Petition

To

National Organic Standards Board

April 26, 2011

Petitioner:

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Action Requested:

We hereby petition the NOSB to add the naturally occurring fatty acid “nonanoic acid” to Section 205.603 of the National Organic Program as a synthetic substance allowed for use as an insect repellent/insecticide in organic livestock production.

Specifically, the action requested is the allowance for combination of nonanoic acid with octanoic and decanoic acids in mineral oil or clay formulations applied directly to the skin of livestock to control biting flies, lice, ticks and other ectoparasites on cattle and horses.

Background:

C8910^R fly repellent is a mixture of 3 medium chain fatty acids, octanoic (C8), nonanoic (C9), and decanoic (C10) formulated in light mineral oil (baby oil) or in clay dusts. All of the actives have Generally Recognized as Safe (GRAS) status with the U.S. FDA and have been approved for use as food additives in the U.S. and elsewhere (see Exhibits A, a summary of safety data for C8, C9 and C10 and Exhibit B for ecotoxicology). The C8 and C10 components are natural sourced from coconut or palm kernel oil by a process of steam hydrolysis. While C9 exists in many plants and is found in the atmosphere from the action of lightning on ambient oxygen and oleic acid present as a film on water droplets (King et al., 2009), a practical source of C9 does not exist in nature.

C8910 was developed under an SBIR grant from the USDA as a natural fly repellent for livestock. The following 2 paragraphs were taken from the 2006 Annual CRIS Report:

Arthropod repellent formulations, based on economical, low-toxicity, all natural ingredients were developed for cattle and horses to provide relief from stable flies (Stomoxys calcitrans), horn flies (Haematobia irritans), and cattle lice (Bovicola bovis, Solenopotes capillatus, and Linoganthus vituli). The repellent also had activity against face flies (Musca autumnalis), house flies (Musca domestica), sand flies (Lutzomyia longipalpis), mosquitoes (Aedes aegypti and Culex quinquefasciatus) and ticks (California black-eyed tick (Ixodes pacificus) and lone star tick (Amblyomma americanum)). Solid formulations having appropriate flow properties were developed for use in dust bags or cattle rubs. Liquid formulations were developed for spray or wipe-on application. Liquid and dust formulations were physically stable. Extraction and assay procedures based on HPLC demonstrated chemical stability of the actives in both types of formulation (over 7 years in the case of the liquid formulation). Horn fly repellency was demonstrated under actual use conditions in three trials using dust bags, and when tested in comparison to pesticide treatments (coumaphos and tetrachlorvinphos), gave similar reductions in horn fly numbers (approximately 90%) on pastured cattle. The liquid formulation provided reduction in stable fly counts when applied to the legs of pastured horses and dairy cattle.

Expected Impact: Animal agriculture contributes significantly towards total U.S. farm income, with one estimate at about 50% or approximately 87 billion in 1994 dollars. The production of range cattle, confined beef and pastured beef cattle and the dairy industry are important segments of this activity. The revenue generated by these activities is adversely affected by arthropod pests, specifically the horn fly and stable fly. Traditional methods of pest control have involved the use of topically applied pesticides (pyrethroids and organophosphorus chemicals). Because of the increasing concerns of the impact of these chemicals on the environment and human health and the increasing costs of maintaining the EPA registration of these compounds, the number of agents available for livestock pest management has declined. Reliance on only a few active ingredients has created additional problems with pesticide resistance.

Since the completion of the USDA SBIR grant, the mixture of fatty acids (trademarked C8910) has undergone additional safety and efficacy tests and a data package was submitted to the US EPA in 2007. In the fall of 2009, the Biopesticides and Pollution Prevention Division of US EPA issued unconditional registration for the use of C8910 on food producing livestock (beef and dairy cattle) and for horses to repel stable flies, horn flies, house flies, ticks, and cattle lice. C8910 has recently been registered by the USEPA for fly control on livestock (Exhibit C). USEPA has further decided that C8910 can be used on food producing animals (Exhibit D).Efforts are underway to register and market C8910 world-wide for use on livestock. A comparison of C8910 efficacy vs. pyrethroid pesticides is given in Exhibit E for horn flies and Exhibit F for stable flies. Exhibit F also contains efficacy data for C8910 against house flies, cattle lice and ticks. Exhibit G is the MSDS for C8910 and the MSDS for nonanoic acid itself is exhibit H.

