

## **3M MEC Eastern Pine Shoot Borer Pheromone 9-Dodecenyl Acetate**

The active ingredient 9-dodecenyl acetate and the associated end-use product MEC Eastern Pine Shoot Borer Pheromone Concentrate are proposed for registration under Section 13 of the Pest Control Products Regulations, having completed the Biopesticide Joint Review process set up between Canada and the United States (U.S.) under the North American Free Trade Agreement (NAFTA) Technical Working Group (TWG) on Pesticides. The active ingredient was developed by Bedoukian Research Inc., and the end-use product by 3M Canada.

These are the first pheromones ever to be registered for pest control in forestry as well as being the first sprayable pheromones marketed in Canada. The Eastern Pine Shoot Borer Pheromone is the only pest control product available that can be used to protect Canada's forests against this destructive insect.

This Proposed Regulatory Decision Document (PRDD) provides a summary of data reviewed and the rationale for the proposed Section 13 registration of these products. The Pest Management Regulatory Agency (PMRA) will accept written comments 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)***

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## **Foreword**

The submissions for registration of Bedoukian 9-Dodecenyl Acetate Technical Pheromone and its end-use product 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate were reviewed jointly by the PMRA and the U.S. Environmental Protection Agency (EPA).

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.

Taking these factors into consideration, a time-limited registration has been granted by the PMRA and the EPA until December 31, 1999 in order to allow users access to this low-risk product, while providing concerned Canadians an opportunity to provide input into the final decision through this PRDD.

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## 1.0 Introduction

3M MEC Eastern Pine Shoot Borer Pheromone Concentrate is manufactured by 3M Canada Company of London, Ontario. The active ingredient in this product, E/Z (20/80)-9-dodecenyl acetate, is manufactured by Bedoukian Research Inc. of Danbury, Connecticut.

3M MEC Eastern Pine Shoot Borer Pheromone Concentrate is a microencapsulated formulation containing 20% of the active ingredient (a.i.) E/Z (20:80)-9-dodecenyl acetate. The end-use product is proposed for control of eastern pine shoot borer (*Eucosma gloriola*) in forests and woodlands through mating disruption. The product is proposed for application at a rate of 15–30 g a.i./hectare (ha) by aerial or ground equipment. The proposed timing of application is one week before the adult moth flight begins.

E/Z-9-dodecenyl acetate has been identified as the sex pheromone for the eastern pine shoot borer. In nature, the sex pheromone is produced and released into the air by the female moth and is used to attract a mate. Mixtures of the (Z) and (E) isomers of 9-dodecenyl acetate at ratios of 9:1 and 8:2 have been shown to be optimum for attracting male moths of eastern pine shoot borer. “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 the male moth does not locate a female and mating does not occur, resulting in subsequent reductions in the pest population. To be effective in reducing insect damage, the product must be applied prior to the beginning of the adult moth flight season, and an ambient level of pheromone sufficient to disrupt communication must last throughout the moth mating period.

E/Z-9-dodecenyl acetate is a “straight-chained lepidopteran pheromone” (SCLP). This category of pheromone products is generally regarded to pose a low risk to human health and the environment based on available studies.

## 2.0 Product chemistry

### 2.1 Identity of the active substance and preparation containing it

Active substance: 9-dodecenyl acetate (E + Z isomers)

Function: pheromone

Chemical name (International Union of Pure and Applied Chemistry):	(Z)-9-dodecen-1-yl acetate
	(E)-9-dodecen-1-yl acetate
Chemical name (Chemical):	(Z)-9-dodecen-1-ol acetate

Abstracts Service [CAS]: (E)-9-dodecen-1-ol acetate

CAS Registry Number: 16974-11-1 for Z-isomer  
35148-19-7 for E-isomer

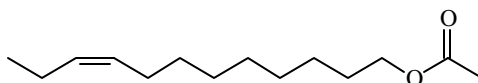
Nominal purity of active: 97%

Identity of relevant impurities of toxicological, environmental and/or other significance: Impurities of toxicological concerns are not expected to be present in the raw materials, nor are they expected to be generated during the manufacturing process.

