FORMAL RECOMMENDATION BY THE NATIONAL ORGANIC STANDARDS BOARD (NOSB) TO THE NATIONAL ORGANIC PROGRAM (NOP)
Date: <u>August 17, 2005</u>
Subject:Sucrose octanoate esters
Chair:Jim Riddle(sign)
Recommendation
The NOSB hereby recommends to the NOP the following: Rulemaking Action: Guidance Statement: Other: Statement of the Recommendation (including Recount of Vote):

The NOSB recommends that sucrose octanoate esters be added to 205.601 for use in organic crop production, with no annotation, and to 205.603 for use in organic livestock production, with no annotation.

Board vote – August 16, 2005

For use in crop production – 13 yes, 0 no, 1 absent For use in livestock production – 13 yes, 0 no, 1 absent

Rationale Supporting Recommendation (including consistency with OFPA and NOP):	
Rationale provided in text of recommendation below.	
Response by the NOP:	
Updated 2/25/05	

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance <u>Sucrose Octanoate Esters</u>

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		
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Esters biodegrade rapidly; are not toxic to mammals and other target organisms; the amount used will not "substantially increase amount of these esters in environment." TAP pg 5, lines 234-241.
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		SOE does not persist; unlikely to interact with other materials used organic production,. TAP pg 5, lines 243-248.
6. Are there adverse biological and chemical interactions in agroecosystem? [§6518 m.5]		X		Non toxic to honey bees and many beneficial insects. Not phytotoxicity to many crops; biodegrades quickly TAP pg 6, lines 253-276.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		No specific data exist on soil organisms but based upon available data, including the rate of decomposition, no adverse impacts are expected. TAP pg. 6 lines 266-276.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Sucrose, fatty acids carbon dioxide and water are the breakdown products. None are toxic. TAP pg 6, lines 281-282.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		SOEs degrade rapidly and do not resist or accumulate in the environment. TAP pg 6, line 287.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		No subchronic, chronic, immune, endocrine issues have been identified. EPA estimates ADI for humans is 2.82 lbs for a 176 lb person. An ocular risk exists but is unlikely if product is used according to label. TAP pg 6, lines 292-300. Used in foods. TAP pg 2, lines 65-67 & pg 3, lines 99-109.
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 Sucrose Octanoate Esters

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]			X	
2. Is there an organic substitute? [§205.600 b.1]			X	
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Other materials, e.g., nonsythetic oil are alternatives for some or all of the targeted crops. TAP pgs 7, lines 309-335. Limited efficacy and a need for alternatives exist.
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Is there any alternative substances? [§6518 m.6]	X			Other approved materials, e.g, soaps, are alternatives for some or all of the targeted crops. TAP pgs 7, lines 340-344 Limited efficacy and a need for alternatives exist.
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Numerous practices are available to reduce the need for this material. These practices would have to be implemented prior use of this material. This material would provide farmers with a means to control insects when other practices have failed. TAP pg 8, lines 351-355.

 $^{^{1}}$ If 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 SOE

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	(1711, petition, regulatory agency, other)
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			This material degrades rapidly, has very low toxicity, its breakdown products are non-toxic. It has minimal to no environmental risk. TAP pg 5, lines 230-248. Is an EPA registered biopesticide TPA pg 2, line 48.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			This material degrades rapidly, has very low toxicity, its breakdown products are non-toxic. It has minimal to no environmental risk. TAP pg 5, lines 230-248 The material increases the long-term viability of organic farms by providing a means to control insect damage with IPM and other tactics fail. This material is consistent with other allowed materials.
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: 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 works as a soap. TAP pg 1, lines 77-78
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		

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

NOSB RECOMMENDED DECISION Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting:	August 2005			Substanc	e: Sucrose Octa	noate	Esters
A. Evaluation Criteria (Documentation attached; committee recommendation attached)							
,					Criteria Satisfie	d?	
Impact on huma			Yes X No [B below)		
Availability crite					Yes X No [
Compatibility &					Yes X No [
							·
		C. F	Proposed An	notation:			
B. Substance fails criteria	a?		·				
		Poo	is for annota	tion			
Criteria category:					0 '' '		
Comments:					Criteria:		
		Othe	er regulatory	criteria:	Citation:		
D. Final Board Action & \	Vote: Motion by	:N	ancy Ostiguy	/ Second	: Andrea Car	<u>oe</u>	
<u>Vote</u> :	Agricultural		Nonagricu	Itural	Crops	Х	7
Yes: 13	Synthetic	Χ			Livestock	Х	-
_ _	Allowed ¹	X	Prohibited	2	Handling		1
No: <u>0</u>	No restriction	X	Deferred4		Rejected ³		-
Abstain: Absent:1							=
Annotation:	1—substance vo	ted to	be added a	s "allowed"	on National List		
Annotation.							-
		be ad	lded to "proh	ibited" para	agraph of National	List	-
Describe why a prohibited	d substance:						-
	3—cubetance wa	e roic	acted by yote	for amend	ling National List		_
Describe why material wa							-
							_
Describe why deferred; if	4-substance was					w-	
up							
							_
E. Approved by NOSB C	hair to transmit to	NOP:	:				
Dave Carter, NOSB Chair Date							
F. NOP Action: Include in FR to amend National List:							
Return to NOSB							
Richard H. Mathews, Pro	ogram Manager	_		Date			

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: A	ugust 2005			Substance:	Sucrose Octano	oate Esters		
Committee: Crops X Liv	vestock Hand	lling						
A. Evaluation Criteria (Do	ocumentation attac	ched;	committee r	ecommendati	on attached)			
					Criteria Satisfied	! ?		
Impact on huma	ans and environm	ent			Yes X No ☐ (see B below)			
Availability crite	ria			Yes X No ☐ (see B below)				
Compatibility &	consistency				Yes X No □	(see B below)		
B. Substance fails criteria	n?	C. F	Proposed An	notation:				
Criteria category:		Bas	is for annota	tion:				
Comments:		To r	neet criteria	above:	Criteria:			
		Oth	er regulatory	criteria:	Citation:			
D. Recommended Comm	nittee Action & Vot							
			Seconded:					
Sucrose Octanoate Esters an insecticidal soap [205.6]					4-47-7 (dioctanoa	ate)] is synthetic and allowed	as	
<u>Vote</u> :	Agricultural		Nonagricul	tural	Crops			
Yes: _3	Synthetic	X	Not synthe	tic	Livestock	X		
No: 0	Allowed ¹	X	Prohibited ²	2	Handling			
Abstain: _1	No restriction		Deferred ⁴		Rejected ³			
Abstairi <u>i</u>								
1—substance voted to be added as "allowed" on National List Annotation:								
Describe why a prohibited				ibited" paragr	aph of National L	List		
Describe why material wa	3—substance was rejected:	ıs reje	ected by vote	for amending	g National List			
Describe why deferred; if tup	4-substance was follow-up is neede				II follow			
E. Approved by Committee Chair to transmit to NOSB:								
Committee Chair			Ī	Date		-		