

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November 2008

Substance: Sorbitol Octanoate

Committee: Crops Livestock Handling Petition is for: Add Sorbitol Octanoate as insect control on the National List § 205.601(e)

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

- | | | | |
|--|---|--|------------------------------|
| 1. Impact on Humans and Environment | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |

B. Substance Fails Criteria Category: 2 and 3 Comments: This material is not essential to organic farming, as there are many alternative insect control methods and materials already available. Adding another synthetic material to the National List in this case would be inconsistent with the original intent of the OFPA, which severely limits the routine addition of exempted synthetics. See section D. 3. below.

C. Proposed Annotation (if any): _____

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

D. Recommended Committee Action & Vote (State Actual Motion): _____

Motion by: Gerry Davis Seconded: Jeff Moyer 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. 601 Describe why material was rejected: _____
 Referring to OFPA, the original legislation was carefully written to prevent widespread additions of exempted synthetics on the national list. To further quote the preamble of OFPA, "Most consumers believe that absolutely no synthetic substances are used in organic production. For the most part, they are correct and this is the basic tenet of this legislation". Please refer to the attached preamble of OFPA: *101 ST CONGRESS, 2nd Session, SENATE REPORT 101-357 FOOD, AGRICULTURE, CONSERVATION, AND TRADE ACT OF 1990 REPORT OF THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY, UNITED STATES SENATE TO ACCOMPANY S. 2830 together with ADDITIONAL AND MINORITY VIEWS JULY 6, 1990 Ordered to be printed Filed under authority of the order of the Senate of June 26 (legislative day, June 11), 1990 Page 289 TITLE XVI—ORGANIC CERTIFICATION PROGRAM The National List.*

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:

Gerry Davis
Committee Chair

September 17, 2008
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance – Sorbitol Octanoate

Question	Yes	No	N/A¹	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		No corrosive residues from the manufacturing process should have to be disposed. Sorbitol octanoate rapidly hydrolyses to sorbitol and octanoic acid, both of which are naturally occurring compounds and common human dietary components of no toxicological concern. (TER line 172-182)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		See ques. #2. Sorbitol octanoate bio-degrades with an apparent post-application half-life of 7-10 days. (TER line 181-182)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X	X		The TER (technical evaluation report) gave little or no information to on which to base a determination.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Minimal effects expected other than toxic effect on soft-bodied insects, including some beneficial insect larvae.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Breakdown products of this material would be expected to be readily used as food by many soil organisms.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		TER line 217-229
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		TER line 234-242
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Severe eye irritation risk for on farm users. (TER line 247-249)
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 to FDA's good manufacturing practices? [§205.600 b.5]			X	
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.

Category 2. Is the Substance Essential for Organic Production? Substance – Sorbitol Octanoate

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			Single step chemical reaction using an esterification catalyst such as sulphuric acid. (TER line 119-139)
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		TER line 120-124
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		
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			Application and use of natural suffocant oils difficult due to insolubility in water. (TER line 254-256) Neem extracts in various formulations are available for similar use. Beneficial insect release is commonly used for target pests.
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			Insecticidal soaps, horticultural oils, sucrose octanoate ester, elemental sulfur.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Beneficial insect management for control of aphids, whiteflies, etc.

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 – Sorbitol Octanoate

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 synthetic material, (see preamble citation from section D line (3) on page one of this recommendation.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		See definition of sustainability in NOSB Policy and Procedures Manual pp. 29-30.
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;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		This material is not a soap per definition of EPA Reference: EPA Document AP42, Chapter 6 - Soaps
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.

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?				
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?				
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?				
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?				
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:				
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
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;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?				

101 ST CONGRESS 2nd Session
SENATE REPORT 101-357
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TITLE XVI—ORGANIC CERTIFICATION PROGRAM
The National List

Most consumers believe that absolutely no synthetic substances are used in organic production. For the most part, they are correct and this is the basic tenet of this legislation. But there are a few limited exceptions to the no-synthetic rule and the National List is designed to handle these exceptions.

