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July 11, 2017

TO: NOSB Handling Subcommittee,

RE: ADDENDUM Documents to Petition: Sodium dodecylbenzene sulfonate (SDBS) to National LIST 205.605 synthetic for use in fruit, vegetable and produce wash

In 2016 and in subsequent 2017 meeting notes, NOSB Handling Committee had requested additional technical support information for the addition of Sodium dodecylbenzene sulfonate (SDBS) to NOP National List. Ecolab provided information through comment in fall of 2016 (to be considered in Dec/Jan Handling committee meetings and again in March as part of the Spring 2017 NOP comments (AMS-NOP-16-0100-0001).

Since that time, Ecolab has been tracking the meeting notes. We want to ensure attached supplemental ADDENDUM documents will be considered as part of NOSB HS August 2017 review of petitioned substance Sodium dodecylbenzene sulfonate (SDBS).

These Addendum documents are attached and we hope they will be helpful for the TR.

#### **Background:**

At Spring 2016 meeting, the NOSB considered the addition of sodium dodecylbenzene sulfonate (SDBS) to the NOP National List. Ecolab and organic grocers and food handlers believe SDBS and its proposed use is in keeping with organic principles. At the Spring meeting, the Handling subcommittee and members of the board asked some important questions and requested additional support and documentation for further consideration of SDBS addition to the List. The information requested is compiled within ADDENDUM documents.

#### **Critical Organic Market Need**

FDA FSMA Rulemaking, particularly Final Rule for Produce Safety - is increasingly pressuring manufacturers and retailers to holistically evaluate their process and incorporate proven intervention strategies that will control and eliminate hazards, particular those that affect public health. FDA 2013 Food Code also provides guidance for retail, grocers and food handlers to incorporate best practices including fruit and vegetable washes to safely remove dirt, microorganisms and other contaminants prior to fruit, vegetable prep. SDBS is an active substance within fruit and vegetable wash used on surfaces of the fruit, vegetable, leafy greens to remove contaminants. This will provide another critical tool for our organic manufacturers and retailers to meet FSMA requirements while providing safe organic foods to the public.

#### Safe Alternative for ensuring safe food prep and production

SDBS is not harmful to health or the environment. It is a safe alternative where natural substitutes (which will provide effective microbiological kill to harmful organisms) are not easily available, and its organic clearance



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would be consistent with organic farming and handling to remove dirt, field contamination, etc. and therefore provide a safe, quality organic product for consumers and their families.

We live in a world where organic foods, once harvested, are <u>transported long distances and sometimes</u> <u>handled multiple times</u> before reaching the organic consumer. This can be an opportunity for crosscontamination and growth of pathogenic bacteria such as *E.coli, Salmonella, Listeria*.

#### **Consumer protection**

Consumers know the value of a safe, clean food supply and although they wish no chemicals were needed; the organic consumer also understands the critical need for food safety to protect theirs and their families' health - especially regarding foods prepared outside the home. If a chemical substance (i.e. SDBS) must be used and tolerated, consumers demand that it is not harmful and it is used safely and at the lowest level necessary. They want to know that it appears on the SCIL and NOP lists. SDBS meets the safety and scientific support for its intended use in combination with the organic acid, lactic acid, in produce wash waters. This will provide public benefit of a wholesome organic food supply.

#### Grocers and restaurant/foodservice user option

SDBS will provide the safe food protection needed for organic handling and is an essential alternative choice to historical gold standards - chlorine and peroxyacetic acid where these substances may not be effective or appropriate in some food handling operations and grocers.

We thank the committee members in advance for their time, consideration and dedication. We urge consideration for the benefit for protecting the organic brand while also providing a safe organic food supply to the consuming public. Attached supplemental information should be helpful in clarifying some misconceptions regarding its use and application for organic produce handling; as well as answer those still outstanding questions by NOSB. We believe SDBS poses no greater risk than chlorine and peroxyacetic acid and will actually be safer and easier to manage in small workplace environment such as grocers and restaurants.

Thank you to all members of the Handling Committee for your valuable time devoted to organic integrity and ensuring a safe and wholesome organic food supply. Please let me know if you have additional questions or concerns.

Abort W. M.

# ADDENDUM to Sodium Dodecylbenzene NOP Petition for National Listing

**Summary:** SDBS was petitioned by Ecolab Inc. for use as an active ingredient in an antimicrobial formulation used in water solution for washing fruits and vegetables in organic establishments, particularly food retail prep facilities.

During the NOSB Spring 2016 meeting in Washington, DC, the handling subcommittee voted to defer a final vote for the addition of SDBS to the National List subject to additional support information requested by members to be reviewed and considered at Fall 2017 agenda.

