Re. CS: List 3 “inerts”

These comments to the National Organic Standards Board (NOSB) on its Fall 2021 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

205.601(m) (2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

One of the most egregious failures of NOP has been its repeated lack of action on so-called “inert” ingredients. Because of that failure, every sunset brings to a new NOSB a listing that has not been changed in response to over a decade of NOSB recommendations. EPA has long since (2006) stopped updating the “inerts” lists. The NOSB, which has been recommending since 2007 to review individual “inert” ingredients, has instead been given the option of relisting the outdated lists.

List 3 “inerts” should be delisted.

The NOSB has already recommended an expiration date for these chemicals.

In the spring of 2012, the NOSB passed a motion to change the listing to:
2) Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on EPA List 3 in passive polymeric dispenser products may be used until December 31, 2015, after which point they are subject to individual review under 205.601, unless already covered by a policy adopted by the NOP for all other inert ingredients.

NOP refused to codify this recommendation. In doing so, NOP has violated the Organic Foods Production Act (OFPA) §6517(d) (2) “No additions. The Secretary may not include
exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List."

The identities of the former list 3 “inerts” are known, and they should be examined in accordance with OFPA criteria.

The CS proposal of spring 2012 identified the “inerts” formerly on List 3 that were covered by this listing. They are BHT (antioxidant), 2-Hydroxy-4-n-octyloxybenzophenone (UV absorber), and 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (UV stabilizer). The former “List 3 inerts,” which were approved for use only in passive pheromone dispensers, have received special treatment—the law did not intend for “inerts” on List 3 to be allowed in organic production. The definition of “passive polymeric dispenser products” that was included in the spring 2012 NOSB recommendation was refused by the NOP. Therefore, this small group of chemicals has questionable status. From our review of these chemicals, we think it quite likely that at least some will be found to be acceptable when reviewed by the NOSB, but the existence of such an exceptional listing undermines the integrity of the organic label.

In addition to the three List 3 “inerts” identified in 2012, a fourth chemical formerly on List 3 has been identified as being in use in passive pheromone dispensers in organic production—benzaldehyde, CAS #100-52-7. Benzaldehyde is not approved for food use. It is approved for nonfood use and as a fragrance in nonfood uses.1 The addition of another chemical to the known List 3 “inerts” used in organic production shows a hazard of delaying the review of these chemicals as recommended by the NOSB.

We submit the following information to help the CS begin its review of these chemicals.

The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.

**Butylated hydroxytoluene (BHT) (CAS# 128-37-0)**

According to the TAP review performed in 2002, BHT is synthesized from p-cresol. The p-cresol is obtained from coal tar (25%), as a by-product of catalytic cracking of petroleum (11%), and by a number of synthetic processes (64%). A major synthetic route is by sulfonation of toluene followed by heating with sodium hydroxide. Toluene is obtained by distillation of petroleum (Fiege, 1987).

The p-cresol is alkylated with isobutylene gas in an acid catalyzed reaction. Products and results are sensitive to the catalyst and conditions. In one process, p-cresol with 5% phosphoric acid is heated to 70°C. Isobutylene gas obtained by catalytic cracking and distillation of petroleum is bubbled through. The catalyst separates and is removed. The product is washed with sodium hydroxide. Crystals settle out in 46% yield (Stillson, 1947).

---

In another process, p-cresol is heated to 40°C with 5% methanedisulfonic acid. Isobutylene is bubbled through for 6 hours. Upon cooling, the catalyst separates. The product is washed with sodium hydroxide solution. Crystals separate in 88% yield and are recrystallized from methanol (McConnell and Davis, 1963).

2-Hydroxy-4-n-octyloxybenzophenone (OHOBP, methanone) (CAS # 1843-05-6)

OHOBP is synthesized by reacting 2, 4-dihydroxybenzophenones with octyl bromide or octyl chloride (1-chlorooctane). Little toxicological information is available concerning octyl bromide, but it is harmful if inhaled and causes eye, skin, and respiratory tract irritation. 1-chlorooctane's production and use in the manufacture of organometallics, as a chemical intermediate, and as a stabilizer may result in its release to the environment through various waste streams. Because it is an aliphatic hydrocarbon, it is a central nervous system depressant and severe pulmonary irritant.

