Propylene Glycol Monolaurate
Crops

Identification of Petitioned Substance

Chemical Names:
Propylene Glycol Monolaurate; Propylene Glycol Monolaureate; Propylene Glycol Laurate; Lauric Acid, Monoester with Propane-1,2-Diol; Dodecanoic acid, ester with 1,2-propanediol; Propane 1,2 diol esters of fatty acids; 1,2 Propanediol, Monolaurate.

Other Name:
PGML

Trade Names:
Acaritouch, Imwitor® 412, Lauroglycol, Riken PL-100, VWX Technology 42 Propylene Glycol Monolaurate

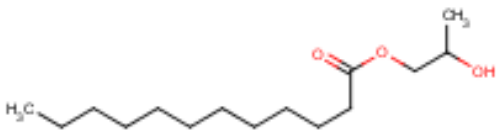
CAS Numbers:
142-55-2; 10108-22-2; 27194-74-7

Other Codes:
EINACS / ELINCS 248-315-4 / 205-542-3; INS 477 (propylene glycol esters of fatty acids)

Characterization of Petitioned Substance

Composition of the Substance:

A monoester of propylene glycol and lauric acid. $C_{15}H_{30}O_3$.



Source: ChemID Plus, 2011.

Properties of the Substance:

The properties of propylene glycol monolaurate are summarized in Table 1.

Table 1
Physical and Chemical Properties of Propylene Glycol Monolaurate

Physical or Chemical Property:	Value:
Physical State	Liquid
Appearance	Light Yellow
Odor	Mild Fatty
Molecular Weight	258.3969
Boiling Point at 0.6 Torr.	138° - 141° C.
Flash Point	178° C.
Melting Point	247° C.
Boiling Point	335°C
Solubility	Soluble in organic solvents; Water solubility 3.3 mg/l; insoluble in propylene glycol.
Vapor Pressure	0.162 Pa/°C @ 25.00° C.
Relative Density at 25°C.	0.92 g/ml
Specific Gravity at 25°C.	0.905-0.915 g/cm^3
Saponification Value	230 to 250
Hydrophilic-Lipophilic Balance	4.5
pH	5.9

Sources: Nikitakis, McEwen and Wich, 1990; STN International, 1995; Toagosei, 2000; Ash, 2004; Riken, 2008; Weatherston, 2009; Chemfinder, 2011.

Specific Uses of the Substance:

Propylene glycol monolaurate (PGML) is petitioned for use as an acaricide (Weatherston, 2009). PGML is also registered with EPA for use as a fungicide, bactericide and viricide used to control post-harvest decay in stored crops (EPA, 2004). Other uses include as an emulsifier, co-emulsifier, deicer, excipient, humectant, adjuvant, emollient, surfactant and skin conditioner, stabilizer and preservative.

Approved Legal Uses of the Substance:

Approved for use as an acaricide by EPA in 2004 (69 *Federal Register* 19844). Declaration of Generally Recognized As Safe (GRAS) status on file with the FDA. Recognized as a direct and indirect food additive 21 CFR §§172.856, 173.340, 175.106, 175.300, 176.170, 176.210, 177.2800.

Action of the Substance:

The mode of action is believed to be as a suffocant and desiccant. The petition states that PGML works by blocking the mite's peritreme and solubilizing the waxy cuticle (Weatherston, 2009).

Combinations of the Substance:

Pesticides formulated with this active ingredient are combined with proprietary inert ingredients. The petitioner names some of the inert ingredients in a formulated product in the non-confidential version of

the petition and indicates that the product can be formulated with non-synthetic and List 4 inert ingredients (Weatherston, 2009).

Status

Historic Use:

There has been no historic use in organic production. This material has been used in conventional production as an acaricide since 2004 (US EPA, 2006).

OFPA, USDA Final Rule:

PGML is not on the National List (7 CFR 205.601 – 205.606) and is not mentioned in the Organic Foods Production Act (7 U.S.C. 6501 *et seq.)*.

