PACIFIC BIOCONTROL CORPORATION

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May 1, 2002

National Organic Standards Board
c/o Toni Strother
USDA/AMS/TM/NOP
Room 4008-So., Ag Stop 0268
Washington, D.C. 20250-0200
Phone: 202-690-2624
E-mail: Toni.Strother2@usda.gov

Dear Ms. Strother,

I have enclosed the following petition for amending the National List of the USDA's National Organic Program:

Petition for 2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole (or Sumisorb 300) as an Inert Ingredient in Mating Disruptant End-Use Products (Solid Polymeric Matrix Pheromone Dispensers) For Inclusion on the National List under Category 205.601: Synthetic Substances Allowed for Use in Organic Crop Production.

The Confidential Business Information has been included in the CBI-Copy. This includes manufacturing and formulation information including research and quality control tests and data. I have included copies of all of the references (by number) with this copy. The CBI-Deleted copy does not include these references. Please contact me at my phone number or e-mail if you have any questions or need additional data. We appreciate your attention to our petition. Thank you.

Sincerely,

Kathy A. Bolan

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PETITION FOR AMENDING THE NATIONAL LIST OF THE USDA'S NATIONAL ORGANIC PROGRAM:

Petition for 2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole (or Sumisorb 300) as an Inert Ingredient in Mating Disruptant End-Use Products (Solid Polymeric Matrix Pheromone Dispensers) For Inclusion on the National List under Category 205.601: Synthetic Substances Allowed for Use in Organic Crop Production

COMMON NAME:

2-(2'-hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole

MANUFACTURER'S NAME:

Sumisorb 300

OTHER NAMES:

Tinuvin 326; Bumetrizole
2-(3-tert-butyl-2-hyrdroxy-5-methylphenyl)-5-chloro-2H-benzotriazole
2-(5-chloro-2H-benzotriazol-2-yl)-6-(1,1-dimethylethyl)-4-methylphenol
2-(5-chloro-2-benzotriazolyl)-6-tert-butyl-p-cresol

LIST OF USES, RATES AND APPLICATIONS FOR CROPS AND LIVESTOCK USES, MODE OF ACTION FOR HANDLING USES:

Pacific Biocontrol's Mating Disruption Formulations and NOP Standards

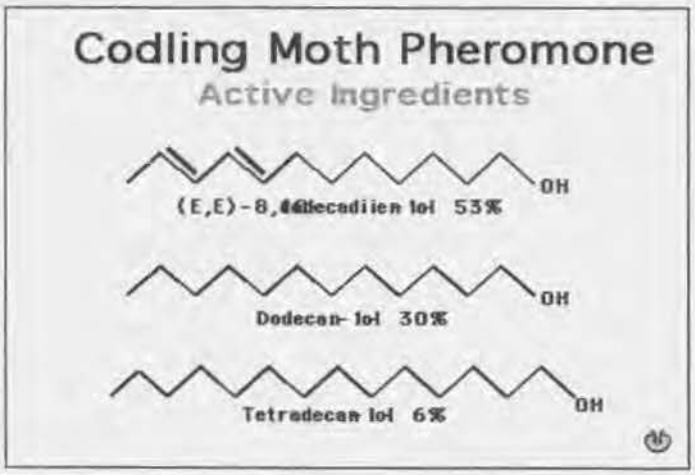
Mating-disruption has become an effective method for control of important insect pests. As of 1997 there were more than 30 mating-disruption products registered with the EPA (1). The number has increased over the past five years. Mating disruption is key component in many area-wide pest management programs often resulting in reduced use of toxic insecticides (2, 3, 4, 5). Furthermore, this technique has become an indispensable tool for organic growers.

The new National Organic Program (NOP) standards threaten the elimination of many mating disruption products, including Pacific Biocontrol's ISOMATE® and PB-ROPE L formulations, due to restrictions on EPA's List 3 inert ingredients. These inert ingredients are used in relatively small amounts and are contained within the plastic slow-release substrates. Contact with fruit or fiber is minimal. Nevertheless, these inerts are on List #3 and therefore not acceptable for organic production under the NOP standards. The elimination of mating disruption for organic growers will create an economic crisis due to much lower levels of control.

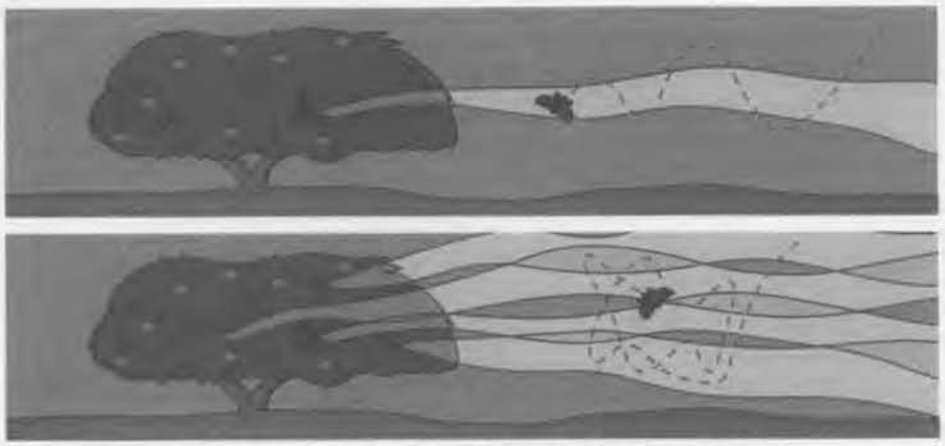
Pacific Biocontrol's Mating Disruption Technology

Pacific Biocontrol's mating disruption technology consists of the biochemical mixture being impregnated in a polyethylene tube, which is slowly released into the atmosphere and affects the mating pattern of the insect to be controlled. This material is very specific to those moths that use the biochemical mixture as part of the sex pheromone.