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (Sumisorb) (CAS #3896-11-5)

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole was petitioned to be added to the National List, and a TAP review was performed in 2003. It says, 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 p-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.

A search of the U.S. 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).

Benzaldehyde (CAS # 100-52-7)

According to PubChem, benzaldehyde is produced principally by the hydrolysis of benzoic chloride or the partial oxidation of toluene. PubChem lists the following sources for a description of the manufacture of benzaldehyde:

---

A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.

**Butylated hydroxytoluene (BHT) (CAS# 128-37-0) preservative/antioxidant**


Safety Review of Checkmate Chemicals, by Don’t Spray California.  
http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%20200608.pdf

**2-Hydroxy-4-n-octyloxybenzophenone (OHOBP, methanone) (CAS # 1843-05-6) UV absorber**


Safety Review of Checkmate Chemicals, by Don’t Spray California.  
http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%20200608.pdf


2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (Sumisorb, bumetrizole) (CAS #3896-11-5)


Human Health Risk Assessment of Isomate®-EGVM by the Pesticide and Environmental Toxicology Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. October 2010. Includes consideration of “inerts” bumetrizole and BHT.

Benzaldehyde (CAS # 100-52-7)

Cameo Chemicals is a database designed for hazardous materials response and planning. Its review of benzaldehyde finds, “Inhalation of concentrated vapor may irritate eyes, nose and throat. Liquid is irritating to the eyes. Prolonged contact with the skin may cause irritation.”

A number of EPA programs track or regulate benzaldehyde. EPA has reviewed benzaldehyde as an “inert” ingredient and approved it for nonfood and fragrance uses. Benzaldehyde is reviewed in EPA’s Integrated Risk Information System (IRIS). EPA has reviewed potentially relevant carcinogenicity and non-cancer data for benzaldehyde for the Superfund program.

The substance's physical properties and chemical mode of action.

Chemical interactions with other substances, especially substances used in organic production

The TAP review of BHT (lines 141-145) said there is little potential for interaction because it is encased in plastic. All reviewers said application devices must be removed at end of season. We have not found information about chemical interactions with methanone. The TAP review of Sumisorb (p. 4) said there is little potential for chemical interaction because the material is encased in plastic and is not volatile at field temperatures, although reviewer 1 said (p. 8), “Millar et al. (1992) found that small amounts of UV stabilizers sometimes accumulate on the surface of field-aged pheromone dispensers.”

Benzaldehyde (CAS # 100-52-7)

Benzaldehyde is “a nontoxic, combustible liquid that reacts with oxidizing reagents. Benzaldehyde must be blanketed with an inert gas at all times since it is oxidized readily by air to benzoic acid. In contact with strong acids or bases it will undergo an exothermic

---

7 https://cameochemicals.noaa.gov/chemical/216.
condensation reaction. A violent reaction was observed on contact with peroxyacids (peroxyformic acid). An explosion occurred when pyrrolidine, benzaldehyde, and propionic acid were heated to form porphyrins.”

Incompatible materials include strong oxidizing agents, strong reducing agents, strong bases, alkali metals, aluminum, iron, phenols, oxygen.

Toxicity and environmental persistence

**BHT**

According to the TAP review of BHT (lines 348-351), “The dispenser products have undergone expedited review by the Environmental Protection Agency and therefore the mammalian toxicity, ecological effects, and environmental fate and groundwater data has for the most part been waived (40 CFR 180.1001(e) (7/1/91)). Therefore, little environmental information is available on the effects of BHT (used as an inert) to terrestrial invertebrates or aquatic invertebrates and vertebrates.” The TAP review (lines 155-158) says, “At least 10 non-volatile polar degradation products are formed by progressive oxidation. Major metabolites are formed by oxidation of the methyl group, forming a BHT alcohol, a BHT acid, and a BHT aldehyde. These are further metabolized at a slower rate completely to CO2 and water. BHT and its degradation products are biodegradable and do not persistent in the soil environment (Mikami et al., 1979a).” An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.

