Sumisorb 300

for use in crop production

Executive Summary

The following petition is under consideration with respect to the USDA NOP Final Rule:

Petitioned: **Addition of 2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole to § 205.601, "Synthetic substances allowed for use in organic crop production," as an inert ingredient in mating disruptant end-use products used in organic crop production.**

2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole, or Sumisorb 300, is an ultraviolet stabilizer used in arthropod mating disruption formulations. The substance is incorporated into at least four commercially available mating disruptant end use formulations used in passive "rope-type" dispensers. Synthesized pheromones have been shown to be unstable in field conditions, and 2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole acts to prolong the effective field life of these compounds by protecting them from UV degradation. The NOP has no prior ruling on the use of this substance specifically. As an inert ingredient classified as List 3 by EPA, 2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole is implicitly prohibited by the Final Rule.

All three reviewers agreed that 2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole is synthetic. The reviewers also were in general agreement that the substance should be allowed on the National List for use in passive mating disruptant end use products. All reviewers felt that the utility conferred by the substance, coupled with the unlikelihood of it interacting with the environment, were compelling reasons to warrant its addition to the National List. Two of the reviewers felt it should be approved conditionally, expressing concern about potential adverse interactions that may occur if the substance escapes its dispenser shell.

Summary of TAP Reviewer Analyses

Synthetic/ Nonsynthetic	**Allowed or Prohibited**	**Notes/suggested annotations:**
Synthetic (3) *Nonsynthetic (0)*	*Allowed (3)* *Prohibited (0)*	*Reviewer 1: Allowed with annotation: for use only as an inert ingredient in pheromone mating disruptant formulations enclosed within plastic dispensers* *Reveiwer 2: Allowed, no annotation* *Reviewer 3: Allowed with annotation: hand-applied pheromone ropes must be retrieved for disposal outside of the agricultural setting*

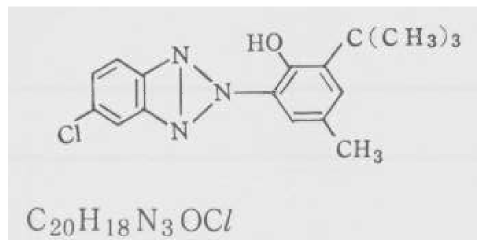
This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the contractor's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA [7 USC 6517(m)]. The information and evaluation presented to the NOSB is based on the technical evaluation against those criteria, and does not incorporate commercial availability, socio-economic impact or others factors that the NOSB and the USDA may consider in making decisions.

Identification

Chemical name:	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	
Trade name:	Sumisorb 300®	
Other names:	Tinuvin 326	
	Bumetrizole	
	2-(3-tert-butyl-2-hydroxy-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-ρ-cresol	
CAS Number:	3896-11-5	
Other Codes	EINECS	223-445-4
	CHIPS	CHP0258
	TSCATS	8EH04283 A

Characterization

<u>Composition:</u>
$C_{20}H_{18}N_3OCl$



<u>Physical Properties:</u>

Appearance:	Pale yellow solid
Odor:	Odorless
Molecular wt.	315.8
Melting point:	137-142°C
Flash Point:	232°C
Specific Gravity:	1.32
Solubility:	Insoluble in water. Soluble in methyl ethyl ketone, toluene, ethyl acetate, styrene monomer, DOP
Stability:	Stable under normal conditions
Reactivity:	None

<u>Specific Uses</u>
Sumisorb 300[∝] is a UV stabilizer. UV stabilizers are used extensively in plastics, cosmetics, and films in concentrations ranging from 0.05-2 percent, with some applications up to 5 percent[1]. Depending on a substrate's sensitivity to UV degradation and desired functional life, numerous UV stabilizers may be used. Categories of UV stabilizers include benzophenones, benzotriazoles, substituted acrylates, aryl esters and compounds containing nickel or cobalt salts. Sumisorb is a benzotriazole. As a family, benzotriazoles are derivatives of 2(-2hydroxyphenyl) benzotriazole and function primarily as UV absorbers. They have also been used for decades as corrosion inhibitors and antifoggants in photographic media (Davis et al 1977). More recently, they have been used extensively in aircraft deicing fluids (Castro et al 2001).

Sumisorb is used in a number of applications. Specifically, it has been evaluated for use in food packaging (MILJØ-KEMI 2001), dental resin composites (Geurtsen, 1998), textiles (Freeman 1995), various plastic polymers (DKL Engineering, no date), and cosmetics (EC, 2002). More recently, it has been added to agricultural pheromone formulations.

<u>How Made:</u>
The manufacturing method for Sumisorb is considered confidential business information (CBI) and was deleted from the petition copy received by the investigator. It is likely that Sumisorb is synthesized from *ρ*-cresol. Cresols are byproducts of petroleum distillation widely used by industry, and are commonly derived via catalytic and thermal cracking of naphtha fractions (ATSDR 1992). Benzotriazoles are produced by reacting substituted and unsubstituted aromatic amines with other nitrogen donors (OPPT 2002).

A search of the US Patent Office yielded a disclosed process for the preparation of 1,2,3-benzotriazole (a less complex chemical precursor to Sumisorb) as follows: continuous addition of acetic acid and orthophenylenediamine to an aqueous solution of sodium nitrate over a period of 1-3 hours at 5-25ºC. This is followed by neutralization of the reaction mixture with sodium hydroxide, then separation of the product from the mixture thereby obtaining a product concentration of 15-25 percent by weight (Chan et al 1981).