Specifically, NOSB HS requested Ecolab address the following areas:

- o Clarification for how AFVT is used
- Retail support for SDBS essential use
- Human Exposure: Worker safety at manufacturing vs worker safety at use-solution
- SCIL provide information from EPA for selection of SDBS on the Safer Choice List (SCIL)
- Human health impact any additional studies/references supporting that SDBS is not toxic to health at levels proposed for use – possible Tox evaluation and modeling support
- o Data studies

**SDBS use in Fruit & Vegetable Wash Solution**. Antimicrobial Fruit and Vegetable Wash (AFVT) is a vital part of a retail establishment's Food Safety program. Over the last several years, Center for Disease Control (CDC) and U.S. Department of Agriculture (USDA) has linked several serious foodborne illness multistate outbreaks to fresh produce and fruits. More illnesses were associated with leafy vegetables (2.2 million [22%]) than any of 17 commodities compared.<sup>1</sup>

Microbial contamination of leafy greens most often occurs in the field or during harvest and processing. Produce and fruit is received by restaurants from a variety of sources, including grocery stores, local or seasonal supplier, farm, distributor (e.g. SYSCO), commissaries or other.

Produce is typically purchased and transported to retail and foodservice establishments where it is prepped, cut, refrigerated or immediately used in salads, sandwiches, wraps, or other ready to eat consumer items or assembled and packaged as a ready to eat item (such as pre-packaged prepared salads, cut fruits, etc.); and additionally as garnishes or in buffets and self-serve.

Washing of fruits and vegetables is now recognized as an important preventative practices and good manufacturing practice (GMP) to reduce contamination and growth of microorganisms.

Grocers, food service, and restaurants know that organic and local produce, fruits, vegetables that they receive/purchase direct from farmers, co-ops, grocers and distribution centers carry at least some level of soil and field contaminants that they must wash/rinse off prior to prepping for sale or serving to customers.

These users want to make sure their customers have a quality safe dining experience. They know how catastrophic a food borne illness can be to their reputation and business if it is associated with contamination from their restaurants, particularly leafy vegetables and cut fruits. In the case of infants, children and elderly – it can be fatal.

Retailers and foodservice include rinsing/washing as part of their produce, fruit and vegetable prepping, butting, and cutting/portioning before they make and package salads, fruits, cut vegetables for sale or meal service. As discussed in the spring meeting, they are using washes for non-organic (Antimicrobial Fruit and Vegetable Wash (AFVT)) but then must switch out their wash chemical to sodium hypochlorite (easiest) to wash their organic produce since SDBT is not yet cleared for organic use.

Grocers, food service, restaurateurs desire to use a single product that they trust has better "kill" such as AFVT (lactic acid formulated with SDBS) for both organic and non-organic; ensuring that they are providing clean and safe produce, fruits and vegetables to their customers. [SDBS amount in the resulting diluted organic wash solution will result in less than 0.01%]. Users recognize the value of good manufacturing practice and following the food code and new FSMA regulations.

During the spring meeting, one board member stated that antimicrobial produce wash solutions are applied directly to the surface of product as a spray. As a clarification, AFVT (containing SDBS) is actually automatically measured and dispensed in water in the facilities' produce prep sink (FIGURE 1).

Fruits, produce, vegetables are then submerged and gently agitated in the solution for 90 seconds, then removed, drained and prepped/cut, assembled for consumer or retail (FIGURE 2)



#### **FIGURE 2**

# Cut Produce Washing Procedure (Further processed)



Fill sink to line with Produce Wash use-solution



Slightly agitate produce. Soak for minimum of 90 seconds.



Place cut produce in a colander.



Remove cut produce.



Submerge cut produce in use-solution.



Drain and store as desired.

SDBS, in solution as part of AFVT, is effective kill step against microbes such as *Escherichia-coli* 0157:H7, *Salmonella enterica*, and *Listeria monocytogenes* in process water for raw fruits and vegetables. Today, with an increasing shift in diets to fresh fruits and vegetables, we are seeing a <u>positive trend shift to</u> <u>local and organic</u> sourcing for our food supply. Retailers, grocers, and foodservice strive to make their Food Safety program comprehensive – focusing on quality and safety. Part of that effort is to source an organic accepted produce wash besides chlorine-based products.

Other fruit and vegetable sanitizers mentioned during the spring meeting are not suitable to the retail and foodservice environment.

- Peracetic acids: These products are less suitable/manageable to retail, grocer, or foodservice storage [most peracids used for industrial manufacture]
  - o Heightened worker concern
    - Pungent vinegar odor
    - New NIOSH IDLH lower exposure limits proposed
  - Typically manufactured and sold in 55 300 gallon quantities taking up valuable storage space
  - Short storage shelf-life <1 year</li>
  - o Concentrate must be handled with PPE

- Chlorine dioxide and ozone:
  - Must be generated on site through complex equipment
  - Worker exposure concerns
  - Breathing exposure limits
  - Advised only to be used by trained employees.
- Chlorine sodium hypochlorite: easy to use, cheap, convenient
  - Difficult to manage and maintain concentrations when washing/rinsing fruits, vegetables, produce coming from the field because of high soil/dirt loads that overwhelms chlorine-treated water and therefore loss of ability to kill microorganisms present
  - Less effective on bacteria attached to produce surfaces<sup>5</sup>

**Retail Support/Comments for SDBS Use.** Several additional comments from SDBS users are submitted (deadline October 26, 2016) supporting the importance of SDBS use in their establishments to protect their customers, consumers, and brand and meet the Food and Drug Administration's new Food Safety Modernization Act (FSMA) efforts.

