

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

Date: October 17, 2012

Subject: Petition to add ascorbyl palmitate (CAS 137-66-6) to section 205.605(b)

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 ascorbyl palmitate as petitioned (CAS 137-66-6) as synthetic.

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

Ascorbyl palmitate as petitioned is synthetic.

Committee Vote:

Moved: Nick Maravell

Seconded: Jean Richardson

Yes: 15

No: 0

Abstain: 0

Absent: 0

Recuse: 0

Statement of Recommendation: (Motion # 2)

Failed

Motion to add Ascorbyl palmitate (CAS 137-66-6) to the National List section 205.605(b) for use as a preservative in infant formula.

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

Ascorbyl palmitate (AP) is not required by the FDA or other regulation to be added to infant formula. Permitted alternatives exist, including fat soluble ones, but none have been evaluated for use in infant processed foods. AP is a synthetic preservative and should not be added to the National List under restriction of 205.600(b)(4).

Committee Vote:

Moved: Nick Maravell

Seconded: Jean Richardson

Yes: 4

No: 11

Abstain: 0

Absent: 0

Recuse: 0

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Ascorbyl Palmitate**

August 14, 2012

Summary of Proposed Action:

Ascorbyl palmitate (AP) is a synthetic ester of ascorbic acid and palmitic acid used in infant formula as a preservative. FDA lists it as GRAS. Ascorbyl Palmitate has antioxidant properties, but, as the TR states “ it remains inconclusive whether or not the body actually utilizes ascorbic acid that is metabolized from AP”.

Ascorbyl palmitate has some advantages as a food preservative because it is fat soluble and very slightly water soluble. AP synergistically improves the effectiveness of other preservatives, such as tocopherols, to protect fats and oils from rancidity and prevent rancid flavor. It is used in cosmetics, animal feeds and margarine to reduce rancidity (Petition page 2). Synthetic AP is currently used in infant formula to stabilize DHA and ARA edible oils. AP, DHA, and ARA are not required by FDA to be added to infant formula.

Use of AP for stabilizing edible oils raises the issue of a lack of an established policy on “other ingredients.” In December 2011 the NOSB approved use of DHA from Algal Oil and ARA from Fungal Oil, and specifically did not approve all the “other ingredients” (which included AP) for broad use in organic food. Approval was specific and explicitly not precedent setting, applying only to the petitioned formulations of DHA and ARA.

Organic alternatives to Ascorbyl palmitate exist, especially rosemary extract and tocopherols. Synthetic tocopherols are also an alternative on the National List if organic rosemary extracts are not suitable. The Petition asserts that tocopherols are currently used in infant formulas, but have limited function without AP. Another alternative is to shorten shelf life date.

Agricultural organic alternatives to AP have not been evaluated for use in infant formula. The TR states, “Other organic agricultural fat-soluble antioxidants which may be potential alternative preservatives include, but are not limited to, alpha-tocopherol (vitamin E), beta-carotene, alpha-lipoic and dihydrolipoic acids, and ubiquinone. ... Like ascorbyl palmitate, ubiquinone and dihydrolipoic acid can function as synergistic antioxidants to regenerate tocopherols. No information was found to indicate whether or not these other fat-soluble antioxidants have been tested as alternatives to ascorbyl palmitate as preservatives in food or cosmetics, or are readily available for commercial use in processed foods.”

According to the petitioner, certain organic alternative preservatives (carnosic acid from rosemary extract) could have effects harmful to pregnant mothers and unknown side effects in infants. No scientific data has been presented to show adverse effects or the

relative degree of efficacy of using rosemary extract in infant formula. However, the NOSB recommendation approving DHA Algal Oil and ARA Fungal Oil recognized that rosemary extract was included in both materials. It must be noted that the Petition (page 7) states “for infant formula rosemary extracts are not a suitable option” and further states that “rosemary extracts have not been tested and accepted for use in infant formula” and it is “not prudent to use these substances in food for young infants” (Petition, page 8).

As reported by the Journal of the European Food Safety Authority (June 2008), a study in rats found no effect of rosemary extract on fetus development or on the ability of the fetus to reach full term. However, this same scientific opinion states, “The toxicological data on the rosemary extracts are insufficient to establish a numerical ADI [Acceptable Daily Intake], because the toxicity data set does not provide reproductive toxicity studies or a long term study. On the other hand, the existing data, including the absence of effects in the 90-day studies on reproductive organs and lack of genotoxicity, do not give reason for concern.”

Ascorbyl palmitate, as petitioned for use in “organic” infant formula, is not used to fortify food or add nutritional value.

AP is not listed for use as a preservative in organic infant formula in European, Canadian or Japanese standards. In European standards it appears that AP as vitamin C is permitted in organic infant formula to the extent it is required by infant formula directives on vitamins (although, as noted above, data is inconclusive on actual potential absorption of ascorbic acid from AP).

According to the TR, AP does not have significant adverse impacts on the environment or on human health, although it is noted in the Petition (page 5) that high levels of ascorbic acid increase oxalic acid production and excretion with potential for oxalate bladder stones.

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 | ☐ Yes | ☐ No | ☒ N/A as Organic (only for § 205.606) |

Substance Fails Criteria Category: [2 &3] Comments:

Proposed Annotation (if any):

Notes:

(state actual motion):

Seconded by: Jean Richardson

Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Seconded by: Jean Richardson

Yes: 0 No: 6 Absent: 1 Abstain: 0 Recuse: 0

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

Annotation (if any):

any):

Describe why a prohibited substance:

Objections to organic rosemary abstract are not supported by scientific data. DHA and ARA, already added to list, contain rosemary extracts. AP is a synthetic preservative and should not be added to the National List under restriction of 205.600(b)(4).

If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

8/14/12

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Ascorbyl palmitate

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		TR
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		
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		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			x	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		
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			At high doses ascorbic acid increases oxalic acid production and excretion with potential for oxalate bladder stones (Petition, page 5)
11. Is there an adverse effect on human health as defined by		x		

applicable Federal regulations? [205.600 b.3]				
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.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?

Substance:

Ascorbyl palmitate

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			Petition; TR lines 227-234
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		Not the petitioned material.
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		Shorter shelf life of product
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	x			Natural alternatives, such as rosemary oil and extracts, for addition to infant formula have not been evaluated.
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			Tocopherols, derived from vegetable oils, and “only when rosemary extracts are not a suitable alternative” TR lines 124-125
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			Breast feeding.

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: Ascorbyl palmitate

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		
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		x		
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		x		TR (lines 317-318) states AP “is used as a preservative, which includes the prevention of off-flavors or bad odors during shelf life of product”.
5. Is the primary use as a preservative? [§205.600 b.4]	x			Petition and TR state; “The primary function of ascorbyl palmitate is as a preservative” (TR line 301)
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			Primary use is to prevent “development of off-flavors or bad odors that would otherwise occur over time” (TR line 303)
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	
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	
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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: Name Ascorbyl palmitate**

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
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: a. Regions of production (including factors such as climate and number of regions); b. Number of suppliers and			x	
			x	

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;			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.