® Sumitomo Chemical Co., Ltd., Tokyo, Japan
∝ As noted above, the chemical name for Sumisorb 300 is 2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole. For the sake of clarity, the substance is referred to henceforth as Sumisorb.
1 Norquay Technology, Inc. website. http://www.norquaytech.com/uvstabilizers.htm

Functionality:

The petition requests the allowance of Sumisorb as a UV stabilizer in arthropod mating disruptant formulations. Currently, the petitioned substance is approved by the EPA for use as an inert ingredient in at least four commercially available mating disruptant end use formulations (EPA Registration No. 53575): Isomate®-C Plus, -CM/LR Pheromone, -BAW Pheromone, and -C TT. Their registered uses are given in Table 1.

Table 1.*

Product	Crop	Pest Controlled		EPA Reg. No.
Isomate -C Plus	Apple, pear, walnut, quince, plum, peach, pecan, nectarine	Codling moth Hickory shuckworm	*Cydia pomonella* *Cydia caryana*	53575-6
Isomate -CM/LR Pheromone	Apple, pear	Codling moth Obliquebanded leafroller Pandermis leafroller	*Cydia pomonella* *Choristoneura rosaceana* *Pandemis pyrusana*	53575-20
Isomate -BAW Pheromone	Alfalfa, asparagus, beans, cabbage, celery, cole crops, cotton, cucumbers, lettuce, onions, peanuts, peas, peppers, soybeans, strawberries, sweet potatoes, tomatoes, tobacco	Beet armyworm	*Spodoptera exigua*	53575-21
Isomate -C TT	Apple, pear, walnut, quice, peach, prune, plum, pecan, nectarine	Codling moth Hickory shuckworm	*Cydia pomonella* *Cydia caryana*	53575-25

*Information according to product label

Several synthesized pheromones have been shown to be chemically unstable in field conditions. Decline in pheromone release rates have been attributed to chemical breakdown of the pheromone by light and air (Brown et al 1992). To increase formulation lifespan, UV absorbers are commonly added to technical pheromones to protect them from polymerization, isomerization and oxidation reactions that would decrease their effectiveness (Ogawa, 1997). Codlemone, the primary active ingredient in Isomate dispensers, suffers degradation via heat, light, and oxygen (Ideses & Shani 1988). Sumisorb significantly prolongs the field life of codlemone in Isomate-based products (PBC, 2002). Even with the addition of a stabilizer, degradation of pheromone components still occurs albeit at a slower rate. Table 2 lists several pheromones, their breakdown products, and the substances commonly used to protect them.

Table 2. Stability of active ingredients

Reaction	Pheromone compound	Product	Stabilizer
Oxidation	aldehyde	acid	UV absorber, antioxidant
Polymerization	aldehyde	trimer	radical absorber, pH adjustment
	conjugated diene	oligomer	UV absorber, filler in polymer
Isomerization	conjugated diene	isomer	UV absorber, filler in polymer
Hydrolysis	acetate	alcohol	fungicide

taken from Ogawa, 1997

Status

OFPA, USDA Final Rule:

The Rule allows the use of synthetically produced pheromones as insect attractants in § 205.601(f), but does not mention UV stabilizers per se. Inerts are prohibited unless classified by the EPA as List 4 (Inerts of Minimal Concern) and used with a permitted active pesticide ingredient in a passive dispenser (7 CFR 205.601(m)(1)), or when recommended by the NOSB (65 *Fed. Reg.* 80612).

Regulatory

EPA

Sumisorb is classified on EPA List 3 – Inerts of Unknown Toxicity, and is regulated under TCSA as a chemical in commerce.

NIEHS

The National Toxicity Program (NTP) database has no information regarding Sumisorb.

FDA

Sumisorb has been approved for use with olefin polymers used in food packaging, not to exceed 0.5 percent by weight of the polymers (21 CFR 178.2010) and only in certain types of food listed under 21 CFR 176.170.

U.S. certifiers

California Certified Organic Farmers (CCOF) Certification Book (2000) – Not listed

Texas Department of Agriculture (TDA) (2000) Organic Certification Program (Materials List) – Not listed.

®Pacific Biocontrol Corporation, Vancouver, WA

Quality Assurance International (QAI) (2000) – Defers to OMRI, Not listed.
Midwest Organic Services Association (MOSA) Standards (2001) – Not listed.
Organic Growers of Michigan (OGM) Standards Manual (2000) – Not listed.
Washington State Department of Agriculture (WSDA) Organic Certification Program – Formerly approved for use in mating disruptants (PBC, 2002)
Oregon Tilth Generic Materials List (1999) – Not listed.

International certifiers
Codex Alimentarius Guidelines CAG/GL 32 (2001) – Not listed.
Int'l Federation of Organic Agriculture Movements (IFOAM) (2002) – Not listed.
Japanese Agricultural Standard (JAS) of Organic Agricultural Products (2001) – Not listed.
European Commission Council Regulation (ECC) No. 2092/91 – Not listed.

Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

1. ***The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.***

Sumisorb appears to have a low potential for detrimental chemical interactions with materials used in organic farming systems. The substance is encased in plastic polymer dispensers similar to twist ties, which are hung on branches throughout an orchard. The substance is nonvolatile at field temperatures, and has a low probability of escaping the dispenser when used appropriately.

2. ***The toxicity and mode of action of the substance and its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.***

Very little technical information is available on Sumisorb, and exact information on the substance's mode of action was not provided to the investigator. As a UV absorber, Sumisorb likely functions as an energy transfer agent by absorbing the energy of the protected polymer and dissipating it as thermal energy before photochemical degradation can occur. The manufacturer's material safety data sheet (MSDS) provides the following toxicity information:

Acute Toxicity

Oral LD_{50} (rats)	>5,000mg/kg
Oral LD_{50} (mice)	>5,000mg/kg
Inhalation LD_{50} (rats)	>0.27g/m^3·4h

Subacute Toxicity
The NOEL (no observable effect level) in rats fed Sumisorb over three months was 2,500ppm. Beagles fed Sumisorb at concentrations >2,500ppm mixed with feed over the course of three months displayed weight loss and increased liver weight.

