Sodium Dodecylbenzene Sulfonate (SDBS)

Handling

Identification of Petitioned Substance

Chemical Names:

Sodium 4-dodecylbenzenesulfonate, Sodium p-dodecylbenzenesulfonate, linear alkylbenzene sulfonate, Decylbenzene sulfonic acid, sodium salt, Dodecylbenzene sulfonic acid, sodium salt, Tridecylbenzene sulfonic acid, sodium salt, Undecylbenzene sulfonic acid, sodium salt, Monoalkylbenzene sulfonic acid, sodium salt, Alkylbenzene sulfonic acid, sodium salt, C10-14 Alkyl deriv benzene sulfonic acid, sodium salt, C10-14 Monoalkylbenzene sulfonic acid, sodium salt, C10-13 Alkyl deriv benzene sulfonic acid, sodium salt, 10-13-sec Alkyl deriv benzene sulfonic acid, sodium salt, n-Dodecyl benzenesulfonic acid sodium salt isomers, Dodecylbenzenesulfonate sodium salt isomers, Sodium dodecylbenzene sulfonate, 2-dodecylbenzenesulfonic acid, sodium; 2-dodecylbenzenesulfonate, 3-dodecylbenzenesulfonic acid, sodium; 2-dodecylbenzenesulfonate, 4-dodecylbenzenesulfonic acid, sodium; 4-dodecylbenzenesulfonate

Other Name:

Linear alkylbenzene sulfonate, benzenesulfonic acid, dodecyl-, sodium salt,

Trade Names:

Nacconol 90G, Calimulse EM-96F, Ufaryl DL 90C

CAS Numbers:

2211-98-2, 1322-98-1, 25155-30-0, 26248-24-8, 27636-75-5, 68081-81-2, 68411-30-3, 69669-44-9, 85117-50-6, 90194-45-9, 127184-52-5, 19589-59-4

Other Codes:

Pubchem: 23671430, 4289524

EC Number: 218-654-2

UNII: HB2D2ZEI04,

InCHL Key: JHJUUEHSAZXEEO-UHFFFAOYSA-M,

Canonical SMILES: CCCCCCCCCCC1=CC-C(C=C1)S(=O)(=O)[O-].[Na+]

Summary of Petitioned Use

The petition requests the allowance of sodium dodecylbenzenesulfonate (SDBS) in organic food processing and handling. Specifically, the petition requests the addition of SDBS to the National List at 7 CFR 205.605(b) as an active synthetic ingredient in antimicrobial formulations used to treat organic fruits and vegetables.

Characterization of Petitioned Substance

Composition of the Substance:

Sodium dodecylbenzenesulfonates (SDBS) are colorless to cream color carbon containing salts with the representative formula $C_{12}H_{25}C_6H_4SO_3Na$. SDBS is generally one identified component of a mixture of compounds with variable alkyl chain lengths ranging from C10-C16. Most SDBS in use today are linear alkylbenzenesulfonates (LAS). The LAS molecule contains an aromatic ring sulfonated at the para, 4- position and attached to a linear alkyl chain at any position, i.e., meta, 2- position and ortho, 3- position, except the terminal carbons (Fig 1). The linearity of the alkyl chains ranges from 87 to 98%. While commercial LAS consists of more than 20 individual components, the ratio of the various homologs and isomers, representing different alkyl chain lengths and aromatic ring positions along the linear alkyl chain, is relatively constant in currently produced products, with the weighted average carbon number of the alkyl chain based on production volume per region between 11.7-11.8. Because the mean carbon chain length is approximately 12, dodecylbenzenesulfonate is considered representative of the entire class of compounds. Linear dodecyl-4-

benzenesulfonate anions can exist in six isomers (ignoring optical isomers), depending on the carbon of the dodecyl group that is attached to the benzene ring. Branched isomers, e.g. those derived from tetramerized propylene, are also known (OECD, 2005; EPA, 2006).

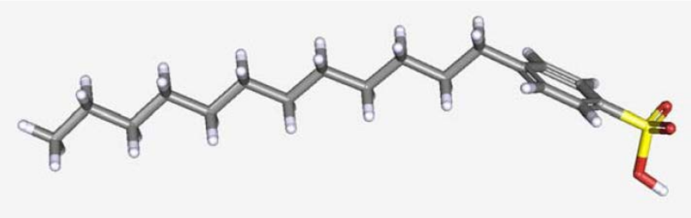

Fig. 1 Linear Sodium Dodecylbenzensulfonate (para isomer)

(hydrogen=white, carbon=grey, sulfur=yellow, oxygen =red)

(Pubchem, 2017)

Source or Origin of the Substance:

In the 1940s and 1950s, before the introduction of SDBS to the surfactant industry, branched dodecylbenzenesulfonate sodium (DDBS) was a popular surfactant widely used in detergents.