International

PGML is not permitted as an acaricide by any international organic standard. It does not appear on the Canadian General Standards Board's Permitted Substances List (CGSB, 2011). PGML does not appear on the Codex Alimentarius Commission's *Guidelines for the Production, Processing, Marketing and Labelling of Organically Produced Foods* Table 2, Substances for Plant Pest and Disease Control (Codex, 2001).

The European Union regulation requires all authorized plant protection products to appear on a list of permitted substances (EC, 2007). PGML does not appear on the list of authorized plant protection products and is therefore prohibited (EC, 2008). PGML does not appear on Appendix 2 of the 2005 IFOAM Basic Standards (IFOAM, 2005). No dossier has been submitted to IFOAM at the time. The Japanese Agricultural Standard for Organic Production does not include PGML on Table 2, Substances for Plant Pest and Disease Control (JMAFF, 2009).

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: What category in OFPA does this substance fall under? (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

Glycol esters do not appear in an OFPA category. In evaluating the petition for sucrose octanoate esters (SOE), the NOSB determined that esters are equivalent in their manufacture and mode of action to 'soap,' which appears as a category of synthetic authorized for use in production on the National List at 7 U.S.C. §6517(c)(1)(B)(i) (NOSB, 2005). SOE is currently on the National List. The NOSB rejected the petition for ester sorbitol octanoate (NOSB, 2005).

Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

PGML is manufactured by a proprietary process that involves the esterification of propylene glycol and lauric acid. Propylene glycol is a double alcohol (diol) that is made by a catalytic reaction that involves the hydration of propylene oxide (Faith, et al., 1975). It is technically feasible to esterify fatty acids using propylene glycol by using the enzyme lipase produced by various microorganisms (Okumura, Iwai, and Tsujisaka, 1979). Research on esterification of glycol esters made agriculturally produced feedstocks using enzymatic methods may make eco-friendly production of a biologically produced form possible someday (Shaw, et al., 2003; Hayes, 2004). No commercial source could be identified that makes propylene glycol or propylene glycol monolaurate from agricultural feedstocks by biological processes at this time.

The feedstock propylene oxide is in turn is made from propylene either by the chlorhydrin process or by oxidation. Most industrial propylene is synthesized from petroleum—either as a sole product or co-product with ethylene, natural gas (methane) or coal (Giacobbe, 2011; Devanney, 2011).

It is also possible to produce propylene glycol from glycerol by hydrogenolysis in the presence of various catalysts (Dasari, et al., 2005). Glycerol in turn may be produced by a number of methods previously reviewed by the NOSB. Some glycerol is derived from petrochemical sources but may also a by-product of soap produced saponification of fatty acids with strong bases, and biodiesel manufacture. What little propylene glycol produced from biological sources is refined to USP grade and is more commonly used in pharmaceuticals.

Lauric acid is a naturally occurring fatty acid. The petition states the source is coconut oil (Weatherston, 2009). Other vegetable and animal oils can be used as the source of lauric acid (Merck, 2006). Lauric acid can also be synthesized from mercaptans obtained from petroleum or shale oil (Ballard, Furman and Finch, 1951).

Evaluation Question #3: Is the substance synthetic? Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

PGML is a product of the chemical process of esterification of propylene glycol and lauric acid, not a biological process, and is therefore synthetic (Weatherston, 2009). PGML may be produced by naturally occurring microbial enzymes; however, the propylene glycol used as the starting material for this process is synthetically produced.

Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Under normal conditions found in the environment, propylene glycol esters of fatty acids are biochemically metabolized by various organisms. Glycol esters generally decompose into propylene glycol and the fatty acid with which it is made—in this case lauric acid. These substances are are rapidly biodegraded in the environment (ACCAEP, 2003). The petition extrapolates biodegradability from other glycol esters and studies that do not necessarily use PGML as the specific glycol ester the model for biodegradability (ACCAEP, 2003).

