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Agricultural Marketing Service | National Organic Program
Document Cover Sheet

<https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

Document Type:

National List Petition or Petition Update

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

Technical Report

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Deborah C. Attwood
202 429 3025
dattwood@steptoe.com



1330 Connecticut Avenue, NW
Washington, DC 20036-1795
202 429 3000 main
www.steptoe.com

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Via EMAIL

Mr. Devon Pattillo
Materials Specialist
National Organic Program
Agricultural Marketing Service
U.S. Department of Agriculture
1400 Independence Avenue, SW
Room 2642-South, Stop 0268
Washington, D.C. 20250-0268

Re: Pure Bioscience Comments on the Technical Evaluation Report for Silver Dihydrogen Citrate

Dear Mr. Pattillo,

This letter provides comments, on behalf of Pure Bioscience, Inc., on the Technical Evaluation Report (“Report”) for Silver Dihydrogen Citrate (SDC) published on the National Organic Program’s (NOP) website in May 2018.¹ Pure Bioscience, as the petitioner seeking to add SDC to the NOP’s National List of Allowed and Prohibited Substances for use in the handling of organic food products, wants to ensure that the Report accurately reflects the SDC that is currently produced and that has been approved by the Food and Drug Administration (FDA), U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS), and Environmental Protection Agency (EPA) for safe use as an antimicrobial processing aid in the production of poultry and fruits and vegetables and as a hard surface disinfectant and food contact surface sanitizer. Pure Bioscience appreciates the comprehensiveness of the Report but wishes to clarify and correct certain aspects of the Report. Most notably, the Report contains inaccuracies in the description of the manufacturing process for SDC and misleadingly includes a discussion of the antimicrobial effects of silver nanoparticles. Pure Bioscience also has comments regarding the

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role of SDC in processing of poultry and produce as compared to other substances on the National List permitted for use in organic processing/handling and other minor comments.

Source or Origin of the Substance

For several reasons, the chemical production methods described in the Report do not represent the SDC product that is manufactured by Pure Bioscience and that is the subject of the NOP petition. Page 2 of the Report (lines 60-91) summarizes information in the scientific literature describing potential manufacturing methods for SDC. Several of the chemical production methods identified do not actually form the SDC product that is the subject of the NOP notification. Specifically, the Report states that SDC can be prepared by dissolving silver citrate in citric acid, citing to a 2008 Djokić study, *Synthesis and Antimicrobial Activity of Silver Citrate Complexes* in support of this claim. Yet while the Djokić study describes the **theoretical** silver complexes that would form by dissolution of silver citrate (in the form of trisilver citrate) in citric acid as $\text{AgH}_2\text{C}_6\text{H}_5\text{O}_7$ (which is the chemical formula for SDC) and $\text{Ag}_2\text{HC}_6\text{H}_5\text{O}_7$, the author notes that this process was not observed in reality and that, in fact, the dissolution of trisilver citrate in an aqueous citric acid solution is best described as forming silver complexes having the formula $[\text{Ag}_3(\text{C}_6\text{H}_5\text{O}_7)_{n+1}]^{3n-}$. The identified silver complex is not SDC as presented for consideration by the National Organic Standards Board (NOSB). Indeed, lines 229-230 of the Report acknowledge that this manufacturing process is not used in commercial processes.

Djokić also reported that this method (i.e., dissolution of trisilver citrate in citric acid) produced a precipitate. This precipitate, which would be an undesirable byproduct of this production method, is not present in Pure Bioscience's SDC and was not evaluated for safety by any of the regulatory agencies that have reviewed SDC for the proposed organic uses.

Finally, the concentrations of both silver and citric acid described in Djokić's work are higher than those in the petitioned SDC. Pure Bioscience's SDC is specifically designed and manufactured (and patented) to ensure long term product stability and broad spectrum efficacy that permits the use of much lower concentrations of silver and citric acid. As the safety of silver is a key aspect of the existing regulatory approvals, it is important that the Report accurately reflects the petitioned product. Consequently, Pure Bioscience recommends that the discussion of the Djokić study either be removed or amended to reflect that it is not a practically achievable commercial product and is not how the petitioned SDC is produced.