**2-Hydroxy-4-n-octyloxybenzophenone**

Ciba submitted 3 adverse effects reports under TSCA for sensitization. It is not readily biodegradable.

**2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole**

From the Sumisorb TAP, p. 4: It is “toxic in aquatic environments... The mortality rate is higher after 96 hours than after 48 hours, suggesting a cumulative toxic effect on fish.” P. 12: “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 monocylic to the bicyclic ring. The chemistry of the conceivable chlorinated bicyclic products possibly produced upon incorporation into soil cannot be assumed to be innocuous.” P. 4: “[I]t appears that no information is available on the fate of Sumisorb specifically.” P. 5: “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.”

---

12 https://cameochemicals.noaa.gov/chemical/216.
13 Sigma-Aldrich; Safety Data Sheet for Benzaldehyde. Product Number: 418099, Version 5.3 (Revision Date 02/26/2015). Available from, as of April 21, 2016: https://www.sigmaaldrich.com/safety-center.html.
Benzaldehyde (CAS # 100-52-7)

Along with more detailed reports, PubChem\(^\text{16}\) gives the following summary of toxicity, from the Hazardous Substances Data Bank (HSDB):\(^\text{17}\)

**HUMAN EXPOSURE AND TOXICITY:** It may cause contact dermatitis. It was positive in sister chromatid exchange assay with human lymphocytes from healthy non-smoking donors. Benzaldehyde was found to induce formation of stable DNA-protein cross-links in cultured human lymphoma cells. Benzaldehyde was found to lack significant activity against most human tumor cells tested. **ANIMAL STUDIES:** It was slightly irritating to the rabbit eye. Histological examination of the trachea and lungs showed a slight irritation of respiratory epithelium for nonsensitized guinea pigs. In the acute studies, benzaldehyde induced deaths and decreased body-weight gain in both sexes of rats given 800 or 1600 mg/kg/day and caused deaths in both sexes of mice given 1600 or 3200 mg/kg/day. In the 90-day studies, deaths occurred in both sexes of rats on 800 mg/kg/day and in male mice on 1200 mg/kg/day. Body-weight gain was depressed in male rats on 800 mg/kg/day, in male mice on 600 mg/kg/day and in female mice on 1200 mg/kg/day. Necrotic and degenerative lesions were seen in the cerebellar and hippocampal regions of the brain in both sexes of rats given 800 mg/kg/day, but not in mice. Renal tubular necrosis occurred in male and female rats on 800 mg/kg/day and in male mice on 1200 mg/kg/day. Mild epithelial hyperplasia or hyperkeratosis of the forestomach was seen in male and female rats on 800 mg/kg/day. In an inhalation study performed with rats, it was found that the principal histopathological change was the development of goblet cell metaplasia in the respiratory epithelium lining of the nasal septum. In 2 year studies, there was no evidence of carcinogenic activity of benzaldehyde for male or female rats receiving 200 or 400 mg/kg per day. There was some evidence of carcinogenic activity of benzaldehyde for male or female mice, as indicated by increased incidences of squamous cell papillomas and hyperplasia of the forestomach. Benzaldehyde was studied for mutagenicity using Salmonella typhimurium tester strains TA100, TA102 and TA104, with or without metabolic activation. It was non-mutagenic under all test conditions with dose ranges from 33 to 3333 ug/plate. No induction of chromosomal aberrations was observed in CHO cells treated with up to 500 ug/mL benzaldehyde without metabolic activation or with up to 1600 ug/mL with metabolic activation.