Additional research has shown that other formulations of C8910 had effective repellency against mosquitoes (Aedes aegypti and Culex quinquefasciatus), house flies, sand flies, and eye flies, insects that are a direct concern for humans. These activities have a global impact, as no new public health insecticides have been developed for vector control in disease ridden counties for 30 years. Mosquitoes are notorious for vectoring such important tropical diseases as malaria, yellow fever, and human filariasis. The ordinary house fly is a world-wide problem; it can transmit typhoid fever, cholera, dysentery, pinworms, hookworms, and some tapeworms. Musca species filth flies are also involved in the spread of trachoma, the lending cause of preventable blindness in the world. Leishmaniasis is a complex of diseases spread by the sand fly. World-wide, approximately 12 million people have leishmaniasis and about 350 million people are at risk for catching the disease. Eye gnats and eye flies (genus Siphunculina) are small insects (1-2 mm) that infest large areas of the tropics and subtropics. They are extremely annoying to humans and domestic animals, feeding on mucous secretions and most surfaces of the host body such as eyes, nose, ears, and lips. Due to annoyance or actual spread of disease, flies inflict billions of dollars of loss in world-wide livestock production. In the developing world, these economic losses have a direct negative impact on human health. Preliminary studies have shown that C8910 has activity against the tsetse fly (personal communication, Brian Weiss, Dept. of Entomology and Public Health, Yale School of Medicine, New Haven, CT, August 3, 2009). The tsetse fly is well known for its role in African trypanosomiasis (sleeping sickness in humans) and trypanosoma-caused nagana has eliminated most animal agriculture throughout large areas of Africa. Field testing and registration activities are underway with a collaborating company, Afrivet, in South Africa to register several formulation of C8910 for livestock as well as for direct application to human skin. Of particular interest are the promising results against *Culicoides* midges which transmit the viral disease, horse sickness, a major concern to the horse breeding and racing industry due to the inadequacies of the vaccines currently available. Similarly, protecting ruminant livestock against mosquitoes transmitting Rift Valley fever, a zoonotic disease which causes abortions and death even of some game species during outbreaks which occur during years of abundant rains, as were seen this year. Mosquito repellent efficacy was confirmed at the South African Bureau of Standards as malaria is an important disease in the north-eastern parts of South Africa and the rest of the continent of Africa. The results above were added to information received from the suppliers and applications for registration of the products for use on man and livestock have been submitted.

OMRI Review: On January 23, 2010, Stratacor submitted a product application, “C8910 Fly Repellent Oil” for consideration as an addition to the OMRI Products List for organic production. In a letter dated May 17, 2010 from Mr. Deder Siedler, Product Review Coordinator for OMRI , Stratacor was informed that the OMRI Review Panel recommended that subject product be prohibited for use in organic production. Specifically, the panel felt that all the active ingredients, octanoic, nonanoic, and decanoic acids were synthetic ingredients, based on their method of commercial preparation. Following receipt of this letter at Stratacor, the Review Panel objections were discussed with Mr. Siedler. He indicated that the process of steam hydrolysis to make octanoic and decanoic acids from palm oil was acceptable and that the primary objection was the commercial preparation of nonanoic acid. Mr. Siedler recommended that Stratacor petition the National Organic Program to have nonanoic acid listed as an allowable synthetic.

Petitioner’s Appeal

On the basis of the data included in this petition, the petitioner believes that all livestock, whether organic or conventional, contain traces of nonanoic acid as well as many other naturally occurring fatty acids. Thus, nonanoic acid is on or in all non-processed meat products and is organic.

Justification:

The many years of academic and USDA testing for new, more effective pesticides for organic farming have not been rewarding. In a 1994 Report entitled “Research and Extension Needs for Integrated Pest Management for Arthropods of Veterinary Importance”, it was stated that “we have no new chemistry for livestock and poultry arthropod pest management for almost 13 years. Sixteen years later, the situation has not changed, as noted in a recent Request for Proposals (June 25, 2010) from the Foundation for the National Institutes of Health: “Despite the great need for environmentally safe insecticides for public health use, industry’s interest in pursuing research and development for new chemical agents to control malaria and other vector-borne diseases traditionally has been limited by the perceived lack of return on investment”. In the malaria areas of Kwazulu Natal, South Africa, pyrethroid resistance in the mosquito population has resulted in the very unpopular use of DDT, as no alternative exists (Personal Communication, Peter Oberem, September, 2010). On February 23, 2011, the Secretariat of the Stockholm Convention issued a notice calling for papers on “Innovative Alternatives to DDT” in support of the Global Alliance for developing and deploying alternatives to DDT for disease vector control established under the Stockholm Convention.