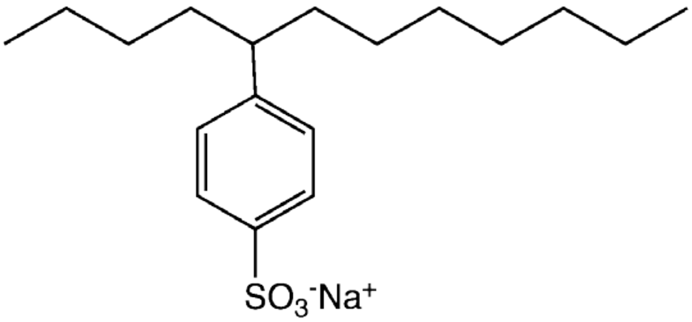

Fig 2. Branched chain dodecylbenzenesulfonate sodium

DDBS differs only slightly in chemical structure from SDBS (Fig 2). It originated from the petroleum feedstocks, propylene and benzene. DDBS was not very biodegradable. As a result, linear alkybenzenesulfonates (LAS) including SDBS have largely replaced DDBS, since the 1960s. LAS is highly synthetic and sourced from crude oil products: paraffin, benzene and sulfur (Vora et al., 1990). Linear alkyl benzene (LAB), the LAS precursor is produced from benzene and C_{10} to C_{14} linear olefins (unsaturated alkyl or hydrocarbon compounds) in a liquid phase under mild conditions (Berna et al., 2000; Imai et al., 1994). The catalytic technology behind the process for alkylating benzene to produce LAB has evolved since the 1960's. Aluminum trichloride and highly corrosive hydrofluoric acid were the first to be used. Both catalysts are still currently used in many manufacturing plants, but more eco-friendly solid state and desilicated zeolite catalysis are in development or have also come into use (Aslam et al., 2014; Aitani et al., 2014). Although sulfuric acid was originally used as the sulfate donor in the sulfonation step for LAS production, sulfonation is now largely carried out with sulfur trioxide (Fig 3). Sulfur trioxide (SO_3) reacts with an alkylbenzene carbon forming a sulfur carbon bond to produce a stable molecule. This reaction is rapid and highly exothermic. There is also a large increase in viscosity associated with sulfonation of LAB. There are many optimizations for this process, one of which is the use of sulfur produced by fossil fuel desulfurization as the SO_3 starting material (Foster, 1997).

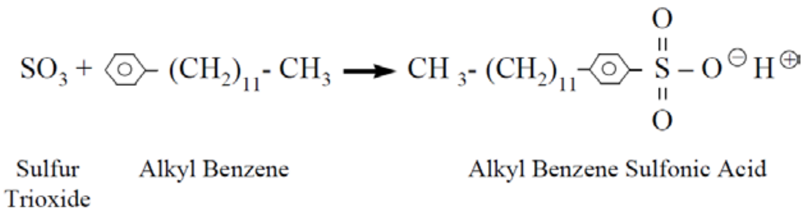

Fig. 3 Sulfonation of linear alkylbenzene

Properties of the Substance:

The molecular weight of SDBS (LAS) ranges from 338 (C11.3) to 356 (C12.6) depending on alkyl chain length. The weight percentage of isomers also varies regionally (Table 1). The representative average C12 linear species, sodium 4-dodeocylbenezenesulfonate, sodium salt has a molecular weight of 348.477 grams/mole. Its melting point is greater than 198.5^{o}C. SDBS boiling point is above the temperature for its decomposition. The melting and boiling points for SDBS increase as the length of the carbon chain increases. SDBS has a relative density of 1.06 grams/cubic centimeter. The bulk density for SDBS ranges from 450-550 kilograms/cubic meter. Commercially prepared SDBS is usually greater than 95% pure, although non-linear alkylbenzene sulfonates like diakyltetralin sulfonates may be present at 1-8% depending on the manufacturing process. SDBS is water soluble with a critical micelle concentration of 0.1 grams (g)/Liter (L) and forms a clear solution in water at concentrations up to 250 g/L. The pH of SDBS is 10.0±0.1. Its PKa is <1 (OECD, 2005).

Table 1 Linear Alkylbenzenesulfonates Carbon Weight Percentage by Region

Region/CAS number	<C10	C10	C11	C12	C13	C14	>C14	Range of Averages	Weighted Average*
United States 1322-98-1** 25155-30-0 26248-24-8** 27636-75-5** 68081-81-2 69669-44-9 85117-50-6 90194-45-9	<2	1-25	7-50	20-50	5-45	<1-10	<1	11.3-12.6	11.7
Canada 68081-81-2	≤1	<16	19-39	20-50	5-27	<3	<1	11.8	11.8
Europe 25155-30-0 68081-81-2 68411-30-3 85117-50-6 90194-45-9 127184-52-5	≤1	8-20	19-39	20-50	5-27	<1-3	<1	11.6-11.8	11.7
Japan 68081-81-2 68411-30-3 69669-44-9	≤1	7-16	19-39	20-50	5-27	<1-3	<1	11.7-11.8	11.8

* Weighted by production volume for each region.

**Manufacture of LAS under these CAS numbers has recently been discontinued.

adapted from OECD, 2005

Specific Uses of the Substance:

SDBS is used as a sanitizer added to fruit and vegetable wash water. SDBS affects the performance of wash water by improving removal of surface bacteria, reducing the transfer of planktonic bacteria, and lowering the risk of cross contamination. Raw and processed fruits and vegetables are immersed for 90 seconds in water that contains SDBS and drained prior to further processing and/or serving. The US FDA does not require produce to be rinsed after treatment, therefore; residual SDBS may remain on the treated product. The treatment is meant to improve product safety and extend shelf life.

Approved Legal Uses of the Substance:

US Environmental Protection Agency (EPA)—40 CFR sections 116.4, 117.3, and 302.4—SDBS has been designated as a hazardous solid substance under section 311(b)(2)(A) of the Clean Water Act. SDBS discharged in quantities greater than 1000 pounds (EPA category C) must be reported to the appropriate agency.

US Food and Drug Administration (FDA)—21 CFR 173.405—SDBS may be safely used in accordance with the following prescribed conditions:

> (a) the additive is an antimicrobial agent used in wash water for fruits and vegetables. The additive may be used at a level not to exceed 111 milligrams per kilogram (mg/Kg) in the wash water. Fruits and vegetables treated by the additive do not require a potable water rinse.
>
> (b) The additive is limited to use in commissaries, cafeterias, restaurants, retail food establishments, nonprofit food establishments, and other food service operations in which food is prepared for or served directly to the consumer.
>
> (c) To assure safe use of the additive, the label or labeling of the additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions to assure use in compliance.