For example, Isomate®-C Plus is the discrete hand-applied synthetic formulation of the sex pheromone of the codling moth, *Cydia pomonella*, and is used to control the codling moth on apples and pears. Isomate®-C Plus consists of the three chemical blend of E,E-8,10-Dodecandien-1-ol, 1-Dodecanol and 1-Tetradecanol. Each of these three chemicals is important in affecting the full range of behavioral events, which are important in successful sexual communication between male and female codling moths.



The mode of action by the female moth is the volatile release of the pheromone into the atmosphere, the diffusion of the biochemicals in the atmosphere, and the antennal reception of the dispersed molecules by the male insect. Mating disruption functions solely by interfering with the insect's mating behavior. This results in diminished reproductive success.



Top picture: a male moth easily finds the female by following the pheromone plume she emits.

Bottom picture: shows how **Isomate®** disrupts normal communication between male and female codling moths.

Pheromone can be very unstable and easily broken down by UV light and oxidation. Therefore, in addition to the biochemical mixture consisting of the active ingredients, the formulated product also includes inert ingredients (stabilizers) that are added to assist in the protection of the pheromone active ingredients from these outside forces. Sumisorb 300 is an inert ingredient that is added to assist in the protection of the pheromone from degradation by UV light during field use of the product.

As the mode of action of this technology is non-toxic, but behavioral, it is not expected that the formulation, consisting of the biochemical mixture and the inert ingredients, would pose any potential hazard to humans, environment, or non-target species.

What is a UV stabilizer?

Some materials absorb UV light more readily than others. These materials are much more susceptible to degradation from ultraviolet light and are more quickly damaged. When UV light is absorbed, it starts to break down the weak chemical bonds, which leads to deterioration. UV stabilizers are a group of chemical agents with the ability to counteract or neutralize the harmful effects of UV light. Therefore, stabilizers like Sumisorb 300 counteract the degradation caused by UV light. The addition of this stabilizer can double the field life of the pheromone formulation and thus greatly improve the economics of mating disruption.

Pacific Biocontrol's Use of Sumisorb 300

At the present, Pacific Biocontrol has four end-use products that are formulated with Sumisorb 300 as an inert ingredient: Isomate®-C Plus, Isomate®-CM/LR Pheromone, Isomate®-BAW Pheromone and Isomate®-C TT. The amount of Sumisorb 300 in Pacific Biocontrol's four products is as follows:

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Codling Moth and Organic Production

Pacific Biocontrol's formulated product, Isomate®-C Plus, is used to control the codling moth on apples and pears. However, the added inert ingredient, Sumisorb 300, is on EPA's List 3 and not acceptable for organic production under NOP standards. Therefore, organic growers will not be allowed to use mating disruption products with List 3 inerts, and lower levels of control could create an economic crisis. This is especially true for the organic apple and pear growers who have few options for control of the codling moth.

Codling moth is a key pest of pome fruits throughout world and is primarily controlled by one or more applications of broad-spectrum insecticides. Much effort has been put into the development of alternative control methods due to limitations and disadvantages conventional insecticides. Mating disruption has become an effective and economical method for controlling codling moth (1). The total pome fruit area treated with mating-disruption formulations worldwide in 2001 is estimated at 90,000 hectares. In the USA the estimated area is 48,000 hectares.

In the USA, codling moth has been one of the most difficult pests to control by organic methods. Without chemical insecticides, pest numbers can increase exponentially. Most organically acceptable alternatives for codling moth control do not provide effective or economical control. These methods include: mass trapping, beneficial insects (including inundative release), microbial insecticides (Bt, virus), botanicals (ryania), sterile male release and parasitic nematodes. Sanitation (removal of infested fruit) and summer oils have provided better control but are still not adequate by themselves.