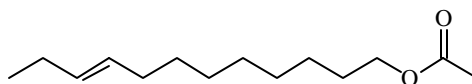
Molecular formula:  $C_{14}H_{26}O_2$

Molecular mass: 226.36

Structural formula:



Z-9-Dodecenyl Acetate



E-9-Dodecenyl Acetate

## 2.2 Physical and chemical properties of active substance

### Technical product: Bedoukian 9-Dodecenyl Acetate Technical Pheromone

Property	Result
Colour and physical state	Colourless liquid
Odour	Mild, fruity
Melting point/range	Not applicable
Boiling point/range	120/C at 0.5 mm Hg
Density	0.877 g/cm <sup>3</sup> at 25/C
Vapour pressure	1.59 × 10 <sup>-2</sup> mm Hg at 20/C Estimated
UV/visible spectrum at 26/C	Not expected to absorb UV at wavelength above 300 nm

Property	Result
Solubility in water	$1.8 \times 10^{-5}$ mol/L Estimated
Solubility in organic solvents	Completely soluble in hexane, acetone and methanol
n-Octanol/water partition coefficient	$K_{ow} = 1.9 \times 10^5$ Estimated
Dissociation constant	Not applicable, there are no dissociable moieties

**End-use product: 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate**

Property	Result
Colour	Bone or pale yellow
Odour	Paraffinic (waxy)
Physical state	Liquid
Formulation type	Microencapsulated suspension
Guarantee	20% E/Z (20/80)-9-dodecenyl acetate
Container material and description	High density polyethylene
Specific gravity	7.99 lb/gal (U.S.)
pH	9.2
Storage stability	Stable for 30 days at 50/C. A one-year ambient temperature testing is under way.

## 2.3 Methods of analysis

### 2.3.1 Method for analysis of the active substance as manufactured

A gas chromatography (GC) method with flame ionization detector was used for the determination of the active substance and significant impurities (content  $\leq 1\%$ ) in the technical product. The method has been shown to have satisfactory precision. Validation data for the accuracy and linear range of the method were waived, as there are no cleanup procedures involved in the sample preparation, and the flame ionization detector usually has a wide linear range.

### 2.3.2 Method for formulation analysis

A GC method with flame ionization detector was used for the determination of active substance

in the formulation. The method has been shown to have satisfactory specificity, linearity, precision and accuracy.

### **3.0 Toxicology evaluation**

#### **3.1 Human health and safety**

Reduced toxicological data requirements have been established for SCLPs. Straight-chained lepidopteran pheromones contain only carbon, hydrogen and oxygen and are poorly soluble in water. They are products of fatty acid metabolism and are biodegradable by enzyme systems present in most living organisms. Health studies have indicated that these substances pose minimal risk and provide effective pest control at low concentrations, similar to those occurring in nature.<sup>1</sup>

The formulated product, 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate, is encapsulated and is not for use on food. Hence, the potential for direct human exposure is considered to be negligible. In addition, since capsule size is ~25 microns, it is not considered to pose any hazard via the inhalation route to applicators.

A detailed review of the toxicity data base available for Bedoukian 9-Dodecenyl Technical Pheromone and its formulation, 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate, 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**

Bedoukian 9-Dodecenyl Acetate Technical Pheromone was considered to be of low acute toxicity by the oral, dermal and inhalation routes to laboratory animals. It was minimally irritating when applied to the skin and instilled into the eyes of rabbits. 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.

Data provided by the applicant indicated that 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate, containing 20% E/Z-9-dodecenyl acetate, was of low acute oral, dermal and inhalation toxicity, slightly irritating to the skin, minimally irritating to the eyes, and was not

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<sup>1</sup> 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.

expected to be a dermal sensitizer.

Based on the results of acute toxicity testing, 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 Bedoukian 9-Dodecenyl Acetate Technical Pheromone was not a mutagenic agent.

### **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/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 or an acute reference dose for Bedoukian 9-Dodecenyl Acetate Technical Pheromone due to the inherent lack of toxicity of this compound, and since it does not pose any significant residue concerns.

### **3.5 United States *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, nor of any potential to disrupt endocrine activity in humans.

## **4.0 Occupational and bystander exposure**

### **4.1 Exposure assessment**

The proposed end-use product contains 20% E/Z-9-dodecenyl acetate as the active ingredient to control the eastern pine shoot borer in forests and woodlots. The proposed end-use product is a microencapsulated formulation that is to be applied at a rate of 15–30 g a.i./ha. The product is to be applied one week before the adult moth flight season begins and may be applied using either ground or aerial equipment.

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

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



## 4.2 Risk assessment

Based on the toxicological profile of the active ingredient, it is concluded that use of the proposed product is not likely to present a risk to workers provided the label specifies appropriate personal protective equipment. The precautionary statements on the label should read: “During mixing, loading and application, personnel should wear long-sleeved shirt, long pants, shoes and socks. In addition, chemical-resistant gloves and goggles should be worn during mixing, loading, cleanup or repair activities.”

