United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☐ **National List Petition or Petition Update**

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

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

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

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

☒ **Technical Report**

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

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

Contractor names and dates completed are available in the report.

Insecticidal Soaps

Crops

Identification of Petitioned Substance

Chemical Names:
Potassium Oleate
Potassium Laurate
Ammonium Nonanoate

Other Names:
Potassium Soaps
Potassium Salt of Fatty Acids
Oleic acid potassium salt
Potassium cis-9-octadecenoate
Potassium cis-9-octadecenoic acid
Lauric acid potassium salt
Potassium dodecanoate
Potassium dodecanoic acid
Castor oil potassium salts
Ammonium Soaps
Ammonium Salt of Fatty Acids
Perlargonic Acid, Ammonium Salt

Trade Names:
Safer®
DES-X®
M-Pede®
PyGanic®

CAS Numbers:
143-18-0 (Potassium oleate)
10124-65-9 (Potassium laurate)
67701-09-1 (Potassium salts of fatty acids C8-C18 saturated and C18 unsaturated)
8013-05-6 (Castor oil potassium salts)
84776-33-0 (Ammonium soaps of fatty acids C8 – C18)

Other Codes:
EPA Registration No.: 66702-22-70051 (DES-X® Insecticidal Soap Concentrate)
EPA Registration No.: 1021-1771 (PyGanic® Insecticide for Organic Crop Protection)
EPA Registration No.: 10163-324 (M-Pede® Insecticide-Miiticide-Fungicide)
EPA Registration No.: 66702-7-39609 (Ammonium soaps of fatty acids)
EPA PC Code: 031801 (Ammonium salts of fatty acids (C8 – C18)
EC No.: 205-590-5 (Potassium oleate)
EC No.: 233-344-7 (Potassium laurate)
EC No.: 266-933-2 (Potassium salts of fatty acids C8-C18 saturated and C18 unsaturated)
EC No.: 232-388-4 (Castor oil potassium salts)
UNII No.: 74WHF607EU (Potassium oleate)
UNII No.: V4361R8N4Z (Potassium laurate)
UNII No.: 54I68KEO6Y (Castor oil potassium salts)

Summary of Petitioned Use

Soap mixtures have been approved by the United States Department of Agriculture's (USDA) National Organic Program (NOP) for a range of uses pertaining to crop production. These uses are listed in 7 CFR 205.601 and include applications such as synthetic substances to act as algicides/demossers ((a)(7)), herbicides ((b)(1)), insecticides ((e)(8)), and animal repellants (d). There have been a variety of technical reports that have covered the various applications of soaps within organic agricultural production, including as herbicides (USDA 2011, USDA 2015a, USDA 2015b), animal repellants (USDA 2019a), and insecticides (USDA 1994).

The purpose of this report is to update the existing technical information available on insecticidal soaps based on more current research (USDA 1994).

Characterization of Petitioned Substance

Composition of the Substance:
Most insecticidal soaps are composed of potassium salts (or ammonium salts, in some cases) of fatty acids (i.e., fats) (PubChem 23665571, EPA 1992, USDA 1994, NPIC 2001, Jianu 2012, EPA 2013, Certis 2015, Vahabzadeh et al. 2018, Gowan 2019). Insecticidal soaps are composed of a mixture of both saturated fats (all single carbon–

carbon bonds) and unsaturated fats (containing multiple carbon–carbon bonds) and contain a variety of carbon chains (Anneken et al. 2012, AMVAC 2015, Thomas et al. 2016, USDA 2019a).

Most commercially relevant fatty acids consist of linear carbon chains with a length of six to twenty-two carbons, with soaps frequently containing eight to eighteen carbon chains. Ammonium nonanoate (9 carbons) is among the most prevalent short-chained soaps while potassium oleate and potassium laurate (18 carbons) are among the most prevalent long-chained soaps (EPA 2000, USDA 2011, Anneken et al. 2012, EPA 2013, USDA 2015a, USDA 2015b, USDA 2019a).

<u>Source or Origin of the Substance:</u>
Insecticidal soaps are manufactured by subjecting natural fatty acids (from both animal and plant sources) to the process of saponification (Equation 1 in Evaluation Question 2). The saponification process hydrolyzes the linkages in the natural fatty acid (derived from animal fats or plant oils) in the presence of a base, specifically potassium hydroxide (KOH) (Nora and Koenen 2010, USDA 2011, Anneken et al. 2012, Jianu 2012). The cation (positively charged ion) for soap molecules is determined by the base used in its production. Potassium soaps are derived from the treatment of fatty acids with potassium hydroxide (KOH), while ammonium soaps are produced by saponification with ammonium hydroxide (NH_4OH) or ammonia (NH_3, which forms NH_4OH when dissolved in water) (Anneken et al. 2012, AMVAC 2015, USDA 2015a, USDA 2015b).

