Nonanoic Acid

Livestock

Identification of Petitioned Substance

Chemical Names:
Nonanoic acid
n-Nonanoic acid
Pelargonic acid

Other Names:
1-Nonanoic acid
1-Octanecarboxylic acid
n-Nonylic acid
n-Nonic acid
Pelargic acid
Pelargon

Trade Names:
Cirrasol 185a
Emfac 1202
Hexacid C-9
Scythe
Enforcer

CAS Number:
112-05-0

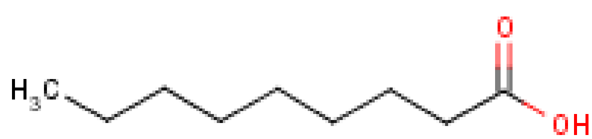
Other Codes:
217500 (U.S. EPA PC Code)
RA6650000 (RTECS Code)
203-931-2 (EINECS number)

Characterization of Petitioned Substance

Composition of the Substance:

Nonanoic acid, $C_9H_{18}O_2$, is a nine-carbon (C9) straight-chain fatty acid that is naturally occurring in the environment (e.g., soil, plants) and is found at low levels in many of the common foods such as grapes, oranges, apples, cheese, and milk (U.S. EPA, 1997). The molecular structure ($CH_3(CH_2)_7COOH$) of nonanoic acid is shown in Figure 1.

Figure 1. Molecular Structure of Nonanoic Acid



Source: ChemIDplus Lite (2011)

Properties of the Substance:

Nonanoic acid is a colorless to slightly yellow, oily liquid with a slight fatty, coconut-like odor (HSDB, 2008). It is stable under normal temperatures and pressures and is soluble in ethanol, chloroform, and ether. It is relatively insoluble in water. When heated to decomposition, nonanoic acid emits smoke and fumes that may be irritating to the respiratory system (HSDB, 2008). Chemical and physical properties of nonanoic acid are provided in Table 1.

Table 1. Physicochemical Properties of Nonanoic Acid

Physical or Chemical Property	Value[a]
Physical state (at room temperature)	Liquid
Appearance	Colorless to slightly yellow, oily
Odor	Fatty, coconut-like aroma
Molecular weight (g/mol)	158.24
Boiling point (°C)	254.5
Melting point (°C)	12.4
Solubility in water (mg/L at 30°C)	284
Vapor pressure (mm Hg at 25°C)	0.00165
Density (g/cm^3 at 20°C)	0.9052

[a]Sources: ChemIDplus Lite (2011); HSDB (2008)

Specific Uses of the Substance:

Nonanoic acid is petitioned for use in organic livestock as a topical fly repellant. Nonanoic acid is currently used in organic synthesis, lacquers, plastics, production of hydrotropic salts, pharmaceuticals, synthetic flavors and odors, esters for turbo jet lubricants, and as a flotation agent, vinyl plasticizer, and gasoline additive (HSDB, 2008). It is an herbicide active ingredient regulated by EPA's Office of Pesticide Programs (OPP) used to prevent growth of weeds and to thin blossoms (OPP code 217500). It also has fungicidal properties for use in crops (Marin Municipal Water District, 2008). FDA has approved its use as a food additive and as an ingredient in solutions used commercially to peel fruits and vegetables (HSBD, 2008). Nonanoic acid is also used for flavoring in alcoholic beverages, baked goods, fats/oils, frozen dairy, gelatins/puddings, meat products, nonalcoholic beverages, and soft candy (HSDB, 2008) and to prevent fungal growth in foods (Marin Municipal Water District, 2008).

Approved Legal Uses of the Substance:

In accordance with 21 CFR § 172.515, nonanoic acid is permitted by FDA for use as a synthetic flavoring substance and adjuvant, provided that it is "used in the minimum quantity required to produce their intended effect, and otherwise in accordance with all the principles of good manufacturing practices." Nonanoic acid is also allowed by the FDA for use as an ingredient in commercial solutions used to peel fruits and vegetables (21 CFR § 173.315).

Nonanoic acid is an EPA-registered fungicide and herbicide (OPP code 217500) that can be used as a weed killer and blossom thinner (U.S. EPA, 2000). According to 40 CFR § 180.1284, ammonium salts of higher fatty acids (including nonanoic acid) "are exempted from the requirement of a tolerance for residues in or on all food commodities when used in accordance with good agricultural practice."

In the fall of 2009, the U.S. EPA issued unconditional registration for the use of C8910, a substance containing nonanoic acid and related fatty acids. It was approved for use in conventionally raised beef and dairy cattle and horses to repel insects such as stable flies, horn flies, house flies, ticks, and cattle lice (USDA, 2010). Nonanoic acid is not currently included on the National List for use as an insect repellent/insecticide in organic livestock.

Action of the Substance:

Nonanoic acid works as an herbicide by desiccating (drying out) the plant it contacts and destroying its waxy cuticle. It is also considered a plant growth regulator, i.e., chemical substances used to alter the growth and development (e.g., fruit set and drop) of a plant (Thurston County Health Dept, 2009).

Nonanoic acid is also a fungicide and is frequently used to prevent fungal growth in foods. Nonanoic acid works by preventing spore germination or postponing germination; at higher concentrations it may be directly toxic to the fungus (Marin Municipal Water District, 2008).