## 5.0 Environmental assessment

The submissions for these products were reviewed jointly with the EPA, with the data/information package apportioned between the PMRA and the EPA. These submissions encompassed a reduced data set agreed to by the EPA, the PMRA, and 3M Canada, where it was decided that the Environmental Assessment Division of the PMRA would review data on toxicity of the products to aquatic invertebrates and fish. Subsequently, the PMRA conditionally accepted waivers for these data.

Upon further review of these waivers, the PMRA concurs with the submitted rationales that the subject product would not pose an appreciable risk to aquatic invertebrates and fish, based on the proposed use and an exposure assessment using an elevated rate of application and a maximum exposure scenario in which the encapsulated pheromone was released instantly in the water body. An assessment of the potential of the end-use product to form a film and surface coverage on water (thus, reducing the transmission of oxygen) following application at an elevated rate also indicated that the product would not present a risk. Finally, a literature search conducted by the applicant yielded no information that microcapsules of an average size of 30 micrometres would interfere with the respiration of *Daphnia* sp. or get caught in the gills of fish.

The EPA has also waived environmental data for the subject products based on the above-mentioned rationales.

## 6.0 Value assessment

### 6.1 Intended uses

3M MEC Eastern Pine Shoot Borer Pheromone Concentrate is a microencapsulated formulation containing 20% of the active ingredient E/Z (20:80)-9-dodecenyl acetate. The end-use product is proposed for control of eastern pine shoot borer (*Eucosma gloriola*) in forests and woodlands through mating disruption. The product is proposed for application at a rate of 15–30 g a.i./ha by aerial or ground equipment. The proposed timing of application is one week before the adult moth flight begins.

## 6.2 Description of pest problem

Eastern pine shoot borer (Lepidoptera: Tortricidae) is a pest of pines in eastern Canada and the northeastern U.S. Its distribution generally follows that of eastern white pine, extending from southeastern Manitoba and Minnesota through to eastern Ontario, New York and Pennsylvania. Particularly susceptible are plantations of red, jack, white, Scots, and Austrian pine; however, white spruce and Douglas fir may also be infested.

Eastern pine shoot borer overwinters as a pupae on the ground. Moths emerge in the spring with peak adult activity occurring from late April to mid-May in Pennsylvania, New York and southern Ontario, but not until late May or early June in northwestern Ontario, Manitoba and Minnesota. Male moths locate females through pheromone communication. The adult flight season generally lasts four to five weeks. Eggs are laid either on the bark, needles, needle sheaths or buds of new shoots and generally hatch within two to four weeks. First instar larvae bore directly into the pith region and tunnel toward the base of the shoot. The insect passes through five larval stages, each of which feeds in a tunnel within the shoot. At the end of feeding, the mature larva chews an exit hole in the shoot, drops to the ground and pupates within a cocoon in the soil. There is a single generation per year.

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

## 6.3 Efficacy trials

Results were submitted from three field trials that assessed the efficacy of 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate. Two of the trials assessed the efficacy of 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate against eastern pine shoot borer in Ontario pine plantations. The third trial was conducted in Chile on a different pest (European pine shoot moth) and with a slightly different formulation from that proposed for registration (100% E/Z-9-dodecenyl acetate as the active ingredient). Products were applied by either helicopter or ground application equipment (mist blower) at rates ranging from 15–40 g a.i./ha. The treatments were timed to coincide with the beginning of the moth flight period. Efficacy was assessed by placing pheromone-baited traps in the treated and untreated plots and recording trap catches of male moths following application. The treatment is assumed to be effective if few or no male moths are caught in the traps in the treated plots and many male moths are caught in the untreated plots. A reduction in trap catches in the treated plots reflects disruption of pheromone communication by male and female moths.

In all three trials, trap catches of male moths in treated plots were reduced by >90% during the moth flight period compared with the untreated plots. This suggests that the treatments were effective in disrupting pheromone communication in eastern pine shoot borer (i.e., disrupt ability of male moths to locate pheromone-baited traps that are used to simulate female moths). However, in the only trial that assessed eastern pine shoot borer damage to trees following treatment, there was no significant correlation between reduction in trap catches of male moths and reductions in insect damage. The apparent lack of reduction in insect damage in the submitted study could be a function of the experimental design of the trial (e.g., small plot sizes that are susceptible to immigration of mated female moths) rather than the pheromone product not being effective in disruption of mating. It is generally accepted that large scale trials under operational conditions (i.e., large plot sizes to mitigate effects of migration of mated female moths) are required to adequately assess the efficacy of pheromone products that act by mating disruption.

