



US Environmental Protection Agency Office of Pesticide Programs

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

(E,Z)-3,13-OCTADECADIEN-1-OL and

(Z,Z)-3,13-OCTACECADIEN-1-OL

Western Poplar Clearwing Moth Pheromone

(PC Codes 129117 and 129118)

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(PC Codes 129117 and 129118)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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I. EXECUTIVE SUMMARY

A. IDENTITY

The new active ingredients (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol are synthetic straight-chain lepidopteran pheromones (SCLPs) used to control the Western Poplar Clearwing moth (WPCM). The manufacturing use product (MP) CheckMate WPCM Technical Pheromone, contains 75.08% (E,Z)-3,13-octadecadien-1-ol and 18.37% (Z,Z)-3,13-octadecadien-1-ol by weight. The end use product (EP), Checkmate WPCM-F, contains 14.02% (E,Z)-3,13-octadecadien-1-ol and 3.55% (Z,Z)-3,13-octadecadien-1-ol. The product chemistry data submitted by the registrant satisfies the requirements for registration of the product.

B. USE/USAGE

WPCM Pheromone, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol, will be incorporated into pesticides products intended to disrupt the mating cycle of the Western Poplar Clearwing moth. The active ingredients have been used in emergency exemptions (FIFRA Section 18) for 3 different formulations in 2003 and 2004 on 34,417 acres in the states of Washington and Oregon. These active ingredients have also been used, in three formulations under Experimental Use Permits (FIFRA Section 5) in 2005 on 29,405 acres in the states of Oregon and Washington.

C. RISK ASSESSMENT

Application to poplar, white birch, willows and locust is generally not a food use. However, SCLPs are already exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1153). Therefore, if any gardens or food crops are treated, the existing tolerance will cover the treatment.

All of the toxicology and environmental data requirements for these active ingredients were waived per the Agency publication OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (<http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>). This document reports that no risks to human health are expected from the use of lepidopteran pheromones based on their low toxicity in animal testing and the expected low exposure to humans. Furthermore, adverse effects on nontarget organisms are not expected because SCLPs are released in very small quantities into the environment, and are specific for the targeted pest. Appropriate precautionary labeling of end use products containing SCLPs will further minimize any risks from exposure to these active ingredients.

The Agency has considered (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects to humans or the environment from the use of these active ingredients. The Agency is basing its risk management decision regarding the registration of

WPCM pheromone products on the known low toxicity of lepidopteran pheromones, the limited exposure to humans, and the precautionary labeling that minimizes exposure and mitigates risk to nontarget organisms. The Agency believes that (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol can be used without causing unreasonable adverse effects to humans or the environment.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps except for storage stability and corrosion characteristics data. As a condition of registration these data will be provided within 18 months of the date of registration of the product containing (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol Checkmate WPCM Technical Pheromone (EPA Reg. No.56336-48) and Checkmate WPCM-F (EPA Reg. No. 56336-40).

II. OVERVIEW

A. ACTIVE INGREDIENTS OVERVIEW

Common Name:	(E,Z)-3,13-octadecadien-1-ol
	(Z,Z)-3,13-octadecadien-1-ol
Chemical Name:	(E,Z)-3,13-octadecadien-1-ol
	(Z,Z)-3,13-octadecadien-1-ol
Chemical Formula:	C ₁₈ H ₃₄ O
Chemical Family:	Insect attractant, repellent and chemosterilant
Trade and Other Names:	CheckMate WPCM Technical Pheromone and Checkmate WPCM-F
CAS Registry Number:	66410-28-4
	66410-24-0
OPP Chemical Code:	129117
	129118
Basic Manufacturer:	Suterra LLC 213 SW Columbia St. Bend, OR 97702

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

Type of Pesticide: Synthetic semiochemical insect attractant (mating disrupter)

Use Sites: Poplar, White Birch, Willow, Locust, and other crops attacked by Western Polar Clearwing Moth.

Target Pests: Western Poplar Clearwing Moth (*Paranthrene robiniae*)

Formulation Types: Liquid, and Solid particles in a liquid suspension

Method and Rates of Application: Traps, lures, puffers, and/or sprayable formulations.