Nonanoic acid repels insects and arthropods causing them to make deliberate movements away from the source of the repellent. One author, who is also the petitioner for the use of nonanoic acid as a fly repellant in organic livestock, indicated that when biting flies were exposed to a mixture of octanoic (C8), nonanoic (C9), and decanoic (C10) fatty acids (the active ingredients in a patented insect repellent called C8910) and then allowed to access sheep's blood, no exposed insects ingested the blood compared with 90% of control insects. The exposed insects also appeared to be "incapacitated" although the exact mechanism of action for the repellent was unclear (Reifenrath, 2005). In a laboratory trial, Mullens et al. (2009) found that a mixture of those same three fatty acids (15% active ingredients in a kaolin carrier) applied to surfaces treated at 1 mg/cm^2 was highly repellent to house flies (*Musca domestica* L.) and horn flies (*Haematobia irritans* L.), two common biting flies affecting cattle. Authors indicated that in general the repellent was effective for <1 day for house flies and for at least 3 days for horn flies. The relatively short-term action of the repellent would require frequent treatments to livestock (Mullens et al., 2009). A recent study (Venter et al., 2011) found that a 15% (w/w) mixture of octanoic, nonanoic, and decanoic acids in light mineral oil was also effective at repelling biting midges (*Culicoides* spp.) in traps placed near cattle. A study performed by Bosch et al. (2000) found that nonanoic acid applied in combination with lactic acid, a compound found in human breath and on human skin that attracts mosquitoes, was successful in repelling mosquitoes.

Combinations of the Substance:

Nonanoic acid is not a precursor to, component of, or commonly used in combination with any substance(s) identified on the National List of Allowed and Prohibited Substances (hereafter referred to as the National List). However, it is often mixed with other fatty acids (specifically, C8 and C10 fatty acids) and used as insect repellent (Mullens et al., 2009). Stratacor, Inc. specifically petitioned the National Organic Standards Board (NOSB) to allow use of C8910 on the skin of organic livestock to control biting flies, lice, ticks and other pests on cattle and horses (Reifenrath, 2011). In order to comply with 7 CFR § 205.603, inert ingredients used in the formulation of this fly repellant would need to be included on EPA List 4 – Inerts of Minimal Concern.

Status

Historic Use:

The efficacy of nonanoic acid as a spatial (area) insect repellent was apparent in studies as early as 1960 (Skinner et al., 1970 in Bernier et al., 2006). EPA registered and licensed for sale the first pesticide products containing nonanoic acid in 1992. In 1999, there were four nonanoic acid-based products registered as weed killers or blossom thinners (U.S. EPA, 2000). In 2005, W. G. Reifenrath applied for a patent for a "topical insect repellent" for animals (with specific reference to livestock) or humans that contained a number of fatty acids including octanoic, nonanoic, and decanoic acids (i.e., C8910 repellent). The formula was intended to repel biting flies and mosquitoes (Reifenrath, 2005).

OFPA, USDA Final Rule:

Nonanoic acid is not currently approved for use as a synthetic substance in organic livestock production (7 CFR § 205.603(b)). While the other components of the C8910 repellent—octanoic acid and decanoic acid—are not listed as allowable synthetics on the National List, these acids can be produced through steam hydrolysis using palm oil (Advanced Biotech, 2011a), which may classify them as nonsynthetic. In addition, nonsynthetic forms of octanoic acid and decanoic acid are not listed as prohibited substances on the National List for organic crop production (7 CFR § 205.602) or organic livestock production (§205.604) and thus could be used in organic agriculture.

International

The Canadian General Standards Board guidelines state that preventative methods followed by mechanical, physical, and biological control methods for managing/controlling weeds, disease, and pests are preferred to pesticide use in organic production systems (Canadian General Standards Board, 2011); however, if needed, chemical substances provided on the Organic Production Systems Permitted Substances List (CAN/CGSB-32.311) may be applied. Nonanoic acid does not appear on the permitted substances list.

Nonanoic acid is not specifically listed as an allowed substance in livestock production by the Codex Alimentarius Commission. However, Section 22 of the Codex guidelines states:

> *Where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted.*

While this clause may only apply to internal parasiticides (as opposed to external pest treatments), there are no other guidelines for the use of insecticidal or parasiticidal products in livestock (Codex Alimentarius Commission, 2010).

European Economic Community (EEC) Council Regulation EC 889/2008 does not list nonanoic acid in Annex II, which provides the list of products allowed for the elimination of insects and other pests in buildings where livestock are kept (EC, 2008).

The International Federation of Organic Agriculture Movements (IFOAM) standards only allow the use of biological pest controls in addition to a select number of substances included in the list of approved substances for pest and disease control and disinfection in livestock housing (Appendix V) of the version 0.2 standards (under review; IFOAM, 2011). Nonanoic acid does not appear on this list (IFOAM, 2011).

The Japanese Agricultural Standard for Organic Livestock Products does not list nonanoic acid as an approved substance for use in livestock production. There is no mention of approved use for any insecticidal products other than metaldehyde, which is allowed for use in insect traps. Sex pheromones are also allowed for pest trapping (JMAFF, 2005).

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

<u>Evaluation Question #1: What category in OFPA does this substance fall 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?

Nonanoic acid is a livestock parasiticide for external use.

Although it is being petitioned as an active ingredient rather than as an inert, nonanoic acid does not appear on List 4A or B for inert ingredients (U.S. EPA, 2004a,b).

<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)).

Synthetic nonanoic acid can be manufactured using various chemical processes including preparation from unsaturated hydrocarbons by the oxo process (the reaction of olefins with carbon monoxide and hydrogen in the presence of a catalyst to yield aldehydes), by oxidation or ozonation of oleic acid, by oxidation of methylnonyl ketone, or from heptyl iodide using malonic ester synthesis (HSDB, 2008). Nonanoic acid is purified by fractional distillation; however, because the commercial manufacturing process often uses natural sources of oleic acid, it typically contains several related C6-C12 fatty acids (~3%) that cannot be completely separated (Swern and Port, 1952; U.S. EPA, 1997).