Organic farmers have used some synthetic substances for several good reasons. For example, some organic farmers use certain synthetic analogues to natural substances when those substances are difficult to obtain. Insect pheromones a often-used biological control substance in organic farming, are very difficult to collect in nature and are therefore synthetically produced. The Committee does not specifically disallow the use of pheromones in organic farming simply because they are synthetically produced when pheromones are effective and ecologically benign.

The Committee does not intend to allow the use of many synthetic substances. This legislation has been carefully written to prevent widespread exceptions or “loopholes” in the organic standards which would circumvent the intent of this legislation. The few synthetic substances that are widely recognized as safe and traditionally used in organic production are explicitly cited in the bill as potential items to be included on the National List if the Board and the Secretary approve of their use.

The Board and the Secretary may consider allowing the use of synthetic active ingredients in the following categories only: pheromones; copper and sulfur compounds; soaps; horticultural oils; toxins derived from bacteria; treated seed; fish emulsions; vitamins and minerals; livestock parasiticides and medicines; and production aids such as machinery cleansers.

Organic farmers also use substances in which the active ingredient is known to be natural but which also contain inert ingredients that are undisclosed as a matter of trade secret law under the Federal Insecticide Fungicide Rodenticide Act. The Committee suspects that many of these inert ingredients are synthetic. For example, adjuvants would fall into this category.

Until such time as FIFRA is altered to require the full disclosure of inert ingredients, organic farmers should be allowed to continue using compounded substances if the active ingredient is natural and if use of the substance is recommended by the National Organic Standards Board and approved by the Secretary for inclusion on the National List. However, in order for the National Organic Standards Board to evaluate whether certain compounds should be listed, the Board will need some information about the inert ingredients in question. The Committee directs the Board to seek the advice of the Administrator of the EPA, who has information on inert ingredients submitted as part of registration, as to whether such inert material would be appropriate for organic production. EPA’s response will not limit its regulatory responsibility for such material.

Almost all state and private organization standards also provide for certain exceptions from the no-synthetic rule, some more explicitly than others. In deciding upon an acceptable list of materials for the Organic Standards Board and the Secretary to consider the Committee surveyed State and private regulations to ensure that the above categories, while more restrictive than most of the current standards, will indeed protect the integrity of the organic product while at the same time provide the producer a reasonable amount of flexibility on production materials.

The Committee understands that just because a substance is natural does not mean that it is safe and appropriate for organic production. The National List may also include natural substances otherwise allowed under this title but which are determined to be harmful to human health or the environment and inconsistent with organic farming. Certain botanical pesticides may be considered by the Organic Standards Board and the Secretary to be inappropriate for organic production because their use poses significant harm to human health or the environment. Whatever natural items appear on the National List shall be prohibited from use in organic production.

Finally, the National List is designed to cover ingredients used in processing. The bill allows that up to five percent of processed food labeled “organically produced” may contain non-synthetic ingredients which are not organically produced if those ingredients are included on the National List. The five percent figure was arrived at after consulting with various organic food processors as the amount of flexibility necessary in processed food. The Committee intends that the guideline for processed food ingredients on the National List be that some ingredients are difficult or impossible to obtain. An example might be certain spices that are unavailable at this time from an organic farm. It may also include items that are not technically organically produced such as yeast.

Several steps must be taken before an item appears on the National List in any of the above categories. First the Organic Standards Board must review the substances in question based upon criteria cited in the bill and with the aid of the Board’s technical panels. The Board may decide what substances require review. As well, individuals may petition the Board to evaluate substances for inclusion on the National List. The Board then constructs a Proposed National List which is submitted to the Secretary as a recommendation for composition of the Final National List.

The Secretary may not include exemptions for synthetic substances other than those exemptions recommended by the National Organic Standards Board. The Proposed National List represents the universe of synthetic materials from which the Secretary may choose. Before establishing the final National List the Secretary shall publish the Proposed National List in the Federal Register and seek Public comment. The same procedures are to be followed for any amendments to the National List.