

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

Date: April 2015

Subject: Petition to add Acidified Sodium Chlorite §205.603(a)

NOSB Chair: Jean Richardson

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation (Motion #1):

Motion to classify Acidified Sodium Chlorite (CAS # 7758-19-2 (sodium chlorite) and CAS # 14998-27-7 (chlorous acid)) as synthetic, passed.

Statement of the Recommendation (Motion #2):

Motion to list Acidified Sodium Chlorite (CAS #s 13898-47-0 (Chlorous Acid), 7758-19-2 (Sodium Chlorite)) at §205.603(a) and 205.603(b) of the National List annotated as follows: Acidified Sodium Chlorite, allowed for use on organic livestock as a pre and post teat dip treatment, passed.

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

Acidified Sodium Chlorite is a material used as a disinfecting teat dip for organic livestock producers. The material breaks down in the environment to water and salt and is more benign than other teat dip materials currently listed on the National List. ASC received broad support from livestock producers and will provide another tool to prevent resistant organisms. It was found to be compatible with all OFPA criteria.

Committee Vote:

Motion to classify Acidified Sodium Chlorite (CAS # 7758-19-2 (sodium chlorite) and CAS # 14998-27-7 (chlorous acid)) as synthetic.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 14 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion passed

Motion to list Acidified Sodium Chlorite (CAS #s 13898-47-0 (Chlorous Acid), 7758-19-2 (Sodium Chlorite)) at §205.603(a) and 205.603(b) of the National List annotated as follows: Acidified Sodium Chlorite, allowed for use on organic livestock as a pre and post teat dip treatment.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 12 No: 2 Abstain: 0 Absent: 1 Recuse: 0

Motion passed

**National Organic Standards Board
Livestock Subcommittee Petitioned Material Proposal
Acidified Sodium Chlorite (ASC), Sodium Chlorite, Acidified
January 27, 2014**

Summary of Proposed Action:

Sodium Chlorite, Acidified - Acidified Sodium Chlorite, (ASC) - CAS#13898-47-0 (Chlorous Acid), 7758-19-2 (Sodium Chlorite) – is a synthetic substance petitioned to be added to the National List at 205.603(a) as a disinfectant, sanitizer and medical treatment, and at 205.603(b) for use as a topical treatment, for the intended use on organic livestock as a pre and post teat dip.

The Livestock Subcommittee proposes to recommend this material be added to the National List.

Background:

The Petition, dated 4/30/12, was received by the NOSB, and a Technical Report was requested. The Technical Report was received in May 2013 and the Livestock subcommittee developed a Proposal with recommendation not to list this materials based on issues of non-essentiality - Proposal and Recommendation dated August 30, 2013.

Acidified sodium chlorite was considered at the NOSB meeting in April 2014 and tabled based on public comment and returned to the subcommittee for further review.

ASC was reviewed but no revisions were made - Proposal and Recommendation dated January 7th, 2014.

On July 29 2014 and July 31 2014 the Petitioner submitted further detailed and lengthy documentation, with References, to address concerns raised by the NOSB and the public.

On January 7 2015 the subcommittee, as part of Sunset Review of Iodine, received a Technical Report on Iodine, an ingredient common in teat dips. This report provides comparative data on ASC and other teat dips.

Discussion:

Preventive health care is an essential part of organic farming, and mastitis prevention through clean milking parlors and clean animals is always of paramount importance on a dairy farm. Organic farmers cannot use antibiotics and thus the use of pre-milking and post milking teat dips is a normal practice and may be the most critical factor in preventing mastitis. Mastitis is caused by several commonly found bacteria. Mastitis causes inflammation and infection and is painful to the animal. There are several teat dips available on the market, but some may be more irritating to the animal than others, and some bacteria may become resistant, and thus a broader array of teat dip ingredient choices for organic farmers seems essential.

Research indicates that alternative practices to teat dipping/spraying or udder washing are not advised, as the exclusion of a disinfecting step from a mastitis control program would significantly increase the likelihood of infection.