Sumisorb is nonvolatile at field temperatures, and the substance should remain encapsulated in the mating disruptant dispensers. The MSDS provides no ecological information on breakdown contaminants; it appears that no information is available on the fate of Sumisorb specifically. Historically, the primary vector for benzotriazoles in the environment has been their use as corrosion inhibitors, and aircraft deicers in particular (Pillard 1995, Wu et al 1998). Hence, there is some limited technical information on degradation of benzotriazoles in general, presented here for risk assessment:

Benzotriazole has a toxic effect on plants. Studies have shown that benzotriazole causes morphological changes in tomatoes (Davis 1954), hastens sprouting in dormant potatoes (Denny 1951), and has toxic effects on cucumber seedlings and bushbeans (Wu et al 1998). Castro et al (2000) reported that triazoles are visibly toxic to plants, inhibiting root growth and plant development at concentrations greater than 100mg/L 5-methyl benzotriazole. Benzotriazole derivates were also shown to impact oat plant growth (Sparatore et al 1978).

Benzotriazole is toxic in aquatic environments (Hartwell et al. 1995):

LC_{LO} (bluegills, minnows)	27.5ppm (48h)
	25ppm (96h)
LC_{LO} (trout)	15ppm (48h)
	12ppm (96h)

The mortality rate is higher after 96 hours that after 48 hours, suggesting a cumulative toxic effect on fish. There are no reports on effects on aquatic plants.

Benzotriazoles tend to persist in the environment for a very long time due to their UV stability and resistance to oxidation, and persistence in the soil ecosystem is likely. Rollinson and Calleley (1986) found that benzotriazole was not biodegradable, and further stated that no reports had been found to suggest a substance capable of degrading benzotriazole. More recently, Wu and colleagues (1998) reconfirmed the phytotoxicity and stability of benzotriazole in soil solution. The group also demonstrated limited success at degradation of benzotriazole and 5-methyl benzotriazole using the fungus *Phanerochaete chrysosporium,* cultured under conditions that induced lignin peroxidase production. The experiment was based on previous observations that benzotriazoles are readily degraded by a Fenton reaction in the presence of peroxide and iron. Ground horseradish root was also shown to be effective due to the plant's ability to supply an effective peridoxase. Another report by Castro and colleagues (2001) noted that some triazoles, including 5-methyl benzotriazole, may be degraded by plant (*Helianthus annuus*) enzymatic reactions when present at levels below the phytotoxic threshold. These studies suggest a latent potential for biodegradation of benzotriazoles in the natural environment, but more information is needed.

3. The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.

Manufacture
The petitioner does not manufacture Sumisorb, but uses it in its product formulations. Information about manufacturing methods is considered CBI and was withheld from the investigator (*see "***How Made***" section, above*). Thus, the potential for environmentally hazardous byproducts of production remains in question. According to ancillary information contained in the petition, Tinuvin 326 (aka Sumisorb 300) is chemically derived from *ρ*-cresol, which is used widely in the formulation of antioxidants and in the fragrance and dye industries (ATSDR 1992). Cresols are themselves derived from petroleum distillates.

Use
Sumisorb is incorporated into pheromone formulations, which are encased in "rope-type" polyethylene dispensers and hand-placed in the field. When used appropriately, Isomate dispensers have a low potential for environmental contamination. Recognizing the unique nature of use, the EPA has granted a tolerance exemption to inert ingredients used in mating disruptant dispensers provided that: exposure be limited to physical contact only; the design of the dispenser must preclude any chance of incidental contamination with raw agricultural products; and the dispensers must be applied discretely (EPA 1993). The Isomate dispensers currently in use conform to these requirements. The EPA has also granted a tolerance exemption to arthropod pheromones when used in "retrievably sized polymeric matrix dispensers with an annual application limitation of 150g active ingredient per acre" (EPA 1994).

The amount of Sumisorb present in the petitioner's end-use products has been withheld from the investigator as Confidential Business Information (CBI). Information contained in Table 3 is derived by the investigator from data provided on the product labels, and is presented here as a means to analyze risks associated with application rates; the numbers are estimates and should be treated accordingly.

Table 3.

Product	Inert/Other Ingredients* (%)	Weight of dispenser contents (mg)*	Estimated wt inert ingredients (mg)	maximum potential inerts (g/acre)
Isomate -C Plus	11.3	205	23.2	9.3
Isomate -CM/LR Pheromone	7.4	246	18.2	7.3
Isomate -BAW Pheromone	20.2	252.65	51.0	12.8
Isomate -C TT	11.3	431.4	48.7	12.2

*taken from product label

Misuse
Given that fact that Sumisorb is a nonvolatile substance encased in a plastic dispenser hung from a tree or stake, the potential for contamination due to misuse is low. Isomate –C Plus and –CM/LR recommend application of up to 400 dispensers per acre per year, with double that rate for orchard edges; Isomate –BAW and –C TT recommend applications not to exceed 250 dispensers per acre per year. Overapplication combined with a practice that destroys the integrity of the dispensers would exacerbate the effects of environmental contamination.

Disposal
The petitioner's product label for Isomate mating disruptants directs users to dispose of dispensers in a landfill or by burning. The manufacturer's MSDS for Sumisorb calls for incineration.