Advanced Biotech claims to produce a nonsynthetic nonanoic acid for use as a food additive/flavoring (Advanced Biotech, 2011b), but the detailed manufacturing process is not available. It is also unclear how large of a commercial supply is available. The company provides an "organic product certificate" that claims the product is manufactured by a physical process in accordance with the USDA NOP regulations using non genetically modified botanical sources (Advanced Biotech, 2011c).

<u>Evaluation</u> <u>Question #3:</u> Is the substance synthetic? 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).

Based on manufacturing information, most nonanoic acid would be considered synthetic because it is synthesized using processes such as oxidation and ozonation (see Evaluation Question #2) (HSDB, 2008). A nonsynthetic nonanoic acid source for use as a food additive/flavoring is available (Advanced Biotech, 2011); however, it is unclear if this supply of nonsynthetic nonanoic acid is commercially available for pesticide use.

<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)).

If nonanoic acid is released to air, its high vapor pressure (see Table 1) indicates that it will exist as a vapor in the atmosphere. Degradation in the atmosphere would likely occur by reaction with photochemically-produced hydroxyl radicals, and the half-life for this reaction is estimated to be 1.6 days (EC, 2010; HSDB, 2008). Another source indicates that nonanoic acid in air would degrade to half of its original concentration in less than one week (Thurston County Health Department, 2009). This half-life suggests that nonanoic acid will not accumulate in the air (EC, 2010).

The European Commission (EC, 2010) indicates that nonanoic acid decomposes rapidly in land and water environments and does not accumulate in media (i.e., its persistence is low). Nonanoic acid is readily biodegradable in soil because it is broken down by soil microbes. Approximately half of the substance dissipates in soil in 2.1 days at 12°C (54°F), and it dissipates more rapidly (1.1 days) at temperatures around 20°C (68°F) (EC, 2010). The organic-carbon-adjusted soil adsorption coefficient (K_{oc}) of nonanoic acid is 1,700 mL/g, indicating that when present in a mix of soil and water, nonanoic acid will bind to soil rather than dissolve in water (Marin Municipal Water District, 2008). However, nonanoic acid does not bind tightly to most soil types (EC, 2010; Thurston County Health Department, 2009). Nonanoic acid also binds with calcium and magnesium salts to form insoluble complexes. This information indicates that nonanoic acid is not very mobile in soil and it will bond strongly to sediments in aquatic ecosystems (Marine Municipal Water District, 2008). Naturally-occurring background levels of nonanoic acid in soil have been estimated at 0.35–0.65 mg/kg soil (EC, 2010).

Because of its rapid biodegradability and low mobility in soil, nonanoic acid is not anticipated to be a significant groundwater contaminant (Marin Municipal Water District, 2008). In surface water, undissociated nonanoic acid is likely to adsorb to suspended solids and sediment (HSDB, 2008). Nonanoic acid does not hydrolyze in water (EC, 2010; Marin Municipal Water District, 2008; HSDB, 2008), but could volatilize from water if microbial degradation or adsorption to suspended solids/sediments does not occur (Marin Municipal Water District, 2008).

Animals rapidly metabolize nonanoic acid; therefore, bioaccumulation potential is low for terrestrial and aquatic organisms (Marin Municipal Water District, 2008; HSDB, 2008).

<u>Evaluation Question #5:</u> 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)).

Because nonanoic acid occurs naturally in many plants, including those consumed by humans, most people are exposed to small concentrations of nonanoic acid regularly (U.S. EPA, 2000). Nonanoic acid is a skin and eye irritant, and its fumes may also be irritating to the respiratory system (HSDB, 2008). In a human exposure study, a 12% nonanoic acid solution applied to the skin for 48 hours caused no irritation or sensitization in human volunteers. However, at a higher concentration (20%), approximately 90% of exposed subjects experienced an irritant reaction, exhibiting skin redness at 48 hours and pigmentation at 96 hours (HSDB, 2008).

In animal studies, nonanoic acid has caused moderate skin irritation in rabbits and severe skin irritation in guinea pigs. Studies of rats dosed via inhalation with aerosols of nonanoic acid showed some airway irritancy, but animals recovered within 14 days after exposure cessation (U.S. EPA, 2011a). A subchronic dermal study found that rabbits exposed to 500 mg/kg-day for 5 days per week lost weight 2 weeks after treatment initiation, but noted no other systemic effects. In vitro genetic toxicity tests in Salmonella were negative at all concentrations, with and without metabolic activation, suggesting that nonanoic acid is not mutagenic. A chronic study in which mice were treated dermally with 50 mg of nonanoic acid twice a day for 80 weeks found no neoplastic (cancerous) or non-neoplastic skin lesions (Marin Municipal Water District, 2008). In an embryo-fetotoxicity study in rats dosed via gavage with 1500 mg/kg-day nonanoic acid on gestation days 6-15, authors reported no maternal toxicity and no reproductive or developmental toxicity (based on observations of the uterus and ovaries, litter size, pregnancy rates, visceral and skeletal alterations, and other examined parameters) (U.S. EPA, 2011a).

Because the petitioned substance would be applied to the skin of livestock, some irritation may occur if an excessive amount is applied.

See Evaluation Question #4 for information on the persistence of nonanoic acid in the environment.

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

No specific information on environmental contamination from nonanoic acid manufacturing could be located. However, because it is widely used in many industrial processes, it may be released in waste streams (HSDB, 2008). There is also potential for small releases of nonanoic acid from the products made using the substance. The Environmental Working Group detected nonanoic in a number of samples of bottled water. Nonanoic acid is used in plastic manufacture and may have leached into the water from the plastic (EWG, 2008).