FDA—21 CFR 178.1010—SDBS sanitizing solutions (not less than 25 mg/Kg, not more than 430 mg/Kg) may be safely used on food-processing equipment and utensils, and on other food-contact articles as specified in this section, within the following prescribed conditions:

> (a) Such sanitizing solutions are used, followed by adequate draining, before contact with food.
>
> (b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval. An aqueous solution containing SDBS may be used on food-processing equipment and utensils, and glass bottles and other glass containers intended for holding milk.

US Department of Agriculture—A petition has been received by the USDA National Organic program for addition of SDBS to the National List.

Action of the Substance:

SDBS is a surfactant (detergent) that dissolves in water. Some surfactants have the potential to disrupt some bacterial membranes, subsequently changing their structure, attachability and permeability (Zhang and Rock, 2008; Henriksen et al., 2010). Surfactants can denature some bacterial proteins and inactivate some bacterial enzymes on the bacterial outer membrane involved in ionic transport. Detergents and surfactants also have the potential to loosen bacterial biofilms from food surfaces, so that they may be more easily washed away with water. Often however, bacterial biofilms are resistant to this type of treatment (Costerton, 1999; Lapidot et al., 2006; Ren et al., 2013). Studies of the efficacy of various commercial detergent formulations in reducing human pathogens on inoculated fruits and vegetables and comparisons with other treatments have been reported for apples, strawberries, cantaloupe, tomatoes, and lettuce. Results from these studies indicate that detergent washes sometimes can achieve bacterial population reductions of 100 to 1000 fold, equaling or surpassing sodium hypochlorite, but in other cases showed no greater efficacy than water (Sapers, 2014). For example, a 0.2% (200 ppm) solution of SDBS had the same efficacy as a water wash in reducing Escherichia coli O157:H7 bacterial load on romaine lettuce (Keskinen and Annous, 2011).

Table 2 Other substances added to SDBS in petitioned produce wash-water additive*

Substance Name	CAS No.	Stated Function	National List Disposition
Lactic Acid	50-21-5/79-33-4	Active, Organic Acid	Allowed for processing
Tween 80	9005-65-6	Surfactant	Allowed with restrictions for pesticides
Xanthan Gum	11138-66-2	Thickener	Allowed for processing
Propylene Glycol	57-55-2	Coupler	Allowed for processing
Silicone Emulsion Antifoam	63148-62-9	antifoam	Prohibited substance for organic production and handling
Sodium Acid Sulfate (Sodium bisulfate)	7681-38-1	acidulant	Petitioned for addition to the National List
Ethylene glycol-propylene glycol polymer	9003-11-6	surfactant	Prohibited substance for organic production and handling
FD&C Green #3	2353-45-9	Dye	Prohibited substance for organic production and handling
FD&C Yellow #5	1934-21-0	Dye	Prohibited substance for organic production and handling

*Source: SDBS Petition. Available on NOP website at https://www.ams.usda.gov/sites/default/files/media/SDBS%20Petition.pdf

Combinations of the Substance:

In addition to SDBS, other active and inert components are added in the petitioned formulation. These are listed in table 2. SDBS has been used in combination with phosphoric acid to reduce Escherichia coli O157:H7 on apples (Wright et al., 2000). Treatments with phosphoric acid and SDBS have an antimicrobial effect reducing bacterial populations by 10 to 100 fold (Sapers et al., 2001). Phosphoric acid is allowed in organic production for use as an equipment cleaner, cleaning of food contact surfaces only and to adjust the pH of liquid fish fertilizer (§. 205.605(b), (j)(7)

Status

Historic Use:

A federal rule entitled "Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate" (Docket No. FDA-2011-F-0853-001), was received in the Office of the President of the US Senate on December 6, 2012 (US Senate, 2012). The rule gave notice of a petition filed by Ecolab, Inc. proposing that the food additive regulations be amended to provide for the safe use of SDBS as an antimicrobial agent in produce wash water without the requirement of a potable water rinse. The final rule became effective December 4, 2012 (FDA-2011-F-0583-0006). Only one comment was received for the petition, but no comments were received for the amendment's final rule. The commenter did not support the use of SDBS as a food sanitizer and indicated a need to wash off the material after use.

Organic Foods Production Act, USDA Final Rule:

SDBS is not listed in the OFPA (7 U.S.C. 6501 *et seq.*) or in current USDA organic regulations (7 CFR Part 205).

International

Canada - Canadian General Standards Board Permitted Substances List. This list was updated in November 2015.

SDBS is not listed in the CAN/CGSB-32.311-2015 — Organic production systems - Permitted substances lists.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

SDBS is not listed in Codex Alimentarius GL 32-1999.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

SDBS is not listed in EC No. 834/2007 or 889/2008.

Japan Agricultural Standard (JAS) for Organic Production

SDBS is not listed in the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) standards for organic production.

International Federation of Organic Agriculture Movements (IFOAM) –

SDBS is not listed in the IFOAM norms for organic production.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Linear alkylbenzenesulfonate (LAS) produced from linear alkylbenzene (LAB) replaced the branched chain product (DDBS) in detergents in the 1960s because of its rapid biodegradation. LAS has since become the surfactant of choice for use in in detergents throughout the world. SDBS the sodium salt of LAS is a mixture of compounds. The mixture is composed of different carbon chain homologs, different phenyl isomers and different amounts of the coproduct dialkyltetralin sulfonate (Fig 4).