According to inspectors from three prominent Western organic certifiers, Isomate dispensers tend to be left on orchard trees indefinitely, or they are shed during pruning. In the latter case, growers commonly incorporate exhausted dispensers into the soil with tree prunings. Occasionally, the prunings are burned (along with the dispensers) for disease control. This practice, while limited, presents a localized risk of exposure to toxins since the substance may generate CO, CO_2, NO_x, or HCl when heated to burning (MSDS).

Under current grower practices, it appears that the highest potential for environmental contamination occurs in instances when dispensers are mulched with tree prunings. This practice incorporates the dispenser casing and exposes to the soil any residual ingredients contained within. Maximum potential accumulation of inerts is estimated in Table 3. The EPA tolerance exemption on inert ingredients (1993) acknowledges the potential for contamination, while noting that these products are more environmentally sound than conventional alternatives. The EPA encourages diligent removal the dispensers and "development of biodegradable forms." As a benzotriazole derivative, Sumisorb may have detrimental impacts on the soil ecosystem, and potential contamination is addressed further in Criterion 5.

4. The effects of the substance on human health.

Very little human toxicity information is available on Sumisorb. Given the nature of use of mating disruptant dispensers, the risk of appreciable human contact appears to be low, provided that proper label precautions are taken during application and removal. According to the EPA, ten years of field use of lepidopteran pheromones have resulted in no adverse human effects (EPA 1991). The low risk of contamination prompted the EPA to exempt from tolerance all inert ingredients used in mating disruptant formulations, including UV stabilizers (EPA 1993). As such, mammalian toxicity data has been waived. The following toxicity information was obtained from the Sumisorb MSDS:

Eye Effects	Irritant to rabbit eyes.
Skin Effects	No skin sensitizing effect reported base don repetitive patch test with humans (0.3% dimethyl phthalate soln).
Carcinogenicity	Not listed by IARC, NTP, or OSHA
Teratogenicity	No observed effect in mice study by oral administration on days 6-15 of pregnancy. NOEL is 1,000mg/kg.
Mutagenicity	Negative results with Ames test.

As noted in the Regulatory section above, the FDA has approved the use of Sumisorb incorporated into food packaging except with certain fat-containing and strongly alcoholic foodstuffs. Sumisorb has been shown to be safe when used in packing materials for most foods (Unde and Horacek 1977). This supports the petitioner's claim that the substance is relatively non-hazardous when used in small amounts, although no comprehensive toxicological studies are available to back up this assertion.

As a benzotriazole derivative, Sumisorb has received very little research attention. Toxicity information on 1,2,3-benzotriazole is more prevalent, and is presented here to assist in risk analysis:

The EPA (1977) conducted a study on the effects of benzotriazole, concluding that the substance was of very low toxicity and posed a low health risk to humans. The EPA document cited reports that some benzotriazole derivatives may be potentially mutagenic. A follow-up report determined that 1,2,3-benzotriazole is noncarcinogenic (NIH 1978). More recently, it was found that 1-amino benzotriazole inhibits the proper functioning of cytochrome P-450s (Ortiz de Motellano & Matthews 1981). The potential for benzotriazoles as a class to interfere with P-450s is significant given their function as detoxifiers of xenobiotics in mammals (Wu et al 1998).

A recent comprehensive report on benzotriazole by the Swedish government occupational health and safety division reported that human contact with benzotriazole-containing industrial oils resulted in contact dermatitis (Stouten et al 2000). In lab animals, the substance was slightly irritating to the eyes and skin. Digestion of benzotriazole (0.2mg/mL) by rat livers was relatively slow. Based on acute lethal toxicity data, benzotriazole was classified as "harmful" (according to European standards) following inhalation and ingestion. The study also indicated that benzotriazole is mutagenic in *in vitro* bacterial cells, but not in mammalian cell systems. The report withholds conclusion, but states that benzotriazole should be regarded as a suspected human carcinogen.

5. ***The effects of the substance on biological and chemical interactions.***

Again, little to no information exists on the effects of Sumisorb on biochemical interactions in an ecosystem. Risk analyses in this context are limited to historical information on pheromone mating disruptant use, and published information on ecological and biochemical interactions of benzotriazole.

Mating Disruptants
By nature, mating disruptants interfere with biological interactions by hindering a male insect's ability to locate a female and reproduce. The effect is highly biochemically specific and pheromones are unlikely to have adverse effects on non-target species or other cropping system interactions (Thomson et al 1999). Sumisorb is added to pheromone-based mixtures to control arthropod pests. Specific uses of the mixtures are summarized in Table 1.

Benzotriazole
Benzotriazole has been shown to be an effective nitrification inhibitor (Puttanna et al 2001). When incorporated into the soil, it retards the conversion of ammonium to nitrate, resulting in increased volatilization of NH_3. Benzotriazole has also been shown to impact wheat yields via chelation of soil copper, causing resulting in male plant sterility and other Cu deficiency symptoms (Graham 1986).

In the absence of ecological studies of Sumisorb, whether the substance will display similar characteristics as 1,2,3-benzotriazole (and if so, to what degree) remains in question. Nonetheless it is worth considering that as pheromone components volatilize out of a dispenser, the relative concentration of nonvolatiles such as Sumisorb, increases. A study with codling moth mating disruption dispensers in a pear orchard showed that field-aged dispensers contain approximately seventy-five percent nonvolatile degradation products (Millar and McElfresh 1994). While the nature of their use in pheromone formulations mostly precludes interactions with a soil ecosystem, inappropriate dispenser disposal practices will raise the potential for adverse biological and chemical interactions (*see Criterion 3*).