**Human Exposure and Worker Safety:** As illustrated (Figure 1), SDBS-containing treatment solutions are automatically measured and dispensed into the wash water vessel (produce wash sink) – simplifying use, dilution management for workers/handlers.

- There is no worker contact with concentrate providing added safety and assurance of proper concentrations.
- SDBS has previously been thoroughly reviewed by FDA and EPA for safety.
  - These linear alkyl benzene Sulfonate (LAS) are readily metabolized, excreted fairly rapidly, and do not accumulate in tissues.
- EPA includes SDBS on their Safer Choice list (SCIL) as Sodium dodecylbenzene sulfonate under the surfactant category.<sup>2</sup>
  - EPA's Safer Choice Program has evaluated SDBS and determined the substance to be safer than traditional chemical ingredients. The SCIL list is designed to help manufacturers/users to find safer chemical alternatives that meet the criteria of the Safer Choice Program.

**SCIL Review and Listing Process:** Before **Safer Choice** decides to include a chemical on the SCIL, a thirdparty profiler (i.e., NSF, International or ToxServices) gathers hazard information from a broad set of resources, including the identification and evaluation of all available toxicological and environmental fate data. The third party profiler submits a report to Safer Choice, with a recommendation on whether the chemical passes the Criteria for Safer Chemical Ingredients. Safer Choice staff performs due diligence by reviewing the submission for completeness, consistency, and compliance with the Safer Choice Criteria. If more than one third-party has evaluated the chemical, Safer Choice also checks for differences in the profiles and resolves any conflicts. In some cases, Safer Choice may also perform additional literature reviews and consider data from confidential sources, such as EPA's New Chemicals Program.<sup>3</sup> Chemicals that exhibit endocrine activity are closely evaluated. Those associated with toxicological hazards are not allowed. Safer Choice (SCIL) products have been evaluated and addressed a broad range of potential toxicological effects, including:

- carcinogens, mutagens, reproductive or developmental toxicants;
- persistent, bio accumulative and toxic chemicals;
- systemic or internal organ toxicants;
- asthmagens;
- sensitizers; and
- chemicals on authoritative lists of chemicals of concern.

Further, Ecolab Inc. was recognized in 2016 Safer Choice Partner of the Year Award Winners in the Innovator category.

Products and substances are carefully evaluated against stringent health and environmental criteria. The substance must be among the safest in its ingredient class to be considered on the SCIL list.

# Human Health Impact.

FDA and US EPA evaluated toxicological data submitted to support SDBS and determined that the dietary risk estimates for the fruit and vegetable wash are below the Agency's level of concern for all age groups (infant, child, adult at less than 71.2% of the cPAD). These risk estimates are based on a number of conservative assumptions, and thus may overestimate the actual risks.<sup>4</sup>

Occupational findings: Post application dermal exposure is <u>not expected to occur or is expected to be</u> <u>negligible</u> based on the application rates and chemical properties. The alkyl benzene sulfonates have a low vapor pressure (less than 10-~rnrn~g), so that any standing solutions that may result in post application exposure were deemed negligible.

**Data Studies (3<sup>rd</sup> party and peer reviewed).** Ecolab did a search and was unable to find requested reference 3<sup>rd</sup> party and peer reviewed studies where SDBS (or AFVT) was specifically tested against chlorine, chlorine dioxide, lactic, citric, peroxyacetic acid.

Footnotes:

<sup>&</sup>lt;sup>1</sup>Painter JA, Hoekstra RM, Ayers T, Tauxe RV, Braden CR, Angulo FJ, et al. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008. Emerg Infect Dis Accessed September 12, 2016 at: <u>http://dx.doi.org/10.3201/eid1903.111866</u>

<sup>&</sup>lt;sup>2,3</sup>Safer Choice Review of Chemicals. Accessed September 12, 2016 at <u>https://www.epa.gov/saferchoice/safer-ingredients#overview</u>

<sup>&</sup>lt;sup>4</sup> Wagner, Pauline. 2006. U.S. Environmental Protection Agency (EPA). Action Memorandum: Inert Ingredient Tolerance Reassessments: Two Exemptions from the Requirement of a Tolerance for Alkyl (C8-C24) Benzenesulfonic Acid and its Ammonium, Calcium, Magnesium, Potassium, Sodium, and Zinc Salts: Accessed September 27, 2016 at <u>https://www.epa.gov/sites/production/files/2015-04/documents/alkylc8.pdf</u>

<sup>&</sup>lt;sup>5</sup> Sapers, Gerald M., E. Solomon, K. Matthews, The Produce Contamination Problem: Causes and Solutions; Academic Press 2009.