Given its rapid biodegradability and low mobility in environmental media and its lack of toxicity and toxic byproducts (see Evaluation Questions #4 and #5), nonanoic acid would not be expected to significantly contaminate the environment when applied as an insect repellent to livestock. Applying nonanoic acid by spraying (on animals or crops) will result in some chemical drift, which may contaminate nearby soil and surface waters, damage nontarget plants, and expose humans and wildlife through inhalation and dermal exposure. However, in general, toxicity of nonanoic acid is low in humans, animals, and nontarget plant species (U.S. EPA, 2000; Marin Municipal Water District, 2008).

<u>Evaluation Question #7:</u> 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)).

Nonanoic acid may interact with other fatty acids and/or other chemicals, and these interactions could affect its properties as a repellent or pesticide. Bosch et al. (2000) tested individual fatty acids (C1-C18) in combination with lactic acid and C3 (propanoic acid), lactic acid and C5 (valeric acid), and lactic acid plus the combination of C3 and C5. Results indicated, for example, that when lactic acid and propanoic acid were combined with individual fatty acids between C_5 and C_8, attractiveness was significantly increased. Neither propanoic nor valeric acid was different in their attractiveness to mosquitoes compared with controls when tested alone (Bosch et al., 2000). However, no information on interactions between nonanoic acid and fatty acids relevant to this petition (C8 and C10) or whether these interactions could affect toxicity or environmental impacts was identified.

Nonanoic acid is often mixed with pyrethrins or other EPA-approved herbicides/pesticides for use in weed control (Enrich-Prast, 2006) and controlling livestock pests (Loftin, undated), which suggests low interaction potential with these common agricultural chemicals. In a study in an aquatic setting, Enrich-Prast (2006) found that there was no cumulative effect on nitrification of a water body when insecticides including malathion and pyrethrin and several herbicides (including nonanoic acid and glyphosate) were applied together. One report indicated that nonanoic acid combined with succinic acid, diammonium succinate, lactic acid, or glycolic acid as other active ingredients significantly increased the visible damage to plants caused by nonanoic acid treatment. This finding suggests that nonanoic acid has enhanced herbicidal activity when combined with some compounds (Marin Municipal Water District, 2008). It should be noted, however, that some of the aforementioned herbicides/insecticides (e.g., malathion and glyphosate) are not permitted for use in organic agriculture. However, substances such as succinic acid and glycolic acid can be produced from natural sources (Advanced Biotech, undated); these nonsythetic forms would be allowable in organic agriculture. Nonsynthetic lactic acid is permitted as an active ingredient for organic handling and processing per 7 CFR § 205.605(a), and is allowed as a synthetic inert ingredient under EPA List 4B (U.S. EPA, 2004b).

<u>Evaluation Question #8:</u> 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)).

Davis et al. (1997) reported that nonanoic acid is toxic to nematodes. Weekly soil treatments with 6.4, 3.2, or 1.6 µL/L of nonanoic acid significantly reduced the number of galls (concentrations of starches and nutrients where larvae develop) on roots and the number of eggs produced by various nematode species (Davis et al., 1997). While this may be an effective insecticidal use for the control of unwanted nematode species, authors did not report whether nonanoic acid may be toxic to beneficial nematode species or earthworms. However, an EC review indicated that nonanoic is not toxic to earthworms in short-term toxicity tests at concentrations up to 202.2 mg/kg soil dry weight (EC, 2010). In aquatic ecosystems, toxicity to algae from nonanoic acid is similar to that of soaps. Marin Municipal Water District (2008) identified a nonanoic concentration of 180 mg/L as the LC_{50} (lethal concentration to 50% of the algae) for *Chlorella vulgaris*.

Because nonanoic acid is applied topically to livestock, it would not be anticipated to cause systemic toxicity in these animals. However, studies that evaluated potential effects in livestock were not found.

Marin Municipal Water District (2008) reported that, given its molecular structure, it is unlikely that nonanoic acid could interfere with endogenous estrogens (hormones) in animals. However, studies to confirm this are lacking.

Evaluation Question #9: Discuss and summarize findings on whether 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)).

As discussed in response to Evaluation Question #4, nonanoic acid decomposes rapidly in land and water environments, does not accumulate in media (i.e., its persistence is low), and is metabolized quickly in animals. Sources have also indicated that the mobility of nonanoic acid in soil is low (Marin Municipal Water District, 2008; HSDB, 2008). Because of its rapid biodegradability and low mobility in soil, nonanoic acid is not anticipated to be a significant groundwater contaminant (Marin Municipal Water District, 2008). Animals rapidly metabolize nonanoic acid; therefore, bioaccumulation potential is low for terrestrial and aquatic organisms (Marin Municipal Water District, 2008; HSDB, 2008). In general, data have indicated that the toxicity of nonanoic acid is low in humans and animals, and significant adverse effects on nontarget plant species would not be expected with proper use of nonanoic acid pesticides (U.S. EPA, 2000). However, nonanoic acid may be toxic to some nematode species (Davis et al., 1997). See Evaluation Question # 8 for more information on toxicity to nematodes.

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)).

Nonanoic acid is naturally occurring in the environment (e.g., soil, plants) and is found at low levels in many foods, such as grapes, oranges, apples, cheese, and milk (U.S. EPA, 1997).

The most often reported human toxicity studies involve dermal exposure. When applied to the skin at 12% concentrations for 48 hours, nonanoic acid caused no irritation or sensitization in human volunteers. However, at a higher concentration (20%) ~90% of patients experienced an irritant reaction, exhibiting skin redness at 48 hours and pigmentation at 96 hours (HSDB, 2008). Nonanoic acid is also a respiratory irritant (HSDB, 2008). Monitoring data suggest that the general population is exposed to small amounts of nonanoic acid on a regular basis from inhaling ambient air, eating food and drinking water, and through dermal exposure; the average daily consumption has been estimated at 0.001016 mg/kg/day (HSDB, 2008). No toxicity studies of ingestion/inhalation exposure at higher doses (combinations of background exposures and herbicidal use situations) were located.