6. Alternatives to using the substance in terms of practices or other available materials.

Materials
It appears that there are few functional alternatives to Sumisorb. As a class, benzotriazoles are highly effective offering strong intensity and broad UV absorption with a fairly sharp wavelength cutoff close to the visible region. Other materials on the market include benzophenones, hindered amine light stabilizers, and a few benzoates, oxanilides and salicylates. Millar (1994) tested twelve antioxidants and UV stabilizers as retardants of codlemone degradation, all of which are synthesized compounds and none of which are considered List 4 by EPA (Inerts of Low Toxicity). Currently, there appear to be no agriculturally-based substitutes to UV absorbers.

Practices
The foundation of organic agriculture is its reliance on a systems approach to productivity, rather than a reductionistic silver-bullet approach. It is well established that no single practice or material will ensure agricultural viability, and mating disruption is no exception. For example, mating disruption is often ineffective at extremely high pest population densities (Ogawa, 1997). Alternatives to mating disruption include trap cropping, predatory pest releases, microbial insecticides, and removal of infested fruit (sanitation). Organically approved insecticide sprays also offer some measure of pest protection. However, use of these sprays may result in secondary pest problems. For example, pyrethrin applications have been shown to induce mite infestations (Ogawa, 1997). While limited options exist for some crops (Granatstein 2001), their viability in organic apple and peach systems appears questionable at best. In general, the options listed here have not been considered widely effective due to agroecological and/or economic limitations.

7. The compatibility of the substance with a system of sustainable agriculture

Mating disruption has proven to be a highly effective pest control technology, as well as an important means of reducing the use of toxic insecticides (Antilla et al 1996, Benbrook et al 1996, Trumble & Alvarado-Rodrigeuz 1993, Jenkins et al 1990). The high cost of implementation is a barrier to adoption for some growers, and Sumisorb helps to ease this burden by prolonging the field life of the technology in a relatively benign fashion. The crux of the petitioner's argument lies on a potential "economic crisis" if mating disruptant technology is restricted. A strong argument can be made that justifying the use of a substance based solely on economic considerations is contrary to the principles of organic agriculture. However, in the past the NOSB has been hesitant to rule against a substance that would deprive the industry of material integral to the production of agricultural goods currently marketed as "organic" (NOSB 2002), and this is evidenced further by the NOSB's continuation on pheromone inerts.

Given the chemical complexity of mating disruptant formulations, it appears unlikely that any *de facto* organic substance (i.e., a byproduct of a living organism, naturally-occurring in the form that it is used) will be a suitable substitute for Sumisorb. A strong argument can be made that the success of mating disruptants is predicated not just on their effectiveness but their affordability. And since their affordability and action are currently dependent on the inclusion of various non-active (inert) ingredients in the dispensers, the question becomes whether the organic industry is willing to accept a *suite* of synthetic materials in this particular agricultural practice.

The basis of these arguments and counterarguments is the assumption that the utility conferred by Sumisorb 300 is integral to the field success of mating disruptant technology. From an agrobiochemical point of view, this not true: Sumisorb is not absolutely necessary for mating disruption formulations in which it is used. Rather, Sumisorb is a preferred additive that prolongs the field life of mating disruptants and hence makes them economically attractive.

Tap Reviewer Discussion

Reviewer 1 *[PhD in Chemistry; 19 years research experience on organic methods of pest control and IPM; extensive publications on IPM, organic and sustainable agriculture; research experience in toxicology; 5 years experience as a technical advisor on organic materials; Pacific time zone]*

Evaluation of Sumisorb 300 against the Organic Farming Production Act Section 2119 U.S.C. 6518(m)(1-7) Criteria:

1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*
   Because Sumisorb 300 is essentially non-volatile and enclosed in a polyethylene dispenser, chemical interactions with other materials used in organic farming should be minimal.

2. *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.*
   Sumisorb 300 has low acute toxicity to mammals (>5000 mg/kg oral rats). Since the *p*-cresol part of the molecule should be quickly degraded in the environment (Mikami et al. 1979ab), any Sumisorb 300 that escapes will probably break down to 5-chlorobenzotriazole, which is more persistent. Benzotriazole is 10x more toxic to mammals (500 mg/kg oral rats) than is Sumisorb, and in fact has similar acute toxicity to EPA Class II pesticides.

   Under field conditions, Sumisorb will mostly stay in the dispenser, though Millar et al. (1992) found that small amounts of UV stabilizers sometimes accumulate on the surface of field-aged pheromone dispensers.

   Benzotriazole is very slowly degraded in the environment. When municipal sludge containing low concentrations was buried, about 70% of the molecule was degraded within 8 months. Benzotriazole probably binds to soil, as little soil mobility was seen, although the molecule is moderately soluble in water. Since the water solubility of benzotriazole is at least 5 g/liter [The MSDS lists a benzotriazole solubility of 1000-5000 mg/liter, and Stouten et al. (2000) list 20,000 mg/liter], some of the 5-chlorobenzotriazole will probably end up in water.

   In water, benzotriazole and 5-chlorobenzotriazole is extremely persistent. Pruell et al. (1984) found 5-chlorobenzotriazole residues at least 10 years old in the water and sediment of Narragansett Bay. Though water soluble, benzotriazole and 5-chlorobenzotriazole are absorbed in fat, and these molecules accumulate in aquatic filter feeders such as clams (Pruell et al. 1984).

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*
   Since the petitioner will not reveal the manufacturing process, any problems will remain in the realm of speculation. One possible synthetic route is a diazo coupling reaction between 2-nitro-4-chloroaniline and 2-*tert*-butyl-*p*-cresol followed by reduction (Milionis and Handy 1963). Diazo reactions in general give fairly toxic waste products, but there is not enough data to make an evaluation here.

   Environmental contamination during use is hard to imagine. The formulation is contained within polyethylene dispensers that are manually applied to the crop.