Livestock health and human health are inseparable. It goes without saying that the economic benefits of a healthy livestock industry have a direct impact on the affordability of human health care. A focus on human health, without consideration of livestock health, can lead to disaster. In Africa, the extensive dependence on pyrethroid treated bednets has lead to a much greater proportion of zoophilic mosquitoes (*Anopheles arabiensis*) over the usual vector of malaria, *Anopheles gambii* (Bayoh, MN, et al., 2010). Since zoophilic mosquitoes can feed on both cattle and humans, as opposed to the anthropophilic *Anopheles gambii*, they are more difficult to control; this effect may be responsible for an upsurge in malaria in parts of Africa (personal communication, Robert Wirtz, CDC Atlanta, October, 2010). Using deltamethrin as a cattle treatment, Rowland showed a significant reduction in malaria incidence in local human inhabitants in Pakistan, where the predominant vector of malaria is *Anopheles arabiensis*, with the added benefit of increased livestock productivity (Rowland, M, et al., 2001).

In 2007, OMRI listed 9 products in the External Parasiticides and Pesticides category for livestock. Four were based on pyrethrum (3 by MGK Corporation and 1 by Farnam), 2 were external parasiticides (Equicite and Natural Fly, Flea, and Tick Control, both by ACM-Texas, LLC), one was based, presumably, on garlic (Garlic Shield, Grotek, Inc.), one was based on Iodine (IoGold, IoGold Systems, Inc.), and one was based on essential oil (Bare Skin Barrier by Natures Balance Care, LLC). Four of the 9 products listed above disappeared from the 2011 OMRI list (the two products by ACM-Texas and the iodine and garlic products). In 2011, one additional pyrethrum product was added by MGK, to make a total of 5 products based on pyrethrum. Five larvacide products based on spinosads were added by Clarke, one essential oil product based on rosemary and peppermint oil (Ecotrol EC for Animal Health), and one soybean oil based product (Meadowland Natural Fly Repellent) was added, making a total of 13. The 5 spinosad products are intended for terrain application to kill larvae in breeding sites and are not intended for topical application to livestock; subtracting these 5 from OMRI's total of 13 leaves a balance of 8 products in the External Parasiticides and Pesticides category, one less than the total in 2007. Five of the remaining 8 have the same active ingredient (pyrethrins), and the remaining 3 are essential oils. Therefore, for external pest control on livestock, there are only two choices of chemistries: pyrethrins or essential oils.

Pyrethrins, the active insecticidal constituents of pyrethrum flowers, suffers from a very short duration, and is intended only for immediate knockdown of flies. It oxidizes readily in air and should be refrigerated and stored in darkness (Merck Index, 1996). Since it is chemically related to the synthetic pyrethroids, cross-resistance further limits it effectiveness. The high cost (e.g. Pyganic at over $100/quart) is a further disadvantage. Pyrethroids, including pyrethrins, are known endocrine disrupters, are highly toxic to fish and bees, and may cause severe allergic reactions in sensitive people, unless specific naturally occurring components are removed. The remaining 3 products are in OMRI's essential oils category (grapeseed oil, jojoba, citronella, lemongrass, lavender, tea tree oil, rosemary oil, peppermint oil, and soybean oil); it has long been known that these products have low activity as mosquito repellents (Handbook of Nonprescription Drugs, 1993) and have not been shown to be competitive in efficacy with organophosphates and pyrethroids for insect control in the field. The vapor pressure of essential oil constituents at 25^{o}C ranges from 2 to 4400 microns, with alpha-pinene, a major component of spearmint oil, at 4400 microns, menthol and menthone, major components of peppermint oil, at 54 and 220 microns respectively, geraniol at 20.5 microns, and cinnamaldehyde at 29.5 microns (Appell, 1970). To put these numbers into perspective, N,N-diethyl-m-toluamide or DEET, the leading insect repellent, has a vapor pressure of 1.67 microns at the same temperature. We measured the evaporative loss of DEET from the skin surface at 65-75% of an applied use dose (Reifenrath et al., 2009), with most of the loss occurring in the first few hours after application. Therefore, it can be appreciated that the essential oils, with much higher vapor pressures, will not have much of a residual effect because of evaporation. The high permeability of cattle and horse skin will further diminish the surface levels of the essential oils, exacerbating the losses caused by evaporation. Peppermint oil is said to be non-toxic and non-irritant at low concentrations. However, if higher doses are applied in an attempt to combat rapid loss by evaporation and penetration, skin irritation and sensitization reactions may occur (http://www.essential oils.co.za/essential-oils/peppermint).