<u>Properties of the Substance:</u>
The chemical and physical properties of insecticidal soaps are dependent on the length of the carbon chain. Longer carbon chains produce a more nonpolar molecule, which increases the hydrophobicity of the soap product (Anneken et al. 2012, EPA 2013, USDA 2015a, USDA 2015b, USDA 2019a). As a result, long chain insecticidal soaps have reduced water solubility compared to soaps with shorter carbon chains, which bear a larger ratio of negative charge per molecular weight.

Since commercial soaps consist of a range of possible chain lengths (8–18), their water solubility varies (although they trend toward low water solubility) (Anneken et al. 2012, USDA 2015a, USDA 2015b, USDA 2019a). The properties of mixed-chain potassium and ammonium soaps, including short and long chain lengths with ammonium nonanoate (short, C9) and potassium oleate and potassium laurate (long, C18), are summarized below in Table 1 (EPA 2000, EPA 2013, USDA 2015a, USDA 2015b, USDA 2019a).

Table 1. Properties of Insecticidal Soaps

Compound	Potassium Oleate	Potassium Laurate	Potassium Soaps C8 – C18	Potassium salts of Castor Oil	Ammonium Soaps C8 – C18	Ammonium Nonanoate
CAS No.	143-18-0	10124-65-9	67701-09-1	8013-05-6	84776-33-0	63718-65-0
Molecular Weight	320.6 g/mol	238.41 g/mol		1101.7 g/mol	N/A	175.27 g/mol
General Appearance	Brown or yellow solid, clear to amber solution when mixed with water, faint soapy odor	Liquid	Yellow to amber liquid, musty or soap odor	N/A	Brown to white/clear liquid, ammonia and/or soapy odor	Clear/pale liquid, slight ammonia odor
Solubility	25 g/ 100 mL water	N/A	Dispersible in water	N/A	Water Insoluble	Water Soluble
Melting Point	235-240 ^{o}C	N/A	N/A	N/A	-1 ^{o}C	N/A
Boiling Point	N/A	N/A	N/A	N/A	101 ^{o}C	104.4 ^{o}C
Specific Gravity	1.1	N/A	1.02 – 1.04	N/A	0.80 – 0.988	1.0
pH	N/A	N/A	8.60 - 10.2		7 – 10	8 – 9

Sources: AMVAC 2015, Certis 2015, Schultz Company 2016, BioSafe Systems 2017, Gowan 2019, PubChem 23675775, PubChem 72941488, PubChem 176286868, PubChem 23665571, PubChem 21902950

Specific Uses of the Substance:
Soaps have a variety of uses for organic agricultural crop production, including as an herbicide for the control of mosses, algae, and weeds (USDA 2015a, USDA 2015b). In addition, soaps are also used as animal repellants and as insecticides (USDA 1994, USDA 2019a). Within organic agriculture, the application of insecticidal soaps includes their use as "acaricides or mite control," as stipulated in 7 CFR 205.601.

Insecticidal soaps are used for the treatment of many crops and ornamental species for the control of aphids, whiteflies, mealy bugs, webworms, lace bugs, leafhoppers, thrips, and other sucking insects and pests (NPIC 2001, Southside 2009, Sarwar and Salman 2015, Qureshi and Stansly 2016, Razze et al. 2016, Alston et al. 2018). Insecticidal soaps are generally broad-spectrum insecticides that have shown little toxicity to non-target species and are known to be effective across a range of crops (Rebek and Hillock 2016, NPIC 2001, Southside 2009, Razze et al. 2016, Alston et al. 2018, Vahabzadeh et al. 2018).

Approved Legal Uses of the Substance:
The United States Food and Drug Administration (FDA) has approved the use of "salts of volatile fatty acids," specifically "ammonium salts of mixed 5-carbon acids," and the "ammonium salt of isobutyric acid" for use "as a source of energy in dairy cattle feed" at 21 CFR 573.914. The FDA has also approved the use of "salts of fatty acids" for use "in food and in the manufacture of food components" at 21 CFR 172.863. However, this usage has not been extended to fatty acid salts with ammonium cations.

The United States Environmental Protection Agency (EPA) has described the manufacture of soap at 40 CFR 417.30 as the "neutralizing refined fatty acids with an alkaline material in approximately stoichiometric amounts." The EPA has designated "soap" as an inert ingredient permitted in minimum risk pesticide products, which has been granted "exemptions for pesticides of a character not requiring [Federal Insecticide, Fungicide, and Rodenticide Act] FIFRA regulation" at 40 CFR 152.25. However, this exemption is specified for "the water soluble sodium or potassium salts of fatty acids produced by either the saponification of fats and oils, or the neutralization of a fatty acid" and therefore has not been extended to soaps with ammonium cations (40 CFR 152.25).

The USDA NOP has approved soaps as "insecticides, including acaricides or mite control," at 7 CFR 205.601(e)(8).

The USDA NOP has relatedly approved ammonium soaps as a "synthetic substance allowed for use in organic crop production" at 7 CFR 205.601. These ammonium soaps have been approved for several organic crop applications, including as an algicide/demosser or herbicide "for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops"(7 CFR 205.601(b)(1)) and "for use as a large animal repellant only, no contact with soil or edible portion of crop" (7 CFR 205.601(d)).