**Other available efficacy information (not submitted by applicant):** Results from published studies have shown E/Z-9-dodecenyl acetate to be effective for mating disruption of the western pine shoot borer (*Eucosma sonomana*, Kearfott), a closely related species to the eastern pine shoot borer (Overhulser et al. 1980; Sower et al. 1982; Sartwell et al. 1980; Sartwell et al. 1983). The pheromone treatments in these studies included hollow fibre formulations applied by aircraft, or polyvinyl strips applied manually. The pheromone treatments in these trials were effective in disrupting pheromone communication (based on trap catch data in treated and untreated plots), and resulted in reductions of damage to terminal leaders by 46–80% compared with untreated plots. Although the formulations and target pest tested in these trials differed from that for 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate, these trials show that pheromone treatments with E/Z-9-dodecenyl acetate are potentially useful in mating disruption of certain *Eucosma* forest insect pests, with resulting deduction in insect damage.

#### **6.4 Adverse effects to crop (phytotoxicity)**

No phytotoxic effects on the treated pine trees were observed in the efficacy field trials conducted with 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate.

#### **6.5 Alternatives**

There are no chemical insecticides registered for control of eastern pine shoot borer. Control with chemical insecticides is considered to be difficult as the larvae are internal feeders (i.e., feed within the shoots). High applications of a systemic insecticide (e.g., aldicarb) as soil treatment have been reported to provide good control of larvae. However, such treatment is considered impractical except for individual high-value trees.

A number of species of hymenopterous parasites are known to attack eastern pine shoot borer (e.g., *Glypta* sp., *Rhorus* sp., *Bracon rhyacioniae*, *Elachertus cidariae*, *Habrocytus* sp.).

There are no known attempts of rearing and release of predators or parasites for control of eastern pine shoot borer.

Pruning and removal of infested shoots may reduce population levels in the following year. However, this activity is labour intensive and is practical only in small, high-value plantations of small trees (e.g., less than two metres tall).

## **6.6 Value conclusions and recommendations**

Results from efficacy studies suggest that 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate is effective in disrupting pheromone communication in eastern pine shoot borer, with potential for disruption of mating. However, there was no significant correlation between reductions in trap catches of male moths and reductions in subsequent insect damage in the submitted studies. The apparent lack of reduction in insect damage in the submitted study could be a function of the experimental design of the trial (e.g., small plot sizes that are susceptible to immigration of mated female moths) rather than the pheromone product not being effective in disruption of mating. Published studies have shown E/Z-9-dodecenyl acetate to be effective for mating disruption of related *Eucosma* species with resulting reductions in pest damage.

The active ingredient in 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate is a straight-chained lepidopteran pheromone that is generally considered to pose a low risk to human health and the environment compared with traditional chemical insecticides. There are currently no practical control measures available for eastern pine shoot borer in large pine plantations. In light of these considerations, and based on the submitted efficacy data that suggest that the product is effective in disrupting pheromone communication, registration of 3M MEC Eastern Pine Shoot Borer Pheromone Concentrate can be supported.

## **7.0 Proposed regulatory decision**

The Agency has established, pursuant to Section 13 of the Pest Control Products Regulations, interim registrations (time-limited to December 31, 1999) of the technical grade active ingredient (Bedoukian 9-Dodecenyl Acetate Technical Pheromone, Registration Number 25893) and the associated end-use formulation (3M MEC Eastern Pine Shoot Borer Pheromone Concentrate, Registration Number 25894), and is open to comments on their future regulatory status.

## 8.0 References

Overhulser, D.L., G.E. Daterman, L.L. Sower, C. Sartwell and T.W. Koerber. 1980. Mating disruption with synthetic sex attractants controls damage by *Eucosma sonomana* (Lepidoptera: Tortricidae, Olethreutinae) in *Pinus ponderosa* plantations II. Aerially applied hollow fiber formulation. *Can. Entomol.* 112: 163-165.

Sartwell, C., G.E. Daterman, D.L. Overhulser and L.L. Sower. 1983. Mating disruption of Western pine shoot borer (Lepidoptera: Tortricidae) with widely spaced releasers of synthetic pheromone. *J. Econ. Entomol.* 76:1148-1151.

Sartwell, C., G.E. Daterman, L.L. Sower, D.L. Overhulser, and T.W. Koerber. 1980. Mating disruption with synthetic sex attractants controls damage by *Eucosma sonomana* (Lepidoptera: Tortricidae, Olethreutinae) in *Pinus ponderosa* plantations I. Manually applied polyvinyl chloride formulation. *Can. Entomol.* 112: 159-162.

Sower, L.L., D.L. Overhulser, G.E. Daterman, C. Sartwell, D.E. Laws and T.W. Koerber. 1982. Control of *Eucosma sonomana* by mating disruption with synthetic pheromone. *J. Econ. Entomol.* 75: 315-318.