The insecticidal activities of the essential oils may be due to reactive double bonds that result in alkylation of proteins on the insect. Cinnamaldehyde (a component of cinnamon oil) has alpha-beta unsaturation to the aldehyde group, and can readily undergo Michael addition with nucleophilic groups on proteins. Pulegone, a component of peppermint oil, and carvone, a component of spearmint oil, have alpha-beta unsaturation to a ketone group, and are similarly reactive. These reactions may contribute to the insecticidal activity. Unfortunately, the same reactions can occur on human skin and are implicated in allergic sensitization reactions.

Peppermint oil has been suspected of potential adverse systemic effects (Dong, et al., 2011). The mint oils, in particular peppermint oil, contain variable quantities of pulegone and menthofuran, depending on where *Mentha peperita* is grown, and these naturally occurring components cause liver toxicity (Opinion of the Scientific Committee on Food on pulegone and menthofuran, European Commission, 2002). The Committee concluded that data were "inadequate for the derivation of an ADI", the acceptable daily intake. Pulegone and menthofuran have been shown to penetrate human skin (Dong, et al., 2011) and since percutaneous absorption in cattle skin is likely to be considerably higher than in human skin (Reifenrath, 2007), the safety of applying large quantities of the mint oils on cattle skin is questionable, as it relates to the health of the cattle and the health of humans eating meat derived from these cattle. Cassia oil or cinnamon oil contain cinnamaldehyde, which ranks in the top ten for skin sensitizers. A survey of essential oil prices (peppermint and spearmint, pennyroyal, rosemary, tea tree, eucalyptus, geranium, lavender, lemon, lemon-eucalyptus, menthol, catnip, cassia and cypress oils) gave a range from $30 to over $170 per pound. Compare these costs to $1-3 per pound for fatty acids. While cost is not a primary criterion for the NOSB Committee, the livestock industry operates on small margins and costs are a primary consideration for a producer considering organic production.

In summary, the ectoparasiticides now acceptable with restrictions under the NOP are not part of the basic mammalian biochemistry as are fatty acids and are clearly inadequate to satisfy those organic farmers that require a safe, economical and effective control method. The purpose of the NOSB is to modify the NOP as new data is acquired. The use of a naturally occurring substance like nonanoic acid, in combination with other naturally occurring fatty acids (octanoic and decanoic acids) are consistent with the NOP, the goals of organic farming and the beliefs of the organic consumer. Therefore, we respectfully request that the NOSB, after studying the Exhibits included with this petition, conclude that nonanoic acid should be added to the NOP as an allowed synthetic ectoparasiticide for insect and arthropod control on or around food producing animals. We believe that it will be beneficial to the entire organic community worldwide, both producers and consumers, and promote the goals of the National Organic Program to increase organic production.

Even chain length fatty acids are most abundant in nature. Odd chain length fatty acids such as nonanoic acid are also present in many fruits, vegetables, and meats. However, the level of nonanoic acid is relatively low. A synthetic route is the only feasible method for production of sufficient quantities for use as a pesticide.

Section 6517 (National List) of the Federal Organic Foods Production Act (OFPA) that defines the permitted use of certain synthetic substances in organic farming is reproduced below. Two paragraphs, (A)(iii) and (B)(i) are pertinent to this petition.

(1) Exemption for Prohibited Substances. The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances (i) would not be harmful to human health or the

environment; (ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products***;*** *and (iii) is consistent with organic farming and handling;*

(B) the substance

(i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock paraciticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers;

The following four points based on the aforementioned regulation in Section 6517 provide clear reasons for the listing of nonanoic acid as an ectoparasiticide:

Point 1A(i) Safety

The use of nonanoic acid, together with octanoic and decanoic acids as an ectoparasiticide would not be harmful to human health is supported by their FDA GRAS status as food additives since 1965 (Opdyke, 1981). The US EPA allowance of the use of C8910 on food producing animals (Exhibit C) provides further support. Ecotoxicologic studies (Exhibit B) support the contention that a fatty acid based ecetoparasiticide would not be harmful to the environment Herbicidal activity of nonanoic acid and related fatty acids can occur when the fatty acids are formulated with surfactants or organic solvents (e.g. emulsifiable concentrates containing petroleum distillates). A 40% solution of ammonium nonanoate, a surfactant itself, in water is registered as a bioherbicide by the EPA as Registration No. 79766-1. Application rates may be as low as 30 gallons of a 4% solution per acre, according to the manufacturer. Overspray on desirable plants is not considered to be a problem, since the product is not a systemic herbicide and high leaf coverage is required for significant plant injury to occur. Significant reduction of ambient mosquitoes occurred with C8910 at a rate of 18 gallons of a 2% dispersion per acre, a level 3 times lower than the lowest recommended application rate for herbicidal activity