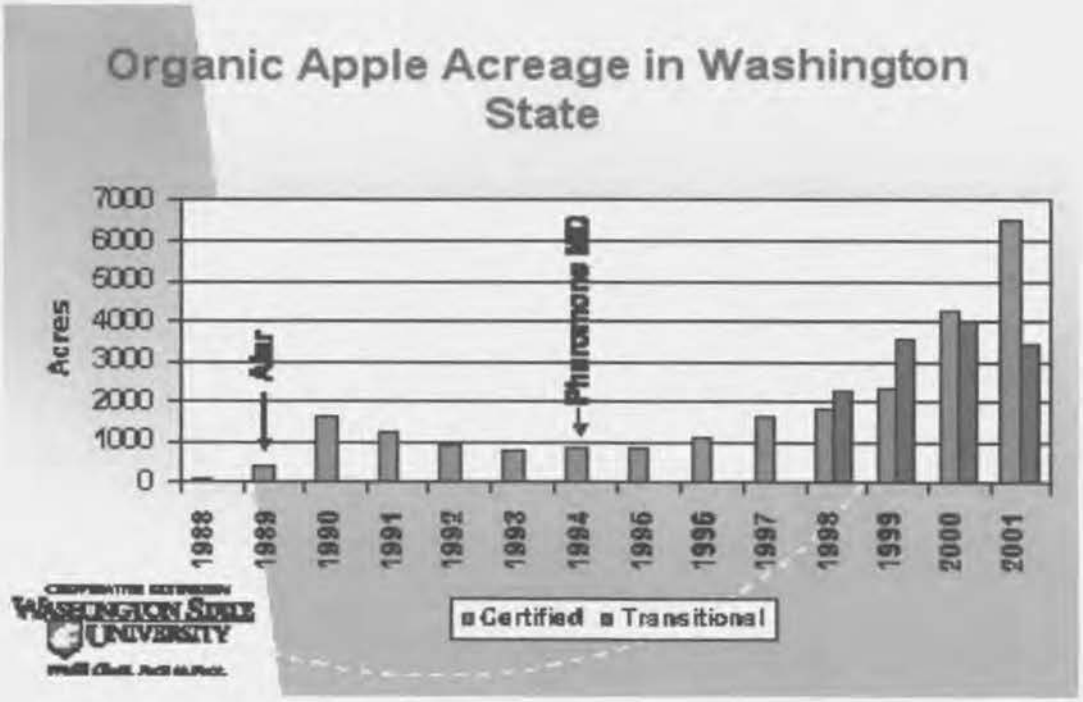
Codling Moth Control - Organic Options

- Mating Disruption
- Summer Oils
- Sanitation: remove infested fruit
- Sterile Males
- Trapping: larvae and adults
- *Bacillus thuringiensis* (Bt)
- Virus (CMGV)
- Nematodes
- Botanicals: ryania, rotenone, pyrethrum
- Parasites: *T. platneri, Ascogaster* sp.
- Predators: birds, beetles, spiders, ants, etc.

Mating disruption, either alone or in combination with other biological and cultural control methods, has proven to be the most effective tool for controlling codling moth in organic apples and pears. This technique is the basis for any codling moth management program in organic apples and pears – most other methods are used to supplement mating disruption.

Approximately 20,000 acres of organic apples and pears are grown in the USA (6). It is estimated that more than 95% of these acres are treated with some type of mating disruption formulation for codling moth control. In the USA it would be very difficult to grow an organic apple or pear for fresh market consumption without the use of mating disruption. Furthermore, with the development of mating disruption for codling moth there has been a steady increase in organic apple acreage in Washington State (6).

U.S. Organic Tree Fruit Acreage - 2001				
	Apple	Pear	Stone Fruit	All Fruit
WA	6540	1308	285	8436
CA	4529	842	3112	8662
AZ	2800	-	-	2830
CO	1535	100	155	1923
ID	503	-	3	506
OR	350	500	305	1180
Others	1015	48	78	1198
US Total	17,272	2798	3038	23,835
WA transition	3411	642	75	4408



D. Granatstein, Center for Sustaining Agricultural and Natural Resources, WSU, Wenatchee, WA.

Pheromone Stability

Codlemone, the sex pheromone for the codling moth, is prone to degradation via exposure to heat, light and oxygen (7). Unprotected Codlemone lasts less than two hours in the field. The decomposition of the pheromone in commercial formulations can result in significant decrease in the effective longevity in the orchard. Small amounts of stabilizers, i.e. Sumisorb 300, are added to protect the pheromone active ingredient from UV degradation and oxidation. The addition of these stabilizers can double the formulation's field life and thus greatly improve the economics of mating disruption. This has led to greater adoption mating disruption by growers.

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In ISOMATE® formulations, these stabilizers are added to the pheromone contained within the plastic tubes. These tubes ("twist-ties" or "ropes") are applied by hand within the crop canopy. The pheromone dispensers do not come into contact with fruit (or cotton fiber).

Two ISOMATE®-C PLUS dispensers in apples applied by hand.

ISOMATE®-C PLUS applied with plastic clip in walnuts.

ISOMATE®-CTT applied with "hoop" applicator in apples.

PB-ROPE L dispenser applied in cotton.

Some Other Uses of This Inert Ingredient

The inert ingredient, referenced as Tinuvin 326, has some of the following uses:

(1) As a stabilizer in polyethylene terephthalate (PET) food packaging. (8)
(2) Used in dental resin composites. (9)
(3) As an organic compound of the textile industry. (10)
(4) "Tinuvin 326 absorbs ultraviolet (UV) light and is added to polyethylene and polypropylene coatings and films for protection against photodegradation." (11)
(5) Tinuvin 326 is also used as a UV absorber in polyethylene molding (sporting equipment and leisure accessories). (12)
(6) Tinuvin 326 is used as a UV inhibitor for Fiberglass Reinforced Plastic (FRP) equipment. "When a piece of FRP equipment is located outdoors, UV inhibitors must be added to the exterior surface coat to prevent damage to the resin by UV light." (13)

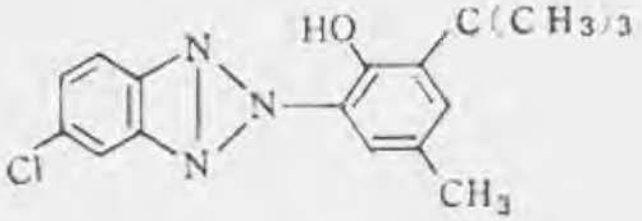
The inert ingredient, referenced as Bumetrizole, is used in cosmetic products as a UV absorber. (14) Bumetrizole is listed on the European inventory of existing commercial chemical substances under EINECS No. 223-445-4.