Studies conducted on rats and chickens found propylene glycol is generally oxidized to lactaldehyde and then to lactate or pyruvate (Ruddick, 1972). The lauric acid is metabolized as a lipid, with the enzyme lipase playing at key role in its decomposition and biodegradation (Casarett and Doull, 1991). Lauric acid

and other fatty acids from decomposed glycol esters may also be stored in the fatty tissue of animals and used as energy (Lepkovsky, et al., 1934).

Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

The toxicity of PGML and other glycol esters is summarized in the petition. The EPA waived most data requirements for the registration of a pesticide because the substance was previously approved by FDA for use in food.

The US EPA based waivers of acute toxicity, hypersensitivity, and subchronic toxicity on data submitted for those parameters conducted on the active ingredient propylene glycol monocaprylate and glycerol monolaurate (Jones, 2003).

PGML toxicity is rated below. Note that the EPA placed eye irritation in Category III, not in Category IV as reported in the petition (Weatherston, 2009) because corneal opacity and iridic effects occurred and were not resolved by 24 hours (Jones, 2003). The results of toxicity studies examined are contained in Table 2.

Table 2
Toxicological Characteristics of Propylene Glycol Monolaurate

Toxicity Parameter	Value	Source
Acute Oral LD_{50} (Rat):	>36,400 mg/kg	Johnson, 1999
Acute Dermal LD_{50} (Rat)	>5,000 mg/kg	Jones, 2003
Primary Eye Irritation (Rabbit):	EPA toxicity category III (slightly toxic)	Jones, 2003
Primary Skin Irritation (Rabbit): Slightly Irritating	EPA toxicity category IV (not toxic)	Jones, 2003
Dermal Sensitization (Guinea Pig)	Negative	Jones, 2003
Acute Toxicity to *Daphnia magna*		
-EC_{50} @48 hs	0.52 mg /L	Shelgren, 2003
-NOEC	0.40 mg /L	Shelgren, 2003
Acute Toxicity to Juvenile Carp (*Cyprinus carpio*)		
-LC_{50} @96 hrs	5.20 mg/L	Shelgren, 2003
-NOEC	3.80 mg/L	Shelgren, 2003
-First mortality	13.89 mg/mL	Shelgren, 2003
Acute Toxicity to Honey Bees (*Apis mellifera*)		
-Oral Acute Toxicity at 0.01%, 0.1% or 1% concentrations	Negative (No mortalities)	Shelgren, 2003
-Contact Toxicity @ 100X	8%	Shelgren, 2003
-Contact Toxicity @ 500X	57%	Shelgren, 2003
-Contact Toxicity @1,000X	88%	Shelgren, 2003
Phytotoxicity	Negative	Heaton, 2003
Carcinogenicity	Negative	NTP, 2010; IARC, 2011; US OSHA, 2011

EC_{50}=Effective Concentration for observed effects on 50% of the individuals in the population
LC_{50}=Lethal Concentration for 50% mortality (ambient exposure)
LD_{50}=Lethal Dose for 50% mortality of the test population (direct feeding)
NOEC=No Observed Effect Concentration

The EPA established a nominal concentration of 75.85% PGML as a Technical Grade Active Ingredient (TGAI). The upper certified limit is 80.84% and the lower certified limit is 70.86%. PGML TGAI will have a minimum of 19.16% impurities with not more than 29.14% impurities (Jones, 2003).

Relatively few toxicity studies have been performed on PGML, with most of the regulatory decisions based on the extrapolation of data from propylene glycol, various fatty acids, and similar glycol esters. Models of high volume production glycol esters served as a model (ACCAEP, 2003). Toxicology studies performed on rats and dogs showed that stearoyl propylene glycol hydrogen succinate was readily metabolized and excreted (King, et al., 1970; King, et al., 1971). The reviewers were not able to find any studies to validate the extrapolations or find the relationship of PGML to model glycol esters.