# References

Buehler EV, Newmann EA, King WR. 1971. Two-year feeding and reproduction study in rats with linear alkyl benzene sulfonated (LAS). Toxicology and Applied Pharmacology. 18:83-91.

Human & Environmental Risk Assessment (HERA). 2013. LAS: linear alkyl benzene sulphonate. Accessed September 27, 2016 at: <u>http://www.heraproject.com/files/HERA-</u> LAS%20revised%20February%202013.pdf

King, H., E. Moorman, *Is It Time for a Kill Step for Pathogens on Produce at Retail?*; Food Safety Magazine, January 2017, pg 36-51.

Sapers, Gerald M., E. Solomon, K. Matthews, *The Produce Contamination Problem: Causes and Solutions*; Academic Press, 2009.

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World Health Organization (WHO). 1996. Environmental health criteria document for linear alkyl benzene sulfonates and related compounds. EHC 169. Accessed September 28, 2016 <a href="http://www.inchem.org/documents/ehc/ehc/ehc169.htm">http://www.inchem.org/documents/ehc/ehc169.htm</a>

# ADDENDUM to Sodium Dodecylbenzene NOP Petition for National Listing

# EPA SAFER CHOICE EXPLANATION REQUEST BY NOSB HS and Safer Chemical Ingredient Listing for Sodium Dodecylbenzene (SDBS)

# EPA 2016 Safer Choice Award Partner:

Ecolab is recognized as an outstanding Safer Choice Innovator. Ecolab was recognized by EPA for taking a leading role in developing innovative institutional cleaning products over the past 20 years. Ecolab developed its first Design for the Environment product in 1996 and has recently increased its offerings, including an innovative product system for use in hospitals. Additionally, Safer Choice commends Ecolab for its leadership in the Safer Choice Walmart Pilot, and its ongoing promotion of the label to purchasers and end-users, its **commitment to product-review-process improvements**, and the development of the Ecolab Water Risk Monetizer tool.

# What does the Safer Choice label mean?

When you see a product with the Safer Choice label, it means that every ingredient in the product has been reviewed by EPA scientists. Only products that meet our <u>Safer Choice Standard</u>, which includes stringent human health and environmental criteria, are allowed to carry the label.

Meeting the Safer Choice Standard is voluntary. Companies who manufacture Safer Choice products have invested heavily in research and reformulation to ensure that their ingredients and finished product line up on the green end of the health and environmental spectrum. These companies are leaders in safer products and sustainability.

Safer Choice products work well and are less toxic. They are safer for:

- You, your family, and pets;
- Workers' health; and
- Fish and the environment.

In addition to safer ingredients, EPA's Safer Choice Standard also includes requirements for:

- performance,
- packaging,
- pH, and
- volatile organic compounds (VOCs).

**Safer Choice uses a rigorous, in-depth approach to review products.** By focusing at the ingredient level and on inherent characteristics, Safer Choice is able to carefully scrutinize formulations and make meaningful calls on potential concerns. Safer Choice starts its product reviews with information that scientists already know about each chemical ingredient, such as how it works in a product and how it affects living things. When that information doesn't tell the full story, EPA looks at an ingredient's chemical structure—its components and shape—to understand how it could impact the environment and people.

A chemical's structure can tell a lot about how the chemical will behave and what types of effects it may have when it comes in contact with people or the environment. Safer Choice uses the special skills of the scientists at EPA who are experts in chemical analysis, hazard and risk assessment, and green chemistry. **Safer Choice review is especially discriminating and protective.** The Safer Choice Program is unique because of two defining characteristics: its assessment methodology and its technical review team. The Safer Choice technical review team has many years of experience and is highly skilled at assessing chemical hazards, applying predictive tools, and identifying safer substitutes for chemicals of concern. The review team applies the Safer Choice assessment methodology by carefully reviewing every product ingredient. (The review includes all chemicals, including those in proprietary raw material blends, which supplier companies share with Safer Choice in confidentiality).

Safer Choice reviews provide an extra measure of protection. Safer Choice uncovers chemicals of concern that can be masked by raw material blends or by dilution in water. By focusing at the ingredient level and on inherent characteristics, Safer Choice is able to carefully scrutinize formulations and make meaningful calls on potential concerns. For example, a surfactant that is acutely toxic to aquatic organisms and environmentally persistent can appear to pose a low concern when blended with other less toxic and less persistent surfactants. Similarly, water, typically the largest percentage ingredient even in concentrated products, can mask the toxicity of a hazardous chemical.