SOURCES AND DETAILED DESCRIPTION OF MANUFACTURING PROCEDURES:

This inert ingredient is not listed in the Merck Index, but the following information has come from its manufacturer, Sumitomo Chemical Co., Ltd. under the Trademark of Sumisorb 300:

Systematic Name	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole
Synonyms	Sumisorb 300; 2-(5-chloro-2H-benzotriazol-2-yl)-6-(1,1-dimethylethyl)-4-methylphenol
CAS Number	3896-11-5
Molecular Formula	$C_{17}H_{18}N_3OCl$
Molecular Weight	315.82

Structure:



$C_{17}H_{18}N_3OCl$

Manufacturing Process

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SUMMARY OF ANY PREVIOUS REVIEWS BY STATE OR PRIVATE CERTIFICATION AGENCIES:

This inert ingredient has been approved for use as a stabilizer in the following mating disruptant, end-use products that have been certified by the Washington State Dept. of Agriculture (WSDA) Organic Food Program: Isomate®-C Plus, Isomate®-CM/LR Pheromone and Isomate®-C TT. These three products meet the current WSDA organic standards. WSDA has acknowledged that these three products do not meet the USDA's NOP standards because of their inert ingredients. WSDA has petitioned the US EPA that these non-approved synthetic ingredients, i.e. Sumisorb 300, be moved from EPA's List 3 to List 4.

Isomate®-C Plus and Isomate®-CM/LR Pheromone was reviewed jointly and approved January 2000. However, when Isomate®-C TT was submitted April 2001, WSDA requested additional information for Sumisorb 300. Pacific Biocontrol provided a MSDS, a copy of the US FDA's approval, and a discussion on the bleeding of the stabilizers in the surface of the dispenser. Since Sumisorb 300 was already approved in Isomate®-C Plus and Isomate®-CM/LR Pheromone and does not contact the food, then this product was approved July 2001.

REGULATORY STATUS WITH EPA, FDA OR STATE AUTHORITIES:

This inert ingredient has been approved for use as a stabilizer in the following mating disruptant, end-use products under the registrant, Pacific Biocontrol Corporation, EPA Company No. 53575:

Pacific Biocontrol's Product Name	EPA Reg. No.	US EPA -Biopesticides and Pollution Prevention Division	California Dept of Pesticide Regulation
Isomate®-C Plus	53575-6	Yes	Yes
Isomate®-CM/LR Pheromone	53575-20	Yes	No
Isomate®-BAW Pheromone	53575-21	Yes	Yes
Isomate®-C TT	53575-25	Yes	Yes

Isomate®-C Plus is registered in 18 states, Isomate®-CM/LR Pheromone is registered in two states, Isomate®-BAW Pheromone is registered in three states, and Isomate®-C TT is registered in six states. Isomate®-C Plus has been registered in Canada under PCP No. 22899 since 1998.

The US FDA approved this inert ingredient, 2-(2'-Hydroxy-3'-tert-butyl-5'-methyl-phenyl)-5-chlorobenzotriazole [2-(3'-tert-buytl-2'-hydroxy-5'-methylphenyl)-5-chlorobenzotriazole], under 21 CFR 178.2010 (15), for use with olefin polymers. The levels allowed are not to exceed 0.5 percent by weight of olefin polymers, provided that the finished polymer contacts only the types of food identified in I, II, IV-B, VI-A & B, VII-b and VIII (listed under 21 CFR Section 176.170, Table 1) (16). These food types include the following:

"I. Non-acid aqueous products; may contain salt or sugar or both (pH>5.0).
I. Acid products may contain salt or sugar or both, and including oil in water emulsions of low or high fat content.
IV. Dairy product and modifications:
B. Oil in water emulsions; high or low fat.
VI. Beverages:
A. Containing up to 8% alcohol.
B. Non-alcoholic.
VII. Bakery products other than those included under Types VIII or IX of this table:
B. Moist bakery products with surface containing no free fat or oil.
VIII. Dry solids with the surface containing no free fat or oil." (16)

The Agency most familiar with these types of mating disruptant products is the US EPA. In 1995, the EPA formed BPPD (Biopesticides and Pollution Prevention Division) to manage and accelerate the regulatory process for biologically-based pesticide products. The goal of the new Division was to streamline the process of registering biological products and to provide a consistently high quality of service to the companies of these types of products. Under BPPD, there are two sub-divisions, Microbials and Biochemicals. Pheromones products are reviewed under the Biochemicals Sub-division.

The US EPA has assisted the regulatory relief for pheromones and other similar semiochemicals by recognizing the difference between semiochemicals and conventional chemical pesticides.

"The Agency has assumed that pheromones and other similar semiochemicals are different from conventional synthetic pesticides, and has attempted to facilitate their registration with reduced data requirements and regulatory relief efforts." (17)

The US EPA had registered 20 pheromones as active ingredients as of November 1999, and more than 60 products had been registered with these active ingredients.