Use Practice Limitations: Applicators must wear personal protective equipment (PPE). PPE is long sleeved shirt and long pants, waterproof gloves, and shoes plus socks. There is a restricted entry interval (REI) of 4 hours. The application rate cannot exceed 150 grams of active ingredient per acre per year.

C. ESTIMATED USAGE

The compounds (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol act as mating disruptors. These active ingredients have been used in three formulations (dispenser, battery operated puffer, and a flowable) under emergency exemptions (FIFRA Section 18) in 2003 and 2004, on 29,405 acres in the states of Washington and Oregon. These active ingredients have also been used, in three formulations, under Experimental Use Permits (FIFRA Section 5) in 2005 on 29,405 acres in the states of Oregon and Washington.

D. DATA REQUIREMENTS

The Agency has supported the registrant's request for waivers from the requirements of studies/data for acute mammalian toxicity and for non-target organism testing. These data were waived based on the following criteria from the Agency publication entitled OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (<http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>): 1) low toxicity in animal testing, 2) expected low exposure to humans, 3) no expected risk to human health, 4) no reported adverse effects during more than 10 years of use as pesticides, and 5) no expected adverse effects to nontarget organisms.

Product analysis data requirements for the manufacturing and end use products were adequately satisfied except for storage stability and corrosion characteristics data. As a condition of registration these data will be provided within 18 months of the date of registration.

The data requirements for granting these registrations under Section 3(c)(7)(A) of FIFRA have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on the submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of WPCM pheromone products as long as they are used as labeled.

E. REGULATORY HISTORY

On November 16, 2005, the Agency received an application from Suterra LLC, to register CheckMate WPCM Technical Pheromone, containing two new active ingredients, 75.08% (E,Z)-3,13-octadecadien-1-ol and 18.37% (Z,Z)-3,13-octadecadien-1-ol by weight. Suterra has previously submitted an application for the end use product, which could not be processed before the technical product. A notice of receipt of the application for registration of CheckMate WPCM Technical Pheromone with the two new active ingredients, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol, for control of the Western Poplar Clearwing moth was published in the Federal Register on March 29, 2006 (Volume 71; Number 60).

The Agency approved the use of the WPCM pheromone containing the active ingredients, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol, under emergency exemptions (FIFRA Section 18) in 2003 and 2004, on 29,405 acres in the states of Washington and Oregon and under Experimental Use Permits (FIFRA Section 5) in 2005 on 29,405 acres also in the states of Oregon and Washington.

F. CLASSIFICATION

(E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol are synthetic straight-chained lepidopteran pheromones and are classified as a biochemical pesticide.

G. FOOD CLEARANCES/TOLERANCES

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1153). These active ingredients are intended to disrupt the mating of a forest tree pest and should not be intentionally applied to food crops.

III. SCIENCE ASSESSMENT

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol are satisfied except for storage stability and corrosion characteristics data. As a condition of registration these data will be provided within 18 months of the date of registration to complete these studies.

1. Product Identity and Mode of Action

- a. Product Identity:** The new active ingredients, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol, represent 75.08% and 18.37% by weight of the manufacturing use product CheckMate WPCM Technical Pheromone, which is a light yellow transparent oily liquid with a mild, waxy sweet odor. The end use product, Checkmate WPCM-F contains 14.02% (E,Z)-3,13-octadecadien-1-ol and 3.55% (Z,Z)-

3,13-octadecadien-1-ol which is a opaque pale crème colored liquid with a waxy, fatty odor.

- b. **Mode of Action:** WPCM pheromone is a synthetic lepidopteran pheromone for monitoring of mating disruption of the Western Poplar Clearwing moth by a non-toxic mode of action. When the pheromone is released into the air where males are looking for females, the males become confused and cannot easily locate the females.

2. Food Clearances/Tolerances

Straight-chained lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1153). These active ingredients are intended to disrupt the mating of a forest tree pest and should not be intentionally applied to food crops.

3. Physical and Chemical Properties Assessment

The physical and chemical characteristics of Checkmate WPCM Technical Pheromone were submitted to support its registration. These are summarized in Table 1.