Safer Choice uses its expert knowledge and predictive tools to supplement lists of chemicals of concern. Few chemicals in commerce have been completely characterized, especially for chronic effects like cancer and developmental toxicity. For this reason, lists of chemicals with these effects can only be considered works in progress. Safer Choice uses its knowledge of the structural similarities between chemicals and its predictive models to flag ingredients with similar potential effects.

# Safer Choice screens all ingredients for chemicals that may present serious health or environ-mental

*effects.* This screening includes ingredients used in small percentages, like fragrances and dyes. Some of the chemicals of most potential concern in products are those used in small concentrations. Chemicals of concern include sensitizers, carcinogens, and environmentally toxic and persistent compounds. Small quantities don't necessarily mean small hazards: a person, once sensitized to a chemical, can have an allergic response even if exposed at minute levels.

Safer Choice recommends safer substitutes for chemicals of concern. Movement toward sustainability requires innovation and continuous improvement. The Safer Choice Program works directly with EPA's green chemistry specialists to identify and recommend safer chemicals to its partners, continuously raising the bar and redefining the meaning of environmentally preferable products. Safer Choice helps partners by sharing information and guiding the development of safer products. This is a win for industry, families, and the environment.

# **Overview of the Safer Chemical Ingredients List**

The Safer Chemical Ingredients List (SCIL) is a list of chemical ingredients, arranged by functional-use class that the Safer Choice Program has evaluated and determined to be safer than traditional chemical ingredients. This list is designed to help manufacturers find safer chemical alternatives that meet the criteria of the Safer Choice Program.

Before Safer Choice decides to include a chemical on the SCIL, a third-party profiler (i.e., NSF, International or ToxServices) gathers hazard information from a broad set of resources, including the identification and evaluation of all available toxicological and environmental fate data. The third party

profiler submits a report to Safer Choice, with a recommendation on whether the chemical passes the Criteria for Safer Chemical Ingredients. Safer Choice staff performs due diligence by reviewing the submission for completeness, consistency, and compliance with the Safer Choice Criteria. If more than one third-party has evaluated the chemical, Safer Choice also checks for differences in the profiles and resolves any conflicts. In some cases, Safer Choice may also perform additional literature reviews and consider data from confidential sources, such as EPA's New Chemicals Program. Safer Choice does not typically examine primary literature (original studies) as part of its review and listing decisions.

The list is not intended to be exclusive. Chemicals may be submitted as part of a formulation that the program has yet to review or a chemical manufacturer may develop a chemical to meet the Safer Choice criteria. If these chemicals meet our criteria, they may be approved for use in Safer Choice-labeled products and added to the SCIL. Chemicals may be removed from the list or have their status changed based on new data or innovations that raise the safer-chemistry bar. Safer Choice will ensure that no confidential or trade secret information appears in this list.

<sup>†</sup>The <u>Safer Choice Standard</u> and the <u>Criteria for Safer Chemical Ingredients</u> are protective and address a broad range of potential toxicological effects, including:

- carcinogens, mutagens, reproductive or developmental toxicants;
- persistent, bio accumulative and toxic chemicals;
- systemic or internal organ toxicants;
- asthmagens;
- sensitizers; and
- chemicals on authoritative lists of chemicals of concern.

# Additionally:

- Chemicals that exhibit endocrine activity are closely evaluated. Those associated with toxicological hazards are not allowed.
- Impurities can be present in chemicals that are used in Safer Choice products. Safer Choice limits impurities that do not meet its criteria to not more than 0.01 percent in the final product. The safer chemicals list does not include impurities.

\*All chemicals in the listing are among the safest for their functional use.

Green circle - The chemical has been verified to be of low concern based on experimental and modeled data.

Green half-circle - The chemical is expected to be of low concern based on experimental and modeled data. Additional data would strengthen our confidence in the chemical's safer status.

→Yellow triangle - The chemical has met Safer Choice Criteria for its functional ingredient-class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. (See <u>Safer Choice Criteria</u>). While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.

Grey square - This chemical will not be acceptable for use in products that are candidates for the Safer Choice label and currently labeled products that contain it must reformulate per <u>Safer</u> <u>Choice Compliance Schedules</u>.

Safer Choice Ingredient Listing Criteria and Clearance process:

# Flowchart of steps to getting a chemical listed on SCIL



Safer Choice will carefully review the profile in the context of its functional class and make a decision on whether the chemical meets the Safer Choice criteria for SCIL listing. If the chemical qualifies for SCIL, the Safer Choice Program will decide on the appropriate geometric-color symbol, to designate the chemical's hazard status. SCIL-listed chemicals are reviewed every three years to ensure appropriate consideration of the latest toxicological information.