Along with more detailed reports, PubChem\(^\text{18}\) gives the following summary of environmental fate, from the Hazardous Substances Data Bank (HSDB):\(^\text{19}\)

Benzaldehyde's production and use as a food additive, as a fragrance in cosmetics, perfumes, and detergents, as a chemical intermediate and as a solvent may result in its release to the environment through various waste streams. Benzaldehyde is also released to the environment in emissions from combustion processes such as gasoline.

and diesel engines, incinerators and wood burning. It is formed in the atmosphere through photochemical oxidation of toluene and other aromatic hydrocarbons. It occurs naturally in many plant species and has been identified in volcanic emissions. If released to air, a vapor pressure of 1.27 mm Hg at 25 °C indicates benzaldehyde will exist solely as a vapor in the atmosphere. Vapor-phase benzaldehyde will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 30 hours. Small quantities of benzaldehyde have been detected in atmospheric aerosol particulates that can be physically removed from air via dry and wet deposition. Benzaldehyde has been detected in rain, snow, fog, and cloud water. Benzaldehyde absorbs UV radiation between 300 and 380 nm and, therefore, may be susceptible to direct photolysis by sunlight. If released to soil, benzaldehyde is expected to have very high mobility based upon an estimated Koc of 11. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 2.67X10-5 atm-cu m/mole. Benzaldehyde may volatilize from dry soil surfaces based upon its vapor pressure. A number of biological screening studies have demonstrated that benzaldehyde is readily biodegradable. If released into water, benzaldehyde is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Utilizing the Japanese MITI test, 66% of the Theoretical BOD was reached in 2 weeks indicating that biodegradation is an important environmental fate process. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 1.5 and 14 days, respectively. An estimated BCF of 4.4 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions. Occupational exposure to benzaldehyde may occur through inhalation and dermal contact with this compound at workplaces where benzaldehyde is produced or used. Monitoring data indicate that the general population may be exposed to benzaldehyde via inhalation of ambient air, ingestion of food and drinking water, and dermal contact with consumer products containing benzaldehyde. (SRC)

Environmental impacts from its use or manufacture

**BHT**

An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.20 Another review cites classifications as hazardous.21

---


21 Safety Review of Checkmate Chemicals, by Don’t Spray California. [http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202002-06-08.pdf](http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202002-06-08.pdf)
2-Hydroxy-4-n-octyloxybenzophenone

It is a solid up to 47-49°C, fairly insoluble in water, with a high octanol/water coefficient, and EPA expects its mobility to be low. EPA also states that its toxicity to mammals, aquatic animals, and plants is low.22

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole

From the TAP, p. 5: “When used appropriately, Isomate dispensers have a low potential for environmental contamination…. Overapplication combined with a practice that destroys the integrity of the dispensers would exacerbate the effects of environmental contamination…. 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, CO2, NOx, or HCl when heated to burning (MSDS).”

Benzaldehyde (CAS # 100-52-7)

Benzaldehyde is harmful to aquatic organisms with long-lasting effects.23,24

Effects on human health

BHT

“Butylated Hydroxytoluene (BHT) is classified as irritating to the eyes, respiratory system, and skin under European classification. Allergic contact dermatitis and contact urticaria are associated with exposure to BHT (HAZ-MAP). It is currently listed as ‘unclassifiable’” in regard to its carcinogenicity in humans (due to limited human test data), however a variety of in vitro and animal studies have shown it to have carcinogenic, tumorigenic, mutagenic, and teratogenic effects in animals as well as in human cells (Sigma-Aldrich MSDS). Studies have also confirmed BHT to have estrogenic activity (Miller et al. 2001; Wada et al. 2004) and MSDS sheets state that chronic exposure to BHT may cause reproductive and fetal effects (Acros MSDS).”25

2-Hydroxy-4-n-octyloxybenzophenone

“[R]elated compounds in the benzophenone family have been shown to form estrogenic photoproducts, upon exposure to UV or sunlight (Hayashi et al. 2006).” 26