Table 1. Product chemistry data requirements			
Guideline No.	Study	Results	MRID No.
151-10 (OPPTS 880.1100)	Product identity	The submitted data satisfy the requirements for product identity.	46776801
151-11 (OPPTS 880.1200)	Manufacturing process	The submitted data satisfy the requirements for the manufacturing process.	46776801
151-12 (OPPTS 880.1400)	Discussion of formation of unintentional ingredients	The submitted data satisfy the requirements for the discussion of the formation of unintentional ingredients.	46776801
151-13 (OPPTS 830.1700)	Analysis of samples	The submitted data satisfy the requirements for the analysis of samples.	46689602
151-15 (OPPTS 830.1750)	Certification of limits	The submitted data satisfy the requirements for the certification of limits.	46689602
151-16 (OPPTS 830.1800)	Analytical method	An acceptable analytical method was submitted.	46689602
Physical/chemical Properties for the MP			
63-2 (OPPTS 830.6302)	Color	light yellow, transparent oily	46776802
63-3 (OPPTS 830.6303)	Physical State	Liquid	46776802
63-4 (OPPTS 830.6304)	Odor	Mild, waxy sweet	46776802

Table 1. Product chemistry data requirements			
Guideline No.	Study	Results	MRID No.
63-5 (OPPTS 830.7200)	Melting point	Not applicable, product is a liquid	46776802
63-6 (OPPTS 830.7220)	Boiling point	180-193EC/66Pa	46776802
63-7 (OPPTS 830.7300)	Density	Specific gravity = 0.849-0.850 g/cm ³ 20EC	46776802

Table 1. Product chemistry data requirements Cont.			
63-8 (OPPTS 830.7840)	Solubility	0.090 mg/L in water Soluble in n-hexane, benzene, n-pentane, toluene, methylene chloride, chloroform, ethanol, ethyl ether, acetonitrile, THF, acetone, DMF. Insoluble in DMSO and ethylene glycol.	46776802
63-9 (OPPTS 830.7950)	Vapor Pressure ^a	0.0005-0.0009 Pa @ 20°C	46776802
63-10 (OPPTS 830.7370)	Dissociation Constant	Not required for MP	46776802
63-11 (OPPTS 830.7550)	Octanol/water partition coefficient	Not required for MP	46776802
63-12 (OPPTS 830.7000)	pH	5.4 at @ 25°C	46776802
63-13 (OPPTS 830.6313)	Stability	Not required for MP. Stable as packaged in stainless steel containers	46776802
63-14 (OPPTS 830.6314)	Oxidation/reduction	Contains no oxidizing/reducing agents	46776802
63-15 (OPPTS 830.6315)	Flammability	Flash point = 168°C	46776802
63-16 (OPPTS 830.6316)	Explosibility	Product is not explosive	46776802
63-17 (OPPTS 830.6317)	Storage stability ^b	This data is required as a condition of registration and must be submitted within 18 month of the registration date.	46776802
63-18 (OPPTS 830.7100)	Viscosity	23-25 cS @ 20°C	46776802
63-19 (OPPTS 830.6319)	Miscibility	Not applicable, product is not an emulsifiable liquid	46776802
63-20 (OPPTS 830.6320)	Corrosion characteristics ^b	This data is required as a condition of registration and must be submitted within 18 month of the registration date.	46776802
63-21 (OPPTS 830.6321)	Dielectric breakdown voltage	Not applicable, not for use in/around electrical equipment	46776802
OPPTS 830.7050	UV/Visible absorption	Not required for MP	

^aAs a condition of registration the registrant must provide the storage stability and corrosion characteristics data within 18 months of the date of registration of the product containing Checkmate WPCM Technical Pheromone (56636-48).

The physical and chemical characteristics of Checkmate WPCM-F were submitted to support its registration. These are summarized in Table 2.

Table 2. Product chemistry data requirements			
Guideline No.	Study	Results	MRID No.
151-10 (OPPTS 880.1100)	Product identity	The submitted data satisfy the requirements for product identity.	45858901
151-11 (OPPTS 880.1200)	Manufacturing process	The submitted data satisfy the requirements for the manufacturing process.	45858901
151-12 (OPPTS 880.1400)	Discussion of formation of unintentional ingredients	The submitted data satisfy the requirements for the discussion of the formation of unintentional ingredients.	45858901
151-13 (OPPTS 830.1700)	Analysis of samples	The submitted data satisfy the requirements for the analysis of samples.	45858902
151-15 (OPPTS 830.1750)	Certification of limits	The submitted data satisfy the requirements for the certification of limits.	45858902
151-16 (OPPTS 830.1800)	Analytical method	An acceptable analytical method was submitted.	45858902
Physical/chemical Properties for the MP			
63-2 (OPPTS 830.6302)	Color	Opaque, pale yellow crème colored	45858903
63-3 (OPPTS 830.6303)	Physical State	Solid particles in liquid suspension	45858903
63-4 (OPPTS 830.6304)	Odor	Waxy, fatty odor	45858903
63-5 (OPPTS 830.7200)	Melting point	Not applicable, product is a liquid	45858903
63-6 (OPPTS 830.7220)	Boiling point	Not required for end use product (EP)	
63-7 (OPPTS 830.7300)	Density	Specific gravity = 0.97	45858903

