Liquid
Formulation type	Slow release generator
Nominal guarantee	Z-8-Dodecen-1-yl acetate 88.5% E-8-Dodecen-1-yl acetate 5.7% Z-8-Dodecen-1-ol 1.0%
Formulants	The product does not contain any U.S. EPA list 1 formulants or formulants known to be TSMP Track-1 substances
Container material and description	High-density polyethylene tubes in foil packet (400 tubes in one packet)
Specific gravity	0.878–0.880 at 20°C
pH	4.7
Oxidizing or reducing action	N/A
Storage stability	Data showed that when stored for 12 months at room temperature and 5°C, losses of 1.9% and 0.9% total active ingredients occur, respectively
Explosibility	Not explosive

2.3 Method for analysis of the active substance as manufactured

A single gas chromatographic method was provided for determination of the three actives and all major impurities. The validation data are shown in Table 2.4.

Table 2.4 Method validation

Method validation data					
Component	Method type	Recovery (%)	SD	Analytical range (mg/mL)	Method acceptability
Z-8-Dodecen-1-yl acetate	GC-FID	Not required	0.012 (n = 5)	0.08–40.0	Acceptable
E-8-Dodecen-1-yl acetate	GC-FID	Not required	0.015 (n = 5)	0.03–2.0	Acceptable
Z-8-Dodecen-1-ol	GC-FID	Not required	0.0016 (n = 5)	0.02–0.12	Acceptable
Major impurities	GC-FID	Not required	0.003–0.01 3 (n = 5)	0.01–0.2	Acceptable

2.4 Method for formulation analysis

The same gas chromatography (GC) method with flame ionization detection (FID) that was used to analyze the technical product was also provided for the analysis of the formulation. 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 Oriental Fruit Moth Pheromone used in the end-use product Isomate-M 100 Oriental Fruit Moth 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 TSMP Track-1 substances as identified in Appendix II of Regulatory Directive DIR99-03. The required physical and chemical properties of technical material and of the end-use product were determined. A GC method for the determination of actives in the formulation was submitted.

3.0 Toxicology evaluation

3.1 Human health and safety

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

The formulated product, Isomate-M 100 Oriental Fruit Moth Pheromone, is contained within a passive, retrievable dispenser, and so the potential for direct human exposure to the formulation ingredients is considered to be negligible.

A detailed review of the toxicity database available for Oriental Fruit Moth Pheromone Technical and its formulation, Isomate-M 100 Oriental Fruit Moth Pheromone, has been completed. The data submitted satisfactorily addressed the current toxicological requirements for registration of a pheromone technical active ingredient and a pheromone end-use product.

3.2 Acute toxicity: technical and formulation

Oriental Fruit Moth Pheromone Technical was considered to be of low acute toxicity by the oral (lethal dose 50% (LD₅₀) > 17.12 g a.i./kg bw), dermal (LD₅₀ > 2.0 g a.i./kg bw), and inhalation (LD₅₀ > 4.74 mg a.i./L) routes to Sprague–Dawley rats. It was slightly irritating when applied to the skin of New Zealand White rabbits and minimally irritating when instilled into the eyes of the same species. There were no reports of human dermal sensitization resulting from exposure to this product.

Based on the results of acute toxicity testing, no signal words are required to be displayed on the primary panel of the label.

Isomate-M 100 Oriental Fruit Moth Pheromone, containing 88.5% Z-8-Dodecen-1-yl acetate, 5.7% E-8-Dodecen-1-yl acetate, and 1.0% Z-8-Dodecen-1-ol, was considered to be of low acute toxicity by the oral, dermal, and inhalation routes, slightly irritating to the skin, and minimally irritating to the eyes. There are no reports of human dermal sensitization resulting from exposure to this product. Since this product is contained within a passive, retrievable dispenser, exposure potential is minimal.

¹ Refer to “*The White Paper—A Review Of The Current Bases For The United States Environmental Protection Agency’s Policies 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, U.S. EPA.

Based on the results of acute toxicity testing, and examination of the Material Safety Data Sheets (MSDSs), no signal words are required to be displayed on the primary panel of the label.

3.3 Mutagenicity: technical

Data provided by the applicant indicated that Oriental Fruit Moth Pheromone Technical was not a mutagenic agent.

3.4 Acceptable daily intake (ADI) and acute reference dose (ARfD) 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 and 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 ADI or an ARfD for Oriental Fruit Moth Pheromone Technical because of the inherent lack of toxicity of this compound and because it does not pose any significant residue concerns.

3.5 Food Quality Protection Act (FQPA) 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 compared to adults which may result from exposure to SCLPs or any potential to disrupt endocrine activity in humans.

