

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: October 16, 2012

Subject: Petition to add Propylene Glycol Monolaurate (PGML) to §205.601 (e)

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: ☐ Petition Failed

Guidance Statement: ☐

Other: ☐

Statement of Recommendation: (Motion # 1)

Passed

Motion to classify Propylene Glycol Monolaurate (PGML) as synthetic.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

PGML is manufactured by a process that involves chemical change.

Committee Vote:

Moved: Colehour Bondera

Seconded: Jay Feldman

Yes: 15

No: 0

Abstain: 0

Absent: 0

Recuse: 0

Statement of Recommendation: (Motion # 7)

Failed

Motion to add PGML to the National List on §205.601(e) as an acaricide.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

While potentially useful as an additional tool for controlling Acari pests, it is not needed as it can be substituted with alternatives including cultural practices and biological controls -- other options are available which do not have the impacts on human and environmental health. As a synthetic product, this material is not consistent with either organic or sustainable production systems. Those who supported adding PGML to the National List found that available organic options are not always effective.

Committee Vote:

Moved: Colehour Bondera

Seconded: John Foster

Yes: 5

No: 10

Abstain: 0

Absent: 0

Recuse: 0

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Propylene Glycol Monolaurate (PGML)**

August 7, 2012

Introduction:

PGML has been petitioned to be added to section 205.601(e) of the National List. PGML is an acaricide; a pesticide that kills members of the Acari group – ticks and mites. Stated in the petition (pg. 5), specifically PGML is seen as, “a broad spectrum antimicrobial agent to control fungi and bacteria that cause decay of post-harvest fruit and vegetables.”

Relevant areas in the Rule:

The National List includes at §205.601(e)

As insecticides (including acaricides or mite control).

Discussion:

While potentially useful as an additional tool for controlling Acari pests, it is not needed as it can be substituted with alternatives including cultural practices and biological controls -- other options are available which do not have the impacts on human and environmental health. That the environmental impacts leave more damage overall than benefit, is of notable concern, when considered in regard to efficacy. As a synthetic product, this material is not consistent with either organic nor sustainable production systems. As a tool made for use in conventional agricultural systems, PGML does not serve as an organic system tool.

Those who supported adding PGML to the National List said that while there are other organic options, they are very sporadic in how well they control the target pests or even under certain circumstances if they will control them at all. The impact on crop quality, and the potential environmental impact when using the alternative materials can be somewhat of a concern, as well. Giving organic farmers another tool that is better than those they currently rely upon is exactly what this process is all about if we can properly look at the risk/ benefit.

Evaluation Criteria:

(Applicability noted for each category; Documentation attached)
“B” below)

Criteria Satisfied? (see

- | | | | |
|---|------------------------------|--|---|
| 1. Impact on Humans and Environment | ☐ Yes | ☒ No | ☐ N/A |
| 2. Essential & Availability Criteria | ☐ Yes | ☒ No | ☐ N/A |
| 3. Compatibility & Consistency | ☐ Yes | ☒ No | ☐ N/A |
| 4. Commercial Supply is Fragile or Potentially Unavailable
as Organic (only for § 205.606) | ☐ Yes | ☐ No | ☒ N/A |

Substance Fails Criteria Category: [1, 2, 3]

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Subcommittee Action & Vote, including classification recommendation
(state actual motion):

Classification Motion:

PGML is synthetic.

Motion by: Colehour Bondera Seconded by: Zea Sonnabend
Yes 8 No 0 Abstain 0 Recuse 0 Absent 0

Listing Motion:

Add PGML to the National List §205.601(e) as an acaricide.

Motion by: Colehour Bondera Seconded by: John Foster
Yes 2 No 6 Abstain 0 Recuse 0 Absent 0

Crops	☒	Agricultural	☐	Allowed¹	☐
Livestock	☐	Non-synthetic	☐	Prohibited²	☐
Handling	☐	Synthetic	☒	Rejected³	☒
No restriction	☐	Commercial unavailable as organic	☐	Deferred⁴	☐

¹Substance voted to be added as “allowed” on National List to § 205. with Annotation (if any):

²Substance to be added as “prohibited” on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

³Substance was rejected by vote for amending National List to § 205.601(e). Describe why material was rejected:

Not needed and environmental impacts too costly.

⁴Substance was recommended to be deferred because

If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair

August 7, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?

Substance: Propylene Glycol
Monolaurate (PGML)

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			There can be with misuse or disposal since beneficials can be destroyed... Human irritation if mis-used. Feedstock for manufacture comes from petroleum, natural gas or coal. Manufacture requires burning of petroleum, thus greenhouse gas production. See TR - line 231 onward.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Fossil fuel dependent (234-6).
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		List 4B.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			Can enhance toxicity of other 'biocides' (255).
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			Both beneficial mites (soil food web & organic matter decomposers) and fungi directly impacted; limited studies (283-299 & 309-316)...
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			Potential impact on soil food web mites (283-299 & 309-316).
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]				Unclear/unknown.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X			Minimal, but can cause short-term skin and eye reactions (328-335). PGML is a "Toxicity Category III" substance in terms of eye irritation (US EPA Fact Sheet, 2004). As listed in 40 CFR 156.62, US EPA establishes the four toxicity categories: I, II, III and IV. Toxicity category I is highly toxic and severely irritating, category II moderately toxic and moderately irritating, category III slightly toxic and slightly irritating, and category IV practically non-toxic and not an irritant. Toxicity category III substances cause eye irritation effects, but the irritation effects are reversible within seven days. Toxicity category IV substances do not cause eye irritation effects.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according			X	

to FDA's good manufacturing practices? [§205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?

Substance: Propylene Glycol Monolaurate (PGML)

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		Manufactured from petroleum, natural gas, or coal by a process involving chemical change.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Could be, however commercially it is not...
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Non-synthetic botanical and fungal-derived acaricides (354).
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances? [§6518 m.6]	X			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 (360-1).
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Rotation, nutrient management, selection of mite-resistant varieties, and the release of predators and parasites (342), dust management, resistant varieties and biological controls (370-398). Water management is a viable practice as well.

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?

Substance: Propylene Glycol Monolaurate (PGML)

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		Toxic to aquatic life.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		No, petroleum based.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
a. copper and sulfur compounds;				
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		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) (116-119). However, the PGML molecule does not have the hydrophilic-lipophilic structure of a soap (27-28), as also seen by its solubility in organic solvents, low water solubility, high saponification value, and low hydrophilic-lipophilic balance value, all of which indicate a substance that is lipophilic, but does not have the hydrophilic-lipophilic structure of a soap (38-44).
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance:** Propylene Glycol Monolaurate (PGML)

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.