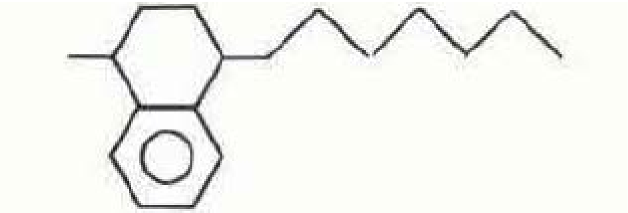

Fig 4. One possible isomer of dialkyltetralin (Smith, 1997)

The manufacturing process determines SDBS's composition and specific application performance level which is evaluated based on surface tension, solubility, viscosity, foam stability and detergency. Viscosity and solubility are affected by the phenyl isomer distribution and the dialkyltetralin sulfonate concentration (Smith, 1997). Linear alkylbenzene is produced from linear paraffins and benzene, both products of crude oil feedstock. There have been three major developments in the production of LAB along with a number of process refinements (Vora et al., 1990). The major developments are improvements in the catalysis of the dehydrogenation of n-paraffins to n-olefins and subsequent alkylation of benzene. The improvements have incorporated environmentally favored processes, and increased selectivity for the 2-LAB isomer. The technologies include: 1) aluminum chloride ($AlCl_3$) catalysis to alkylate benzene with a mono-chloroparaffin, 2) hydrofluoric acid catalysis of benzene alkylation with dechlorinated, wax cracked linear olefins or dehydrogenated linear paraffins and 3) solid state (zeolite) catalysis of linear paraffins (Kocal et al., 2001; Han et al., 2003; Aslam et al., 2014). Fig 5 shows the effects of each of the catalytic methods for producing LAB on its quality: high 2-phenyl/low diakyltetralin is the most desirable and environmentally friendly result (Smith, 1997).

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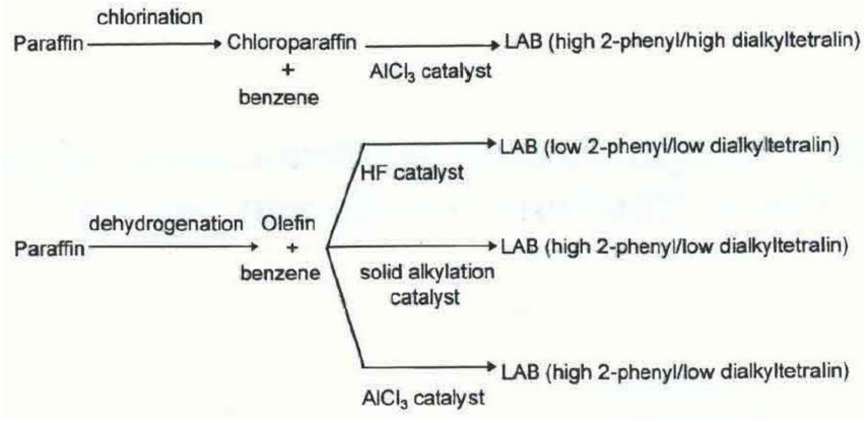

Fig 5. Various catalytic technologies and their effect on LAB quality *from* Smith, 1997.

Linear alkylbenzene sulfonate (LAS) is predominantly made by sulfonation of LAB with sulfur trioxide, although in the past sulfuric acid was widely used and is still not completely obsolete in this role. Production scale sulfonation plants commonly have a dedicated sulfur burning/catalytic conversion unit to produce a gaseous mixture of sulfur trioxide and air which is fed directly to the sulfonation reactor (Roberts, 2003). Figure 6 shows the reaction for producing a sulfonate. Sulfur trioxide (SO_3) reacts with LAB to form a sulfur-carbon bond resulting in alkyl benzene sulfonic acid, a stable molecule (Foster, 1997).

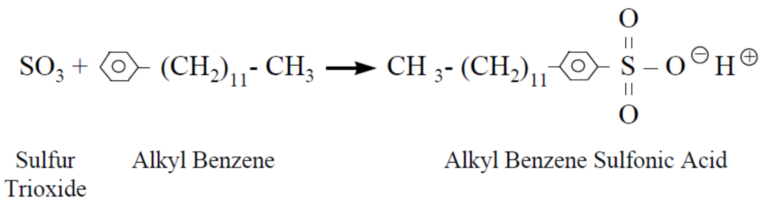

Figure 6. Sulfonation of LAB (*from* Foster, 1997)

<u>Evaluation Question #2:</u> Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

SDBS manufacture is based on a chemical synthesis production scheme from petroleum feedstocks: dehydrogenation, alkylation and sulfonation with potentially halogenated intermediates. There is no natural process for producing SDBS. SDBS is produced from kerosene or paraffin and benzene from crude oil feedstocks. Sulfonation requires the use of sulfuric acids or burning elemental sulfur also from fossil fuel feedstocks. There is no agricultural source or feedstock for the production of SDBS.

<u>Evaluation Question #3:</u> If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

There is no natural source or feedstock for SDBS.

<u>Evaluation Question #4:</u> Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

SDBS is included in the US FDA Food Additive Status list. It is a substance that has a miscellaneous technical effect and is a food additive for which a petition has been filed and a regulation issued. It is specified in this list for < 0.2% in wash water as a surface active agent in commercial detergents used in washing fruits & vegetables, or to assist in lye peeling these products, 21 CFR 173.315. However, SDBS is not GRAS.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

SDBS is added to water as a washing aid. Fruit and vegetable products are washed with water and sanitizing agents primarily to remove soil and pesticide residues, but also to remove or inactivate human pathogens and spoilage causing bacteria. Reducing microbial populations through washing potentially improves the shelf life of produce. However, this effect does not constitute evidence that SDBS is a preservative (Sapers, 2014). In addition to its action as a sanitizer, detergents have been shown to be useful in removing pesticide residues from the surface of fruits and vegetables (Wang et al., 2013).

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

SDBS is added to fresh produce wash-water as an aid in the removal of surface bacteria. Except for residual SDBS remaining on the produce at produce species dependent levels up to 10 ppm, SDBS does not contribute to the flavor, color, texture or nutritive value of the product (Watanabe et al., 1972).