4.0 Occupational and bystander exposure

4.1 Exposure assessment

The method of application is described in section 7.1.1.

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 reentry exposure are 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 used according to label directions.

The precautions statements should be amended to read the following: “When handling dispensers, wear chemical-resistant gloves and eye protection.”

5.0 Food residue exposure

The PMRA has no objections to the registration of Isomate-M 100 Oriental Fruit Moth Pheromone, since neither the technical grade active ingredient nor the end-use product are considered to pose any significant residue concerns. Furthermore, no ADI or ARfD were established for Oriental Fruit Moth Pheromone Technical due to the inherent lack of toxicity of this compound. Therefore, it is unlikely that this pheromone will pose any dietary concerns to any segment of the population.

6.0 Environmental assessment

The method of application is described in section 7.1.1. The active ingredients in the subject products are SCLPs.

The PMRA has determined that exposure of the environment to the end-use product will be very limited because the product is to be manually attached to fruit trees for control of the pest.

7.0 Value assessment

7.1 Effectiveness

7.1.1 Intended use

This product is formulated into slow-release “twist-tie” polythene dispensers, each containing 243.8 mg of pheromone. These are attached manually or by means of a pole applicator to the branches of trees at a rate of 250–375 dispensers/ha prior to moth emergence in the spring. As the dispensers release pheromone for up to 90 days, a second application may be required for late-season varieties of peach. If a second application is required, the product should be applied prior to the start of subsequent moth flights.

7.1.2 Mode of action

Isomate-M 100 Oriental Fruit Moth Pheromone acts through mating disruption (i.e., through disruption of pheromone communication) rather than by killing the pest. This non-toxic mode of action differs from that of traditional chemical insecticides.

Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol have been identified as sex pheromone components of Oriental fruit moth (OFM). In nature, sex pheromone is produced and released into the air by the female moth and is used to attract a mate. “Mating disruption” refers to the process of releasing synthetic pheromone into

the air at concentrations above background levels produced by female moths, thus disrupting communication between male and female moths. Although the exact mechanism by which disruption occurs is not known, the end result is that normal mating behaviour between male and female moths is disrupted, resulting in suppression 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, and an ambient level of pheromone sufficient to disrupt communication must continue throughout the mating period of the moth.

7.1.3 Nature of the pest problem

The Oriental fruit moth (*Grapholita molesta* (Bsk.)) is the most significant insect pest of peaches and nectarines in Ontario (it is not a pest in British Columbia). Although peaches and nectarines are the preferred host, apricots, apples, and pears may also be attacked. The OFM overwinters as a mature larva, and the moths appear in late May or early June. The first generation of larvae attack the developing shoots and fruit. There are three or four generations of the OFM per year. Larvae of the second, third, and fourth generations feed primarily on the fruit. Affected fruit are rendered unmarketable. Current control strategies involve application of chemical insecticides targeting larvae of each generation of the OFM. The economic threshold for OFM injury in most commercial peach orchards is <1% of the total crop at harvest.

7.1.4 Effectiveness against the pest

Results were reviewed from three field trials conducted between 1987 and 1998 which assessed the efficacy of the sex pheromone of the OFM (Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol) for mating disruption of this pest in the United States and Canada. The results are given in the following sections.

California 1996

This study presented results from efficacy trials conducted using Isomate-M 100 Oriental Fruit Moth Pheromone at the rate of 250 dispensers/ha in two California peach orchards. Efficacy was assessed by monitoring male moth catches (in four pheromone-baited traps per block) and by measuring OFM damage to shoots (sample size not specified) and fruit (1000/treatment) in treated and untreated blocks.

At the Yuba County site, where populations were reported to be low to moderate, trap catches in the block treated with Isomate-M 100 Oriental Fruit Moth Pheromone were near zero throughout the trial and were significantly reduced compared with the untreated block. Damage to shoots (assessed at the beginning of the third moth flight period) and damage to fruit at harvest were significantly lower in the plots treated with Isomate-M 100 Oriental Fruit Moth Pheromone compared with the untreated check (damage to fruit was 0.0% in the pheromone-treated block and 2.7% in the untreated block).

At the Sutter County site, where the population of the OFM was reported to be low, trap catches of male moths in the block treated with Isomate-M 100 Oriental Fruit Moth Pheromone were reduced to zero throughout the trial. Shoot damage and fruit damage were reported to be low in all blocks at the Sutter County site. The trap catch data from both sites suggest that Isomate-M 100 Oriental Fruit Moth Pheromone is effective in disrupting pheromone communication but do not demonstrate unequivocally that mating was disrupted. However, the results do show that under the conditions of low to moderate OFM populations encountered in the trial, Isomate-M 100 Oriental Fruit Moth Pheromone was effective in reducing both shoot and fruit damage compared with the untreated check and provided commercially acceptable control.