#### SDBS appears on the list by its CAS RN 25155-30-0.

Sodium lauryl benzene sulfonate 25155-30-0 Surfactants

• Safer Choice's labeling program is different from other eco-labels in several important ways:

**First**, we are focused on chemistry and identifying safer chemicals. Our approach to product review is grounded in EPA's more than 40 years of experience in evaluating the human health and environmental characteristics of chemicals. This expertise enables us to go beyond established lists of 'bad actor' chemicals and to use expert judgment to determine the likely health and environmental hazards of chemicals that haven't been widely studied.

**Second**, we look at a full set of health and environmental endpoints based on a range of data, experimental and modeled, and expert judgment.

Finally, we work closely with companies to help them find safer chemicals for their products.

#### **Reference:**

Safer Choice Criteria Standard: Accessed June 30, 2016 at: <u>https://www.epa.gov/saferchoice/safer-ingredients#about</u> Safer Choice Partner of the Year Award 2016 Ecolab, Inc. Accessed at: <u>https://www.epa.gov/saferchoice/safer-choice-partner-year-award-winners-2016</u>

#### NOSB Evaluation Critieria for Substances Added To the National List - Handling

| Question  | Yes | No | N/A | Comments/Documentation. (TAP;Petition;regulatory agency; other)  |
|---|-----|----|-----|--|
| 1. Are there adverse effects on the environment,<br>or is there a probability of environmental<br>contamination during use or misuse of the<br>substance? [§205.600(b)(2), [§6518(m)(3)]                      |     | x  |     | Information provided in the EPA 2006 Registration Eligibility Document (RED) states: No environmental exposure is expected to occur from the majority of linear alkylbenzene sulfonate uses and it is unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur from limited commercial down-the-drain use because of the very small number of pounds for these uses plus their rapid degradation in the environment.   |
| 2. Are there adverse effects on the environment<br>or is there a probability of environmental<br>contamination during manufacture or disposal of<br>the substance? [§6518(m)(3)]                              |     |    |     | See answer to question 5 below.  |
| 3. Are there any adverse impacts on biodiversity?<br>(§205.200)   |     | x  |     |  |
| 4. Does the substance contain inerts classified by<br>EPA as 'inerts of toxicological concern'? [§6517<br>(c)(1)(B)(ii)]  |     | х  |     |  |
| 5. Is there undesirable persistence or<br>concentration of the material or breakdown<br>products in the environment? [§6518(m)(2)]  |     | x  |     | It is biodegraded rapidly under aerobic conditions with a half-life of<br>approximately 1- 3 weeks; oxidative degradation initiating at the alkly<br>chain. Under anaerobic conditions it degrades very slowly or not at all,<br>causing it to exist in high concentrations in sewage sludge. This is<br>thought to not be of a concern as it will rapidly degrade once returned<br>to an oxygenated environment. (Jenson, John February 1999, "Fate and<br>effects of linear alklybenzene sulfonates (LAS) in the terrestrial<br>environment").   |
| 6. Are there any harmful effects on human health<br>from the main substance or the ancillary<br>substances that may be added to it?<br>[§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4),<br>205.600(b)(3)] | x   |    |     | According to the New Jersey Department of Health and Senior Services<br>Hazardous Substance Fact Sheet (revised May, 2002) and the MSDS for<br>this material, it can be a skin irritant, could possibly cause eye damage,<br>and if inhaled can be an irritant to the nose, throat, and lungs. Repeated<br>exposure could cause bronchitis to develop, according to the N.J.<br>Dept.of Health Fact Sheet. This information relates to SDBS substance<br>only. SDBS will be used as an ingredient with lactic acid in the fruit and<br>vegetable wash sold as "Antimicrobial Fruit and Vegetable Wash". This<br>product is then mixed and diluted in water in a produce-wash<br>sink/container. SDBS, once diluted, will result in a wash solution<br>containing less than 0.01% of SDBS maximum |
| 7. Is the substance, and any ancillary substances,<br>GRAS when used according to FDA's good<br>manufacturing practices? [§205.600(b)(5)]   |     | x  |     |  |
| 8. Does the substance contain residues of heavy<br>metals or other contaminants in excess of FDA<br>tolerances? [§205.600 (b)(5)]   |     | x  |     | SDBS contains impurities that include neutral oil (unsulfonated materials), arsenic (As), iron (Fe), and lead (Pb). (Estrin et al.1982). The level of these impurities was not defined. It is not clear if the new methods for formulating SDBS (as stated in the petition) further remove any of these impurities or not. SDBS used will be at least 91% pure.  |