"As of November 1999, EPA has registered (licensed for sale) approximately 20 moth mating pheromones as pesticide active ingredients and more than 60 individual pesticide products containing these active ingredients." (18)

The first regulatory relief measures that the US EPA established for pheromone products were the tolerance exemptions for the following:

(1) In 1993, inert ingredients of semiochemical dispensers. (19)
(2) In 1994, arthropod pheromones in retrievably sized polymeric matrix dispensers. (20)
(3) In 1995, lepidopteran pheromones (as defined) in any mode application. (17)

"Based on the information considered, the Agency concludes that tolerances are not necessary to protect the public health for the inert ingredients in the semiochemical dispenser products." (19)

"In the proposal, EPA set forth its reasons for determining that a tolerance for these pheromone products is not necessary to protect public health." (20)

"Lepidopteran pheromones that are naturally occurring compounds, or identical or substantially similar synthetic compounds, designated by an unbranched aliphatic chain (between 9 and 18 carbons) ending in alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the aliphatic backbone, are exempt from the requirement of a tolerance in or on all raw agricultural commodities." (17)

The EPA has recognized that pheromone products in retrievable sized, polymeric matrix dispensers pose minimal risk with their low use rates and has significantly eased the regulatory guidelines for registering these types of products.

"Most recently the Agency has recognized that a special category of pheromone products dispensed from larger sized polymeric matrices with low annual use rates represent minimal risk for dietary and environmental exposure and has greatly eased the burden to register these items." (17)

As indicated above, the first approved exemption from tolerance was for the inert ingredients of a semiochemical dispenser. This includes UV stabilizers like Sumisorb 300.

"All inert ingredients of semiochemical dispenser products formulated with and/or contained in dispensers made of polymeric matrix materials (including the monomers, plasticizers, dispersing agents, antioxidants, UV protectants, stabilizers and other inert ingredients), are exempted from the requirement of tolerance when used as carriers in pesticide formulations for application to growing crops only." (19)

The US EPA has been using many methods to expedite the registrations of these types of products (lepidopteran pheromones in polymeric matrix dispensers). Product chemistry data is usually the only data that is needed for registration by the US EPA. Mammalian toxicity data has been waived. For these types of products, many times the ecological effects, environmental fate and ground water data is also waived.

"Recognizing the low toxicity (Toxicity categories III and IV) and low expected exposure to humans from contact with pheromones in point source applications (e.g., in solid matrix dispenser), the Agency has waived the requirement for certain mammalian toxicity studies, such as subchronic (90-day) oral and inhalation toxicity, immunotoxicity, and developmental toxicity. Due to the low use rate and target species specificity, the Agency has been using a variety of measures to facilitate the development registration of pheromone products.

To expedite the registration of lepidopteran pheromone products, the Agency usually only considers product chemistry data, and if needed, inert clearance data for pesticidal used of these compounds on food crops." (21-Isomate-BAW Pheromone, Registration Eligibility Document, II. Overview, F. Data Requirements)

CHEMICAL ABSTRACT SERVICE (CAS) NUMBER OR OTHER PRODUCT NUMBER, SAMPLES OF LABELS:

CAS Number: 3896-11-5

Attached in the appendix are the labels of Pacific Biocontrol's four products (22), Isomate®-C Plus, Isomate®-CM/LR Pheromone, Isomate®-BAW Pheromone and Isomate®-CTT, which are formulated with Sumisorb 300 as an inert ingredient.

Isomate®-C Plus has been registered by the US EPA since July 1993. Isomate®-CM/LR Pheromone has been registered since September 1997. Isomate®-BAW Pheromone has been registered since September 1999. Isomate®-CTT has been registered since March 2001.

The percentage of this inert ingredient as referenced under "Other Ingredients" in the Ingredient Statement of each of the labels is as follows:

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PHYSICAL PROPERTIES OF THE SUBSTANCE AND CHEMICAL MODE OF ACTION: INCLUDING ENVIRONMENTAL IMPACTS, INTERACTIONS WITH OTHER MATERIALS, TOXICITY AND PERSISTENCE, EFFECTS ON HUMAN HEALTH, EFFECTS TO SOIL ORGANISMS, CROPS OR LIVESTOCKS:

Physical Properties of Sumisorb 300:

Properties	Results
Appearance	Pale Yellow Solid
Odor	Odorless
Melting Point	137-142°C
Specific Gravity	1.32
Solubility in Water	Insoluble
Solubility	Soluble in methyl ethyl ketone, toluene, ethyl acetate, styrene monomer, DOP
Flash Point	232°C
Reactivity	None
Stability	Stable under ordinary conditions

Chemical Mode of Action:

This inert ingredient functions as an UV absorber.

Environmental Impacts:

The US EPA has recognized that these types of pheromone products are expected to have no adverse effects and minimal exposure since they are very specific to the insect that they are controlling and have a small release rate in the environment.

"IV. Assessing Risks to the Environment
Adverse effects on nontarget organisms (mammals, birds, and aquatic organisms) are not expected because these pheromones are released in very small amounts to the environment and act on a select group of insects." (18)

In the registration of Isomate®-BAW Pheromone, the US EPA did not require ecological effects, environmental fate and ground water data because of the product's use pattern and lack of exposure. Since the formulation is impregnated in a polyethylene dispenser and slowly released, then there is expected to be little exposure and transport. Minimal to no exposure and risk was expected to non-target terrestrial and aquatic species.