Action of the Substance:
Insecticidal soaps are effective against a broad range of insects, especially soft-bodied insects (Southside 2009, Razze et al. 2016, Vahabzadeh et al. 2018). Insecticidal soaps are also effective against hard-bodied insects when treated at the larvae or crawler stages (Rebek and Hillock 2016, Quesada and Sadof 2017, Alston et al. 2018).

While the exact mode of action may differ from species to species, insecticidal soaps generally act through the disruption of cellular membranes (NPIC 2001, Tremblay et al. 2008, Cating et al. 2010, Quesada and Sadof 2017). The disruptions to cellular membranes include the penetration and disruption of insect exoskeletons, resulting in the insect losing cellular fluids and asphyxiating (EPA 2013, Quesada and Sadof 2017, Vahabzadeh et al. 2018).

Combinations of the Substance:
When used as approved, the insecticidal soap (usually potassium soap salts [K^+]) is the active ingredient in the formulation. Currently, the NOP does not list any additives that may be found in commercial

formulations. For commercial formulations to be approved for use in organic agriculture under USDA regulations, all additional inert substances would need to be nonsynthetic and not prohibited at 7 CFR 205.602 or be an allowed synthetic substance found at §205.601.

Additionally, commercial mixtures of insecticidal soaps may include other ingredients for many reasons. Commercial formulations may introduce the presence of an emulsifier or alcohol (e.g., ethanol) to increase the solubility of the soap molecules (Woodstream 2015, Woodstream 2016). These additions are more important to soap mixtures containing longer carbon chains due to their decreased solubility (EPA 2000, EPA 2013, USDA 2015a, USDA 2015b, USDA 2019a). Alcohols such as ethanol are allowed by the NOP as a "synthetic substance allowed for use in organic crop production." However, its use is currently limited "as an algicide, disinfectant, and sanitizer, including irrigation system cleaning systems," as stated at 7 CFR 205.601 (a)(1). An additional inert additive to commercial formulations is mineral oil, which increases the environmental longevity of the insecticidal soap, enabling fewer applications of the substance (Rebek and Hillock 2016, Qureshi and Stansly 2016, Woodstream 2016).

Commercial insecticidal soaps may be paired with synergistic substances like pyrethrins to increase the efficacy of the mixture (Rebek and Hillock 2016, Muntz et al. 2016, Qureshi and Stansly 2016, Woodstream 2016, Quesada and Sadof 2017). Pyrethrins are extracts of horticultural oils, however, not all pyrethrins are approved for organic use (USDA 2016). The USDA NOP has designated pyrethrum as an allowed natural botanical extract, while other extracts have been labeled as synthetic pyrethroids and are not allowed in organic crop production, as stipulated at 7 CFR 205.105 (USDA 2016). The literature does not always distinguish between the synthetic and nonsynthetic forms, which are both termed as pyrethrins, although only the nonsynthetic form (pyrethrum) is allowed for organic use (Muntz et al. 2016, USDA 2016, Woodstream 2016).

Pyrethrins provide an alternative mode of action to insecticidal soaps by disrupting both the nervous system of insects as well as respiratory processes, resulting in immobilization and asphyxiation (Woodstream 2016, Quesada and Sadof 2017, USDA 2019b). Furthermore, pyrethrins are proven to be more effective against hard-bodied insects, increasing the effectiveness of the mixture when applied in concert with insecticidal soaps (Qureshi and Stansly 2016, Woodstream 2017, Quesada and Sadof 2017). Using pyrethrins with insecticidal soaps takes advantage of the fact that insecticidal soaps disrupt cellular membranes and increases pyrethrin efficacy and absorption into the nervous system (Quesada and Sadof 2017). While not all pyrethrins are allowed by the USDA NOP, horticultural oils, the parent mixtures, are approved as insecticides when used as "narrow range oils as dormant, suffocating, and summer oils," as stated at 7 CFR 205.601 (e)(7).

Status

Historic Use:

Soaps have several historic applications within organic agricultural production, as detailed at 7 CFR 205.601. These include use in farmstead maintenance as an herbicide to prevent the growth of algae, moss, and undesirable weeds, as well as use as animal repellants.

Specific to this report, soaps have long been used as an insecticide. The first recorded use of soaps in modern agricultural production was as the active ingredient for a pesticide registered in 1947 (EPA 1992). Since their incorporation into agriculture during the middle of the 20th century, soaps have gained popularity as a low toxicity treatment of unwanted insects on large-scale farms and vegetable gardens (Rebek and Hillock 2016, Southside 2009, Muntz et al. 2016, Qureshi and Stansly 2016).

Organic Foods Production Act, USDA Final Rule:

The Organic Foods Production Act of 1990 (OFPA) includes soaps as substances that may be considered for "exemption for prohibited substances in organic production and handling operations."

Insecticidal soaps are allowed, "as insecticides (including acaricides or mite control)," as stipulated in 7 CFR 205.601(e)(8).

Ammonium soaps are listed as a "synthetic substance allowed for use in organic crop production" as an "algicide/demosser," "herbicide," and in "large animal repellant" in the USDA organic regulations at 7 CFR 205.601.