Point 1A(ii). Necessity

Currently approved ectoparasiticides for organic livestock production include a number of essential oils that act as insect repellents. Their efficacy against mosquitoes is significantly less than that of DEET (N,N-diethyl-m-toluamide) and they are even less effective against horn flies and stable flies, the major pests of livestock causing significant economic loss. Pyganic, based on pyrethrum extract of chrysanthemums, is the only traditional insecticidal product approved for organic livestock production. It is imported from Africa, and unless specifically purified, pyrethrum extract can contain allergenic components. Pyrethrum is available only from foreign sources with the potential risk of an unreliable supply. Pyrethrum is very unstable in light and air, limited the areas where they are effective (Casida, 1980), so its use is limited to fly knockdown at the time of spraying. In recent decades, the use of pyrethrum extract has largely been replaced by synthetics that are more stable, safer, and much less costly. For example, Pyganic costs over $100 per quart, compared to synthetic based products at 1/5 the cost. Pyganic dust costs approximately $30 per pound, compared to roughly $2 per pound for synthetic pyrethroid dusts. Because the livestock industry operates at small margins, Pyganic's cost could discourage some producers from organic production. It may also cause producers to accept the economic losses caused by flies, sacrificing the welfare of the animals.

Pesticides are frequently formulated as emulsifiable concentrates(e.g. pyganic concentrate) to be diluted in water by the end user. This saves on transportation costs and water is a low cost vehicle. However, because of the presence of surfactants and organic solvents, skin penetration of the actives can be high. Changing the vehicle for permethrin from ethanol to an emulsifiable concentrate resulted in an increase in estimated human skin absorption from about 2% to 30% (Reifenrath, 2007). Absorption through cattle skin is even higher at 60%. Fatty acid absorption also occurs, but the fatty acids are rapidly metabolized to carbon dioxide, so the absorption is not of toxicological significance.

In summary, the wholly natural products now available to organic farmers as permitted in Sec. (A)(iii) are inadequate for safe, effective economical control of biting flies under the provisions of § 205.603.

Point 1A(iii). Consistency with Organic Practice

Natural Occurrence. None of above described essentials oils or pyrethrins that are considered organic are part of the normal human diet. The fatty acids are a significant part of the daily diet, for they occur in dietary lipids (Exhibit A).

The subject fatty acids are naturally occurring in a wide variety of plants, fruits, and oils and are ***not*** synthetic substances. Small amounts of octanoic acid are reported to occur in the essential oils of Cupressus Torulosa, Cryptomeria japonica, Andropogon iwarancusa, Cymbopogon javanensis, camphor, nutmeg, lemongrass, line, tobacco (flowers), Artemisia herba-alba, chamomile, hops and other plants and to be found in apple aroma, coconut oil (as glyceride) and wine (as an ester), and (both free and esterified) among the constituents of petitgrain lemon oil (Opdyke, 1981). Octanoic acid is also found in apple, banana, cherries, citrus fruits, grape, papaya, peach, pear, raspberry, blackberry, strawberry, sauerkraut, tomato, cinnamon, mint, breads, milk products including

cheeses, heated lab, beef and pork, beer, grape brandy, rum, whiskey, cider, sherry, wine, cocoa, coffee, tea, roasted peanuts and wild marjoram, plum brandy and pear brandy (Opdyke, 1981).
Low levels of nonanoic acid were reported to occur in several essential oils, including those of rose, geranium, orris, Litsea cubeba, Artemisia arborescens L., hops, Chamaecyparis pisifera Endl., Eremocitrus glauca L. and French lavender, and in oak moss (Opdyke, 1981).
Decanoic acid is reported to occur at low levels in several essential oils, including chamomile, lemongrass, hop, American pennyroyal, lime, pha-chium, aniseed and fusel oil from grape bagasse. It is also found in apples, banana, cherry, citrus fruits, grape, papaya, peach pear, strawberry, potato, aniseed, cinnamon, mint, bread, cheeses, milk and milk products, heated beef, lamb and pork, beer, grape brandy, rum, whisky, cider, sherry, wine, cocoa, coffee, tea, roasted peanut, American potato chips, soya beans, Arctic bramble, cloudberry, passion fruit, mushroom, wild marjoram and plum brandy (Opdyke, 1981) .