Ontario 1997–1999

The efficacy of an integrated and a conventional OFM management program was compared at three farms in the Niagara Peninsula of Ontario during the 1997, 1998 and 1999 growing seasons. This study is described by Trimble et al (2001). At each farm, an ≈4-ha block of peach orchard was treated with the integrated program and an ≈4-ha block of peach orchard was treated with the conventional program. There was at least a 200 metre buffer zone between blocks within a farm. In the integrated program, insecticide treatment (chlorpyrifos) was used to control the first generation of OFM and mating disruption using Isomate-M 100 Oriental Fruit Moth Pheromone was used to control the second and third generations of OFM. Isomate-M 100 Oriental Fruit Moth Pheromone was applied at the rate of 250 dispensers/ha 7–10 days before the beginning of the second flight of moths. In 1997, farm #1 was also treated with cypermethrin to control 2nd generation OFM larvae, and pirimicarb was applied to control green peach aphid, *Myzus persica*. In the conventional program, insecticide treatment was used to control OFM; chlorpyrifos was used against the first generation of OFM and 2–4 applications of cypermethrin targeted the second and third generations. Efficacy was assessed by recording catches of male moths in pheromone-baited traps and recording damage to shoots and fruit in blocks treated with the integrated and conventional management program for OFM. Traps baited with terpinyl acetate and sugar were placed in blocks managed by both programs. Captured moths were dissected and females were checked for the presence of spermatophores.

Following the application of pheromone dispensers, trap catches in blocks treated with the integrated program were reduced by 96–99% (1997), 98–100% (1998), and 99–100% (1999) compared with blocks on the conventional program. This demonstrated disruption of pheromonal communication between male and female OFM in plots treated with Isomate-M 100 Oriental Fruit Moth Pheromone.

There were significant differences between OFM injury to shoots and fruits when results from the integrated and convention management programs were compared for individual farms. However, when data from all three farms were pooled over the three-year study (1997–1999), there was no significant difference between mean percentage of shoots damaged by first generation OFM larvae in plots on the integrated program and those in

conventionally-treated plots; the same was true for mean percentage of shoots damaged by second generation OFM larvae, and for OFM feeding damage to fruits.

Data were provided on numbers and fertility of females captured in food bait traps in pheromone-treated and conventionally treated plots in one of the sites used in the study. Trap catch of females and percent fertility was reduced by 26–84 % and 14–53%, respectively, in plots treated with the integrated program relative to the conventional program during each OFM generation in each of the three years (with the exception of the first generation of OFM, which was not treated with pheromone). As in many other species of tortricids, captures of OFM females in traps baited with terpinyl acetate and sugar (plus water) tend to be biased towards mated and “spent” females (i.e. females that have laid their eggs and are low on energy). Although the use of food bait traps is probably not an accurate method for estimating the proportion of mated females in an orchard population, numbers of females captured and percent fertility were reduced in plots treated with the integrated program.

Ontario 1987–1990

This published study was not submitted by the applicant, but was referenced in a study report for the Ontario trials conducted in 1997–1999. This study reported on the results from efficacy field trials conducted at the Jordan Experimental Farm and a commercial peach orchard in Ontario during the years 1987–1990. The product tested was Isomate-M (each dispenser contained 75 mg pheromone and was applied at a rate of 1000–1300 dispensers/ha; this rate is similar to that proposed for Isomate-M 100 Oriental Fruit Moth Pheromone, for which dispensers contain 243.8 mg of pheromone and are proposed for application at 250–375 dispensers/ha). Efficacy was evaluated using virgin female baited traps and pheromone-baited traps and by assessing damage to shoots and fruit.

At the commercial orchard, where OFM densities were relatively low, commercially acceptable control (in terms of damage to fruit) was obtained in the pheromone-treated blocks during two successive growing seasons. However, Isomate-M 100 Oriental Fruit Moth Pheromone failed to provide commercially acceptable control of the OFM at the Jordan Experimental Farm plots where OFM population densities were high. The pheromone treatments appeared to be most effective in reducing fruit damage at the Jordan Experimental Farm in plots where OFM populations were first reduced by insecticide treatment during the previous year.