International

Canadian General Standards Board Permitted Substances List —
Soaps are listed in Table 4.3 "Crop production aids and materials," with the definition that "soaps (including insecticidal soaps) shall consist of fatty acids derived from animal or vegetable oils."

Soaps are listed as a formulant in Table 4.3 "Crop production aids and materials," when "classified in [Pest Management Regulatory Agency] PMRA List 4A or 4B or nonsynthetic." As noted above, nonsynthetic means derived from animal or vegetable oils.

Soaps are listed as a surfactant in Table 4.2 "Soil amendments and crop nutrition," and Table 4.3 "Crop production aids and materials," with the requirement of being "nonsynthetic." Soaps are listed as a surfactant with no restrictions in Table 7.4 "Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory."

Soaps are listed as a wetting agent in Table 4.3 "Crop production aids and materials," and Table 7.4 "Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory," with the requirement of being "nonsynthetic."

Ammonium soaps are listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances lists.

Ammonium soaps are listed in Table 4.3 "Crop production aids and materials," as "a large animal repellant," with the requirement that "direct contact with soil or edible portion of crop is prohibited." Ammonium soaps are also listed in Table 8.2 "Facility pest management substances," with the requirement that "direct contact with organic products is prohibited."

Soap-based algicides (demossers) are listed in Table 7.4 "Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) —
Insecticidal soaps are not listed in the CODEX.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 —
Potassium soaps are listed in EC No. 889/2088 as "fatty acid potassium salt," as an insecticide with applications "from traditional use in organic farming."

Japan Agricultural Standard (JAS) for Organic Production—
Soaps are listed in the JAS for Organic Production Notification No. 1608 as an "agent for cleaning or disinfecting of housing for livestock."

Potassium soap is also listed in the JAS for Organic Production Notification No. 1606 as a "chemical agent," except for "the purpose of pests control for plants."

International Federation of Organic Agriculture Movements (IFOAM) —
Potassium soaps are listed in IFOAM as "an equipment cleanser and equipment disinfectant," with the requirement that "an intervening event or action must occur to eliminate risks of contamination."

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

<u>Evaluation Question #1: Indicate which category in OFPA that the substance falls under:</u> (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

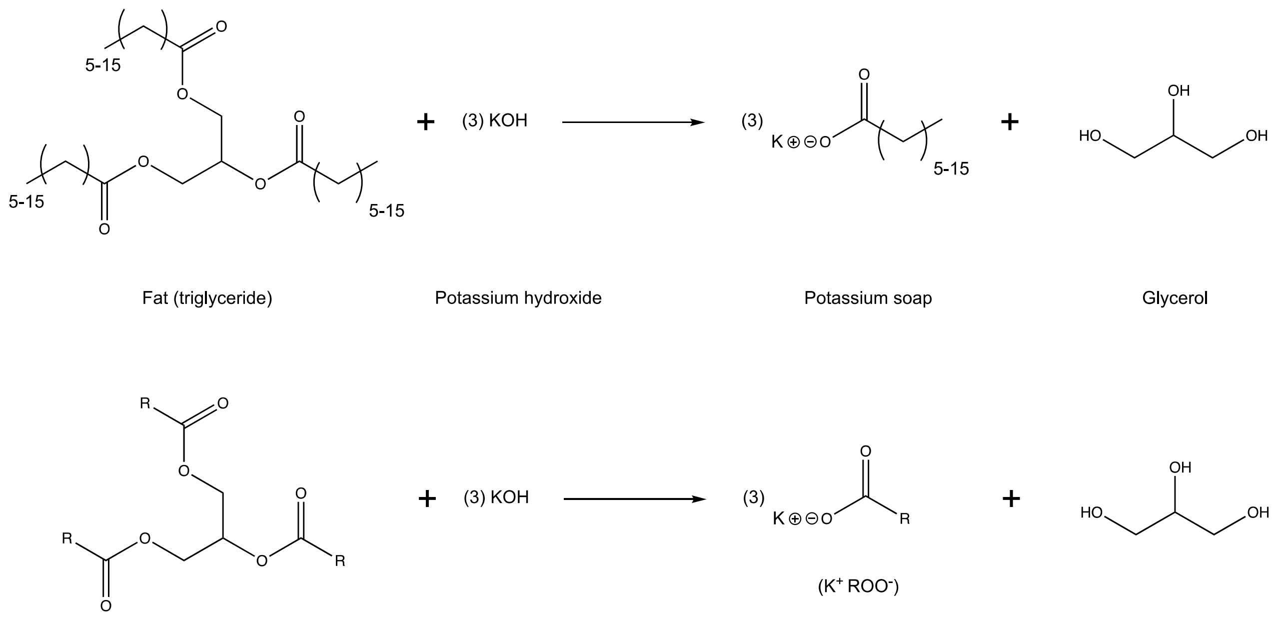
A) The substance is categorized as a soap, but the substance does not contain additional active ingredients from any of the following categories listed in Evaluation Question #1(A). Insecticidal soaps are composed of a cation, usually potassium (K^+) associated with the carboxylate anion of a neutralized fatty acid (ROO^-) with a chain length eight to eighteen carbons long and are commonly referred to as "soaps" (Equation #1 in Evaluation Question #2).