Table 2. Product chemistry data requirements Cont.			
63-8 (OPPTS 830.7840)	Solubility	Not required for EP	45858903
63-9 (OPPTS 830.7950)	Vapor Pressure	Not required for EP	45858903
63-10 (OPPTS 830.7370)	Dissociation Constant	Not required for EP	45858903
63-11 (OPPTS 830.7550)	Octanol/water partition coefficient	Not required for EP	45858903
63-12 (OPPTS 830.7000)	pH	6.5 to 7.0	45858903

63-13 (OPPTS 830.6313)	Stability	Not required for EP.	45858903
63-14 (OPPTS 830.6314)	Oxidation/reduction	Contains no oxidizing/reducing agents	45858903
63-15 (OPPTS 830.6315)	Flammability	Non-flammable solid in aqueous suspension	45858903
63-16 (OPPTS 830.6316)	Explosibility	Product is not explosive	45858903
63-17 (OPPTS 830.6317)	Storage stability ^b	This data is required as a condition of registration and must be submitted within 18 month of the registration date.	45858903
63-18 (OPPTS 830.7100)	Viscosity	Not appropriate for a solid in aqueous suspension.	45858903
63-19 (OPPTS 830.6319)	Miscibility	Not applicable, product is not an emulsifiable liquid	45858903
63-20 (OPPTS 830.6320)	Corrosion characteristics ^b	This data is required as a condition of registration and must be submitted within 18 month of the registration date.	45858903
63-21 (OPPTS 830.6321)	Dielectric breakdown voltage	Not applicable, not for use in/around electrical equipment	45858903

^bAs a condition of registration the registrant must provide the storage stability and corrosion characteristics data within 18 months of the date of registration of the product containing Checkmate WPCM-F (56636-40).

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Assessment

The active ingredients, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol, are straight chain lepidopteran pheromones. The registrant requested waivers for all Tier I mammalian toxicity studies.

The Agency has previously reviewed the mammalian toxicity data and other information submitted for numerous straight chain lepidopteran pheromones and found them to be adequate for their registration. It is the Agency's position that based on low toxicity in test animals, and the expected low exposure to humans, no risk to human health is expected from the use of lepidopteran pheromones, and consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (<http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>)). The Agency therefore granted the request for waivers for all Tier I mammalian toxicity studies (Table 3).

Guideline No.	Study	Results	MRID No.
152-10 (OPPTS 870.1100)	Acute oral toxicity	Waiver accepted	46698604

152-11 (OPPTS 870.1200)	Acute dermal toxicity	Waiver accepted	46698604
152-12 (OPPTS 870.1300)	Acute inhalation toxicity	Waiver accepted	46698604
152-13 (OPPTS 870.2400)	Primary eye irritation	Waiver accepted	46698604
152-14 (OPPTS 870.2500)	Primary dermal irritation	Waiver accepted	46698604
152-15 (OPPTS 870.2600)	Hypersensitivity	Waiver accepted	46698604
152-16 (885.3400)	Hypersensitivity incidents	Incidents must be reported.	46698604
152-17 (OPPTS 870.5100-5395)	Studies to determine genotoxicity	Waiver accepted	46698604
152-20 (OPPTS 870.3100)	90-Day feeding	Waiver accepted	46698604
152-21 (OPPTS 870.3250)	90-Day dermal	Waiver accepted	46698604
152-22 (OPPTS 870.3465)	90-Day inhalation	Waiver accepted	46698604
152-23 (OPPTS 870.3700)	Teratogenicity	Waiver accepted	46698604

2. Dose Response Assessment

Based on of the available information, no toxicity endpoints were identified.