No male moths were caught in the virgin female baited traps in the pheromone-treated blocks, suggesting that male moths would have been unable to locate wild female moths. However, trap catches and levels of damage to fruit for the trials at the Jordan Experimental Farm were not correlated. The study authors suggested reasons for the failure of the pheromone treatment, including (i) the immigration of mated females into treated areas from adjacent untreated or insecticide-treated areas, (ii) the relatively small plot size used in the trials (0.3–0.5 ha), and (iii) the ability of male moths to locate females in the pheromone-treated blocks (however, catch results from traps baited with virgin

female moths suggest that this might not be the case). The study authors recommended that further efficacy research be conducted in larger commercial plantings over a number of consecutive seasons (e.g., as conducted during the submitted 1997–1999 trials in Ontario).

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

No adverse effects to the treated crop were reported in the efficacy field trials conducted with Isomate-M 100 Oriental Fruit Moth Pheromone.

7.3 Observations on undesirable or unintended side effects, e.g., on beneficial and other non-target organisms, succeeding crops, other plants, or parts of treated plants used for propagating purposes (e.g., seeds, cuttings, runners)

Due to its non-toxic mode of action, Isomate-M 100 Oriental Fruit Moth Pheromone is not expected to negatively impact beneficial and other non-target organisms.

7.3.1 Impact on succeeding crops

Isomate-M 100 Oriental Fruit Moth Pheromone is not expected to impact on succeeding crops.

7.3.2 Impact on adjacent crops

Isomate-M 100 Oriental Fruit Moth Pheromone is not expected to impact on adjacent crops.

7.3.3 Impact on seed viability

Isomate-M 100 Oriental Fruit Moth Pheromone is not expected to impact on seed viability.

7.4 Economics

Although registered for use on peaches, nectarines, apricots, apples, and pears, the primary use of Isomate-M 100 Oriental Fruit Moth Pheromone would be on peaches and nectarines in Ontario, as the OFM is not a pest in British Columbia. Approximately 3600 ha of peaches and nectarines are grown in Ontario.

7.5 Sustainability

Isomate-M 100 Oriental Fruit Moth Pheromone has potential as a tool to assist growers in the management of resistance by the OFM to other chemical insecticides (e.g., synthetic pyrethroids). The mode of action of Isomate-M 100 Oriental Fruit Moth Pheromone is

through disruption of pheromone communication rather than direct toxicity to the target pest. Pheromone pest control products are generally more target-specific than conventional pesticides, are used at concentrations close to those which occur in nature, and tend to dissipate fairly rapidly. For these reasons, it is expected that most pheromone pest control products would pose a low potential risk to human health or the environment compared with conventional pesticides.

Although Isomate-M 100 Oriental Fruit Moth Pheromone would be an alternative to chemical insecticides currently used for control of the OFM, it is likely that its use in a pest management program would be to complement the use of insecticide treatment rather than replace chemical insecticides completely. This is illustrated in the submitted efficacy study in Ontario (1997–1999), where Isomate-M 100 Oriental Fruit Moth Pheromone was used as part of an integrated program for OFM management.

7.5.1 Survey of alternatives

The OFM has developed resistance to most classes of insecticides registered for its control (e.g., organophosphates, carbamates). Synthetic pyrethroids are still effective in most orchards, however, low-level resistance to this class of insecticide has been reported in some areas. The need for repeated applications of insecticides for control of this pest (i.e., applications targeting each of several generations) presents a resistance management problem given that Ontario growers currently have only a single effective chemistry for use against this pest.

7.5.2 Compatibility with current management practices including integrated pest management (IPM)

Due to the high degree of target specificity of Isomate-M 100 Oriental Fruit Moth Pheromone, this product is compatible with orchard management practices including IPM.

7.5.3 Contribution to risk reduction

Due to the non-toxic mode of action of Isomate-M 100 Oriental Fruit Moth 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 development of resistance to pheromone products has been established.

7.6 Conclusions from value assessment

Results from the evaluated studies show that Isomate-M 100 Oriental Fruit Moth Pheromone can reduce damage to shoots or fruit by OFM to a commercially acceptable level when used under low population densities or when used in a program combining pheromone and insecticide treatment (e.g., following application of insecticide for control of first generation larvae). Although trap catch data for pheromone-baited traps suggest that Isomate-M 100 Oriental Fruit Moth Pheromone is effective in disrupting pheromone communication, the data do not unequivocally demonstrate that mating has been disrupted. Catch results from traps baited with virgin female moths during trials conducted in Ontario (1987–1990) suggest that the ability of male moths to locate female moths is reduced in pheromone-treated plots.

