NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: May 2009	**Substance:** Sodium Chlorite, acidified for use in handling

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

1.	Impact on Humans and Environment	Yes **X**	No ☐	N/A ☐
2.	Essential & Availability Criteria	Yes **X**	No ☐	N/A ☐
3.	Compatibility & Consistency	Yes **X**	No ☐	N/A ☐
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☐	No ☐	N/A **X**

B. Substance fails criteria?

Criteria category: ___none_____

Comments:

C. Proposed Annotation: Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

Basis for annotation: See discussion in summary narrative below

To meet criteria above: ____ Criteria: _____

Other regulatory criteria: ____ Citation:_____

D. Final Board Action & Vote (State Actual Motion): To list sodium chlorite, acidified on §205.605(b) with the annotation as recommended by the Handling Committee

Motion: Joe Smilie Second: Steve DeMuri Yes: 12 No: 2 Recuse: 0 Abstain: 0 Absent: 1

Agricultural		Nonagricultural	X	Crops	
Synthetic	X	Not synthetic		Livestock	
Allowed[1]	X	Prohibited[2]		Handling	X
No restriction		Deferred4		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 Handling committee voted to recommend this material because (1) it is more effective in some situations as a sanitizer than other materials already on the National List (see petitioner's response to Handling Committee questions attached); (2) the solution breaks down to citric acid, water, and common table salt so the breakdown products are fairly benign; (3) there is broad regulatory approval for the substance (FDA, USDA's Food, Safety and Inspection service, EPA, and multiple other food safety agencies around the world); and (4) a European food safety authority has reviewed this material and determined that trihalomethanes, reaction materials that form when other chlorine materials on the list (sodium and calcium hypochlorite) react with organic compounds and are of environmental concern, have not been reported to be formed when this material is used. One committee member voted not to list this substance because of concern with adding any synthetic substances to the National List.

The Handling Committee included a recommended annotation for the listing of Sodium Chlorite, acidified (ACS) on the National List. The recommended annotation reflected the committee's review of the April 20, 2003 recommendation by the NOSB Processing Committee on the clarification of chlorine contact with organic food. There is quite a history on the annotations of these materials that reflect some confusion about whether or not they can be used in direct food contact and then at what levels. The Handling Committee wanted to recognize that confusion and be consistent with a past Board's recommendation.

Public comment on ACS reflected that the rationale for adding the annotation was not clear and that the annotation was not clear. Also, one public comment reinforced that current annotations for chlorine materials in general are not clear with regard to direct food contact, and said that the annotations should be made consistent with practice or practice consistent with the annotations.

The Handling Committee, after hearing public comment at the May 2009 NOSB meeting met during the meeting to review the annotation. The annotation has three parts:

1. The first part addresses how ACS may be used. The Handling Committee wanted to be clear in our recommendation that this could be used for direct anti-microbial food treatment and indirect food contact surface sanitizing. This part of the annotation reflects public comment that current annotations for chlorine materials are not clear on how these materials may be used.

2. The second part of the annotation addresses the residual chlorine levels in water discussed in the April 30, 2003 NOSB Processing Committee recommendation. That recommendation reflected a concern the Board had at the time about residual chlorine on food that consumers would consume. After further review, this concern is not relevant to ACS because after contact with food it breaks down to water, citric acid and table salt. After the motion to add ACS to the National List with the Handling Committee's recommended annotation, a friendly amendment was made and accepted to remove this part of the annotation. Later in the discussion, the NOP recommended that this part of the annotation be retained if ASC was to be

listed as a separate listing from the other chlorine materials already on the list. Further discussion clarified for the NOP that that no residual chlorine exists after use. The NOP said that this addressed their concern and there was no further discussion on the friendly amendment meaning that this second part of the Handling Committee's recommended annotation was removed for the final NOSB recommendation.