#### Category 1. Adverse impacts on humans or the environment? Sodium dodecylbenzene sulfonate (SDBS)

# Category 2. Is the Substance Essential for Organic Production? Sodium dodecylbenzene sulfonate (SDBS)

| Question                                     | Yes | No | N/A | Comments/Documentation. (TAP;Petition;regulatory agency; other) |
|--|-----|----|-----|---|
| 1. Is the substance agricultural? [§6502(1)] |     | х  |     |   |

| 2. Is the substance formulated or manufactured                                       | х |   |   | There are multiple ways to manufacture SDBS: One process is by                |
|--|---|---|---|---|
| by a chemical process? [§6502(21)]   | X |   |   | reacting dodecylbenzene with sulfuric acid (Oleum Process) or air/SO2         |
|  |   |   |   | to produce dodecylbenzene acid (CTFA 1991a). The dodecylbenzene               |
|  |   |   |   | sulfonic acid is then neutralized with sodium hydroxide. The most             |
|  |   |   |   | common process is: Benzene is alkylated by long chain monoalkenes             |
|  |   |   |   | (e.g. dodecene) using hydrogen fluoride as a catalyst. The purified           |
|  |   |   |   | dodecylbenzenes (and related derivatives) then form dodecylbenzene            |
|  |   |   |   | sulfonic acid, which is then subsequently neutralized with sodium             |
|  |   |   |   | hydroxide (Kurt Kosswig, "Surfactants in Ullman's Encyclopedia of             |
|  |   |   |   | Industrial Chemistry, Wiley-VCH, 2005). The final slurry can then be          |
|  |   |   |   | dried by either drum drying (this forms flakes or powder) or by using a       |
|  |   |   |   | spray drier system (this forms beads). According to information provided      |
|  |   |   |   | in the petition the sulfonation technology has been considerably              |
|  |   |   |   | improved, with the modern systems beginning to use falling film               |
|  |   |   |   | reactors (FFR) (mono-tube or multi-tube) and SO3, in many of the              |
|  |   |   |   | sulfonation facilities in Europe. Also mentioned in the petition: in the      |
|  |   |   |   | mid 90's there was a new form of alkylation technology introduced that        |
|  |   |   |   | is now being used in Europe, based on heterogeneous catalyst in a fixed-      |
|  |   |   |   | bed reactor. This new   |
|  |   |   |   | technology offers: process simplification,                                    |
|  |   |   |   | elimination of acids handling and disposal                                    |
|  |   |   |   | (HF, HCI) as well as an overall production                                    |
|  |   |   |   | yield improvement and improved LAB  |
|  |   |   |   | quality.  |
|  |   |   |   |   |
|  |   |   |   |   |
|  |   | х |   |   |
| 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)]  |   |   |   |   |
| 4. Is the substance created by naturally occurring biological processes? [§6502(21)] |   | х |   |   |
| 5. Is there a natural source of the substance? [§                                    |   | х |   |   |
| 205.600(b)(1)]   |   |   |   |   |
|  | х |   |   |   |
|  |   |   |   | According to information provided by the petition citric or lactic acid       |
|  |   |   |   | could serve as possibly substitutes (For the AFVT product's intended          |
|  |   |   |   | use). AFVT is actually formulated with both lactic acid and SDBS. Lactic      |
|  |   |   |   | acid's microbial kill is enhanced with the addition of SDBS. Citric is an     |
| 6 is there an erganic substitute $2[8205,600(h)(1)]$                                 |   |   |   | organic acid that is approved for use on organic but is not commonly          |
| o. is there all organic substitute: [9205.000(D)(1)]                                 |   |   |   | משבע מש מ איוטעענים שמשוו עעם נט ונש וווצוו נטשג (4-שג נוום נטשג טו ומכנוכ).  |
| 7. Is the substance essential for handling of  |   | × |   |   |
| organically produced agricultural products?  |   |   |   |   |
| [9205.600(D)(6)]   |   |   |   |   |
|  | x |   |   |   |
|  |   |   |   | According to information provided by the petition either citric or lactic     |
|  |   |   |   | acid could possibly be used as a substitute for this material for microbial   |
|  |   |   |   | control. AFVT is actually formulated with both lactic acid and SDBS.          |
|  |   |   |   | Lactic acid's microbial kill is enhanced with the addition of SDBS. Citric is |
| 8. Is there a wholly natural substitute product?                                     |   |   |   | an organic acid that is approved for use on organic but is not commonly       |
| [9b517(C)(1)(A)(II)]   |   |   | I | used as a produce wash due to its high cost (4-5x the cost of lactic).        |