Evaluation Question #7*:* Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

SDBS is introduced into wash water service to improve the removal of soil and bacteria attached to the surface of produce. If used according to the US FDA instructions it does not penetrate into the produce being wash and subsequently its application does not affect the nutritional quality of the food (Sapers, 2014).

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

SDBS in the form and purity used in produce wash water does not normally contain toxic levels of the heavy metals or contaminants listed by the FDA in its list of chemical contaminants, metals, natural toxins and pesticides guidance documents and regulations, e.g. Aflatoxins, acrylamides, dioxins, PCBs, melamine or radionuclides.

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Detergents such as SDBS, are developed ostensibly according to green chemistry principles, i.e. producing environmentally benign products in environmentally friendly ways. Branched long chain alkylbenzenesulfonate detergents were introduced in the 1940s and because of their improved detergency largely replaced natural soaps in household laundry and dishwashing applications and in industrial applications. This increase of use and subsequent disposal led to accumulations in rivers and streams resulting in environmental damage. Linear alkylbenzenesulfonates (LAS) replaced the branched products in the 1960s improving biodegradability and environmentally acceptability of the product. There are still stringent product characteristics to ensure acceptability and prevent reintroduction of the branched product into the environment. Current manufacturing practice for (LAS) requires chemical catalysis which depending on the specific catalyst used can produce environmental pollution and equipment corrosion. For example, in 2014 aluminum chloride, hydrofluoric acid and solid acid, all corrosive and potential pollutants respectively accounted for catalysis of 2.7, 64 and 33.3 percent of the 3.6 million ton/year world capacity for SDBS production. The use of homogeneous zeolite catalysis can reduce much of the pollution associated with current catalytic methods, but the zeolite method is still in the developmental stages and there is still much work ahead in improving the manufacturing process (Aitani et al., 2014).

After use, surfactants are mainly discharged into sewage treatment systems and dispersed into the environment as effluent discharge into surface waters and sludge disposal on agricultural land (Ying, 2006). The average LAS concentration found in many municipal wastewater treatment systems is 1-10 milligrams per liter, mg/L (Manousaki et al., 2004). Anionic surfactants such as LAS are not readily adsorbed to soil, but are degraded by microbes in the environment except under anaerobic conditions. Under anaerobic conditions, the half-life of LAS in sludge amended soils is estimated to be 7 to 33 days. As a result, LAS may be amended into agricultural soils. LAS is not acutely toxic to organisms at environmental concentrations. Aquatic chronic toxicity of surfactants occurs at concentrations usually greater than 0.1 mg/L (Ying, 2006). However, LAS has been shown to be environmentally present in various parts of the world at levels above accepted no effect concentrations (Rebello et al., 2014). Treatment of LAS from effluents using low frequency sonochemical degradation has been found to improve its biodegradability (Manousaki et al., 2004).

Because the preferred method for disposal of sewage sludge is as a soil fertilizer it is important to consider that LAS is slow to biodegrade under anaerobic conditions where oxygen is limited. However, several government public safety evaluators have concluded that LAS does not represent an environmental problem (HERA, 2013; OECD, 2005; EPA, 2006). The fate of LAS in the environment is described in Fig 7.

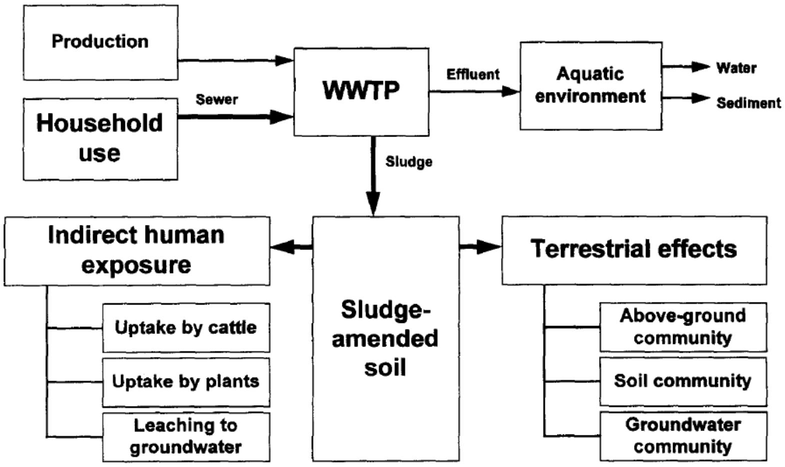

Fig. 7 Fate of linear alkylbenzene sulfonate in the environment. WWTP=Waste Water Treatment Plant. (Wolf and Feijtel, 1998).

The lowest reliable values for acute lethal concentration 50%(LC50), effective concentration 50%(EC50), and effective reduction of growth rate 50% (ErC50) based on an Organization for Economic Cooperation and Development (OECD) review of the aquatic toxicity data on commercially representative LAS (C11.6-C11.8) respectively were 1.67, 1.62 and 29.0 mg/L for fish, *Daphnia magna*, and algae. Chronic freshwater toxicity studies following guideline exposures (28-30 days for fish, 21 days for invertebrates and 3-4 days for algae provided the following no observable effect concentration (NOEC) values: fish NOEC = 1 mg/L (two studies, two species); Daphnia, NOEC = 1.18-3.25 mg/L (six values, two studies, one with 5 diets); algae, NOEC = 0.4-18 mg/L (four studies, two species). In addition all of the available, reliable chronic single species aquatic toxicity data on SDBS have been evaluated, including three freshwater species in which multiple studies were reported and nine freshwater species for which single studies were reported. Single NOEC values and geometric mean NOEC values (calculated for species with multiple results) were normalized to C11.6 LAS. These NOEC values range from 0.25 to 6.1 mg/L for freshwater species, including fish, invertebrates, algae and higher plants. Geometric mean NOEC values for marine species ranged from 0.025 to 5.0 mg/L. Based on the model ecosystem studies, a NOEC of 0.27 mg/L (0.37 if normalized to C11.6 LAS) was determined for the freshwater ecosystem. This value is based on model stream ecosystem studies of over 250 species, and is consistent with the single species chronic freshwater data. NOEC values for sediment exposures were greater than or equal to 81 mg/kg dry matter based on studies in four species, including GLP studies in *L. variegates* (survival, reproduction and growth over 28 days) and *C. elegans* (egg production, 3 days). Field studies indicate no adverse effects of LAS in sludge-amended soil from LAS levels of 15 mg/kg dry matter in the soil (9 microbial functions/processes and abundance/diversity of microarthropods and earthworms, short-term and 4 years) or 31,300 mg/kg dry matter in sludge, function of microbial community, short-term and 1 year (OECD, 2005).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