   It is also hard to imagine the ways the product could be misused other than overapplication. Since the pheromones are somewhat costly, overapplication is unlikely. There would also be no reason to cut or compromise the polyethylene matrix.

   The label specifies disposal of Isomate dispensers by burying in landfill, by burning, or by burying with prunings. The 400 dispensers used on an acre weigh about 1/4 pound. Though the dispensers would degrade very slowly in a landfill, the total amount of plastic from this source appearing in landfill should be negligible compared to the total waste stream.

   Incineration might lead to air contamination if dispensers are improperly burned on the farm, and not in an EPA approved incinerator. The label says to "avoid the smoke."

   As the reviewer suggested, chopping dispensers up with tree prunings and composting or mulching them could lead to soil contamination. Amounts of degradation products released would be small, less than 10 grams from an acre of prunings. There is some risk that the persistent benzotriazole decomposition product might move into water over time (sol. 5000-20000 mg/liter). Benzotriazole escaping from the compost pile or mulch could inhibit nitrifying bacteria and plant growth in the immediate area might be stunted (see TAP review draft).

4. *The effects of the substance on human health.*
   As the reviewer mentions, there is very little toxicity data available on Sumisorb 300. There is much more data available on benzotriazole, but this material is 10x more toxic to mammals. A number of benzotriazoles are mutagenic in microbial systems, but not in animal assays. Animal tests were suggestive of carcinogenicity but not conclusive. From a review of the toxicology, Stouten et al. (2000) concluded that "benzotriazole should be considered a suspected human carcinogen."

Though Tinuvin P (which is Sumisorb 300 without the t-butyl group) is a skin sensitizer and induces contact dermatitis in humans, apparently Sumisorb 300 (Tinuvin 326) does not (Ikarashi et al. 1994).

Apparently, an epidemiological study has not been conducted with either Sumisorb or benzotriazole, although an occupational exposure survey showed about 320,000 workers in 1981 through 1983 were exposed to benzotriazole, and about 570,000 were exposed to the methyl derivative (CDC 1983).

5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*
   If Sumisorb escapes into the soil, it will probably degrade to 5-chlorobenzotriazole. As mentioned by the reviewer, benzotriazole will inhibit nitrifying bacteria in the soil. Soil concentrations large enough (100 ppm) will be phytotoxic (see draft of TAP review).

6. *The alternatives to using the substance in terms of practices or other available materials.*
   There may be other UV stabilizers that would work as well as Sumisorb 300. Millar (1995) tested a number of antioxidants, UV stabilizers and other materials for stabilization of codlemone. These inerts were added at 5% concentration levels to a 50:50 mixture (100 mg) of codlemone and dodecanol in polyethylene tubes. The tubes were exposed to sunlight and aged in the field. After 180 days, the best protectant was finely divided carbon. This material protected codlemone better than antioxidants such as BHT and a benzotriazole UV stabilizer. Carbon is on EPA inert list 4, and would be acceptable in organic agriculture.

   A black polyethylene pheromone dispenser might be an option for protection of pheromones against photodegradation. However, I do not know if addition of carbon or use of black polyethylene would change the pheromone emission characteristics of the product.

   As mentioned by the reviewer, other methods of organic pest control are available including cultural methods, biocontrol, and even physical barriers. For instance, hail nets are used to stop codling moth migration in Switzerland. Prepupal stages can be killed with nematodes. Trichogramma, codling moth granulosis virus and BT can be employed for egg and larval stages. Overhead watering can reduce larval populations, and postharvest stripping of fruit can reduce numbers in the first flight. Used together in an IPM approach, these methods could significantly reduce crop damage. However, none of these methods provide the elegance and convenience of pheromone mating disruption, and damage to the final product would generally be higher without the pheromones.

7. *Its compatibility with a system of organic agriculture.*
   Though I have no doubts that pheromones are compatible with a system of organic agriculture, I do have doubts about 2-(3-*tert*-butyl-2-hydroxy-5-methylphenyl)-5-chloro-2H-benzotriazole. If this chemical were just added for some reason to the soil or water of an organic farm, my conclusion would be that use was incompatible with the principles and philosophies of organic farming.

   The best case that can be made is that small amounts are used, and that when used properly, the animals, crop, soil, and water will not be impacted because the material is isolated from the farm environment by a plastic dispenser.

Do you have any additional references?

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Little technical information on Sumisorb 300 exists, and the TAP draft has been supplemented with information on 1,2,3-benzotriazole to aid in assessment on Sumisorb. In what ways, and to what degree, can information on benzotriazole be extrapolated to predict the behavior of Sumisorb 300?
Roughly speaking Sumisorb 300 can be thought of as the 5-chlorobenzotriazole derivative of butylated hydroxy toluene (BHT). BHT breaks down quickly in the environment (Mikami et al. 1979ab), and most likely Sumisorb 300 is rather quickly degraded to 5-chlorobenzotriazole. Since this molecule is persistent and hard to degrade, choosing this molecule to evaluate environmental problems seems to be a reasonable approach.

A big difference between Sumisorb 300 and benzotriazole is water solubility. The MSDS for Sumisorb 300 says that it is insoluble in water. Benzotriazole is moderately soluble in water (5-20 mg/ml (Stouten et al. 2000; MSDS). If Sumisorb somehow escapes from the dispensers, environmental degradation could produce 5-chlorobenzotriazole, which would persist in soil and water (Pruell et al. 1984).

Benzotriazole is not a good model for mammalian toxicity of Sumisorb 300 except to represent the most toxic case. Benzotriazole is 10x more toxic to rats than Sumisorb 300. Part of the difference in toxicity might be due to pharmacokinetics. Apparently, no data on the pharmacokinetics of Sumisorb 300 are available.