Acidified Sodium Chlorite (ASC) was petitioned for use as a pre and post teat dip treatment in organic livestock production. ASC, also listed as Sodium Chlorite, Acidified, is currently on the

National List as an allowed disinfectant for direct food contact under 205.605(b). After reviewing the ASC petition, along with the Technical Evaluation Report prepared for the NOSB in 2013, the NOSB found that ASC satisfies the criteria related to impact on humans and the environment, and is compatible with organic agriculture. However, in preparation for a vote on ASC at the spring 2014 NOSB meeting, the Livestock Subcommittee had unanimously recommended not adding ASC to the National List because of current alternatives available and a lack of written comments from organic dairy producers in support of listing ASC, leading the Subcommittee to believe ASC did not meet the essentiality criteria. However, at the spring 2014 NOSB meeting the NOSB received a number of public comments indicating a strong need for ASC as an effective alternative teat dip that could be used in cases of microbiological resistance to teat dips currently listed. Therefore, the NOSB voted to table ASC at the spring 2014 meeting in order to further review ASC.

The Livestock Subcommittee has reviewed the additional data provided by the petitioner in summer of 2014, and reviewed all written and oral public comment. In addition, as part of the Sunset Review process, the Livestock subcommittee has been reviewing iodine, in both its primary molecular form and in the various complexed iodophor forms. Iodine is widely used in teat dips. As part of this iodine review the subcommittee requested a Technical Report for iodine. This report, received on January 7th 2015, provides some recent research information and comparative data on iodine based teat dips and on teat dips whose primary ingredient is acidified sodium chlorite.

The following is excerpted from the Iodine Technical Report in its discussion of Alternatives to Iodine in teat dips:

“Information regarding the availability of natural, non-synthetic agricultural commodities or products that could substitute for iodine and iodophor disinfectants is limited. Nisin, a naturally occurring antimicrobial protein known as a bacteriocin, has been incorporated into pre- and post-milking teat dips and is highly effective against Gram-positive as well as Gram-negative bacteria (citation provided). Formulated products containing nisin, are currently available for mastitis prevention (citation provided). Nisin naturally present in milk is also instrumental in preventing milk spoilage due to bacterial contamination (citation provided). The antimicrobial mode of action for nisin involves lysis of the cytoplasmic membrane phospholipid components (citation provided).

Nisin, generally considered a natural product, is not listed as a prohibited non-synthetic substance in organic livestock production (7 CFR 205.604). However, the NOSB classified nisin as synthetic during their 1995 review of the substance for organic processing (USDA, 1995a). Nisin was not recommended for inclusion on the National List for use in the processing of food labeled as “organic” and “made with organic ingredients” (USDA, 1995b; OMRI, 2014).

Small-scale milk producers use homemade udder washes containing lavender essential oil, water, and apple cider vinegar (i.e., acetic acid) as the active antimicrobial agent (citation provided). Other procedures for pre- and post-milking treatments include an udder wash (warm water or warm water with a splash of vinegar) in combination with a teat dip (1 part vinegar, 1 part water, plus 3–4 drops Tea Tree oil per ounce). Naturally-derived acids (e.g., lactic acid) may be used as standalone germicides or further activated through the synergistic interaction with hydrogen peroxide to provide a bactericidal teat cleansing treatment (citation provided). In addition to the natural substances mentioned above, a small number of synthetic substances are currently allowed as disinfectants, topical treatments, and external parasiticides in organic livestock production (7 CFR 205.603 (a) and (b)... “. Iodine TR, 2015, 723-744.