Propylene glycol, one of the starting material for the synthesis of PGML, has a very low order of acute and chronic toxicity with no accounts of fatality (Casarett and Doull, 2001). When ingested, propylene glycol is metabolized as a carbohydrate (Ruddick, 1972). Exposure of monkeys and rats to propylene glycol via inhalation found no significant difference in both acute and chronic toxicity (Robertson, et al., 1947; Suber et al., 1989).

Lauric acid is readily metabolized by most organisms by means of hydroxylation and enzymatic digestion with lipase (Casarett and Doull, 2001).

Lauric acid is non-toxic and is a common component of edible oils.

The petitioner states that the mode of action is suffocation by blocking spiracles and also dissolves the waxy cuticles of certain insects, causing moisture loss and desiccation (Weatherston, 2009).

Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Most propylene glycol, the starting material for synthesis of PGML, is a by-product of petroleum extraction and refining, with most of the remainder being from natural gas or coal. All three processes are based on fossil fuels that contribute to greenhouse gas emissions. The feedstocks for most propylene glycol are non-renewable. While it is possible to produce propylene glycol mostly or even entirely from renewable resources, it is not economically feasible at the present time.

Lauric acid is a naturally occurring biological product and a renewable resource. While it is possible to produce lauric acid from petroleum, plant- and animal-based sources are abundant.

The first end-use acaricide product with PGML as an active ingredient is sprayed at a concentration of up to 25 oz/100 gal of water with a minimum application of 50 gallons/acre (EPA, 2004). For post-harvest handling, the first product registered as a fungicide / biocide is applied after the crop is harvested and ready for storage as a liquid containing less than 1% by weight of active ingredient (EPA, 2004). In both cases, allergic or sensitive mixer / loaders and applicators could suffer irritation, but face minimal risk of any serious injury or fatality if misused.

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

As a surfactant and emulsifier, PGML has the potential to enhance the toxicity of other biocides applied. A study that used estradiol as a model drug showed that PGML resulted in significantly greater transport of the drug estradiol into the skin than a silicone-based excipient (Irion, Garrison and Abraham, 1995). Substances with similar transport mechanisms may, in theory, also enter the skin and bloodstream faster when applied with PGML.

Other non-synthetic acaricides to be considered for possible use in tank mixes with PGML include neem and spinosad.

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil) crops, and livestock (7 U.S.C. § 6518 (m) (5)).

Non-ionic and anionic surfactants are generally non-toxic to bacteria (Kosswig, 1994). PGML was tested as an antimicrobial teat dip with other propylene glycol esters. Such esters were found to be effective in significantly reducing the populations of *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus uberis, Escherichia coli,* and *Pseudomonas aeriginosa.* PGML was deemed inferior to other esters of glycol ether such as propylene glycol monoester of capric or caprylic acid as a topical antimicrobial because it would not stay in solution at higher concentrations (Andrews, 1996).

PGML is known to have some known fungicidal activity and is registered for use as a fungicide (EPA, 2004). While no studies were found that specifically tested PGML on actinomycetes and soil-borne fungi in a field environment, one can infer that the mode of action may have a temporary effect on those soil microorganisms. The substance is thought to decompose quickly into its constituent parts propylene glycol and lauric acid. These constituents are expected to biodegrade rapidly in the environment. As such, the EPA believed PGML and other similar glycol esters of fatty acids to be not persistent (Jones, 2003). If this is true, then soil microorganisms can be expected to recover rapidly after application.

While the petition focuses on the impact on pestiferous and predacious mites, the impact of the substance on other mites is not addressed. Mites play a significant role in the soil food web and decomposition of organic matter (Coleman, Crossley and Hendrix, 2004). Data on the impact of PGML on annelids and other soil decomposition organisms was not found. Given the toxicity, mode of action, breakdown products, and persistence, the impact on soil organisms is unlikely to pose a serious risk. However, there is no empirical data to support the conclusion, which was also the basis for waivers of other toxicological and environmental studies. Biocidal products may have unexpected effects on soil ecosystems and without specific data it is difficult to predict the impact (Edwards, 2002).