---

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole

TAP 6: “FDA has approved the use of Sumisorb incorporated into food packaging except with certain fat-containing and strongly alcoholic foodstuffs. From a review of the toxicology, Stouten et al. (2000) concluded that ‘benzotriazole should be considered a suspected human carcinogen.’” EPA lists it for nonfood use only.27

Benzaldehyde (CAS # 100-52-7)
PubChem28 gives the following summary from HSDB:29

HUMAN EXPOSURE AND TOXICITY: It may cause contact dermatitis. It was positive in sister chromatid exchange assay with human lymphocytes from healthy non-smoking donors. Benzaldehyde was found to induce formation of stable DNA-protein cross-links in cultured human lymphoma cells. Benzaldehyde was found to lack significant activity against most human tumor cells tested. ANIMAL STUDIES: It was was slightly irritating to the rabbit eye. Histological examination of the trachea and lungs showed a slight irritation of respiratory epithelium for nonsensitized guinea pigs. In the acute studies, benzaldehyde induced deaths and decreased body-weight gain in both sexes of rats given 800 or 1600 mg/kg/day and caused deaths in both sexes of mice given 1600 or 3200 mg/kg/day. In the 90-day studies, deaths occurred in both sexes of rats on 800 mg/kg/day and in male mice on 1200 mg/kg/day. Body-weight gain was depressed in male rats on 800 mg/kg/day, in male mice on 600 mg/kg/day and in female mice on 1200 mg/kg/day. Necrotic and degenerative lesions were seen in the cerebellar and hippocampal regions of the brain in both sexes of rats given 800 mg/kg/day, but not in mice. Renal tubular necrosis occurred in male and female rats on 800 mg/kg/day and in male mice on 1200 mg/kg/day. Mild epithelial hyperplasia or hyperkeratosis of the forestomach was seen in male and female rats on 800 mg/kg/day. In an inhalation study performed with rats, it was found that the principal histopathological change was the development of goblet cell metaplasia in the respiratory epithelium lining of the nasal septum. In 2 year studies, there was no evidence of carcinogenic activity of benzaldehyde for male or female rats receiving 200 or 400 mg/kg per day. There was some evidence of carcinogenic activity of benzaldehyde for male or female mice, as indicated by increased incidences of squamous cell papillomas and hyperplasia of the forestomach. Benzaldehyde was studied for mutagenicity using Salmonella typhimurium tester strains TA100, TA102 and TA104, with or without metabolic activation. It was non-mutagenic under all test conditions with dose ranges from 33 to 3333 ug/plate. No induction of chromosomal aberrations was observed in CHO cells treated with up to 500 ug/mL benzaldehyde without metabolic activation or with up to 1600 ug/mL with metabolic activation.

27 http://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:2:0::NO.
Effects on soil organisms, crops, or livestock.

**BHT**

TAP review (lines 268-271): “Soil microbes, sunlight and air quickly metabolize BHT. About 85-90% is degraded within 24 hours (Mikami et al., 1979a). Amounts reaching the phylloplane or soil should be low due to its low vapor pressure and encapsulation within a polyethylene matrix. Adverse effects on soil organisms, crops and livestock should be negligible, since very little should escape the dispenser (PBC, 2002).”

**2-Hydroxy-4-n-octyloxybenzophenone**

We have not been able to find any information on impacts on soil organisms, crops, or livestock.

**2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole**

The TAP review, p. 4, says: “From what is known about other benzotriazoles, it has toxic effects on plants.”

**Benzaldehyde (CAS # 100-52-7)**

Benzaldehyde is toxic to nematodes and soil microorganisms and has been suggested as a soil fumigant. It may be toxic to crops.

**Conclusion**

The NOSB should sunset List 3 “inerts” and refer the NOP to the 2012 NOSB recommendation. We understand the importance of pheromones to organic production, and it is not our intention to remove pheromones through this action (though further investigation of specific pheromones may be necessary). Rather, we want to ensure that the materials used in organic production are consistent with all OFPA criteria.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors
tshistar@gmail.com

---