EPA classifies nonanoic acid as "not acutely toxic" (not toxic in short-term exposure scenarios). Nonanoic acid has not been evaluated for chronic toxicity or carcinogenicity by the EPA (Marin Municipal Water District, 2008).

Evaluation Question #11: 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)).

Advanced Biotech claims to produce a nonsynthetic nonanoic acid for use as a food additive/flavoring (Advanced Biotech, 2011). However, the company does not specify in detail how the nonanoic acid is obtained and processed. The company provides an "organic product certificate" that claims the product is manufactured by a physical process in accordance with the USDA NOP regulations using non genetically modified botanical sources (Advanced Biotech, 2011c), but this information has not been independently confirmed.

Alternative repellent/insecticide substances include nonsynthethic pyrethrin sprays made from chrysanthemum flowers (e.g., PyGanic®; synthetic pyrethrins such as pyrethroid are not approved for use in organic agriculture by the USDA). Drawbacks of pyrethrin sprays include the possibility for pest resistance over time and the possibility that pyrethrin sprays will kill natural fly enemies like adult parasitoids (see Evaluation Question #12). If using pyrethrin with parasitoids, the pyrethrins should be sprayed at least two weeks before the parasitoids are released to protect the natural fly predators (NYSDAM, 2011). Furthermore, some sources question the effectiveness of pyrethrin insecticides, nonanoic acid, and other topical treatments. According to University of Arkansas entomologists, there are a variety of factors that may reduce the efficacy of topical applications including the size of the fly (requiring higher concentrations of insecticide); the brief amount of time an insect spends on the animal while feeding, limiting time it is in contact with the insecticide; the continued emergence and host seeking of numerous species over a relatively long period of time; the ability of insects to fly far distances in order to be protected from applications; and the wide range of larval habitat, which makes larval control difficult (University of Arkansas, undated).

Biting insects also can be controlled through the application of cedar oil. Cedar oil kills adult insects and dissolves insect eggs and larvae. An example product is the Nature's Defender line, manufactured by Nature's Own Solutions, which contains cedar oil and ethyl lactate/lactic acid (CAS 97-64-3, EPA List 4A inert) (Nature's Own Solutions, undated). This product is not listed by OMRI, but it would be allowed in organic agriculture if the cedar oil is nonsynthetic and the inert ingredients were listed on former EPA List 4. Synthetic oils are not listed on the allowable substances for livestock; therefore, it is presumed that any oil or other ingredient used in the livestock treatment would have to be nonsynthetic.

Various other nonsynthetic, essential oil-based repellents and treatments are also available to control livestock pests in both organic and conventional livestock. Peppermint oil, rosemary oil, soybean oil, thyme oil, geranium oil, and other plant-based oils are active ingredients exempted under the Federal Insecticide, Fungicide, and Rodenticide Act 25 (b) when used as pesticides to kill, destroy, mitigate, or repel pests (U.S. EPA, 2011b). Meadowland Natural Fly Repellent (soybean oil base) is one available product registered with OMRI (OMRI, 2011) under the classification of "livestock external parasiticides and pesticides." EcoExempt® IC, which is made of rosemary and peppermint oils in mineral oil, is another naturally-derived, oil-based product that is sprayed topically to repel biting insects (EcoSMART, 2005). Nature's Balance Livestock insect control formulations, which include combinations of lemongrass, citronella, and geranium, are topical products that can be applied to livestock's entire body, including the ears and the face (Nature's Balance Care, 2011). Khater et al. (2011) suggest that essential oils are sufficiently toxic to certain fly species. Authors tested lettuce, rosemary, chamomile, and anise essential oils on the green bottle fly (which affects humans and horses worldwide) and found that pupation rates were decreased with 8% lettuce oil, and adult emergence was reduced when applying 2% chamomile or lettuce oil. Authors also noted morphological abnormalities after treatment with any of the oils (Khater et al., 2011). Other research showed that peppermint oil (*Mentha piperita*) was extremely effective against house flies in the laboratory and the field, with high larval mortality rates, suppressed emergence of adult flies, and reductions in fly density on treated cattle. Lemongrass, while slightly less effective, was also fairly well performing in laboratory repellency, larvicidal, and pupicidal tests (Kumar et al., 2011). Laboratory tests also indicate that essential oils including *Citrus sinesis* (a plant used to make Chinese tea), *C. aurantium* (bitter orange), and *C. cinerea* (eucalyptus) were toxic to the house fly (Palacios et al., 2009).

<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)).

An alternative method to manage biting flies and other livestock pests is through the use of integrated pest management (IPM). IPM relies on monitoring, biological and mechanical pest management methods, and the use of only the least toxic chemical substances when nonchemical pest management efforts are ineffective. Researchers at New York State Department of Agriculture & Markets (NYSDAM; 2011) recommend that dairy farmers monitor biting fly populations through the use of sticky traps in 5–10 locations in the animal housing area. IPM also involves sanitation activities such as waste removal on a weekly basis during warmer months. Because house and stable flies both require decaying, moist matter for breeding, removing manure, moist hay, wet grain, and other waste will help reduce fly populations. Turning over compost (to expose immature flies to inner compost heat which kills them) and maintaining proper drainage will also help reduce flies (NYSDAM, 2011).

Mechanical fly control techniques include sticky tapes, strings, and ribbons, which can be used for small to moderate fly populations. However, effectiveness varies and these traps may need to be replaced every 1–2 weeks due to drying out or becoming completely covered in flies. Dairy barns can also be equipped with tightly closing screen doors in the milking area to keep flies away. Fans are helpful for drying out bedding and other moist areas (NYSDAM, 2011).