Saturated fatty acids C7 to C18, including octanoic, nonanoic, and decanoic acids, were identified on the skin surface of human subjects (Skinner et. al., 1977). Insects share the fatty acid biosynthetic pathways with humans and a review of the literature shows that fatty acid biosynthesis can play a key role in the production of pheromones. For example, fatty acids in emanations or extractions from a variety of insects (ants, mosquitoes, sand flies, black flies, reduvid bugs, ticks) have been implicated in modifying or directing their behavior (The Pherobase, database of pheromones and semiochemicals). Straight chain fatty acids in the range of C6 to C12 have been found in the foraging trails of ants (Huwyler et al., 1973) and fatty acids may have a role in ant necrophoresis (removal of dead ants from the nest, Haskins et al., 1974). Nonanoic (pelargonic) acid was identified (Schoni et al., 1984) as a contributing chemical to pheromone activity for the tropical bont tick (*Amblyomma variegatum Fabricius*). Octanoic and nonanoic acids have been identified in volatiles excreted by Brindley's gland of adult *Triatoma infestans*; many of their behaviors (e.g. aggregation, sexual communication, host location, alarm responses) appear to be mediated by semiochemicals (Gonzalex et al., 2007). Fatty acids (octanoic, nonanoic, decanoic, and lauric acid) were identified as defining, in part, the differences in male and female cuticular washes of black flies (*Wilhelmia equina* L., Buda et al., 2003).

<u>Commercial sources of fatty acids</u>. The commercial preparation of the fatty acids contained in C8910 mirrors the processes by which the free fatty acids are created in nature. The commercial source of octanoic and decanoic acids starts in triglyceride form with coconut or palm kernel oil, Reaction with water, analogous to the digestion of fats by animals, results in the production of free acids.

The commercial source of nonanoic acid occurs at Emery Oleochemicals, Cincinnati, Ohio. Natural organic oleic acid is the only starting material. This basic raw material is isolated from agriculturally produced edible fats and oils.

Oleic acid is exempt from EPA registration (FIFRA (25)(b)). The oleic acid content of some edible fats and oils are shown in the table below.

SOURCE	% OLEIC ACID
Butterfat	20.4
Canola oil	53.8
Corn oil	24.2
Olive oil	72.5
Sunflower oil	19.5
Soybean oil	22.3
Tallow (animal fat)	36.0

J.A.Kent, ed., *Riegel's Handbook of Industrial Chemistry, Ninth Edition*, pg. 278, 1992

In the Emery plant, oxygen from the atmosphere is blown through oleic acid. Just as in nature, the result is a 50/50 mixture of nonanoic acid and azelaic acid, another substance widely distributed in nature. The two are separated by distillation. The isolated nonanoic acid is a water-insoluble liquid, while azelaic acid is a solid material used in cosmetics, skin treatments (e.g. anti-acne), polymers, hydraulic fluids and lubricants. There is no environmental impact of this process. All products of this process are consumed; as a result, there is no landfill disposal.

Mechanism of Action. Traditional insecticides are neurotoxins and can be divided into 4 classes (Cassida, et.al., 1983): 1) chlorinated hydrocarbons acting on nerve membranes or synapses such as DDT and lindane, 2) organophosphorus compounds (e.g. malathion and parathion) and 3) carbamates (e.g. carbofuran) that act as acetyl cholinesterase inhibitors, and 4) pyrethroids (e.g. pyrethrum, permethrin, cypermethrin) that interfere with sodium ion and perhaps calcium ion transport (Gassner et al., 1997). The neonicotinoids, with a mode of action similar to the natural insecticide nicotine, represent a newer class of neurotoxic insecticides (e.g. imidacloprid) that act selectively at post-synaptic nicotinic acetylcholine receptors and do not appear to have cross resistance to organophosphorus, carbamate or pyrethroid types of insecticides. The only traditional pesticide that is currently allowed for fly control in organic production is based on the pyrethrum extract, which is also a neurotoxin. The remaining fly control products for organic production are based on essential oils whose duration of action is severely limited by their high volatility. Repellents utilizing oils of citronella, turpentine, pennyroyal, cedarwood, eucalyptus and wintergreen are relatively ineffective against mosquitoes (Handbook of Nonprescription Drugs, 1993) and less effective against flies. The best commercial insect repellent, N,N-diethyl-m-toluamide, is disallowed for organic production. Even if it were allowed, its repellency against flies of economic concern for livestock (horn flies, stable flies) is very poor (Blume et al., 1971)

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Point 1B (the substance)

Section 6517 (B)(i) of the OFPA lists the categories of synthetic substances that may be considered for use in organic farming. Nonanoic acid, as a component of C8910 ectoparasiticide, is one of them.