LAS is readily absorbed from the gastrointestinal tract. Most of the absorbed dose is eliminated in the urine with sulfophenyl butanoic and sulfophenyl pentatonic acid as metabolites (Michael, 1968). Rats fed a diet of radiolabeled LAS (mixed isomers), eliminated only 8% of the radioactivity after a one week clearance diet began. Most of this radioactivity was in the feces. In contrast, 84.7% of an abdominal injection of radiolabeled LAS was cleared by rats within 24 hours (Lay et al., 1983). The position of the benzene sulphonate moiety substitution in SDBS affects the route of SDBS removal in rats. While the 2-isomer is mostly found in the urine, the 6-isomer is mostly found in feces (Rennison et al., 1987). Toxicity studies in rats determined the lethal dose 50 (LD50) at 0.65 g/kg. At doses below this level, rats did not exhibit developmental abnormalities, except diarrhea (Osar and Morgaeidge, 1965). Rats fed a diet supplemented with up to 0.5% LAS for 90 days did not show any adverse effects (Kay et al., 1965). After a diet supplemented with LAS, rats exhibited a reduction of glucose tolerance compared to controls (Antal, 1973). LAS after administration of single and repeated oral and subcutaneous doses to rhesus monkeys was mostly excreted in the feces and urine within the first 24 hours. The excreted material was unchanged LAS (Cresswell et al., 1978). Undiluted LAS is an irritant to the skin and eyes. In general at the concentrations used in practice, LAS is not a sensitizer or an irritant (HERA, 2013). A systemic no observed adverse effect level (NOAEL) of 68 mg/kg has been established. In a rat study where LAS was administered in drinking water a NOAEL was determined at 85 mg/kg BW/day (OECD, 2005). Based on an evaluation of oral exposure from LAS use on dinnerware and for food washing (fruits and vegetables) the oral exposure for people is 1.94 x 10^{-3} mg/kg body weight/day. LAS is not carcinogenic or teratogenic (HERA, 2013).

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Keeping fresh produce products free of soil and reducing the potential for bacterial contamination of produce during pre and postharvest is a FDA requirement (Public Law 111-353, 111th Congress, Food Safety Modernization Act). Several documents address postharvest contamination including: Guide to minimize microbial food safety hazards for fresh fruits and vegetables, and General principles of food hygiene.

SDBS use is limited to commissaries, cafeterias, restaurants, retail food establishments, nonprofit food establishments, and other food service operations in which food is prepared for or served directly to the consumer. It is a surfactant that when dissolved in water reduces its surface tension. Reducing the surface tension of water also reduces the ability of bacteria to adhere to the surface of fresh produce (Brandl and Huynh, 2014). The addition of SDBS to produce wash water facilitates the removal of bacteria from the surface of produce (Sapers, 2014). However, it is much easier to prevent contamination of products from the first steps of the food production process than to remove contamination later in the process or at the point of use (Sapers, 2003). For example by washing, temperature control, proper food handling and good food worker hygiene.

Much of pre and post-harvest contamination is considered to be of fecal origin, but there is no scientific evidence to imply that the use of manure in cultivation plays a role in microbial contamination if produce is properly washed and preparation facilities are appropriately cleaned and sanitized (Oliveira et al., 2010; Seow et al., 2012). According to the FDA revised microbial load limits, generic *Escherichia coli* in water or any product should remain less than 2.35 colony forming units per gram (cfu/gm) for any single sample (FDA, 2015). No one washing method is completely effective to maintain this microbial load, or equivalent microbial loads for other bacterial species, and even the most effective method only can reduce microbial loads by about one thousand fold without affecting the quality of the produce (Sapers, 2015a). However, SDBS is not effective for every microbial pathogen found on produce and is not significantly different than washing with water for some pathogens. For example, SDBS reduces Escherichia coli O157:H7 by less than ten-fold when used for washing romaine lettuce (Keskinen and Annous, 2011).

Epidemiological outbreak data repeatedly identify 1) improper holding temperatures, 2) contaminated equipment, 3) food from unsafe sources, and 3) poor personal hygiene as major foodborne illness risk factors related to employee behaviors and preparation practices for produce in retail and food service establishments. The FDA Food Code addresses controls for these risk factors as demonstration of knowledge, employee health controls, controlling hands as a vehicle of contamination, time and temperature parameters for controlling pathogens and consumer advisory. The Food Code establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities and provides for food establishment plan review, permit issuance, inspection, employee restriction, and permit suspension (FDA, 2013).

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. It is also important that food handlers are knowledgeable concerning the temperatures at which produce is kept during storage and preparation and the use of thermometers for this determination, i.e. washing with water that is 41°F or less (Pilling et al., 2008).