Propylene glycol monoesters have long been recognized as effective spermicides (Elias, 1949). PGML does not appear on the endocrine disruptor database. No studies were found to examine the reproductive impact of the release of PGML or propylene glycol monoesters in general into the environment.

Evaluation Question #9: Discuss and summarize findings on whether the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The petitioned substance received waivers on most environmental testing requirements from the US EPA in registering the product as an acaricide.

The EPA concluded that "Adverse effects on birds and higher organisms are expected to be low due to the low mammalian toxicity found in animal testing and the ability of most organisms to metabolize these substances. Testing has demonstrated, however, that the acaricide is moderately toxic to fish and algae and very toxic to aquatic invertebrates. Direct feeding studies to honey bees found it to be non-toxic (Shelgren, 2003). However contact studies conducted on honeybees found that up to 88% of the population was killed at higher concentrations (Shelgren, 2003).

PGML can harm natural enemies. One study that compared various spiracle-blocking and microbial active ingredients on the model beneficial predator mirid bug (*Nesidiocoris tenuis*) conservatively rated PGML in Acaritouch® as 'slightly toxic' to both the younger nymphs and adults, with a mortality rate of between 60% and 70% on the treated organisms (Nakaishi and Arakawa, 2011). The mortality rates on the beneficial flower bug (*Orius strigicollis*) were reported to be about 80% (Otsuka, 2008). Acaritouch® was rated as 'Moderately Harmful' (33%-66% mortality) on the beneficial predatory mite *Galendromus occidentalis* and

'Safe' (less than 33% mortality) on the beneficial predatory mites *Neoseiulus fallacis* and *Amblyseius andersoni* raised on hops (James, 2004a) and grapes (James, 2004b).

The label on the first registered acaricide product must specifically warn users not to apply the product to bodies of water or to contaminate bodies of water during application, cleaning, or disposal." (EPA, 2004). The water solubility of nearly 4 mg/liter and potential toxicity to aquatic organisms appear to be the basis for this warning (Jones, 2003; Shelgren, 2003).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

No reported adverse effects were found from the use of the substance other than possible irritation of allergic individuals. The EPA concluded that "In studies using laboratory animals, the fatty acid monoesters showed no adverse effects except for mild eye irritation for both the glycerol and the propylene glycol monoesters and dermal sensitization for the propylene glycol monocaprylate. Therefore, special precautions were put on some of the propylene glycol monoester labels to warn users that the product might cause an allergic response: An example of a precautionary statement is: 'Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals exposed to this product.'" (EPA, 2004).

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Preventive measures such as rotation, nutrient management, selection of mite-resistant varieties, and the release of predators and parasites are the preferred alternatives (Caldwell, et al., 2005). Under the National Organic Program regulations, synthetic substances may be used only if biological, cultural, mechanical or physical methods are insufficient to prevent or control pests [7 CFR 205.206(e)].

As noted in the petition, various naturally occurring and nature identical essential oils have been registered by EPA as acaricides with a non-lethal mode of action, including farnesol, nerolidol, geraniol and citronellol. The synthetic forms of these substances were determined to be pheromones by the US EPA (EPA, 2009) and have been permitted for organic production since the NOP was first implemented (OMRI, 2002). Other vegetable oils, such as soy, corn and cottonseed oil can also be used as suffocants (Caldwell, et al., 2005).

Various non-synthetic botanical and fungal-derived acaricides are also used. Neem is labeled for use in the United States for mites in general as well as spider mites, broad mites and rust mites on a number of crops (Certis, 2009). Spinosad is registered in the US for use on spider mites, two-spotted mites and other mites (Dow, 2011). Spinosad resistant pests are a noted concern with spinosad and alternative materials and practices are needed to manage resistance (Caldwell, et al., 2005).