B) Insecticidal soaps are not listed by the EPA as an inert ingredient of toxicological concern. The EPA has designated "soap" as an "inert ingredient permitted in minimum risk pesticide products," and it has been granted "exemptions for pesticides of a character not requiring FIFRA regulation" at 40 CFR 152.25. However, this exemption is specified for "the water-soluble sodium or potassium salts of fatty acids produced by either the saponification of fats and oils, or the neutralization of a fatty acid."

<u>Evaluation Question #2:</u> 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)).

Insecticidal soaps are manufactured by the hydrolysis of fats (triglycerides) with an alkaline source in a process known as saponification (Equation 1) (Anneken et al. 2012). In this process, the base (potassium hydroxide, KOH) reacts with the fat, resulting in the formation of a salt with the cation of the base (K^+) and the carboxylate anion (ROO^-) that remains at the end of the hydrolysis (Anneken et al. 2012, Jianu 2012). In saponification, potassium hydroxide (KOH) is commonly used as the base for the hydrolysis reaction, as shown in top of Equation 1.

Due to the numerous differences in fats and carbon chains present in soaps, the abbreviated form is also provided in the second line of Equation 1. Within this representation, R is a chain of hydrocarbons that may be either saturated (all single bonds) or unsaturated (including double bonds).



Equation 1

A wide range of fats may be used in the saponification process, including both plant and animal fats. These fats are commonly sourced by further processing crude by-products (palm oil, sunflower oil, vegetable oil, coconut oil, olive oil, and tallow sources) from human nutritional industries (Kostka and McKay 2002, Anneken et al. 2012, Rahimov and Asadov 2013, Burns-Moguel 2014). Due to the abundance of fat sources, the final soap salt is composed of a range of carbon chain lengths, rather than a consistent chain length throughout the final product.

Alternative manufacturing processes exist to produce synthetic soaps from long-chain hydrocarbons. However, due to the relative abundance of fats and their low-cost, most soaps are produced by the saponification of natural fats isolated from plant and animal sources (Anneken et al. 2012).

<u>Evaluation Question #3:</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)).

Soaps do not naturally exist but are manufactured by the treatment of fats with a strong base (see Evaluation Question #2) (Anneken et al. 2012, Jianu 2012). Potassium cations (K^+) and fatty acid carboxylate anions (ROO^-) both exist in nature; however, they are not typically associated in salt form (as soaps).

Fatty acids are important molecules in the metabolic cycles of a range of animals and microbes, and they provide both with key sources of energy (EPA 1992, EPA 2013, Anneken et al. 2012, Rahimov and Asadov 2013). Potassium is a natural and prevalent ion in the environment and plays an important role in the metabolic pathways of many organisms and in the control of the cellular structure (PubChem 813, Atkins et al. 2008).

Due to the relative abundance and low-cost of natural plant and animal fats, natural sources provide the carboxylate anion in commercial soaps (Anneken et al. 2012).

<u>Evaluation Question #4:</u> Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Studies conducted by the EPA estimate that insecticidal soaps will undergo rapid degradation in the environment, primarily through microbial metabolism, yielding an environmental half-life of less than one day (EPA 1992, EPA 2008, EPA 2013). Both the potassium cation (K^+) and carboxylate anion (ROO^-) are important molecules for the metabolic cycles of many animals and microorganisms (Atkins et al. 2008, Rahimov and Asadov 2013). Due to the prevalence of both ionic components (potassium cations (K^+) and fatty acid anions (ROO^-)) of potassium fatty acid salts (soaps) in metabolic pathways, the complete soap substance does not persist in the environment (EPA 1992, EPA 2013).

Fatty acids are involved with diverse metabolic pathways that result in the production of thousands of different chemical products (EPA 1992, EPA 2013, Rahimov and Asadov 2013). The involvement of these products in the metabolic and respiratory cycles of microorganisms, animals, and plants makes the persistence and accumulation of potassium soap by-products impossible to track (EPA 1992, EPA 2013, Rahimov and Asadov 2013). However, since these products are involved in diverse systems and are naturally abundant, it likely results in a negligible contribution from the application of insecticidal soaps.

Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

The toxicological profile of the substance differs based on the environment in which it is located. Insecticidal soaps are widely regarded as having low toxicity to terrestrial organisms, like mammals and avian animals (EPA 2013). The EPA has placed the substance in Toxicity Category IV, the lowest available classification (EPA 1992, EPA 2008). Moreover, there have been no long-term studies on the environmental toxicity of insecticidal soaps due to their rapid degradation (EPA 2013).

Insecticidal soaps are moderately toxic in aquatic environments (EPA 2008, EPA 2013). The substance has a much larger effect on aquatic invertebrates and has been classified as "highly toxic" to crustaceans (EPA 1992, EPA 2008, EPA 2013). Due to the potential toxicity to aquatic environments, insecticidal soap product labels stipulate that the products are not intended for applications to aquatic systems, including ponds and streams, or to soil (EPA 2008, Gowan 2019).

