NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting:	May 2009		Substance:	Sodium Ch	lorite, acidifi	ied		
Committee: Crops National List § 205. 60	☐ Livestock ☐ Han 05b	dling X Petiti	on is for: <u>Incl</u>	usion of Soc	dium Chlorite	e, acid	lified on the	
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) 1. Impact on Humans and Environment 2. Essential & Availability Criteria 3. Compatibility & Consistency 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) B. Substance Fails Criteria Category: 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 Livestock	Agricultural Non-Synthetic		Allowed ¹ Prohibited	j²	X		
	Handling X No restriction	Synthetic Commercially L Available as Or		Rejected ³ 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

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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]		х		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 agroecosystem? [§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 its breakdown products? [§6518 m.2]		X		See above – Category 1, #3			
9. Is there undesirable persistence or concentration of the material or		X		See above – Category 1, #3			

breakdown products in		
environment?[§6518 m.2]		
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]	х	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.
bred 14 1 1 1 C		There is no other published information to suggest that other heavy metals or contaminants may or may not be present in the petitioned substance."

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 – Sodium chlorite, acidified

Category 2. Is the Substance Esse		l	line 110a	substance – Sodium chiorite, acidified
Question	Yes	No	N/A ¹	Documentation
				(TAP; petition; regulatory agency; other)
1. Is the substance formulated or	X			See petition and Technical Evaluation Report
manufactured by a chemical				
process? [6502 (21)]				
2. Is the substance formulated or	X			See petition and Technical Evaluation Report
manufactured by a process that				
chemically changes a substance				
extracted from naturally occurring				
plant, animal, or mineral, sources?				
[6502 (21)]				
3. Is the substance created by		X		See petition and Technical Evaluation Report
naturally occurring biological				
processes? [6502 (21)]				
4. Is there a natural source of the		X		See petition and Technical Evaluation Report
substance? [§205.600 b.1]				
5. Is there an organic substitute?		X		See petition and Technical Evaluation Report
[§205.600 b.1]				
6. Is the substance essential for	X			Chlorine and peracetic acid, already on the National List, can
handling of organically produced				be used in some applications in place of ASC solution.
agricultural products? [§205.600				However, depending on the application ASC may be the most
b.6]				effective antimicrobial. For a full discussion, see the
				petitioner's 2/24/09 response to questions.
7. Is there a wholly natural		X		See petition and Technical Evaluation Report
substitute product?				
[§6517 c (1)(A)(ii)]				
8. Is the substance used in	X			
handling, not synthetic, but not				
organically produced?				
[§6517 c (1)(B)(iii)]				
9. Is there any alternative		X		See above – Category 2, question 6
substances? [§6518 m.6]		<u></u>		
10. Is there another practice that		X		Sanitizing of food contact surfaces or, where needed, direct
would make the substance				food contact surfaces is required. See above Category 2, #6for
unnecessary? [§6518 m.6]				discussion of alternative substances.

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Category 3. Is the substance compatible with organic production practices? Substance—Sodium chlorite, acidified

				<u>acidified</u>
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;		х		
b. toxins derived from bacteria;		Х		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		Х		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		х		

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)]

$Substance - \underline{\text{Sodium chlorite, acidified}}$

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