Food handler education, particularly in providing training in handling potential microbial contamination, e.g. cleaning and drying food contact surfaces, use of potable water and disclosure of microorganisms with testing is critical for sustainable food safety (Walters, 1951). Post-harvest produce may be washed and rinsed with potable water. Even if peeling or otherwise altering the form of the produce is intended, it is still important to remove soil and debris first (FDA, 2013). An aerated water wash can reduce bacterial loads on vegetables by 10 to 100 fold. Since the quality of wash water and the potential for its contamination affect the quality of the washing process, water must be frequently changed between washes. Aqueous sodium or calcium hypochlorite can reduce the bacterial load 300 to 20000 fold on food surfaces and equipment and it is effective for pathogens such as Salmonella, Listeria and E. coli O157:H7 (Gil et al., 2009). A combination of disinfectant agents including lactic acid, citric acid and thyme essential oil solution, citric acid has been reported to maintain both sensory and microbial quality of the produce (Allede et al., 2006).

As an example, external leaves of whole lettuce have been found to have bacterial counts approximately 10 fold higher than subsequent inner leaf layers. Only a slight decrease in count was noticeable as interior layers were sequentially removed. A standard washing in tap water resulted in the removal of an average of 92.4% of the lettuce leaf microflora. Thus, removal of the outer leaf layer is an essential first step in reducing the overall contamination on prepared lettuce. Washing in tap water removes an additional 92%. Washing at 4°C and extending the wash time from 10 minutes to 20 minutes further increased the bacterial reduction (Adams et al., 1989).

The source of food is important because pathogenic microorganisms may be present in the farm environment, in waters, and in soils in which plant crops are grown (FDA, 2013).

Handwashing is not done frequently enough in many food service establishments and recommended methods are not always followed. Handwashing is frequently skipped between handling unwashed or ready to eat food. Improving handwashing frequency can improve hygiene (Strohbin et al., 2008). A before–after study conducted on 150 randomly selected food handlers revealed microbial contamination the hands of 72.7% of food handlers. Within one month after training in personal sanitation and handwashing, there was a significant decline in hand contamination of the food handler from 72.7% to 32% demonstrating the affect that simple handwashing can have on sanitation (Shojaei et al., M., 2006).

<u>Evaluation Question #12:</u> Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

The safe drinking water act requires that drinking water depending on its source meets specific criteria determining the need for a combination of filtration and treatment with chlorine to remove pathogenic organisms. Chlorine is described in the Safe Drinking Water act as an alternative to filtration. Water can also be filtered through a 0.22 micron or less filter to remove bacteria (CDC, 2008). Water can be used to rinse surfaces and food. Hot water, near 100°C will reduce microbial contamination. Chlorine solutions are considered to be highly corrosive, especially at low pH, and will shorten the life of tanks and other stainless steel equipment used in produce processing. In addition potential mutagenicity and carcinogenicity from exposure of food constituents to chlorine reaction products has caused some concern resulting in regulatory restriction (Sapers, 2015a). Electrolyzed water, sodium and calcium hypochlorite and peroxyacetic acid are synthetic alternatives.

Sanitizing washes are the most practical means of decontaminating raw produce. Solutions containing chlorine compounds (with concentrations varying from 50-200 ppm) and with contact times of 2 minutes or greater can provide a decrease in the bacterial load by <1 log colony forming units (CFU)/gram (g) to 3.15 log CFU/g (Keskinen et al., 2009).

Essential oils are known to be effective against a wide spectrum of micro-organisms leaving no detectable residues. *Cinnamomum zeylanicum* (L.), commonly known as cinnamon is rich in cinnamaldehyde as well as β-caryophyllene, linalool and other terpenes. Cinnamaldehyde is the major constituent of cinnamon leaf oil and provides the distinctive odor and flavor associated with cinnamon. Cinnamon oil is produced by steam distillation. It is used worldwide as a food additive and flavoring agent, and the Food and Drug Administration lists it as "Generally Recognized as Safe-GRAS." Cinnamon oil is one of a number of fungistatic essential oils, also including lemongrass, rosemary, lavender and basil oils (Tzortzais, N., 2009). Other essential oils extracted by steam distillation from rosemary, oregano, lemongrass, sage, clove, thyme, turmeric and tea bush have also proven microbiocidal against a number of bacterial pathogens including *Listeria monocytogenes*, *Salmonella typhimurium*, *Escherichia coli O157:H7*, *Shigella dysenteria*, *Bacillus cereus* and *Staphylococcus aureus* (Burt, 2004).

Grapefruit Seed Extract (GSE) has been shown to possess antibacterial, antiviral, antifungal and antiparasite properties. Containing polyphenolic compounds and the citrus flavonoid, e.g. naringenin, GSE alone or in combination with organic acids has be shown to be effective as a washing aid in significantly reducing *Salmonella spp.* and *Listeria monocytogenes* on cucumber and lettuce (Xu et al., 2007).

Although soap should not be used to clean produce or food, organically produced soap can be used to wash and clean food contact surfaces. Sodium chloride at concentrations greater than 10% can be used to disinfect surfaces and water (Somani et al., 2011).

<u>Evaluation Information #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

Hypochlorous acid has been used as a broad spectrum microbial decontamination agent. This solution is generated by the electrolysis of a diluted water-sodium chloride solution passing through an electrolysis chamber facilitating the conversion of chloride ions and water molecules into chlorine oxidants (chlorine gas, hypochlorous acid, and hypochlorite ion) within the anode chamber. At an acidic to neutral pH, the predominant chemical species is hypochlorous acid (HOCl) with a high oxidation reduction potential (ORP) of ≥1,000 mV (Guentzel et al., 2008).

Organic Acids (e.g., ascorbic acid, citric acid, lactic acid, lactates, tartaric acid, malic acid and organic vinegar (acetic acid)) and organic essential oils have been used as organic disinfectants (Table 3) with varying amounts off microbial pathogen reduction (Cooper, 2007; Ricke et al., 2012). The antimicrobial efficacy of citric acid has been documented against foodborne microorganisms in fluid medium (Ricke et al., 2012). The bacteriocins are bacterial polypeptides with antimicrobial properties (Ricke et al., 2012).