"1. Ecological Effects Hazard Assessment
All Tier I ecological effects data requirements are waived based on the proposed use pattern and lack of exposure.

2. Environmental Fate and Ground Water Data
Environmental fate and groundwater data are not required for biochemical pesticides unless adverse effects on nontarget species are observed as a result of acute testing for ecological effects (Tier I).

3. Ecological Exposure and Risk Characterization
Because Isomate®-BAW Pheromone is enclosed in a solid matrix dispenser and is slowly released by volatization, transport and exposure is expected to be very limited. This system is generally accepted as posing minimal to no exposure and risk to non-target terrestrial and aquatic species." (21- III. Science Assessment, C. Environmental Assessment)

Sumitomo Chemical Co. lists the fish toxicity for Sumisorb 300 s LC_{50}=94ppm at 48 hours (Killfish).

Interaction with other materials:

Sumisorb 300, as a UV stabilizer, is added to the pheromone active ingredients. Sumisorb 300 is incorporated entirely within the lumen of the dispenser and separated from the surface by the thickness of polymer. The only interaction of Sumisorb 300 will be with the active ingredients. Sumisorb 300 will act as an UV stabilizer to help prevent degradation of the active ingredients from UV light.

TOXICITY AND PERSISTENCE, EFFECTS ON HUMAN HEALTH:

Fact Sheets are created for each new active ingredient that the US EPA registers. Instead of creating individual fact sheets for each new lepidopteran pheromone active ingredient, the US EPA created a Generic Fact Sheet for all lepidopteran pheromones since they are very similar with low toxicity and low exposure. The EPA states in this Fact Sheet that during the more than 10 years of use of lepidopteran pheromones, there have been no reports of adverse effects. Therefore, no risk is expected to humans from use of these types of pheromones.

"Based on low toxicity in animal testing, and expected low exposure to humans, no risk to human health is expected from the use of these pheromones. During more than 10 years of use of lepidopteran pheromones as pesticides, no adverse effects have been reported." (18)

For Pacific Biocontrol's Isomate®-BAW Pheromone, the US EPA determined that there is negligible exposure to the handlers and the public, since it is contained in a dispenser and slowly released in small amounts. The dietary exposure is concluded as minimal based on the EPA's assessment of these types of compounds as volatile, with low application rates and from their metabolism.

"Because the active ingredients contained in Isomate®-BAW Pheromone are slowly released in very small amounts by dispenser, the potential for dermal, eye and inhalation exposure to pesticide handlers and to the general public is expected to be negligible. Further, the Agency has concluded that the potential for dietary exposure is expected to be minimal based on volatility of the compounds, the low application rates and known metabolism of similar compounds." (21-I. Executive Summary, b. Human Exposure)

The US EPA also stated that the potential risk to humans is minimal, since there is low exposure by this type of product, and there are no significant toxicological concerns.

"The potential risks to humans are considered negligible based on low exposure and the lack of significant toxicological concerns. A determination has been made that no unreasonable adverse effects to the US population in general, and to infants and children in particular, will result from the use of this compound when label instructions are followed." (21-I. Executive Summary, c. Risk Assessment)

Under Occupational, Residential, School and Day Care Exposure and Risk Characterization for Pacific Biocontrol's Isomate®-BAW Pheromone, the US EPA determined that no adverse effects and minimal exposure and risk are expected based on the product's use pattern. All of Pacific Biocontrol's products are exempt from Worker Protection Standard labeling. These formulations are in solid, polymeric matrix dispensers.

"Human exposure and risk to these compounds is expected to be minimal in occupational, residential, school and day care settings.

a. Occupational Exposure and Risk Characterization
Based on the use pattern, the potential for dermal, eye and inhalation exposure to pesticide handlers is expected to be negligible. No adverse health effects to workers are expected from the use of this product. According to Regulation (PR) Notice 93-7, "Labeling Required by the Worker Protection Standard (WPS)," WPS does not apply to attractants used in insect traps. Since Isomate®-BAW Pheromone is to be used in solid matrix device, it is exempt from WPS labeling requirements." (21- III. Science Assessment, B. Human Health Assessment)

Under Drinking Water Exposure and Risk Characterization, the US EPA stated that exposure from the residues of this type of product in water is not expected based on the product's application method.

"Exposure is not expected from an accumulation of Isomate®-BAW Pheromone in the aquatic environment due to the application method. The Agency does not anticipate exposure to residues of Isomate®-BAW Pheromone in drinking water." (21- III. Science Assessment, B. Human Health Assessment)

The potential health effects for Sumisorb 300 are listed on Sumitomo's MSDS (23). The inhalation and oral effects are non-toxic in normal industrial use. The dermal effects are that is not skin sensitizing. The eye effects may cause irritation. No mutagenicity or teratogenic effect was observed. The toxicological information from the MSDS is listed as follows:

Inhalation: The inhalation LC_{50} in rats is >0.27g/m³ at 4 hours.