If Sumisorb 300 is metabolized like BHT, the t-butyl group is oxidized by liver enzymes, and about 50% of an applied dose is excreted within 24 hours in the urine. Because of fat solubility, the rest would be eliminated more slowly (Madhavi and Salunkhe 1995).

Benzotriazole is degraded slowly by rat liver enzymes (Stouten et al. 2000). Without metabolic degradation, the material would be partitioned between water and fat. Some of it might be eliminated unchanged in urine.

Recommendations to the NOSB:
a) The substance should be considered **synthetic** on the National List

b) The substance should be **allowed with restrictions** as an inert ingredient in mating disruptant end-use products used in organic crop production. Annotation should read “allowed for use only as an inert ingredient in pheromone mating disruptant formulations enclosed within plastic dispensers.”

My recommendation relies heavily on the presumption that the material will remained enclosed in the dispenser. I believe that other means of pheromone stabilization should be explored, especially inclusion of carbon black, which is a list 4 material.

* * *

Reviewer 2 *[PhD, organic chemistry; 20 years experience in isolation, identification, synthesis, and development of applications for insect pheromones and related compounds; 14 years university extension specializing in transfer of pheromone technology to users; Pacific time zone]*

Evaluation of Sumisorb 300 against the Organic Farming Production Act Section 2119 U.S.C. 6518(m)(1-7) Criteria:
1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*
There is insignificant potential for detrimental interactions of Sumisorb 300 with other materials because the Sumisorb 300, used as a very minor component as a stabilizer in the pheromone formulation, will be fully contained inside the retrievable, sealed plastic tube dispensers. Even if the tube is breached, for example, if prunings with the depleted dispensers are mulched, Sumisorb 300 has negligible potential for any type of chemical or other interaction with other components in the system because of the chemical stability of the compound, the minimal toxicity of the compound, and the very small amounts per acre used. For example, Sumisorb or a similar stabilizer typically might be used at a rate of 1-2% of the pheromone formulation. Taking a conservative estimate that 100 grams of pheromone might be applied per acre per season (which is about 2.5 times the typical application rate), that would mean that 1-2grams of Sumisorb 300 per acre seasonlong would be deployed. This conservatively estimated total amount per acre is still well below the LD_{50} for rats, which is >5 grams/kilo.

2. *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.*
This compound protects formulations from damage by sunlight, by absorbing and dissipating the light energy as heat. The acute and subacute toxicity data provided indicates that it presents no risk to animals or plants in the formulation in which it will be used, i.e., a few milligrams per dispenser sealed inside retrievable plastic dispensers. Furthermore, the compound is probably more biodegradable than benzotriazole, for which data is presented, because the additional phenolic group on Sumisorb 300 will provide a site at which biodegradative reactions can begin.

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*
   The probability of environmental contamination during manufacture is not an issue; the compound itself and the dispensers in which it is formulated are made by a large, well-established, and reputable company that operates under good laboratory and manufacturing standards as by law. The probability of contamination during use or misuse is negligible because the compound is contained inside a sealed plastic tube. The probability of contamination during disposal will vary with disposal method. Assuming that the depleted dispensers are burned with prunings, for example in a cogeneration plant, the amount of toxic byproducts released will be negligible, and certainly much less than are released from burning the prunings themselves.

4. *The effects of the substance on human health.*
   The acute and subacute toxicity data provided indicate negligible risk to human health, particularly in the proposed sealed tube formulation. If there was thought to be a significant risk to human health from this substance, it would not be registered for use in food packaging, dental resin composites, and cosmetics.

5. *The effects of the substance on biological and chemical interactions.*
   The major effect of this compound is as a UV protectant, dissipating harmful UV radiation as heat. In the proposed formulation, Sumisorb 300 presents negligible risk of causing any effects or interfering with biological and chemical interactions, other than its function in protecting the insect pheromone from degradation by sunlight.

6. *The alternatives to using the substance in terms of practices or other available materials.*
   Several decades of experience with slow-release formulations of insect pheromones has unequivocally demonstrated that they must be protected from UV and oxidative degradation. Hence, any pheromone formulation must contain stabilizers in order to be efficacious for its projected field lifetime. There are many other possible UV stabilizers that could be used in place of Sumisorb 300 in this formulation. However, most if not all of them may present a greater risk of toxicity, nontarget effects, etc. than Sumisorb 300.

7. *Its compatibility with a system of organic agriculture.*
   Sumisorb 300 in the sealed tube formulation proposed should be fully compatible with organic farming practices. The agricultural product will not come in contact with the material. Furthermore, the whole point of using insect pheromone formulations for crop protection is to switch from using toxic insecticides with all their problems to nontoxic insect pheromones, i.e., to exploit and manipulate the natural, organic chemicals produced by insects for their management and control.

No additional references were provided.

Little technical information on Sumisorb 300 exists, and the TAP draft has been supplemented with information on 1,2,3-benzotriazole to aid in assessment on Sumisorb. In what ways, and to what degree, can information on benzotriazole be extrapolated to predict the behavior of Sumisorb 300?
The information presented on benzotriazole indicates that it is a relatively stable compound that resists biodegradation. However, Sumisorb 300 has at least three activating groups/sites for degradative attack that are not present in benzotriazole itself, namely the chlorine on the aromatic ring, which will serve to activate certain positions in the aromatic system to attack, and the phenolic and methyl groups on the other part of the molecule.

Recommendations to the NOSB:
a) The substance is a man-made compound that to my knowledge has not yet been found in nature. Thus, it is a **synthetic** compound.
b) The substance should be **allowed** as an inert ingredient in mating disruptant end-use products used in organic crop production, particularly in formulations such as that proposed, in which the UV stabilizer is incorporated into a retrievable, sealed tube dispenser.