Egg white lysozyme has also been used as an antimicrobial (Ricke, 2012). A one hundred milligrams per kilogram sprayed on solution of egg white lysozyme has been shown to be effective in reducing inoculated *Listeria moncytogenes* in some vegetables. Lysozyme is often used in combination with ethylene diamine tetraacetic acid, a chelator which is prohibited in organic production, to improve its effectiveness (Hughey et al., 1989; Cunningham et al., 1991).

Biocontrol agents are envisioned as viable and sustainable alternatives for pathogen control in fresh produce. Their purpose is to control both pathogens that cause spoilage of fruits and vegetables and human pathogens that colonize produce. Only a handful of products have been made available commercially targeting mostly plant pathogens. Many of these are epiphytic yeasts and bacteria, but results have been inconsistent (Droby et al., 2016). The use of bacteriocinogenic bioprotective bacterial strains and probiotics in edible gellan or alginate coatings are also being investigated as a quality preservation method (Corbo et al., 2015). Bacteriocins and endolysins are molecules that specifically induce the lytic destruction of other bacteria. They are produced by lactic acid bacteria, but other bacterial species make them as well. The bacteriocins are very effective in controlling both plant and human pathogens on fresh produce. The delivery methods for both isolated bacteriocins and the bacteria that produce them are still under commercial development (Barcia et al., 2010).

Table 3. Alternative disinfection methods with their advantages and disadvantages*

Treatment	Advantages	Disadvantages
Ozone	Effective disinfectant kills rapidly	Must be produced on site, harmful to humans
Hydrogen Peroxide (H_2O_2)	Potential as disinfectant	Affects sensory qualities of some products, harmful to humans and not applicable to all products
Organic Acids	Effective alone or in combination with other sanitizers, simple products such as lemon juice, or vinegar may be used	Not useful for all products, may have adverse effects on sensory qualities, may lead to loss of germination percentage when used on seeds
Organic Essential Oils	Most effective for gram positive bacteria	Gram negative bacteria are more resistant, adverse sensory effects
High Temperatures	Successful disinfection method	Not applicable to all products consumed raw
Biocontrol and non-thermal process	Not well tested in fruit and vegetable products	High cost, not enough research.

*Adapted from Cooper et al., 2007

Interactions between foodborne pathogens and plants as well among the naturally occurring microbial communities contribute to endophytic and epiphytic colonization of fresh produce. There are a number of factors, such as produce type, cultivar, and physiological state of the plant and pathogen that influence the colonization of foodborne pathogens on produce. Table 4 shows how bacteria can colonize produce. For example in soils contaminated with pathogenic bacteria, members of the Brassicaceae family (radish, turnip, and broccoli) had a higher prevalence of Salmonella contamination than did lettuce, tomatoes, and carrots. The leafy greens, radicchio and endive are contaminated more frequently than lettuce, spinach, parsley, or cilantro. Bacteria colonize produce differently depending both on the bacterial serovar and the plant cultivar: this is especially true for Salmonella colonization of lettuce varietal cultivars and *Escherichia coli* O157:H7 colonization of spinach cultivars, respectively where some cultivars are resistant to Salmonella or E. coli O157:H7. Bacterial attachment varies among serovars, the bacterial appendage for attachment to alfalfa and tomatoes is present on E. coli O157:H7 but not on non-pathogenic E. coli K12. Thus, good colonization of normal E. coli will exclude E. coli O157:H7. Biofilm formation is also influenced by the bacterial serovar and the plant's surface determined by its variety (Critzer and Doyle, 2010).

There is variability in the internal defense systems for producing bacteriocins to defend against specific bacteria and in the oxidative response against general pathogen colonization between many plant cultivars of many crop species making the choice of cultivar very important to prevent human bacterial pathogen colonization (Critzer and Doyle, 2010). Plant microbiota interactions also play a critical role in colonization or inhibition of enteric pathogens in the soil, roots, stems, leaves and fruits of fresh produce. Two epiphytes, *Wausteria paucula* and *Enterobacter asburiae*, differentially interact with E. coli O157:H7 on lettuce leaves and roots. Because *E. asburiae* utilizes many of the same carbon and nitrogen sources as *E. coli* O157:H7, and W. *paucula* utilizes only four of the tested substrates also metabolized by E. coli O157:H7, *E. asburiae* is better able compete for available nutrients than *E. coli* O157:H7, adversely affecting *E. coli* O157:H7 survival. *E. asburiae* colonization decreases E. coli O157:H7 by 20–30-fold on foliage when co-inoculated onto seeds. In contrast, *W. paucula* enhanced E. coli O157:H7 survival by sixfold (Cooley et al., 2006; 2003).

Natural ecology of plants plays a major role in the colonization of fresh produce, and whether enteric pathogens survive as endophytes or epiphytes. This relationship depends on the bacterial species as well as plant cultivars. The preparation of the natural microbiome and choice of plant cultivars influences both biocontrol and the production of pathogen free food long before it is served to the consumer (Critzer and Doyle, 2010).

Table 4. How fresh fruits and vegetables are colonized by enteric foodborne pathogens.

Sources of enteric foodborne pathogens	• Contaminated water • Feces • Contaminated manure/compost • Contaminated soil • Insects • Contaminated seeds
Mechanisms of attachment for epiphytic colonization	• Biofilms • Fimbriae • Flagella
Mechanisms of endophytic colonization	• Natural openings (stomata) • Damaged tissue of stem and leaves or roots and tubers • Chemotaxis to metabolites within the plants or found in plant exudates

**from Critzer and Doyle, 2010*

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