Another mechanical control mechanism is the use of a walk-through fly trap, which is used to dislodge flies from livestock as they pass through the trap (Loftin et al., undated). The insects then remain trapped until they die. Because animals have to move through these traps to remove flies, traps should be placed where animals must pass through to reach water or other necessities. Several studies have found that trapping methods are moderately effective, reducing flies by 57% and/or lowering insecticide (e.g., pyrethrin) use by 50–75% (Loftin et al., undated). Another mechanical treatment option is the back rubber, which is equipped with a face flap to remove flies on the face. While prohibited substances such as fuel oil are used in conventional back rubbers, organic producers can use soybean or vegetable oil instead (Loftin et al., undated).

Biological fly control techniques include the use of predators (e.g., birds and predator insects) and parasites (e.g., parasitic wasps). *Muscidifurax raptor* and *Muscidifurax raptorellus* wasps have been shown to significantly reduce house and stable fly populations when released on a farm. According to NYSDAM (2011), costs for parasitoid treatments usually range from $2.80–$3.36 per cow depending on the frequency and duration of releases. These estimates were based on research indicating that 200 parasitoids per milking cow or 1,000 parasitoids per calf were effective to control house and stable flies (NYSDAM, 2011). Other types of flies, including horn and face flies, that breed in fresh droppings (rather than decomposing material) can be controlled through the use of a number of arthropods including scarab and dung beetles. The efficacy of parasitoids can vary, with mixed results depending upon the species used, the numbers of parasitoids released, and the frequency of releases. The beetle *Carcinops pumilio* kills between 10 and 100 immature flies per day depending upon temperature, competition, and other prey; and populations in the field tend to be stable (Geden, 2005). Petersen and Curry (1996) found that when 200,000 *Muscidifurax partorellus* wasps were released in a beef cattle operation, there was a 96% parasitism of the fly populations within 2 weeks of release. In addition, stable and house fly emergence was reduced to 15.5% and 37.2%, respectively. The mortality of flies fell to background levels after an additional 3 weeks, indicating the need for multiple releases spaced ideally every 2–3 weeks (Petersen and Curry, 1996). Floate et al. (2000) also had positive results with a one-time release of 220,000 *Muscidifurax partorellus* wasps at two sites 200 meters apart, reporting 34% parasitism of house fly pupae. The chances of success with parasitoid methods might be best when combined with waste/water management methods, chemical controls (e.g., pyrethrins) (Townsend, 1994), and/or the use of combinations of predator species with complimentary characteristics (Geden, 2005).

Mites such as *Macrocheles muscaedomesticae* can also be used to control fly populations as mites attack fly eggs and newly hatched larvae. Mites are naturally found in cattle, poultry, pig, and sheep manure. Biological controls like these are probably most effective in areas such as calf hutches or newly cleaned poultry houses where resident mites and other fly predators are less prevalent. There were no commercial producers of *M. muscedomesticae* as of 2005 (Geden, 2005).

Another technique is allowing poultry to range close to cows because birds feed indiscriminately on flies. The presence of insect-eating birds such as swallows can also be encouraged through the placement of nesting boxes (NYSDAM, 2011). However, certain species, like barn swallows, are messy and it may be necessary to place a board under nests to keep droppings off of the barn walls and floor (Harwood, 2006).

An emerging biological fly control method is the use of viruses or other pathogens. For example, baculovirus (SGHV) causes hyperplasia of the fly's salivary glands and stops ovarian production in females. Researchers have found infection rates of up to 30% in field studies of flies (Geden, 2005). These viruses are highly specific to a particular genus and/or species and thus have no harmful effects on plants, mammals, birds, fish, or nontarget insects in the field (D'Amico, undated). Baculoviruses can be isolated from infected larvae in the field and replicated in the laboratory (Grzywacz et al., 2001). However, it is unclear if commercial baculovirus production methods would render it a synthetic substance. Because baculoviruses do not appear on the National List of approved synthetics for use in livestock, these products would have to be nonsynthetic to be allowed for use in organic livestock production.

References:

Advanced Biotech. 2011a. Organic product certificate: Caprylic acid natural/Capric acid natural. Retrieved December 8, 2012 from http://www.adv-bio.com/ProductDocs/IsOrgComp.aspx?ProdNo=1044 and http://www.adv-bio.com/ProductDocs/IsOrgComp.aspx?ProdNo=1193

Advanced Biotech. 2011b. National Organic Program Questionnaire – National Organic Program Use. Nonanoic acid. Accessed October 31, 2011 from http://www.adv-bio.com/ProductDocs/QAIOCDoc.aspx?ProdNo=1419

Advanced Biotech. 2011c. Organic product certificate: Nonanoic acid natural. Retrieved December 8, 2012 from http://www.adv-bio.com/ProductDocs/IsOrgComp.aspx?ProdNo=1419

Advanced Biotech. Undated. Product details: Succinic acid. Retrieved November 21, 2011 from http://www.adv-bio.com/ProductDetail.aspx?ProdNo=1288

Bernier, U.R.; Kline, D.L.; Posey, K.H. 2006. Chapter 4: Human emanations and related natural compounds that inhibit mosquito host-finding abilities. Armed Forces Pest Management Board. Retrieved October 20, 2011 from http://www.afpmb.org/sites/default/files/pubs/dwfp/publications/FY06/30-2006_Insect_Rep_Book.pdf

Bosch, O.J.; Geier, M.; Boeckh, J. 2000. Contribution of fatty acids to olfactory host finding of female *Aedes aegypti*. Chem Senses 25:323-330. Retrieved October 26, 2011 from http://chemse.oxfordjournals.org/content/25/3/323.full.pdf+html

Canadian General Standards Board. 2011. Organic Production Systems General Principles and Management Standards: CAN/CGSB-32.310-2006. Retrieved October 21, 2011 from http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/norms-standards/internet/bio-org/documents/032-0310-2008-eng.pdf