3. The third part of the annotation addresses the citric acid that is used as part of ACS. The NOSB Handling Committee wanted to note that only citric acid allowed for use in organic handling should be used when using ACS. The need for this portion of the annotation was discussed at length during Board deliberation. The petitioner confirmed that other acids can be used to acidify the sodium chlorite. After the motion to add Sodium Chlorite, acidified to the National List, a friendly amendment was made and accepted to remove this part of the annotation. A further friendly amendment was made and accepted to add "Acidified with citric acid only." These two friendly amendments reflected Board discussion that the acid used to acidify the sodium chlorite should be compatible with organic methods and that the listing on 205.605(a) does not apply to sanitizers but to the 5% of non-organic ingredients allowed in food.

With regards to the public comment received that the annotation for chlorine materials already listed on the National List 205.605(b) are confusing, the National Organic Program suggested having the board recommend that the annotation be changed to read "Disinfecting and sanitizing food and food contact surfaces." Then ACS could be added at the end of the list. The board asked for NOP guidance on the appropriate process with which to make that recommendation. After discussion, the NOSB decided to proceed with this substance, but asked that when reviewing the recommendation the program review the annotations for the other chlorine materials as well. If a correction based on the April 30, 2003 recommendation is not possible, we ask that the NOP let the NOSB Executive Committee know and the NOSB will consider a further recommendation.

1—substance voted to be added as "allowed" on National List on National List to § 205.605(b) with Annotation (if any): **Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.**

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.____ 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

Jeff Moyer — May 6, 2009

Chair — Date

F. **NOP Action: Include in FR to amend National List:**
Return to NOSB Reason: _____

_____ _____
Date

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: ____May 2009_____	**Substance: Sodium Chlorite, acidified**

Committee: Crops ☐ Livestock ☐ Handling X Petition is for: Inclusion of Sodium Chlorite, acidified on the National List § 205. 605b

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

1.	Impact on Humans and Environment	Yes X	No ☐	N/A ☐
2.	Essential & Availability Criteria	Yes X	No ☐	N/A ☐
3.	Compatibility & Consistency	Yes X	No ☐	N/A ☐
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☐	No ☐	N/A X

B. Substance Fails Criteria Category: Comments:

C. Proposed Annotation (if any): Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Residual chlorine levels in the water in direct crop or food contact shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. Citric acid used must meet requirements as listed in § 205.605(a)

Basis for annotation: To meet criteria above: _x__ Other regulatory criteria: _____ Citation:__For a thorough discussion of the recommended annotation see the April 30, 2003 NOSB Processing Committee recommendation titled "Measuring Effluent: Clarification of Chlorine Contact with Organic Food"

D. Recommended Committee Action & Vote (State Actual Motion): __Recommend Sodium Chlorite, acidified for listing on 205.605b

_____

Motion by: Katrina Heinze Seconded: Steve Demuri Yes: 3 No: 1 Absent: 1 Abstain: 1

Crops		Agricultural		Allowed[1]	X
Livestock		Non-Synthetic		Prohibited[2]	
Handling	X	Synthetic	X	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. 605b with Annotation -- Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Residual chlorine levels in the water in direct crop or food contact shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. Citric acid used must meet requirements as listed in § 205.605(a)

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 § 205.606 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:

___Steve Demuri_____ **March 11, 2009_____**

Committee Chair **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?
Substance – Sodium chlorite, acidified

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		Technical Evaluation Report (lines 188-202) – Chloride is ultimate byproduct. No environmental impact is expected at expected concentration levels.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		Sodium chlorite is manufactured in a manner similar to other materials already on National List (i.e., sodium hypochlorite, calcium hypochlorite and chlorine dioxide). From 3/15/06 Crops Committee recommendation on Chlorine materials – "Review of the current Technical Evaluation Report supplied to the NOP shows that calcium and sodium hypochlorite, and chlorine dioxide are all synthetic materials not produced from naturally occurring sources or processes. The report states that no information is available from EPA or FDA to suggest that environmental contamination results from the proper manufacture, use, or disposal of calcium or sodium hypochlorite." One concern with the sodium and calcium hypochlorite materials already on the National List is the potential formation of trihalomethane compounds when hypochlorite ions react with organic material in the environment (page 1, Crops Committee recommendation of 3/15/06). The petition (page 12) references a European Food Safety Authority report that states, "When examining the possibility for reaction products, no halomethanes have been reported to be formed in treatments with chlorine dioxide in water. No chlorinated organics have been found after treatments of poultry carcasses with acidified sodium chlorite."
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		Petition, p. 16 (Section 12) – breakdown products of ACS are citric acid, salt and water. Technical Evaluation Report (lines 188-202) – Chloride is ultimate byproduct. No environmental impact is expected at expected concentration levels.
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		See above – Category 1, #3
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		x		See above – Category 1, #3
8. Is there a toxic or other adverse action of the material or		x		See above – Category 1, #3