3. Dietary Exposure and Risk Characterization

This is not a food use, therefore the Agency has no toxicity concerns.

4. Occupational and Residential Exposure

- a. **Occupational Exposure and Risk Characterization:** The potential for dermal, eye, and inhalation exposures to the pesticide exists for the pesticide handlers and applicators of any end-use products formulated with the manufacturing-use product (MP). The Agency will require the appropriate signal word, precautionary statements, and personal protective equipment to mitigate any risk from exposure via these routes for any end-use products containing these active ingredients.
- b. **Residential, School and Daycare Exposure and Risk Characterization:** No indoor residential, school, or day care uses appear on the product labels.

5. Drinking Water Exposure and Risk Characterization

(E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol are synthetic semiochemicals that act via a non-toxic mode of action on a specific insect pest. The end use product containing these active ingredients, Checkmate WPCM-F is applied to poplars, white birch, willows, locusts and other crops where Western Poplar Clearwing Moth is a pest, by both ground and aerial method. The Agency publication OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (<http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>) reports that no risks to human health are expected from the use of lepidopteran pheromones based on their low toxicity in animal testing and the expected low exposure to humans. Furthermore, SCLPs are released in very small quantities into the environment, and are specific for the targeted pest. Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected. In the event that drinking water sources are exposed to these active ingredients no significant risk expected from an accumulation of (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol in drinking water due to the low toxicity of SCLPs, the small amount used (150 g/a.i./acre/year), species specificity of SCLPs, and no reported adverse effects during more than 10 years of use as pesticides.

6. Acute and Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

The Agency has concluded that the potential for residues of (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol are not a dietary hazard to the general population, including infants and children. This decision was based on low toxicity in animal testing, expected low exposure to humans, no expected risk to human health, and no risk from consumption of food containing residues of these pheromones (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (<http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>)). In addition the use pattern should generally not result in residues on food.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

(E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol are synthetic semiochemicals that act via a non-toxic mode of action on a specific insect pest. Due to the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected. Consumption of food containing residues of these pheromones presents no risk (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (<http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>)). Based on this information, the Agency has concluded that aggregate exposure to (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol over a lifetime will not pose appreciable risks to human health. Moreover, the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol. The Agency has considered the various routes of exposure and potential risks of the product and determined that the proposed use of these active ingredients does not pose significant risk to all populations, including infants and children.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol have a non-toxic mode of action. Thus, there is no indication or any evidence to suggest that these biochemical pesticides share any common mechanisms of toxicity with other substances. Therefore, cumulative exposure concerns are not anticipated.

9. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate. Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of the active ingredients, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an "endocrine disrupter" produced by these active ingredients. Based on the low potential exposure level associated with the proposed use of this pesticide, the Agency expects no incremental adverse effects to the endocrine or immune systems.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The registrant requested waivers for all non-target organism toxicity requirements (Guidelines 154-6 through 154-15 and Guidelines 155-4 through 155-13). The registrant's data for similar straight-chain lepidopteran pheromones show no toxicity issues for non-target organisms. The Agency has previously reviewed the registrant's substantially similar products and found that the non-target organism data/information submitted was adequate to support their registration. It is the Agency's position that adverse effects on non target organisms (mammals, birds, and aquatic organisms) are not expected because these straight-chain lepidopteran pheromones are released in very small amounts to the environment and act on a select group of insects (OECD - Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (<http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>)). The Agency therefore granted the request for waivers for all non-target organism Tier I (Guidelines 154-6 through 154-11) toxicity studies (Table 3). Based on the decision to waive Tier I data requirements, Tier II tests (Guidelines 155-4 through 155-14) and Tier III tests (Guidelines 154-12 through 154-15) were not required.

TABLE 3: Non-target organism toxicity requirements			
Guideline	Study	Results	MRID No.
154-6 (OPPTS 850.2100)	Avian acute oral toxicity	Waiver accepted	46689605
154-7 (OPPTS 850.4100)	Avian dietary toxicity	Waiver accepted	46689605
154-8 (OPPTS 850.1075)	Freshwater fish LC ₅₀	Waiver accepted	46689605
154-9 (OPPTS 850.1010)	Freshwater invertebrate LC ₅₀	Waiver accepted	46689605
154-10 (OPPTS 850.4000-4800, as applicable)	Non-target plant studies	Waiver accepted	46689605
154-11 (OPPTS 880.4350)	Non-target insect testing	Waiver accepted	46689605

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data [Tier II, 40 CFR 158.690(d)] was not triggered because the Tier I studies were waived. Risk is minimal due to low toxicity.