ChemIDplus Lite. 2011. Nonanoic Acid, RN: 112-05-0. Retrieved October 18, 2011 from http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp

Codex Alimentarius Commission. 2010. Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods. Retrieved October 20, 2011 from http://www.codexalimentarius.net/download/standards/360/cxg_032e.pdf

D'Amico. Undated. Biological control: Baculoviruses. Cornell University, College of Agriculture and Life Sciences, Department of Entomology. Retrieved November 7, 2011 from http://www.biocontrol.entomology.cornell.edu/pathogens/baculoviruses.html

Davis, E.L.; Meyers, D.M.; Dullum, C.J.; Feitelson, J.S. 1997. Nematicidal activity of fatty acid esters on soybean cyst and root-knot nematodes. Supplement to the Journal of Nematology 29 (4S):677-684. Retrieved October 26, 2011 from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2619835/pdf/677.pdf

EC (European Commission). 2010. Inclusion of active substances in Annex I to Directive 98/8/EC: Nonanoic acid. Retrieved October 21, 2011 from http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/review_programme/ca_reports/private_disinfectants/doc_ipdf/_EN_1.0_&a=d

EC (European Commission). 2008. Commission Regulation EC 889/2008. Retrieved October 20, 2011 from http://www.ceres-cert.com/portal/fileadmin/externdocs/889_2008_compressed.pdf

EcoSMART. 2005. MSDS: EcoEXEMPT IC. Retrieved November 8, 2011 from http://www.biconet.com/botanicals/infosheets/EcoExempt/ecoExemptIC2MSDS.pdf

Enrich-Prast, A. 2006. Effects of nitrification in aquatic sediment. Braz J Biol 66(2A):405-412. Retrieved October 26, 2011 from http://www.scielo.br/pdf/bjb/v66n2a/a04v662a.pdf

EWG (Environmental Working Group). 2008. Bottled water quality investigation: 10 major brands, 38 pollutants. Retrieved October 20, 2011 from http://www.ewg.org/book/export/html/27010

Floate, K.D.; Coghlin, P.; Gibson, G.A.P. 2000. Dispersal of the filth fly parasitoid *Muscidifurax raptorellus* (Hymenoptera: Pteromalidae) following mass releases in cattle confinements. Biological Control 18(2):172-178.

Geden, C.J. 2005. Biological control of pests in livestock production. Proceedings of the International Workshop "Implementation of Biocontrol in Practice in Temperate Regions – Present and Near Future." Research Center Flakkebjerg, Denmark, November 1-3, 2005. Retrieved November 7, 2011 from http://www.centre-biological-control.dk/proc2005.pdf

Grzywacz, D.; Parnell, M.; Kibata, G.; Odour, G.; Ogutu, W.; Miano, D.; Winstanley, D. 2001. The development of endemic baculoviruses of *Plutella xylostella* (diamondback moth, DBM) for control of DBM in East Africa. Proceedings of the 4th International Workshop, Nov. 2001, Melbourne, Australia. Retrieved November 7, 2011 from http://web.entomology.cornell.edu/shelton/diamondback-moth/pdf/2001papers/2001DBM38.pdf

Harwood, E. 2006. What's bugging you? Natural insect control or small acreages. Washington State University, Clark County Extension. Retrieved November 7, 2011 from http://clark.wsu.edu/horticulture/smallAcreageProgram/natural-insect-control.pdf

HSDB (Hazard Substances Data Bank). 2008. Nonanoic acid. Retrieved October 18, 2011 from http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

IFOAM (International Federation of Organic Agriculture Movements). 2011. The IFOAM norms, Version 0.2 (under development). Retrieved June 6, 2011 from http://www.ifoam.org/about_ifoam/standards/norms.html

JMAFF (Japan Ministry of Agriculture, Food, and Fisheries). 2005. Japan agricultural standard for organic livestock production. Notification No. 1608 of the Ministry of Agriculture, Food, and Fisheries. 5 pp. Retrieved October 20, 2011 from http://www.maff.go.jp/e/jas/specific/pdf/4.pdf

Khater, H.F.; Hanafy, A.; Abdel-Mageed, A.D.; Ramadan, M.Y.; El-Madawy, R.S. 2011. Control of the myiasis-producing fly, *Lucilia sericata*, with Egyptian essential oils. International Journal of Dermatology 50(2):187-194. [abstract] Retrieved November 7, 2011 from http://onlinelibrary.wiley.com/doi/10.1111/j.1365-4632.2010.04656.x/abstract

Kumar, P.; Mishra, S.; Malik, A.; Satya, S. 2011. Repellent, larvicidal, and pupicidal properties of essential oils and their formulations against the housefly, *Musca domestica*. Medical and Veterinary Entomology 25(3): 302-310. [abstract]. Retrieved November 7, 2011 from http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2915.2011.00945.x/abstract

Loftin, K.M.; Pennington, J.A.; Brazil, S.M. Undated. Fly control for organic dairies. University of Arkansas, Division of Agriculture, Cooperative Extension Service. Retrieved November 7, 2011 from http://www.uaex.edu/Other_Areas/publications/PDF/FSA-7072.pdf

Marin Municipal Water District. 2008. Vegetation management plan: Herbicide risk assessment. Chapter 7: Pelargonic acid. Retrieved October 26, 2011 from http://www.marinwater.org/documents/Chap7_PelargonicAcid_8_28_08.pdf

Mullens, B.A.; Reifenrath, W.G.; Butler, S.M. 2009. Laboratory trials of fatty acids as repellents or antifeedants against houseflies, horn flies and stable flies. Pest Manag Sci 65:1360-1366. Retrieved October 26, 2011 from http://www.afpmb.org/sites/default/files/pubs/dwfp/publications/fy09/Mullens_Reifenrath_Butler_2009.pdf