NOP Actions on Related chemicals:

Ammonium nonanoate (CAS# 63718-65-0) is a chemical combination of ammonia and nonanoic acid. Ammonium nonanoate is a naturally occurring soap. It forms in the environment when ammonia, a substance constantly being generated from the decomposition of nitrogen-containing waste, comes in contact with nonanoic acid that volatilizes from leaf surfaces of most plants (washes onto soil from rain), certain flowers and the biodegradation of fats. Both are widespread in air, water and ground. The process of soap formation with ammonia is reversible, as soaps of fatty acids will gradually lose ammonia in the environment (e.g. ammonium acetate, ammonium octanoate, Merck Index, 1996), to liberate the free fatty acids, in this case nonanoic acid. Ammonium nonanoate can therefore be considered a natural precursor to nonanoic acid.

Fatty acids are in all edible vegetable and animal fats. Soaps or salts of fatty acids are allowed “on” organic food crops as insecticides under the usual restrictions. Ammonium soaps are allowed as animal repellants in the NOP.

At the November, 2008 NOSB meeting in Washington, DC, the discussion indicated that ammonium nonanoate may meet the broad definition of a soap. The NOSB originally reviewed soaps for herbicide use in 1996. Soap based herbicides are allowed on the National List for non-food use; that is, for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

A petition to expand the allowance of ammonium nonanoate for food use was withdrawn at the 2008 NOSB meeting following an NOSB committee recommendation to reject the petition. An additional petition has been submitted for food use of ammonium nonanoate and this petition is pending. A petition for herbicide use of nonanoic acid was also considered by the NOSB at the November 2008 meeting. This petition was also withdrawn by the petitioner at that meeting following an NOSB committee recommendation to reject the petition.

In reviewing the minutes of the November 2008 meeting, the NOSB committee felt that for criterion one, impact on humans and environment, that fatty acids satisfied the criteria “…as far as the evaluation criteria, again, relatively benign in the environment; in fact, all these fatty acids would be consumed by soil bacteria and degraded very quickly. They would use it as a food source and actually grow on it, probably” On criterion two, whether it was essential for organic farming, the committee voted "…that it was not, based on many, many alternative practices, and weed control". This ruling has been disputed by the petitioner for ammonium nonanoate (Exhibit L).

Substances Report for Nonanoic Acid from the National Institute of Environmental Health Studies. The subject report does not exist. We have instead added Exhibits I and J, which contain peer reviewed literature regarding the toxicology of nonanoic acid.

Research Information Presenting Contrasting Positions. To our knowledge, research information does not exist in support of the position that nonanoic acid should not be included on the National List of allowable synthetic substances.

Conclusion:

The scientific data supports the conclusion that nonanoic acid, used in conjunction with other natural non-synthetic fatty acids, is a safe, effective, and economical product for insect and arthropod control on livestock in a manner that is consistent with organic practice. Natural and synthetic nonanoic acid, produced as described in this petition, cannot be distinguished, even by isotopic abundance or carbon dating. Even if this simple molecule had memories, the synthetic process for production of nonanoic acid mirrors the process by which it is generated in nature. The NOSB Committee has the authority to list nonanoic acid as an allowable synthetic for use on livestock. Such an action will facilitate organic production worldwide and will promote both livestock and human health.

References:

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Appendices:

EXHIBIT A

Study Title

C8, C9, and C10 n-Carboxylic Acids
Summary of Toxicology
And Waiver Request

Data Requirement

US-EPA Guideline Number OPPTS 870 Series

Author

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Sponsor

Stratacor, Inc.
1315 So. 46th Street, Bldg. 154
Richmond, CA 94804

Study Completion Date

December 21, 2007

Report Number

SI-2007T

Total pages: 10

Statement of Data Confidentiality

No information is claimed confidential on the basis of its falling with in the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company: Stratacor, Inc.