its breakdown products? [§6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		x		See above – Category 1, #3
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		x		Technical Evaluation Report (lines 263-266) -- The ASC solution is not listed as generally recognized as safe (GRAS). However, both sodium chlorite and citric acid, which are the components used in preparation of ASC solution, are approved by FDA as GRAS. In addition, both sodium chlorite and citric acid are listed under indirect and direct food substances affirmed as GRAS in 21 CFR §186.1750 and 21 CFR §184.1033, respectively.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x		See above – Category 1#10 See also Technical Evaluation Report lines 212-222
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		x		See above – Category 1#10
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x		From Technical Review – "Since ASC is a mixture of sodium chlorite solution and citric acid, any impurities in the resulting ASC solution are expected from both components. Currently there are no set purity criteria for ASC (Rao, 2007). Sodium chlorite solution is commonly prepared by using technical-grade of sodium chlorite solid, which is comprised of 80% sodium chlorite, with sodium chloride, sodium carbonate, sodium hydroxide, sodium sulfate, and sodium chlorate making up the remainder of the compositions. In general, the manufacturing process employed in the production of sodium chlorite does not include any specific purification steps. Heavy metal, lead, may occur in the final product as a result of their occurrence in the starting material that are obtained from natural sources. Lead must be limited by the specifications indicating maximum levels of 5 mg/kg (Rao, 2007). In addition, the citric acid used to acidify sodium chloride solution must meet FDA specifications of its identity and purity. There is no other published information to suggest that other heavy metals or contaminants may or may not be present in the petitioned substance."

[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 2. Is the Substance Essential for Organic Production?
Substance – Sodium chlorite, acidified

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			See petition and Technical Evaluation Report
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			See petition and Technical Evaluation Report
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		x		See petition and Technical Evaluation Report
4. Is there a natural source of the substance? [§205.600 b.1]		x		See petition and Technical Evaluation Report
5. Is there an organic substitute? [§205.600 b.1]		x		See petition and Technical Evaluation Report
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	x			Chlorine and peracetic acid, already on the National List, can be used in some applications in place of ASC solution. However, depending on the application ASC may be the most effective antimicrobial. For a full discussion, see the petitioner's 2/24/09 response to questions.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		x		See petition and Technical Evaluation Report
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 above – Category 2, question 6
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		x		Sanitizing of food contact surfaces or, where needed, direct food contact surfaces is required. See above Category 2, #6for discussion of alternative substances.

[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 – Sodium chlorite, acidified

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]				
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			See Technical Evaluation Report lines 227-240
5. Is the primary use as a preservative? [§205.600 b.4]		x		See Technical Evaluation Report lines 245-250
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		See petition See also Technical Evaluation Report lines 256-258
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		
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.

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 – Sodium chlorite, acidified

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. UIs the comparative description providedU 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 U**form**U 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 U**quality**U 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 U**quantity**U 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);			x	
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	

Petitioner's Response to NOSB Handling Committee Questions:

DAN R DAHLMAN
Regulatory Analyst
Product Registration & Compliance-
Food Additives
T 651.225-3297
F 651.225-3122

2/24/09

TO: Bob Pooler
USDA/AMS/TMP/NOP

RE: Response to 2/17/09 questions

Mr. Pooler,

Ecolab has been informed of your questions regarding the petition to add Acidified Sodium Chlorite (ASC) to the National List and provides the following response to address both of your inquiries.