3. Ecological Exposure and Risk Characterization

(E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol are synthetic lepidopteran pheromones that act on a specific insect and have a non-toxic mode of action. The waiver requests for submitted data for non-target organisms are summarized in Table 3. In addition, mitigating label language will further reduce the risk to aquatic organisms. The precautionary language on the end-use product label containing, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-stipulates, “Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning equipment or disposing of equipment washwaters.” The precautionary labeling of manufacturing use product containing, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol, stipulates “Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority.”

D. EFFICACY DATA

No efficacy data were required to be submitted to the Agency because no public health uses are involved.

IV. RISK MANAGEMENT DECISION

A. DETERMINATION OF ELIGIBILITY

Section 3(c)(7)(A) of FIFRA provides for the conditional registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria “A” above, products formulated from the use of this manufacturing use product are not expected to cause unreasonable adverse effects when used according to label instructions. Criteria “B” is satisfied by the current label and by data presented in this document. It is believed that (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol will not cause any unreasonable adverse effect, and are effective biochemical pesticides for lepidopteran pests, satisfying Criteria “C.” Criteria “D” is satisfied in that the pesticide is not expected to cause unreasonable adverse effects when used as described on the label. Therefore, Checkmate WPCM Technical Pheromone and Checkmate WPCM-F are eligible for an conditional registration. The technical compound will be formulated into end use products to use to control lepidopteran pests in/on agricultural commodities.

B. REGULATORY POSITION

1. Conditional Registration

The data submitted are sufficient for a conditional registration of the product containing (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol as a manufacturing use product and an end-use product. The condition of registration is the storage stability and corrosion characteristics data be submitted to the Agency within 18 months of the date of registration of the product.

2. Tolerance Reassessment

This is a not a food use, and therefore does not require a tolerance. However, any food uses are covered because straight-chain lepidopteran pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1153).

3. Codex Harmonization

There are no Codex harmonization considerations since there is currently no Codex tolerance for residues of (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol.

4. Nonfood Re/Registrations

These new active ingredients are for non-food uses to pulp and saw timber, chiefly poplar, white birch, willows, and locust. This is a non-food use registration.

5. Risk Mitigation

There is minimal to negligible potential for risks to non-target organisms (plants and wildlife) or for ground or surface water contamination through the proposed use of (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol as an insect mating disruptor for Western Poplar Clearwing moth. Should any risks occur from occupational exposure to these active ingredients, appropriate mitigating labeling language would be required.

6. Endangered Species Statement

The Agency has determined that the active ingredients, (E,Z)-3,13-octadecadien-1-ol and (Z,Z)-3,13-octadecadien-1-ol, will not adversely effect (NA) any threatened or endangered species when used according to label directions.

C. LABELING RATIONALE

It is the Agency's position that the labeling for the manufacturing product CheckMate WPCM Technical Pheromone containing 75.08% by weight (E,Z)-3,13-octadecadien-1-ol and 18.37% by weight (Z,Z)-3,13-octadecadien-1-ol, and Checkmate WPCM-F containing 14.02% by weight (E,Z)-3,13-octadecadien-1-ol and 3.55% by weight (Z,Z)-3,13-octadecadien-1-ol comply with the current pesticide labeling requirements.

1. Human Health Hazard

- a. **Worker Protection Standard:** The manufacturing use product does not come under the provisions of the Worker Protection Standards (WPS). The end-use product does fall under the WPS. The PPE for the end use product are: Long-sleeved shirt, and long pants, water proof gloves, and shoes plus socks.
- b. **Non-Worker Protection Standard:** There are no non-WPS human health hazard issues.
- c. **Precautionary Labeling:** The Agency has examined the toxicological data base for Checkmate WPCM Technical Pheromone and Checkmate WPCM-F and concluded that the precautionary labeling required during this conditional registration process (i.e. Signal Word, First Aid Statements, and other label statements) adequately mitigates the risks associated with the proposed uses. For the end use product containing, Checkmate WPCM-F, "CAUTION." "Hazard to humans and domestic animals. Harmful if swallowed or absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse."
- d. **Manufacturing Use Product Precautionary Labeling:** For the manufacturing use product containing, Checkmate WPCM Technical Pheromone, "CAUTION." "Hazard to humans and domestic animals. Harmful if swallowed or absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse."
- e. **Spray Drift Advisory** No spray drift advisory statement is necessary for this use.