As discussed in the Action of the Substance section of the report, insecticidal soaps work through disrupting cellular membranes (NPIC 2001, Tremblay et al. 2008, Cating et al. 2010, Quesada and Sadof 2017). This includes the penetration and disruption of insect exoskeletons, resulting in the insect losing cellular fluids and asphyxiating (EPA 2013, Quesada and Sodof 2017, Vahabzadeh et al. 2018).

Relatively short-chain fatty acid salts have increased mobility compared to the longer carbon chains (e.g., nonanoate soaps) that are also found in insecticidal soap formulations. This increased mobility allows for increased penetration of cellular membranes in soft-bodied insects (e.g., aphids), disrupting cellular respiration and other processes (Sarwar and Salman 2015).

As discussed in Evaluation Question #4, insecticidal soaps are not expected to persist in the environment.

Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Environmental contamination from the insecticidal soaps is unlikely when used as approved. The rapid metabolism of the substance by microorganisms, coupled with the low toxicologic effect of soaps on terrestrial animals, makes even the overapplication of pesticides unlikely to result in soil contamination (EPA 1992, EPA 2008, EPA 2013, Rahimov and Asadov 2013).

Insecticidal soaps (which are predominantly potassium-based) have a much higher toxicological impact on aquatic environments, making misuse and application to bodies of water the most likely means of environmental contamination (EPA 1992, EPA 2008, Gowan 2019). Since potassium soaps are moderate to highly toxic in aquatic environments, a large-scale contamination could have a dramatically negative impact on the ecological system. However, longer chain soaps would have reduced water solubility compared to short-chain soaps (e.g., ammonium nonanoate), which may mitigate the environmental impact of misuse through aquatic application (Anneken et al. 2012, EPA 2013).

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

Insecticidal soaps have undesirable chemical interactions with lime sulfate, hydrate lime, copper sulfate, ferric phosphate, magnesium sulfate, and micronutrient salts that all have been approved for use in organic crop and livestock production at 7 CFR 205.601 and §205.603.

This interaction is because insecticidal soaps are incompatible with a range of multivalent metal ions (metal ions that have greater than a plus one charge ($M^{>+1}$)) due to the aggregation and precipitation of the resulting salts (EPA 2013). The increased positive charge of multivalent metal ions results in an association to multiple carboxylate anions (fatty acid chains), increasing the hydrophobicity of the salt. The resulting precipitate removes both the metal ion and carboxylate ion from the solution.
This is a common problem in areas high in minerals (hard water), which leads to the precipitation of soap aggregates (soap scum) (EPA 2013).

These undesirable interactions are unlikely to result in any effects to the environment or human health as the nature of the soap does not change dramatically upon cation exchange. However, the aggregation would also serve to remove the multivalent metal ions from the agro-ecosystem. This may result in the sequestration of metal ions that have been added as soil amendments (e.g., micronutrients, pH adjusters), which would no longer be bioavailable following their aggregation in a fatty acid salt.

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

The insecticidal soaps are a broad-spectrum insecticide, affecting most soft-bodied insects: aphids, mites, crickets, earwigs, caterpillars, leaf hoppers, scale crawlers, thrips, whiteflies, and beetles, and may also extend to include earthworms and grubs (Davis et al. 1997, Southside 2009, USDA 2011, USDA 2015a, USDA 2015b, Qureshi and Stansly 2016, Razze et al. 2016, USDA 2019a).

Studies have shown insecticidal soaps to be non-toxic to desirable insects such as lady bugs (*Oenopia conglobata*) and the coccinellid beetle (*Delphastus catalinae*) (Razze et a. 2016, Vahabzadeh et al. 2018). The discrepancy between toxicity to pest and desirable species is due to the difference in the insect body type, with pests being typically soft-bodied insects and desirables being hard-bodied insects (Southside 2009, Razze et al. 2016, Vahabzadeh et al. 2018). The toxicological difference is due to the mode of action of the insecticide, which can disrupt membranes of soft-bodied insects more efficiently than hard-bodied insects (described in greater detail in the Action of the Substance section).

Additionally, as discussed in Evaluation Question #4, fatty acid salts, such as soaps, are a major component of the metabolic cycles of a range of organisms. The substance is rapidly metabolized by microorganisms in the soil, resulting in an environmental half-life of less than one day (EPA 1992, EPA 2008, EPA 2013). The combination of short environmental lifetime and low toxicity to terrestrial animals makes negative impacts to crop and livestock production unlikely.

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

There is little to suggest that insecticidal soaps pose a threat to the environment when used as approved. The substance is readily metabolized by a range of organisms, resulting in short environmental persistence (half-life of less than one day) (EPA 1992, EPA 2008, EPA 2013). Furthermore, the substance has been documented as having low toxicity to terrestrial and avian species, limiting the impact of the substance even when used improperly (EPA 1992, EPA 2008).