* * *

<u>**Reviewer 3**</u> *[Ph.D. in Entomology; 30 years research experience in chemical ecology of insects, with emphasis on managing insects via pheromones and other behavior-modifying natural products; broad experience in analytic chemistry and natural product chemistry; Midwest time zone]*

The materials [UC SAREP] and the petitioner supplied were highly informative. Combined with some searches of electronic resources, I was able to come to a clear conclusion that use of Sumisorb 300 in organic agriculture is justified, but, with the following critical restriction. A requirement should be imposed that the hand-applied dispensers releasing insect pheromone must be retrieved at the end of the growing season for proper disposal outside of the agricultural setting. Responses to Criteria 1-7 below are being viewed primarily from the perspective that the Sumisorb 300 will be: 1) retained in the pheromone dispenser while in use in the field, and 2) this chemical will be physically removed at the end of the growing season. Such a restriction vastly simplifies answering to the below criteria.

Evaluation of Sumisorb 300 against the Organic Farming Production Act Section 2119 U.S.C. 6518(m)(1-7) Criteria:

1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*
   Given that it is a large (molecular weight 312), tricyclic, and branched molecule, the preponderance of Sumisorb 300 will remain inside the plastic rope dispenser. If the pheromone dispensers containing Sumisorb 300 are retrieved, there will be no significant interaction of this chemical with any other materials used in organic farming systems. If broken open when cultivated into the soil, the approximately 25 mg of Sumisorb 300 that would leak out of each rope would cause a localized hot-spot of chemical that, given its apparent chemical stability, could remain in the soil for an extended period of time and interact in unknown ways with soil flora and fauna.

2. *The toxicity and mode of action of the substance and its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.*
   Sumisorb 300's LD_{50} is > 5 g /kg of rodent. Thus, the parent compound is remarkably non-toxic. Although this compound is reported to be quite stable, the electron-withdrawing properties (nitrogens and chlorine) of the bicyclic ring lead one to postulate eventual cleavage of the bond connecting the monocyclic to the bicyclic ring. The chemistry of the conceivable chlorinated bicyclic products possibly produced upon incorporation into soil cannot be assumed to be innocuous. On the other hand, if the Sumisorb 300 is never released into the environment, it is not a threat.

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*
   The safety record for Sumisorb 300 is very good. It has been widely used in industry, including the food industry, without known incident. Disposal by burning is recommended for expended pheromone ropes retrieved from the field. I have no concerns about human, animal, plant, or environmental impacts during use and disposal.

4. *The effects of the substance on human health.*
   Given that the Sumisorb 300 remains inside the pheromone dispensers and is never released into the environment, and given its very low toxicity to vertebrates, there is very little to no risk to human health.

5. *The effects of the substance on biological and chemical interactions.*
   Again, provided the Sumisorb 300 is retained in the dispensers until disposal, there is no probability of biological or chemical interactions.

6. *The alternatives to using the substance in terms of practices or other available materials.*
   The justification for employing insect sex pheromones for management of moth pests is compelling. Insect pheromones act by means of behavioral effects on the receiver. Compared to both synthetic and natural organic insecticides, pheromones are innocuous to humans, other animals, and the environment. Moreover, pheromones offer pest control that is highly species specific. Incorporation of the technique of pheromone disruption into pest insect control represents a notable advance away from broad-spectrum toxins and toward biorational and sustainable pest control. Pheromone disruption using exact copies of these natural chemicals seems highly compatible with all aspects of organic agriculture.

   A challenge in implementing broad-scale adoption of pest control by pheromone disruption is economics. Today's markets cannot support multiple applications of sex pheromones. Rather, the longevity of each unit of pheromone employed must be maximized. Currently, the costs of hand-applied pheromone and labor to deploy it dictate that the treatment be effective for a full season. Most growers simply cannot afford to use pheromones unless their longevity is prolonged.

   Unfortunately, some pheromone molecules, like the sex pheromone of codling moth (codlemone), are unstable when encountering light and oxygen for prolonged periods. Such pheromones need to be protected from these degradative forces. Compounds like Sumisorb 300 are effective in shielding polyunsaturated pheromone compounds like codlemone from excitation by high-energy wavelengths of light. Without such protectants, pheromone disruption is untenable. Sumisorb 300 is one on the most effective and economical UV screening agents. This reviewer can suggest no substitute agent that will be equally efficacious and affordable. Moreover, there is no promise that any equally affordable screening agents is any safer. Thus, the case for using Sumisorb 300 is justifiable, especially if it remains contained in dispensers that are retrieved.

7. *Its compatibility with a system of organic agriculture.*
   In the judgment of this reviewer, use of Sumisorb 300 – protected insect sex pheromones is compatible with organic agriculture. The advantages of suppressing populations of moth pests by behaviorally active natural products is a great advance in biorational pest control. This type of pest control should be welcomed by the organic agriculture community. However, if moth control by pheromone disruption is to be economical and practical for certain important pest species like codling moth, some provision must be made to stabilize certain pheromones. Protection of some pheromones by UV screening agents like Sumisorb 300 seems reasonable, particularly if this protectant is not released into the environment.

No additional references were provided.

The reviewer did not directly address the additional question.

Recommendations to the NOSB:

a) This reviewer considers Sumisorb 300 to be a **synthetic** product rather than non-synthetic. However, Sumisorb 300 qualifies as an acceptable synthetic as outlined under [the Final Rule].

b) This petition should be **approved** based upon the above facts and reasoning. Approval should be **conditional**: **when used in organic agriculture, hand-applied pheromone ropes containing Sumisorb 300 should be retrieved for disposal outside of the agricultural setting** (see above).

* * *

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