

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: <u>May 2009</u>		Substance: <u>Isoparaffinic Hydrocarbon</u>	
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below)			
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 606)	Yes ☐	No ☐	N/A ☒
B. Substance fails criteria?		C. Proposed Annotation: _____	
Criteria category: <u>1, 2, and 3</u>		Basis for annotation:	
Comments: It is a synthetic which fails all three categories. See evaluation criteria citing TR information and PAN (Pesticide Action Network Database). There are strong pyrethrum extraction alternatives available.		To meet criteria above: _____ Criteria: _____	
		Other regulatory criteria: _____ Citation: _____	
D. Final Board Action & Vote (State Actual Motion): inclusion of Isoparaffinic Hydrocarbon under Synthetic substances allowed for use in organic crop production on the National List § 205.601			
Motion: Tina Ellor Second: Barry Flamm Yes: <u>0</u> No: <u>14</u> Abstain: <u>0</u> Absent: <u>1</u>			
Agricultural	☐	Nonagricultural	☐
Synthetic	☒	Not synthetic	☐
Allowed ¹	☐	Prohibited ²	☒
No restriction	☐	Deferred ⁴	☐
		Crops	☒
		Livestock	☐
		Handling	☐
		Rejected ³	☐
Provide a summary narrative here or attach a more complete narrative, and attach the original committee recommendation that includes the evaluation criteria checklist:			
The material is a synthetic which failed three categories. It was determined that there are strong, commercially available pyrethrum extraction alternatives.			
1—substance voted to be added as “allowed” on National List on National List to § 205. _____ with Annotation (if any): _____			
2—substance to be added to “prohibited” paragraph of National List to § 205. _____ Describe why a prohibited substance: _____			
3—substance was rejected by vote for amending National List to § 205. <u>601</u> Describe why material was rejected: _____			
4—substance was recommended to be deferred § 205. _____ Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up _____			
E. Approved by NOSB Chair to transmit to NOP			
Chair _____ Date _____			
F. NOP Action: Include in FR to amend National List:			
Return to NOSB Reason: _____			
_____ Date _____			

Attach Committee Recommendation here along with the completed evaluation criteria checklist and any attachments

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Spring 2009

Substance: Isoparaffinic Hydrocarbon

Committee: Crops ☒ Livestock ☐ Handling ☐ Petition is for: inclusion of Isoparaffinic Hydrocarbon under Synthetic substances allowed for use in organic crop production on the National List § 205.601

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

- | | | | |
|--|------------------------------|--|---|
| 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 606) | Yes ☐ | No ☐ | N/A ☒ |

B. Substance Fails Criteria Category: 1,2 & 3 Comments: It is a synthetic which fails all three categories. See evaluation criteria citing TR information and PAN (Pesticide Action Network Database). There are strong pyrethrum extraction alternatives available. Substance is not essential due to the existence of other pyrethrin extraction methods and materials that are available and better meet the evaluation criteria.

C. Proposed Annotation (if any): _____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): To include Isoparaffinic hydrocarbon

On the National List §205.601

Motion by: Gerry Davis Seconded: Tina Ellor Yes: 0 No: 5 Absent: 1 Abstain: 0

Crops	☒	Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling		Synthetic	☒	Rejected ³	
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	

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

2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____

Describe why a prohibited substance: _____

3) Substance was rejected by vote for amending National List to § 205. _____ Describe why material was rejected: _____

4) Substance was recommended to be deferred because _____
 _____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Tina Ellor
Committee Chair

Date

3/09/2009

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Isoparaffinic Hydrocarbon

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		TAP lines 224-238: only references information from the manufacturer.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		TAP lines 247-258
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			TAP lines 263-266 "Isoparaffinic hydrocarbon (CAS 64742-47-8) produces some harm to the environment. According to the US EPA (2008) in Table 3 of 40 CFR Part 63, Subpart MMMM, the petitioned substance solvent produces 0.001 mass fraction of toluene that serves as a organic hazardous air pollutant (HAP)."
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]	X			This was a list 2 inert
5. Is there potential for detrimental chemical interaction with other materials used?[§6518 m.1]	X			Strong oxidizers Petition page 13 (Isopar M Fluid MSDS)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			TAP lines 283-288 "...there is potential for impairing the hatching of bird eggs according to the U.S. EPA (2006), if the spray substance is applied directly to eggs in the nest."
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			TAP lines 293-300 "...the petitioned substance has detrimental physiological effects on citrus crops and foliage, fruit, and seedlings of other plants."
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			TAP lines 305-315 "Isoparaffinic hydrocarbon and its breakdown products only exhibit slight acute toxicity or other adverse action according to S. E. Kegley (2009). It is not a cholinesterase inhibitor in humans (Kegley 2009). According to the US EPA (2008) in Table 3 of 40 CFR Part 63, Subpart MMMM, isoparaffinic hydrocarbon contains just 0.001 mass fraction of toluene as hazardous air pollutant (HAP) in the solvent. According to ExxonMobil Chemical (2008) the petitioned substance contains typical toxic chemical concentrations of <0.4ppm of benzene, <1ppm naphthalene, and <1ppm ethylbenzene. Thus the benzene content in the petitioned substance is negligible. This is significant since benzene is linked to increased incidence of leukemia in humans."
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		TAP Lines 320-324
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X1	X2		X1: TAP Supplemental Information lines 359-364-1 st S & T TAP X2: TAP Lines 329-337-2 nd S & T TAP
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X1	X2		X1: TAP Supplemental Information lines 359-364-1 st S & T TAP X2: TAP Lines 329-337-2 nd S & T TAP

12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		X		TAP lines 279-288—although the TAP states it does not need to be GRAS listed because of its place on 21 CFR 172, § 172.882. Natamycin is also on this list. This information is missing from the more recent TAP from S & T
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		TAP lines 307

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

Category 2. Is the Substance Essential for Organic Production? Substance - Isoparaffinic Hydrocarbon

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			TAP lines 220-228
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		TAP lines 234-236
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		TAP lines 241-242
4. Is there a natural source of the substance? [§205.600 b.1]		X		TAP lines 214-217-information from previous S & T Tap, not present in more recent edition.
5. Is there an organic substitute? [§205.600 b.1]		X1		TAP lines 219-222-Question not addressed in newer version of S & T TAP
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			US Pat#4,281,171 Liquid Carbon Dioxide Extraction of Pyrethrins. Also there are commercially available pyrethrins extracted by other means for example Pyganic Crop Protection EC 1.4 and EC 5.0; Safer Brand Yard and Garden Insect Killer and Insect Killer Concentrate. Their extraction methods, however, are confidential.
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			See #7 above
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Alternative extraction methods as listed in #7 above; also other insecticides approved for use in organic agriculture without this petroleum product extraction ingredient. See also TAP lines 360-365.

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

Category 3. Is the substance compatible with organic production practices? Substance - Isoparaffinic Hydrocarbon

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		This is a petroleum product which is present in the final pesticide formulation and to which there are alternatives without the petroleum extraction.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		As above.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			1X	TAP says yes (lines 253-259) but refers only to non-food use.
5. Is the primary use as a preservative? [§205.600 b.4]			1X	It is used as a preservative, but that is not what the petition is for. TAP lines 270-277. The newer version has an approved use for pickles and froth-flotation cleaning of vegetables-Line 167.
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		TAP lines 17-22
a. copper and sulfur compounds;		X		TAP lines 17-22
b. toxins derived from bacteria;		X		TAP lines 17-22
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		TAP lines 17-22
d. livestock parasiticides and medicines?		X		TAP lines 17-22
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		TAP lines 17-22

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

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 - _____

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> 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	