Potassium soaps have moderate to high toxicities in aquatic environments (EPA 1992). However, the substance has not been approved for aquatic applications. The insecticidal nature of the substance may negatively impact populations of non-target insects, including earthworms and grubs (USDA 2011, USDA 2015a, USDA 2015b, Qureshi and Stansly 2016, Razze et al. 2016, USDA 2019a)

<u>Evaluation Question #10:</u> 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)).

The EPA has classified soap salts the lowest possible toxicity (Toxicity Category IV) (EPA 1992). Like many other organisms, humans employ fatty acids in their metabolic cycle as a key source of energy and building blocks for other biologically important molecules, contributing to the low toxicity of potassium soaps in humans (EPA 1992, EPA 2013, Rahimov and Asadov 2013). Moreover, the EPA has concluded that the oral intake of dangerous levels of the substance is highly unlikely due to the recognizable and undesirable soap taste (EPA 2008).

Despite the low toxicity of soaps to humans, the substance does pose some health risks. Intentional overconsumption of insecticidal soaps has been reported to cause dyspepsia and emesis (Thomas et al. 2016). However, most soap hazards are irritation-based. Potassium soaps have been documented to cause occasional skin irritation upon prolonged exposure (Certis 2015, Gowan 2019). Potassium soaps are also highly corrosive to eyes and may cause severe irritation and possible blindness (reversible) upon direct exposure (USDA 2011, Certis 2015, Thomas et al. 2016, Woodstream 2016, Gowan 2019).

<u>Evaluation Question #11:</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)).

There are a variety of natural substances that may be used in place of insecticidal soaps as a means of pest control. The most prominent natural alternative to insecticidal soaps is the use of horticultural oils and pyrethrum extracts (Rebek and Hillock 2016, Muntz et al. 2016, Qureshi and Stansly 2016, Woodrteam 2016). Pyrethrum is isolated from horticultural and essential oils. Many essential oils have been exempted from EPA regulations, including cornmint, cedar, cinnamon, citronella, lemongrass, linseed, peppermint, rosemary, soybean, and thyme oils (Woodstream 2016). These parent oils offer a plethora of possible pyrethrin extracts, many of which have displayed insecticidal properties (Zobitne and Gehert 2003, Muntz et al. 2016, Woodstream 2016). Pyrethrum has been reported to work by disrupting the nervous system of the insect and are considered most effective against hard-bodied insects (Woodstream 2016). Like insecticidal soaps, pyrethrum has been reported to be environmentally benign and are considered non-toxic to mammals (Rebek and Hillock 2016, Muntz et al. 2016, Woodstream 2016).

However, horticultural oils and pyrethrum compounds are easily degraded under common conditions like UV-radiation and are vulnerable to oxidative processes (Woodstream 2016). Moreover, differences in the mode of action and in their targets (hard-bodied vs soft-bodied insects) between pyrethrum and insecticidal soaps make one a poor substitute for the other, and they are often combined as a mixture (Rebek and Hillock 2016, Muntz et al. 2016, Qureshi and Stansly 2016, Woodstream 2016, Quesada and Sadof 2017).

Additional alternatives to insecticidal soaps include applications of water-based sprays that are infused with garlic cloves and chili powder. Garlic and chili sprays have been reported to be effective against a range of undesirable insects: aphids, cabbage loopers, and flea beetles (Southside 2009). Other substances such as beer, fruit and vegetable materials, and diatomaceous earth have all been reported to have some effect in pest management (Rebek and Hillock 2016, Southside 2009, Muntz et al. 2016).

However, these alternatives provide a limited scope in terms of treated pests compared to relatively broad-spectrum treatment options such as pyrethrins and insecticidal soaps (Southside 2009). These alternatives may be better suited for treatment of a specific crop or pest.

The USDA has approved a range of synthetic substances that serve as an alternative to insecticidal soaps. Aqueous potassium silicate provides another alternative to insecticidal soaps. This substance provides insecticidal protection by the incorporation of silicon into the pant structure in the form of phytoliths (USDA 2014a). The resulting phytolith formations help to ensure the health of the plant by strengthening a range of structural components, increasing the plant's resistance to insects (Menzies et al. 1992, USDA 2014a). However, the ability to uptake silicates and incorporate them into cellular structures varies by plant species (USDA 2014a).

Elemental sulfur has been approved by the USDA as an organic insecticide for treatment of mites and arachnids (USDA 2017). Sulfur acts as an insecticide by (1) reacting with oxygen species in the environment, (2) producing the acids species hydrogen sulfide (H_2S) and sulfuric acid (H_2SO_4) in soils, (3) softening insect exoskeletons, and (4) interfering with insect respiration pathways (Hetz and Bradley 2005, USDA 2017). Lime sulfur has been approved by the USDA as an organic insecticide, and it also produces hydrogen sulfide through reactions within the agricultural environment and disruptions to the respiration pathways in insects (Venzon et al. 2013, USDA 2014b).