Sufficient efficacy data have been submitted to support full registration of Isomate-M 100 Oriental Fruit Moth Pheromone. A value summary for Isomate-M Oriental Fruit Moth Pheromone is shown in Table 7.1

Table 7.1 Value summary for Isomate-M 100 Oriental Fruit Moth Pheromone

Site	Peaches, nectarines, apricots, apples and pears (USC 14)
Product	ISOMATE-M 100 ORIENTAL FRUIT MOTH PHEROMONE (Reg. No. 26981; Z-8-Dodecen-1-yl acetate (88.5%), E-8-Dodecen-1-yl acetate (5.7%), Z-8-Dodecen-1-ol (1.0%))
Rate of application	250–375 dispensers/ha (each dispenser contains 243.8 mg of pheromone). Attach one dispenser per tree.
Number of applications	Up to 2 applications per year may be required.
Application methods	Attach dispensers securely to lateral branches in upper third of tree canopy, preferably 0.7–1 metre below treetop. Dispensers twisted too tightly might girdle branches. Can be applied efficiently from a moving trailer or with a pole applicator.

Application timing	<p>Apply prior to moth emergence in the spring. Dispensers release pheromone for up to 90 days depending on temperature. In crops with long field seasons (i.e., more than 90 days), or in orchards with high pest populations, a second application is recommended. If subsequent applications are required, apply prior to the start of subsequent flights. Consult your local extension specialist or certified crop advisors for proper timing.</p> <p>In crops which are late season hosts of Oriental fruit moth, such as pears, ISOMATE-M 100 ORIENTAL FRUIT MOTH PHEROMONE will not prevent crop damage resulting from immigration of mated female moths. Treatment of these crops with pheromone is recommended when they are within or nearby blocks treated with ISOMATE-M 100 ORIENTAL FRUIT MOTH PHEROMONE.</p>
Note	<p>It is critical that ISOMATE-M 100 ORIENTAL FRUIT MOTH PHEROMONE be applied as directed. Growers using this product must maintain careful records of damage within their orchard. Thorough sanitation programs consisting of removing and destroying infested fruit from trees and the ground are important. Careful monitoring of adult populations is essential since the use of ISOMATE-M 100 ORIENTAL FRUIT MOTH PHEROMONE is dramatically different from traditional broad-spectrum insecticides registered for Oriental fruit moth control. Designing successful programs with ISOMATE-M 100 ORIENTAL FRUIT MOTH PHEROMONE depends on ongoing discussion with IPM specialists, extension horticulturists, and company representatives. ISOMATE-M 100 ORIENTAL FRUIT MOTH PHEROMONE reduces mating of Oriental fruit moth. 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 unsprayed host species within 300 metres of treated field. This can be overcome by:</p> <ul style="list-style-type: none"> 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-M 100 ORIENTAL FRUIT MOTH PHEROMONE (e.g. a strip at least 50 metres wide nearest the treated field). c. Treatment of infestation sources with an effective insecticide. d. Treatment of 4–6 rows along border of pheromone treated orchard with insecticide. <p>Supplementary applications of insecticide are advised when ISOMATE-M 100 ORIENTAL FRUIT MOTH PHEROMONE is used to control high populations of Oriental fruit moth. Other pests must be monitored so that timely intervention with conventional insecticides is possible.</p>
Pests managed	Oriental fruit moth, <i>Grapholita molesta</i>

8.0 Proposed 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 Oriental Fruit Moth Pheromone Technical and associated end-use product Isomate-M 100 Oriental Fruit Moth Pheromone, containing Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol. The PMRA has concluded that the use of Oriental Fruit Moth Pheromone Technical and associated end-use product Isomate-M 100 Oriental Fruit Moth Pheromone, containing Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol 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 Oriental Fruit Moth Pheromone Technical and associated end-use product Isomate-M 100 Oriental Fruit Moth Pheromone, containing Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate, and Z-8-Dodecen-1-ol, for mating disruption of Oriental fruit moth in peach, nectarine, apricot, apple, and pear 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.

List of abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
CAS	Chemical Abstracts Service
FID	flame ionization detection
FQPA	<i>Food Quality Protection Act</i>
GC	gas chromatography
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	<i>n</i> -octanol–water partition coefficient
LD ₅₀	median lethal dose
MSDS	Material Safety Data Sheet
OFM	Oriental fruit moth
PCP	Pest Control Products
PMRA	Pest Management Regulatory Agency
SCLP	straight chain lepidopteran pheromones
SD	standard deviation
TSMP	Toxic Substances Management Policy
U.S. EPA	U.S. Environmental Protection Agency
UV	ultraviolet

References

Trimble, R.M., D.J. Pree, and N.J. Carter. 2001. Integrated control of Oriental fruit moth (*Lepidoptera: Tortricidae*) in peach orchards using insecticide and mating disruption. *Journal of Economic Entomology* 94: 476–485.