Eye Effects:	Irritant to rabbit eyes.
Skin Effects:	No skin sensitizing effect has been reported based on the repetitive patch test with human
Acute Effects:	The oral LD_{50} in rats is >5,000mg/kg. The oral LD_{50} in mice is >5,000mg/kg
Sub-acute Effects:	NOEL in the 3-month oral study in rats is 2,500ppm. Reduction of weight, increasing of liver weight occurred after oral administration >2,500ppm (mixed with feeds) during 3-month beagle (0,250, 500, 1,000, 2,500, 5,000, 10,000ppm)
Mutagenicity:	The negative results have been obtained in Ames test.
Carcinogenicity	Not listed by IARC, NTP or OSHA
Teratogenic Effect	No teratogenic effect was observed in mice study by oral administration on day's 6-15 pregnancy (0, 300, 1,000, 3,000mg/kg/day). NOEL is 1,000mg/kg.

EFFECTS OF SOIL ORGANISMS, CROPS OR LIVESTOCKS:

From a clean safety record, US EPA has stated that there is no risk in consuming food containing residues from these lepidopteran pheromone products. The Agency also allows the experimental use up to 250 acres with these types of products instead of the 10 acres allowed on conventional pesticides.

"The safety record for lepidopteran pheromones has allowed the Agency to conclude that consumption of food containing residues of the pheromone presents no risk. In addition, these pheromones can be used experimentally without a permit on up to 250 acres, versus the 10-acre limit imposed on other pesticides." (18)

Under Dietary Exposure and Risk Characterization of Pacific Biocontrol's Isomate®–BAW Pheromone, the US EPA determined that the dietary exposure is minimal since this type of product is contained in a dispenser and not applied directly to the crop.

"These compounds are incorporated into dispensers and are not directly applied to the growing plants. Therefore, dietary exposure to these compounds is expected to be minimal." (21-III. Science Assessment, B. Human Health Assessment)

Under Dietary Exposure and Risk Characterization, the US EPA has also determined from previously registered lepidopteran pheromones and their known chemical structure of long chain fatty acids that since they have low acute toxicity, low application rates and minimal exposure, then there will be no dietary hazard from residues on the treated crops.

"The Agency has concluded that residues on treated crops are not a dietary hazard for the following reasons: low acute mammalian toxicity in lepidopteran pheromones registered to date, the known metabolism of long chain fatty acids, low application rates, and nominal human exposure due to application rate and to volatization." (21-III. Science Assessment, B. Human Health Assessment)

Under Ecological Risk Assessment, the US EPA stated that exposure is to be minimal to no risk to non-target terrestrial and aquatic species, since this type of product is contained in a dispenser and slowly released.

"Because Isomate®-BAW Pheromone is enclosed in a solid matrix dispenser and is slowly released by volatization, transport and exposure is expected to be very minimal to no exposure and risk to non-target terrestrial and aquatic species." (21- I Executive Summary, C. Risk Assessment)

Sumisorb 300, as a UV stabilizer, is added to the pheromone active ingredients, which are impregnated in plastic dispensers and then hand applied to the crop. Since the dispensers are applied on the branches (i.e. Isomate®-C Plus, Isomate®-CM/LR Pheromone and Isomate®-C TT) or on stakes at the canopy level of the crop (i.e. Isomate®-BAW Pheromone), then there shouldn't be any contact with soil organisms or livestock. The ISOMATE® dispensers should have little or no contact with the crop itself.

Description of an ISOMATE® Dispenser with Isomate®-C Plus

CBI-deleted

CBI-deleted

CBI-deleted

SAFETY INFORMATION, INCLUDING MSDS AND A REPORT FROM THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH STUDIES (NIEHS):

The manufacturer of Sumisorb 300 that is formulated as an inert ingredient in mating disruptant products for Pacific Biocontrol Corp. is Sumitomo Chemical Co. Ltd., Tokyo, Japan. The MSDS (23) from the manufacturer is attached in the appendix.

A search within NIEHS web site found no documents for CAS No. 3896-11-5.

The US EPA has recognized these types of products, with inert ingredients like Sumisorb 300, as having low exposure and minimal risks, since they have low acute toxicity and low application rates, are contained in solid, polymeric matrix dispensers, are released slowly and have little or no contact with the crop. Mating disruption is a non-toxic, behavioral method for the control of insects. It does not affect the crop, the grower, the environment, or other non-target insects.

RESEARCH INFORMATION, INCLUDING RESEARCH REVIEWS AND BIBLIOGRAPHIES:

Only one research article was found for this inert ingredient. This article studied the UV absorption on low-and high-pressure polyethylene and polypropylene. It showed that it is acceptable to use polyolefines in packing materials for most foods, and that there are no concerns about the effect of photosensitizing of Sumisorb 300. The article is in German, but the summary is in English and is as follows:

> "Studies on the use of an ultraviolet-absorbing agent based on hydroxybenzotriazole for commodities of low-pressure and high-pressure polyethylene and polypropylene show that the migration is only slight in aqueous and acidic foods and in foodstuffs with low alcohol content. Sunflower oil, n-heptane (as a fat-simulating test solution) and 50% ethanol as test solutions yielded higher migration values. Gas chromatographic, polargraphic and thin-layer chromatographic methods were used to determine the ultraviolet -absorbing agent. Concerns about a possible photosensitizing effect of 2(2'hyrdroxy 3'tert butyl 4'methylphenyl) 5 chlorobenzotriazole were experimentally tested and turned out to be unfounded. From the viewpoint of safety, there were no contraindications to the use of polyolefines in packing materials for most foods. As to fat-containing and strongly alcoholic food-stuffs, the authorization should be conditioned on the circumstances of use." (24)

PETITION JUSTIFICATION STATEMENT – THAT STATES WHY THE SYNTHETIC SUBSTANCE IS NECESSARY, ALTERNATIVES THAT COULD BE USED, BENEFICIAL EFFECTS TO THE ENVIRONMENT, ETC:

Why the Synthetic Substance is Necessary:

Sumisorb 300, 2-(2'-hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole, is an inert ingredient formulated in four of Pacific Biocontrol's mating disruptant end-use products. This inert ingredient is a stabilizer that protects the pheromone formulation from UV degradation when it is applied in the field.