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: The following statements are required on the label for Checkmate WPCM-F: "Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean highwater mark. Do not contaminate water by cleaning of equipment or disposing of equipment washwaters."

3. Application Rate

The maximum application rate for Checkmate WPCM-F is 150 grams of active ingredient per year per acre.

D. LABELING

The manufacturing use product and the technical grade active ingredients are one and the same substance.

ACTIVE INGREDIENT

(E,Z)-3,13-octadecadien-1-ol	75.08%
(Z,Z)-3,13-octadecadien-1-ol.....	18.37%
Other ingredients.....	6.55%
Total.....	100.00%

The manufacturing use product label shall comply with Agency labeling requirements and must contain the following information:

- Product name
- Ingredient statement
- Registration number
- “Keep out of reach of children”
- Signal word (CAUTION)
- Precautionary statements

The end use product.

ACTIVE INGREDIENT

(E,Z)-3,13-octadecadien-1-ol	14.02%
(Z,Z)-3,13-octadecadien-1-ol.....	3.05%
Other ingredients.....	82.43%
Total.....	100.00%

The end-use product label shall comply with Agency labeling requirements and must contain the following information:

- Product name
- Ingredient statement
- Registration number
- “Keep out of reach of children”
- Signal word (CAUTION)
- Precautionary statements

V. ACTIONS REQUIRED BY REGISTRANTS

Registrants are required to provide reports of incidents of adverse effects to humans or domestic animals under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes

and other responses necessary for the reregistration of the product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. For the same reason, there are also no existing stocks provisions at this time.

VI. APPENDIX A

Table 4 lists the use sites for the product. The label for the product is also attached.

TABLE 4: Manufacturing Use Only. Registration/Reregistration	
CheckMate WPCM Technical Pheromone <u>Use sites:</u> Manufacturing use; and direct application to poplars, white birch, willows, locust and other crops where Western Poplar Clearwing Moth is a pest	Official date registered:

APPENDIX B – REFERENCES

Lepidopteran Pheromones Fact Sheet issued 09/01. U.S. EPA.

http://www.epa.gov/oppbppd1/biopesticides/ingredient/factsheets/factsheet_lep_pheromones.htm

Fresh, R.W. Product Toxicology for CheckMate WPCM Technical Pheromone. Suterra LLC, 213 SW Columbia St., Bend, OR 97702. Study No. WPCM Tech/PT. November 11, 2005. MRID 46689604

Fresh, R.W. Non-Target Organism, Fate, and Expression Requirements for CheckMate WPCM Technical Pheromone. Suterra LLC, 213 SW Columbia St., Bend, OR 97702. Study No. WPCM Tech/NTO. November 11, 2005. MRID 46689605.

OECD. 2001. OECD Environment, Health, and Safety Publication; Series on Pesticides No.12; Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control. <http://www.epa.gov/pesticides/biopesticides/regtools/index.htm>

Senoh, H., and R.W. Fresh. Product Chemistry for CheckMate WPCM Technical Pheromone. Suterra LLC, 213 SW Columbia St., Bend, OR 97702. Study No. WPCM Tech/PC. November 11, 2005. MRID 46776801.

Senoh, H., and R.W. Fresh. Product Chemistry for CheckMate WPCM Technical Pheromone. Suterra LLC, 213 SW Columbia St., Bend, OR 97702. Study No. WPCM Tech/PC. November 11, 2005. MRID 46689602.

Senoh, H., and R.W. Fresh. Product Chemistry for CheckMate WPCM Technical Pheromone. Suterra LLC, 213 SW Columbia St., Bend, OR 97702. Study No. WPCM Tech/PC. November 11, 2005. MRID 46776802.

Touhey, J.G. (1990) "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. Part No. 1, Straight Chain Alcohols, Acetate Esters and Aldehydes". (Unpublished report, 474 pp.)