“Suppliers of livestock and dairy products have indicated that iodine is traditionally the preferred germicide used as a teat dip for mastitis prevention. Recent natural disasters in Japan and water shortages in Chile led to increasing prices for iodophor products and resultant interest in alternative teat dips (citation provided). Animal health researchers recently found that acidified sodium chlorite (ASC)-chlorine dioxide solutions are equally effective in preventing new intramammary infections (IMI) in lactating dairy cows naturally exposed to mastitis pathogens when compared to an established iodophor teat dip product (citation provided). Alternatively, the results of experimental challenge studies (cows intentionally exposed to mastitis pathogens) suggest that ASC may actually provide enhanced antimicrobial activity against the mastitis bacteria *Staphylococcus aureus* and *Streptococcus agalactiae* relative to a commercial iodophor (citation provided). These studies also indicate that the tested ASC products had no deleterious effects on teat condition. Further, ASC components exhibit minimal persistence in the environment and are highly unlikely to contaminate the milk from treated animals (USDA, 2013). Commercial ASC teat dips are being increasingly used in conventional dairies. (iodine TR, 2015, 761-776).”

ASC thus appears to be a potentially important ingredient in teat dips and the Livestock subcommittee recommends its addition to the National List as petitioned.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x Yes	No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	x Yes	No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	x Yes	No	<input type="checkbox"/> N/A

Subcommittee Action & Vote

Classification Motion: Motion to classify Acidified Sodium Chlorite (CAS # 7758-19-2 (sodium chlorite) and CAS # 14998-27-7 (chlorous acid)) as synthetic.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 5 No: 0 Abstain: 0 Absent: 3 Recuse: 0

Listing Motion: Motion to list Acidified Sodium Chlorite (CAS #s 13898-47-0 (Chlorous Acid), 7758-19-2 (Sodium Chlorite)) at §205.603(a) and 205.603(b) of the National List annotated as follows: Acidified Sodium Chlorite, allowed for use on organic livestock as a pre and post teat dip treatment.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 4 No: 1 Abstain: 0 Absent: 3 Recuse: 0

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

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB January 27, 2015

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 1. Adverse impacts on humans or the environment? Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse,? [§6518(m)(3)]		x		Risk is minimal. TR page 9, lines 359-369.
2. Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)]		x		TR page 9, lines 359-390.
3. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		x		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		Breakdown products are citric acid, salt and water (2009 handling recommendation).
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		When used as petitioned, SCA and its components exhibit minimal likelihood of persistence in the environment. TR page 7 lines 296-298.
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		x		“When used as petitioned, acidified sodium chlorite and its component chemicals exhibit minimal likelihood of persistence or accumulation in the environment.” TR page 10, lines 436-428. The material is both GRAS and on the USDA National List for handling.
8. Are there adverse biological and chemical interactions in the agroecosystem, including biodiversity? [§6518(m)(5)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.
9. Are there detrimental physiological effects on soil organisms, crop- s, or livestock? [§6518(m)(5)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.

Category 2. Is the Substance Essential for Organic Production: Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		x		TR page 7, lines 280-293.

2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	x			TR page 6, lines 222-279
3. 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		The substance is synthetically produced. TR page 7, lines 280-293.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		x		The substance is synthetically produced. TR page 7, lines 280-293.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		x		TR page 7.
6. Is there an organic substitute? [§205.600(b)(1)]		x		Nisin, a natural material that may be a substitute, is not authorized for use as a teat dip due to earlier rejection by NOSB as an antibiotic . A number of essential oils and organic acids may also be used as teat dips. TR page 12, lines 503-514
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x			See above.
8. Are there any alternative substances? [§6518(m)(6)]	x			There are a number of alternative substances, including iodine, alcohols, chlorine materials, hydrogen peroxide, chlorhexadine and certain essential oils may function as alternatives. TR 524-539 At the spring 2014 NOSB meeting, comments from dairy industry representatives indicated that there was a need for another effective teat dip to be available to organic dairy producers as a substitute in cases of microbiological resistance to teat dips on the National List.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		Teat dips are critical in commercial dairy production to prevent mastitis. TR page 12.

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 3. Is the substance compatible with organic production practices? Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	x			TR, petition. Substance is already allowed for use in handling in direct food contact.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			x	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			x	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			x	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);		x		TR page 6, lines 210-221
copper and sulfur compounds				
toxins derived from bacteria		x		TR page 6, lines 210-221
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		x		TR page 6, lines 210-221
livestock parasiticides and medicines		x		TR page 6, lines 210-221
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		x		TR page 6, lines 210-221