Why Use Light Stabilizers?

Some materials absorb UV light more readily than others. These materials are much more susceptible to degradation from ultraviolet light and are more quickly damaged. Pheromone can be very unstable and easily disintegrated by UV light. When UV light is absorbed, it starts to break down the weak chemical bonds, which leads to deterioration.

UV stabilizers are a group of chemical agents with the ability to counteract or neutralize the harmful effects of UV light. Therefore, stabilizers like Sumisorb 300 counteract the degradation caused by UV light and lengthen the longevity of products that absorb UV light. Without these type of stabilizers, the longevity of the dispenser is shorten, and the pheromone may dissipate too rapidly to control multiple generations of the treated insect and provide season-long control.

Longevity of the Dispenser

Mating disruption technology is applied prior to the moth's emergence, and the pheromone releases over a range of days depending on temperature. These dispensers are designed to provide longevity, eliminate the need for multiple applications and reduce the probability of uncontrolled mating between applications. Under certain conditions, a single application may provide season-long control.

Since the application of these types of products is time-consuming and additional applications can be costly, the longevity of these dispensers is important to the grower and his pocketbook. Growers want convenience, cost-effectiveness and season-long control.

Possible Alternatives to UV Stabilizers:

There are not many alternatives to UV Stabilizers like Sumisorb 300. The other UV Stabilizers/Absorbers on the market are benzophenones, hindered amine light stabilizers (HALS), and to a much lesser extent, benzoates, oxanilides and salicylates. However, a quick review indicated that none of these alternatives are on EPA's List 4. Therefore, they are not suitable substitutes for Sumisorb 300.

An alternative that Pacific Biocontrol has considered is formulating their products without this inert ingredient. The product will still work but at a very shorten interval. Multiple applications will be needed for season-long control. This will force organic growers to use a product that is much more costly and more time-consuming and less effective in its control. A new product will also take to field test and to register. (Mr. Jenkins and Ms. Bolan met with the EPA in February 2002 to discuss the possibility of submitting a petition for registration of this type of product. The EPA estimated that the review time would be at least a year. That does not include the time to field test the product, which would be at least a season.)

Possible Alternatives to Mating Disruption Technology for Organic Use:

Most organically acceptable alternatives for mating disruption do not provide effective or economical control. These methods include: mass trapping, beneficial insects (including inundative release), microbial insecticides (Bt, virus), botanicals (ryania), sterile male release and parasitic nematodes. Sanitation (removal of infested fruit) and summer oils have provided better control but are still not adequate by themselves. Mating disruption, either alone or in combination with these types of biological and cultural controls, has proven to be an effective tool for controlling insects.

Beneficial Effects to the Environment:

Mating disruption is a non-toxic, behavioral method for the control of insects. It does not affect the crop, the grower, the environment, or other non-target insects.

Mating disruption is an essential tool for pest management in organic production. Organic production, especially in apples and pears, will be severely affected by the elimination of mating disruption products like Isomate®-C Plus. Therefore, it will be very difficult to grow organic apples, without mating disruption for control of the codling moth, when 95% of the acreage is treated with mating disruption.

The inert ingredient, Sumisorb 300, is added to protect the inherently volatile pheromone active ingredients. Without stabilizers, the longevity of the pheromone formulation will be significantly reduced resulting in less effective, economical control. There are no acceptable alternative inert stabilizers that provide adequate protection of the pheromones. The use of the inert stabilizer lengthens the formulation's field life and thus greatly improves the economics of mating disruption.

CBI-deleted

The inert ingredients that are contained in ISOMATE®'s dispensers have little or no contact with crop fruit or fiber.

The US EPA has the most familiarity with these type of pheromone products as it has registered more than 20 lepidopteran active ingredients and more than 60 products containing those active ingredients. The Agency has recognized the difference between semiochemicals and conventional chemical pesticides and facilitated regulatory relief to ease the burden of registering these types of products.

The first regulatory relief measure that the US EPA established was the tolerance exemption for inert ingredients of semiochemical dispensers. This included UV stabilizers like Sumisorb 300. In addition, the US EPA recognized that these lepidopteran pheromone products are expected to have no adverse effects and minimal exposure because of the following:

- They have low acute toxicity.
- They have low application rates.
- They are contained in dispensers.
- They are slowly released.
- They have no contact with the crop.

The US EPA has four registered products under Pacific Biocontrol with Sumisorb 300 as an inert ingredient.

Note: ISOMATE® is a registered trademark for pheromone products manufactured by Shin-Etsu Chemical Co. PB-ROPE L is used in cotton for the control of the pink bollworm. Pacific Biocontrol Corporation holds the US EPA registrations of the ISOMATE® and PB-ROPE L products. Pacific Biocontrol sells the ISOMATE® and PB-ROPE L products in the USA and Canada.

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