| 9. Are there any alternative substances?<br>[§6518(m)(6)]   | x |   | Yes for the overall intended use of the material (when used in the<br>finished product that the petitioner is requesting this material be added<br>to the National List so it can be used as one of two active ingredients in),<br>then acidified sodium chlorite or peracetic acid could be used instead.<br>But they do mention that these materials are more apt to be used in<br>commercial food processing establishments and not in restaurants,<br>kitchens, etc. as is the intended area of use proposed by the AFVT<br>product label.   |
|---|---|---|--|
| 10. Is there another practice (in farming or<br>handling) that would make the substance<br>unnecessary? [§6518(m)(6)]                       | x |   | Current processes in place utilizing materials already allowed for use in organic handling and processing.   |
| 11. Have the ancillary substances associated with<br>the primary substance been reviewed? Describe,<br>along with any proposed limitations. |   | x | Yes. SCIL - Review and Listing Process: Before Safer Choice decides to<br>include a chemical on the SCIL, a third-party profiler (i.e., NSF,<br>International or ToxServices) gathers hazard information from a broad<br>set of resources, including the identification and evaluation of all<br>available toxicological and environmental fate data. The third party<br>profiler submits a report to Safer Choice, with a recommendation on<br>whether the chemical passes the Criteria for Safer Chemical Ingredients.<br>Safer Choice staff performs due diligence by reviewing the submission<br>for completeness, consistency, and compliance with the Safer Choice<br>Criteria. If more than one third-party has evaluated the chemical, Safer<br>Choice also checks for differences in the profiles and resolves any<br>conflicts. In some cases, Safer Choice may also perform additional<br>literature reviews and consider data from confidential sources, such as<br>EPA's New Chemicals Program. SDBS limited to maximum 111 ppm in<br>diluted wash water.<br>Chemicals that exhibit endocrine activity are closely evaluated. Those<br>associated with toxicological hazards are not allowed. |

#### Category 3. Is the substance compatible with organic handling practices? Sodium dodecylbenzene sulfonate (SDBS)

Yes No

N/A Comments/Documentation. (TAP;Petition;regulatory agency; other)

|  | х |   |   |  |
|--|---|---|---|--|
| 1. Is the substance consistent with organic            |   |   |   |  |
| handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]     |   |   |   |  |
| 2. Is the manner of the substance's use,               |   | х |   |  |
| manufacture, and disposal compatible with              |   |   |   |  |
| organic handling? [§205.600(b)(2)]                     |   |   |   |  |
| 3. Is the substance compatible with a system of        |   |   | х |  |
| sustainable agriculture? [§6518(m)(7)]                 |   |   |   |  |
| 4. Are the ancillary substances reviewed               |   |   | х | none   |
| compatible with organic handling [?                    |   |   |   |  |
|  |   | х |   | No impact on nutritional quality. SDBS is a processing aid with no |
| 5. Is the nutritional quality of the food              |   |   |   | ongoing technical function/effect on or in food.                   |
| maintained with the substance? [§205.600(b)(3)]        |   |   |   |  |
| 6. Is the primary use as a preservative?               |   | х |   |  |
| [§205.600(b)(4)]                                       |   |   |   |  |
| 7. Is the primary use to recreate or improve           |   | х |   |  |
| flavors, colors, textures, or nutritive values lost in |   |   |   |  |
| processing (except when required by law)?              |   |   |   |  |
| [§205.600(b)(4)]                                       |   |   |   |  |

| Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? Sodium dodecylbenzene sulfonate |     |    |     |   |  |  |
|---|-----|----|-----|---|--|--|
| Question  | Yes | No | N/A | Comments/Documentation. (TAP;Petition;regulatory agency; other) |  |  |
|   |     |    |     |   |  |  |

|  | х | Few viable offerings in this space that are proven safe and effective and   |
|--|---|---|
| 1. Is the comparative description as to why the<br>non-organic form of the material /substance is<br>necessary for use in organic handling provided?   |   | easy to use by the foodservice handler  |
| 2. Does the current and historical industry<br>information, research, or evidence provided<br>explain how or why the material /substance<br>cannot be obtained organically in the<br>appropriate form to fulfill an essential function in<br>a system of organic handling?     | x |   |
| 3. Does the current and historical industry<br>information, research, or evidence provided<br>explain how or why the material /substance<br>cannot be obtained organically in the<br>appropriate quality to fulfill an essential function<br>in a system of organic handling?  | x | Citric is expensive; lactic not as effective by itself in the presence of high<br>organic loading (soil, field and microbiological contaminants) naturally<br>present on produce, fruits, vegetables coming in from the farm. |
| 4. Does the current and historical industry<br>information, research, or evidence provided<br>explain how or why the material /substance<br>cannot be obtained organically in the<br>appropriate quantity to fulfill an essential<br>function in a system of organic handling? | x |   |
| 5. Does the industry information about<br>unavailability include (but is not limited to) the<br>following?: a. Regions of production (including<br>factors such as climate and number of regions);   | × |   |
| b. Number of suppliers and amount produced;  | ^ |   |
| c. Current and historical supplies related to<br>weather events such as hurricanes, floods, and<br>droughts that may temporarily halt production or<br>destroy crops or supplies;  | × |   |
| d. Trade-related issues such as evidence of<br>hoarding, war, trade barriers, or civil unrest that<br>may temporarily restrict supplies; or  | x |   |
| e. Other issues which may present a challenge to a consistent supply?  | х |   |