The synthetic substances horticultural oils (petroleum distillates), soaps, sulfur and sucrose octanoate esters (SOE) also appear on the National List and are used to control mites in organic production. All are relatively broad spectrum. SOE has a mode of action and toxicological profile similar to PGML by disrupting the waxy cuticle of mites and soft-bodied insects (EPA, 2006a). The petitioner claims that PGML causes less plant damage than soap (Weatherston, 2011).

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Mites are often secondary pests that rapidly grow in population when broad-spectrum biocides destroy their natural enemies (Gerson and Smiley, 1990). As such, mites are seldom a problem for organic farmers Cultural practices such as optimal fertilization and rotation have long been organic farmers' first lines of defense against mites (Yepson, R.B., 1984). The literature provides conflicting results of the correlation of phytophagous mite population with fertilization. A review of the literature found that in some crops, such as apples and cucurbits showed a strong correlation between increased nitrogen fertilization and mite reproduction and survival (Wermelinger et al., 1991). Studies of other crops were more ambiguous. Red citrus mite populations were found in one study to be highest with a combination of low nitrogen fertilization and the use of a gibberellin plant growth regulator (Hare, 1989).

Habitat management with moisture is another cultural strategy. Dust is a vector for mites. Preventing dust from getting on foliage through windbreaks and dust suppression can be an effective means to prevent localized outbreaks that have the possibility of spreading. Mites are also correlated with water stress and drought stricken crops are seen as more susceptible (Wermelinger, et al., 1991).

Certain varieties of crops such as strawberries (Dabrowski, Rodriguez and Chaplin, 1971), cucumbers (Da Costa and Jones, 1971), eggplants (Soans, Pimentel and Soans, 1972), tomatoes (Yepson, 1984) and other vegetables (Painter, 1951) have been identified as resistant to mites.

Biological control has long been used to control various acarine pests (DeBach, 1974; Gerson and Smiley, 1990). A number of predatory mites are commercially available and effective at keeping mite populations in check. Among the most widely available are *Phytoseiulus persimilis*, *Mesoseiulus longipes*, *Galendromus occidentalis*, *Neoseiulus* spp., (Hunter, 1997).

Mites can also be controlled by the generalist predatory insects lady beetles (*Hippodamia convergens*), minute pirate bugs (*Orius insidiosus*), and green lacewings (*Chrysopa carnea*). Minute pirate bugs are in the same genus as the flower bug and may be adversely affected by the application of PGML. The six-spotted thrips, spider mite destroyer beetle (*Stethorus picipes*) and the mite midge, *Feltiella acarisuga*, are important specific predators of spider mites (Flint, 1990; Olkowski, et al., 2003).

Additional Information Requested from NOSB Crops Committee:

1. A thorough review and comparison of the alternatives including physical, cultural, and natural (soaps and oils, farnesol, nerolidol, geranoil, citrolellol) and other materials already on the National List.

See Evaluation Questions 11 and 12. The efficacy data presented in the petition and in the literature indicates that the degree of control is similar.

2. If PGML blocks the spiracles and de-waxes, why does it not harm other insects?

Mortality rates vary by species, with PGML non-toxic to certain pests and beneficial organisms. According to studies conducted, PGML will cause mortality of certain non-target insects and predatory mites (James, 2004a; James, 2004b, Nakaishi and Arakawa, 2011). At higher concentrations, contact with PGML killed 88% of honey bee populations (Jones, 2003).

PGML is more effective against mites and soft-bodied insects of the *Homopteran* family than against pests and other insects. Insects with hard shells, such as in the *Coleopteran* family have greater protection than a waxy cuticle and their shells are not easily dissolved by the ester. At the same time, PGML would be completely ineffective against pests in these families or with similar physiology.

Mites are not insects. There are anatomical and physiological differences that account for PGML's varying degrees of toxicity and selective mode of action. As arachnids, they have two body parts instead of three and eight legs instead of six.