Nature's Balance Care. 2011. Livestock-barn products. Retrieved October 31, 2011 from http://www.naturesbalancecare.com/Livestock-Barn_Products.html

Nature's Own Solutions. Undated. Farm care. Retrieved November 8, 2011 from http://www.naturesownsolutions.com/store/farmcare.htm

NYSDAM (New York State Department of Agriculture and Markets). 2011. Integrated pest management guide for organic dairies. Retrieved October 31, 2011 from http://www.nysipm.cornell.edu/organic_guide/dairy.pdf

OMRI (Organic Materials Review Institute). 2011. Fast Products, LLC. Retrieved November 8, 2011 from http://www.omri.org/manufacturers/65842/fasst-products-llc

Palacios, S.M.; Bertoni, A.; Rossi, Y.; Santander, R.; Uzrua, A. 2009. Efficacy of essential oils from edible plants as insecticides against the house fly, *Musca domestica* L. Molecules 14:1938-1947. Retrieved November 7, 2011 from www.mdpi.com/1420-3049/14/5/1938/

Petersen, J.J.; and Currey, D.M. 1996. Timing of releases of gregarious *Muscidifuras raptorellus* (Hymenoptera: Pteromalidae) to control flies associated with confined beef cattle. Journal of Agricultural Entomology 13(1):55-63. Retrieved November 7, 2011 from http://scentsoc.org/Volumes/JAE/v13/1/00131055.pdf

Reifenrath, W.G. 2011. Petition to National Organics Standards Board. April 26, 2011. Provided to ICF International by U.S. EPA.

Reifenrath, W.G. 2005. Natural insect repellent, Washington D.C.: U.S. Patent and Trademark Office, 2005, U.S. Patent No. 6,953,814. Retrieved October 20, 2011 from http://www.patents.com/us-6953814.html

Skinner, W.A.; Tong, H.C.; Maibach, H.I.; Skidmore, D. 1970. Human skin-surface lipid fatty acid—Mosquito repellents. Experientia 26(7):728-730. Cited in Bernier et al., 2006.

Swern, D.; and Port, W.S. 1952. Polymerizable derivatives of long-chain fatty acids. VI. Preparation and applicability of urea complexes of vinyl esters. Journal of the American Chemical Society 74 (7): 1738–1739. [abstract] Retrieved November 7, 2011 from http://pubs.acs.org/doi/pdf/10.1021/ja01127a039

Thurston County Health Department. 2009. Pelargonic acid (nonanoic acid); review date: 7/1/2009. Retrieved November 15, 2011 from http://www.co.thurston.wa.us/health/ehipm/pdf_terr/terrestrial%20actives/Pelargonic%20acid.pdf

Townsend, L. 1994. Biological control of flies. University of Kentucky College of Agriculture. Retrieved November 7, 2011 from http://www.ca.uky.edu/entomology/entfacts/ef502.asp

University of Arkansas. Undated. Horse flies and deer flies on cattle. Division of Agriculture, Cooperative Extension Service. Retrieved November 4, 2011 from http://www.uaex.edu/Other_Areas/publications/PDF/FSA-7035.pdf

USDA (U.S. Department of Agriculture). 2010. USDA SBIR success. SBIR Impact, July 2010. Retrieved October 18, 2011 from http://www.csrees.usda.gov/newsroom/newsletters/sbir/sbir_1007.html

U.S. EPA (U.S. Environmental Protection Agency). 2011a. High production volume information system (HPVIS). Detailed chemical results: Nonanoic acid. Retrieved October 21, 2011 from http://iaspub.epa.gov/oppthpv/quicksearch.display?pChem=100241

U.S. EPA (U.S. Environmental Protection Agency). 2011b. Minimum risk pesticides. Retrieved December 8, 2011 from http://www.epa.gov/oppbppd1/biopesticides/regtools/25b_list.htm

U.S. EPA (U.S. Environmental Protection Agency). 2004a. List 4A - Minimal risk inert ingredients - By chemical name. U.S. EPA, Office of Pesticide Programs. Retrieved October 20, 2011 from http://www.epa.gov/opprd001/inerts/inerts_list4Aname.pdf

U.S. EPA (U.S. Environmental Protection Agency). 2004b. List 4B - Other ingredients for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment. U.S. EPA, Office of Pesticide Programs. Retrieved October 20, 2011 from http://www.epa.gov/opprd001/inerts/inerts_list4Bname.pdf

U.S. EPA (U.S. Environmental Protection Agency). 2000. Pelargonic acid (217500) fact sheet. Retrieved October 20, 2011 from http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_217500.htm

U.S. EPA (U.S. Environmental Protection Agency). 1997. Pelargonic acid; tolerance petition 1/97. Retrieved November 15, 2011 from http://pmep.cce.cornell.edu/profiles/herb-growthreg/naa-rimsulfuron/pelargonic-acid/pelargonic-acid-tol.html

Venter, G.J.; Labuschagne, K.; Boikanyo, S.N.B.; Morey, L.; Snyman, M.G. 2011. The repellent effect of organic fatty acids on *Culicoides* midges as determined with suction light traps in South Africa. Veterinary Parisitology 181(2-4):365-369. Retrieved October 26, 2011 from http://www.sciencedirect.com/science/article/pii/S0304401711002950 [abstract]

Watson, D.W.; Denning, S.S.; Zurek, L.; Stringham, S.M.; Elliott, J. 2003. Effects of lime hydrate on the growth and development of darkling beetle, *Alphitobius diaperinus*. Retrieved November 2, 2011 from http://www.pjbs.org/ijps/fin68.pdf