1. **Why are materials currently on the list not suitable for applications where Acidified Sodium Chlorite solution is suitable?**
   See response below.

2. **Why are currently allowed substances not appropriate substitutes for ASC solution?**

   The demand for an improvement of food safety has induced changes in the methods used for pathogen control in food processing. The adoption of new technologies allows the processors the ability to achieve a safer food product through reduced pathogen levels. This is especially important given the focus on food safety as a result of the recent recalls of peanut butter, jalapeno peppers, and ground beef. Food manufacturers today each face different challenges depending on the type of food produced, the size of the facility, the level of production, temperature, environment, time of day and physical pressures to name a few.

   The food industry has adopted a multi-hurdle approach to food safety interventions since the implementation of the HAACP standard in the 1990s. Ecolab believes that no single product or chemistry is appropriate for the wide variety of intervention points and application methods used to improve food safety in the modern manufacturing process. Put simply, there is no "silver bullet" antimicrobial intervention on the market today that is capable of or appropriate to tackling all of the issues that these processors face. We believe that offering processors multiple intervention formulas will allow for each individual processor to tailor its interventions to its specific needs. Our goal is to provide our customers with enough intervention options to help meet those needs and ensure a safer food supply. What works for one processor may not necessarily work for another. The availability of multiple choices of antimicrobial interventions will only help bolster the arsenal that a food facility can use to combat outbreaks of food-borne illness.

According to the National List, the only offerings currently approved for food contact surface sanitizers in organic processing are chlorine and peracetic acid. Both substances have a crucial impact on the food supply, and are widely used today. Chlorine has a variety of applications, including water disinfection/sanitization and hard surface sanitization. Peracetic acid has a broad use of applications in the meat and poultry industries as well as in the fruit and vegetable industry, and as a component of a sanitizer for food processing equipment. ASC has an even broader range of applications including red meat, poultry, seafood, and fruits and vegetables.

It was mentioned in the Technical Evaluation Report that peracetic acid can be substituted for ASC. Ecolab strongly opposes this viewpoint. While both substances exhibit oxidative chemistry to control bacterial growth, each substance has its place in the processing environment and each provides its own advantages. For example, a typical poultry processor may purchase both a peracetic acid product and an ASC product for their facility. Ecolab currently markets Inspexx 100 (peracetic) and Sanova (ASC) for poultry processors. Inspexx 100 is typically used in poultry chillers when a low temperature and longer contact time occur to ensure the greatest reduction in bacterial contamination. Sanova, on the other hand, is used in situations where a much shorter contact time is required, and is typically used in the pre-chill or post-chill processing steps where contact time is limited, yet the same level of control is needed. Inspexx 100 and Sanova are both effective against Salmonella typhimurium, Campylobacter jejuni, Listeria monocytogenes, and E. Coli O157:H7. Depending on the customers needs, Ecolab can adapt and tailor its product line to satisfy those specific needs and offer a complete antimicrobial control package.

Ecolab currently lists 2 organic processing aids with OMRI that use peracetic acid as its active ingredient. Tsunami 100 is an EPA registered (1677-164) water additive for pathogen reduction in fruit and vegetable processing waters and for controlling the growth of spoilage and decay causing organisms on fruit and vegetable surfaces. Oxonia Active is also an EPA registered product (1677-129) for use as an acid liquid sanitizer for food processing equipment. The addition of ASC to the National List would allow Ecolab the opportunity to have OMRI review and comment on the red meat and poultry antimicrobial, Sanova.

The availability of chlorine, peracetic acid, and ASC antimicrobial products in various types of organic facilities provides processors with an effective and complete package to control food borne outbreaks. Ecolab respectfully requests the inclusion of ASC on the National List in the interest of food safety. We urge you to vote to include ASC in the National List of Allowed Substances as a synthetic ingredient allowed in or on processed products.

Respectfully,

Dan Dahlman