More relevant to the mode of action and specific toxicity of PGML, the respiratory systems of insects and arachnids are functionally different (Barnes, 1982). Arachnid abdominal segmentation is inconspicuous or apparently absent (Gerson and Smiley, 1990). Arachnid species commonly have a single spiracle located on the ventral aspect of the abdomen (Comstock, 1912). Many mites lack a respiratory system entirely (Levi, 1967). Insects will almost invariably have multiple spiracles—at least two and as many as eleven. These are commonly recessed between abdominal segments.

Many insects have filtering hairs or lips on the peritreme to protect the trachea and the ability to open and close their spiracles (Daly, Doyen and Purcell, 1998). Mites also have mouthparts that are formed differently from insects. Spiracle blockage is more likely to result in mortality of non-target arthropods.

Evaluation Question 9 has a summary of the results of toxicity studies conducted on natural enemies and other beneficial organisms.

3. How do the environmental hazards of PGML compare to the alternatives?

PGML may reduce environmental hazards compared with sulfur, pyrethrum or spinosad due to its lower toxicity and more selective mode of action. Organic farmers are concerned about pesticide-resistant pests and additional least-toxic pesticides may offer tools for resistance management. Based on the EPA Fact Sheets and other data, the environmental hazards of PGML are closest to those of sucrose octanoate esters (SOEs). Both substances received substantial waivers for environmental studies and toxicology and the studies conducted showed them both to be low impact. The remaining alternatives have either equal or lower environmental hazards.

4. This product requires a 4 hour re-entry time. How does this compare to the alternatives?

See Table 2 for a comparison of the re-entry times for various commercial products that are labeled for at least some of the same crops and pests as PGML. Soap is the only active ingredient that does not have a re-entry period on the label. Four of the alternatives have longer re-entry periods. Three have the same withdrawal period.

Table 2

Re-entry Times of Selected Acaricides

Active Ingredient(s)	Manufacturer / Trade Name	US Label Re-entry
Propylene Glycol Monolaurate	Otsuka / Acaritouch®	4 hours
Farnesol, nerolidol, geraniol and citronellol	Natural Plant Protection / Biomite®	4 hours
Horticultural Oil	Superior 415	12 hours
Neem	Certis / Trilogy®	4 hours
Pyrethrum	MGK / PyGanic™ EC 1.4	12 hours
Soap	Woodstream Safer® Insect Killing Soap Concentrate	None specified (0)
Spinosad	Dow Entrust®	4 hours
Sucrose Octanoate Ester	Natural Forces / Sucrashield™	48 hours
Sulfur	Martin / CSC 80% Thiosperse Micronized Wettable Sulfur	24 hours

Sources: Certis, 2009; Dow, 2011; Martin, 2006; MGK, 2011; Natural Forces, 2011; Natural Plant Protection, 2009; Otsuka, 2009; Wilbur Ellis, 2006; Woodstream, 2004. Products selected as representative examples and do not exhaustively list all alternatives or US re-entry times. Check the current label of any product before use.

5. Since PGML is a broad spectrum anti-microbial for controlling fungi and bacteria post-harvest on fruits and vegetables, what effects does it have on soil microorganisms?

See Evaluation Question 8. PGML's anti-microbial activity on soil organisms is temporary due to its lack of persistence and its biodegradation. Foliar application would result in only a fraction of what is applied to expose soil organisms on the surface. Any adverse effect on soil organisms would likely be temporary, even in the event of a direct accidental spill on the soil.

6. Are there natural ways to make PGML, e.g. extractions from fungi, bacteria, or plants or by fermentation? Is anyone selling naturally produced PGML?

See Evaluation Questions 2 and 3. PGML is not known to occur in nature. PGML may be produced by naturally occurring microbial enzymes; however, the propylene glycol starting material for this process is synthetically produced. No commercial source of propylene glycol produced using naturally occurring enzymes is known at the time of this report.

If esterification is considered a synthetic manufacturing process in all cases, then it would not be possible to produce natural PGML even if all the feedstocks were deemed non-synthetic.

7. A thorough description of the raw materials used to manufacture this active ingredient; their origin and their manufacture as well as their environmental impact.

See Evaluation Questions 2 and 6.

References:

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