However, the efficacy of potassium silicates, elemental sulfur, and lime sulfur is limited to treatment and prevention of arachnid and mite infestations (USDA 2014a, USDA 2014b, USDA 2017). The limited scope of insecticidal treatments makes them poor replacements for the board-spectrum properties of insecticidal soaps.

Sticky barriers have been approved by the USDA for organic crop production. These substances eliminate insect infestations by capturing insects that land on them, providing insect treatment without the application of chemicals to the agricultural environment (USDA 1995). However, the application of sticky barriers results in an indiscriminate reduction of insect populations, effecting both pest and desirable species.

Sucrose octanoate esters are a broad-spectrum insecticide approved by the USDA for organic crop production (USDA 2005). Sucrose octanoate esters have a similar chemical structure to insecticidal soaps, both featuring a long hydrophobic carbon chain and a polar head group (PubChem 5484222). The major structural difference is the identity of the polar head group, which is a carboxylate anion for insecticidal soaps and a sugar molecule for sucrose octanoate esters. Both substances also share a similar mode of action, the ability to disrupt cellular membranes and waxy protective coatings found on target insects (NPIC 2001, USDA 2005, Tremblay et al. 2008, Cating et al. 2010, Quesada and Sadof 2017).

<u>Evaluation Question #12:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

There are many alternative practices that would reduce the necessity for the application of insecticidal soaps. These alternatives come in several general forms, including mechanical removal/treatments, physical barriers, agro-ecosystem management, and predatory management.

Mechanical removal/treatment

Mechanical removal of undesirable insects can be achieved by manually expelling them from affected crops by hand, with water streams, with other implements (e.g., toothpicks, skewers, etc.), and by trapping (Rebek and Hillock 2016, Southside 2009, Muntz et al. 2016). These methods are typically most effective against large insects such as cabbage lopper, Colorado potato beetles, cucumber beetles, cutworms, and tomato hornworms, which are easier to spot and remove (Southside 2009). These alternative practices are desirable as there is no risk of unintended contamination, and they are also relatively low-cost and low technology options.

Mechanical removal techniques are limited in by the type and size of the insect that may be treated (see larger insects listed in above paragraph), as small insects are difficult to remove by these methods. Mechanical removal techniques are also limited by the degree of infestation. As such, the time-consuming and labor-intensive nature of mechanical treatments limit their utility to relatively small-scale agricultural applications.

Physical barriers

Physical barriers include netting and other barriers including "cutworm collars" (Rebek and Hillock 2016, Southside 2009). The installation of insect barriers prevents crop infestation and have been most effective against cucumber beetles and leafminers (Southside 2009). However, physical barriers are limited to use with specific crops and only offer protection from specific insects.

Agro-ecosystem management

Management of the agro-ecosystem takes many forms. Management can include proper care for the environment through weeding. Weeding around crops eliminates their ability to harbor populations of undesirable insects (Rebek and Hillock 2016, Southside 2009, Muntz et al. 2016). Proper care can also be taken in the form of irrigation, fertilization, and mulching around vulnerable crops. This approach works by limiting access of the insects to the crop and by promoting the growth of robust crops that will become less prone to infestation (Rebek and Hillock 2016, Southside 2009, Muntz et al. 2016). This approach can be especially effective against thrips, which are subsequently unable to cause substantial damage to healthy plants (Southside 2009).

Another means of agro-ecosystem management is to employ crop rotations and to plant strategically (Muntz et al. 2016). Crop rotations and strategic planting schedules offer a means to stagger crop growth to avoid seasonal highs in detrimental insect populations (Rebek and Hillock 2016, Muntz et al. 2016). Effective crop rotations also help to avoid the buildup of specific insect populations by eliminating its food source when crops are rotated that lack the nutritional requirements of the present insect populations.

Additionally, insect control may be aided by populating nearby pollen and nectar bearing plants (Southside 2009, Muntz et al 2016). The planting of these plants near crops encourages the growth of bee, wasp, and other pollenating insects, many of which act as natural predators to undesirable insects (Southside 2009).

Predatory Management

Introducing predatory insects to insect populations is the most common application of predatory control (Rebek and Hillock 2016, Southside 2009, Muntz et al. 2016, Qureshi and Stansly 2016, Rezze et al. 2016). The predatory insect population may be cultivated by planting pollen and nectar-producing plants (discussed above under *Agro-ecosystem Management*), or predatory insects may be directly introduced as a treatment to mitigate undesirable insects (Rebek and Hillock 2016, Southside 2009, Muntz et al. 2016, Qureshi and Stansly 2016, Rezze et al. 2016).

However, the entire agro-ecosystem should be considered when introducing predatory insects as a treatment option. These considerations include effects of other treatments (e.g., natural or synthetic insecticides, fertilization protocols, etc.) so that the population of the beneficial insects is not reduced (Rezze et al. 2016). This is especially true when treatment protocols include a broad-spectrum insecticide such as insecticidal soaps, pyrethrum, or horticultural oils. The use of predatory insects has been most effective when used in conjunction with other treatments, as they offer more variability than chemical or mechanical strategies (Qureshi and Stansly 2016, Rezze et al. 2016).

Report Authorship

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