Properties of the Substance

The Report inexplicably and misleadingly includes a discussion of silver nanoparticles in the description of the substance, when **SDC is not comprised of and does not contain any silver nanoparticles**. Specifically, in the last paragraph of this section (lines 109-121) the Report discusses the antimicrobial effects of silver nanoparticles and appears to suggest that silver nanoparticles could be added to SDC in order to augment antimicrobial efficacy. It is unclear why this discussion was included because nowhere in its petition for SDC did Pure Bioscience

indicate that the use of silver nanoparticles was intended or desired. SDC is formulated so as to permit exact dosing of the product to achieve an antimicrobial effect with a low level of silver ion. The inclusion of silver nanoparticles could result in unnecessarily high concentrations of silver ion. Moreover, the presence of silver nanoparticles would have represented a key safety aspect that would need to have been reviewed as part of the existing regulatory approvals, so the suggestion that silver nanoparticles could simply be added to augment the efficacy of SDC is inaccurate. Because this section of the Report is inaccurate and misleading, Pure Bioscience requests that it be removed from the report.

Other Comments and Clarifications

Identification of Proposed Substance

As Pure Bioscience is the petitioner for SDC, we suggest that the trade names for Pure's product, Pure Control and Pure Hard Surface, should be included in the identity of the petitioned substance (lines 16-27).

Approved Legal Uses of the Substance

The Report conflates the existing approved legal uses in its description. Specifically, lines 147-149 state "As a food contact surface sanitizer, aqueous solutions of SDC are not intended for use on any citrus fruit nor is it for use on grapes intended for winemaking nor for use in combination with any other silver containing antimicrobial," which combines two different uses. One use of SDC is as a hard surface disinfectant and food contact surface sanitizer, a use that is regulated by EPA. The food processing use, which excludes use on citrus fruit and grapes for winemaking, is a separate use regulated by FDA.

Evaluation Question #5

Pure Bioscience confirms that the primary technical function and purpose of SDC is for use only as a food processing aid and hard surface disinfectant and food contact surface sanitizer. SDC is not intended for use as a preservative in food. Lines 282-283 of the Report state "There is no published information to suggest that the petitioned substance is being used primarily as a preservative"; we can confirm this statement. We also note that use of SDC as a preservative in food would have prevented FDA from approving use of SDC through the Food Contact Notification (FCN) program. The FCN program is jurisdictionally limited to premarket approvals for food contact substances, including some processing aids. The FCN program cannot be utilized for premarket approval for direct food additives, such as preservatives.

Evaluation Question #12

Pure BioScience submits that there are no “natural (non-synthetic)” substances or products that could be used in place of SDC without compromising antimicrobial efficacy. While organic acids can have some utility in preventing foodborne illness, there is no organic acid that can provide the same broad spectrum antimicrobial efficacy as SDC. While *Salmonella* continues to be a bacterium of concern that may be addressed by organic acids, the reduction of *Listeria*, *Campylobacter*, and other pathogens also are significant issues in poultry and produce processing. Moreover, as noted in the Report, organic acids can adversely impact the organoleptic properties of the treated foods, whereas SDC does not affect sensory changes on treated foods.

With regard to other synthetic antimicrobials that SDC could replace, SDC provides comparable efficacy with an odorless and non-corrosive product and, as noted in the Report, does not present concerns regarding antimicrobial resistance.

Evaluation Question #13

Pure BioScience submits that there are no organic agricultural products that could be appropriate and efficacious alternatives to SDC. The extensive discussion of natural plant extracts and essential oils in this evaluation question is largely irrelevant to the intended use of SDC. The description of these products is for as preservatives in food (i.e., to have a technical effect in the finished food), whereas SDC is a processing aid with no on-going technical effect in the food. SDC has no impact on the organoleptic properties of the food and, again, has broad spectrum antimicrobial efficacy that the natural plant extracts and essential oils discussed in the Report cannot match.

We appreciate your consideration of these comments. If you have any questions or concerns, please do not hesitate to contact me. We would also be happy to set up a teleconference or meeting with the subcommittee in order to facilitate discussion of these comments.

Sincerely yours,



Deborah C. Attwood