Submitter Elizabeth Anne Brown, Ph.D.

Title: Steptoe & Johnson, LLP, agent for Stratacor Inc.

Signed: Elizabeth Anne Brown

Date: 12/21/2007

Good Laboratory Practices Statement

The following discussion and presentation of information is not subject to the principles of 40 CFR 160, GOOD LABORATORY PRACTICE STANDARDS (FIFRA), as promulgated in the United States Federal Register, 54, No. 158, 34067-34704, 17 August 1989.

Author/ Submitter: Elizabeth Anne Brown   Date: 12/21/2007

Elizabeth Anne Brown, Ph.D.
Steptoe & Johnson, LLP

Sponsor: William G. Reifenrath   Date: 12/21/2007

William Reifenrath
Stratacor, Inc.

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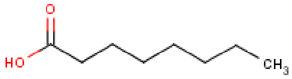
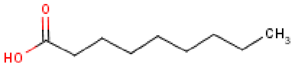
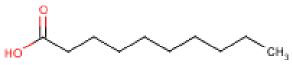
INTRODUCTION

The C8, C9, and C10 n-carboxylic acids (fatty acids) are naturally occuring, well-understood compounds that are essential components of energy production in vertebrate systems. The compounds are closely associated, readily interconverted in energy production, metabolized similarly, and have similar toxicological profiles. Because of the natural and normal metabolism of these compounds and their close chemical structures, they can be considered together.

As concluded by EPA in its decision on C8-12 fatty acid monoesters, "…vertebrate systems are capable of metabolizing each of the acids in the range of C8 to C18 with equal facility. In fact, oxidation of fatty acids is a primary source of energy in vertebrate systems. Fatty acids are supplied in the diet in the form of triacylglycerols (fats) which are hydrolyzed by pancreatic lipase enzymes to form free fatty acids…" EPA concluded that there are no known adverse toxicological effects from the fatty acids which include the C8-C10 forms. (69 FR 34937, June 23, 2004).

The following are the specific compounds of interest:

Basic ID	C8 Octanoic Acid	C9 Nonanoic acid	C10 Decanoic Acid
CAS RN	124-07-2	112-05-0	334-48-5
Other names	Caprylic Acid n-Octoic acid	Pelargonic acid	Capric acid 1-nonanecarboxylic acid
EPA PC	128919	217500	128955
Structure			
Molecular formula	C8-H16-O2	C9-H18-O2	C10-H20-O2

ChemID Plus also lists CAS 68937-75-7 for Fatty Acids, C8-10; no specific information has been located for the group CAS RN.

These C8-10 fatty acids are saturated and are considered to be mid-chain in length, compared to the longer C12-18 fatty acids. However, all these fatty acids are well-known and understood and all are metabolized by oxidation for production of energy in animals and humans. These fatty acids are not considered to be mutagenic, genotoxic, or carcinogenic, nor are they reproductive or developmental toxicants. These is consistent with their natural, endogenous occurrence, as well as long history of safe use as food and feed additives.

US EPA (2002) has reviewed the potential health effects of the free fatty acids (C8 to C18) and concluded there is "low concern for human health hazard." EPA further states that the free fatty acids "have a history of safe use as natural components of many foods, as direct food additives and as cosmetic ingredients. Furthermore, fatty acids are processed by known metabolic pathways within the body and contribute to normal function. Considering this information as well as the FDA, WHO, CIR, and SAR evaluation findings, adequate data are available to determine that the use of these materials in pesticide products is unlikely to pose a significant hazard to the general public or any population subgroup from consumption of residues of fatty acids. No additional information is needed to assess their safety." EPA determined there is no concern for potential sensitivity to infants and children. EPA classified C12-C18 as 4A and C8-C10 as 4B list inerts during tolerance reassessment. The 4B listing for the C8-C10 was associated solely with severe eye irritation.

The Agency has, on multiple occasions, determined that compounds which metabolize to the naturally occurring free fatty acids, when there is no concern for the remaining component(s) of those compounds, are of minimal risk. An example of this is a listing under 40 CFR 180.950(e) for "Soap (The water soluble sodium or potassium salts of fatty acids produced by either the saponification of fats and oils, or the neutralization of fatty acid" which is specifically listed because these water soluble salts are not naturally occurring. However, the basis on which the Agency made that determination is that those soap salts are metabolized into the naturally occurring edible fats (EPA 1992, 2003). Those naturally occurring fats include the C8, C9, and C10 FFA. In its decision on glycerol esters of fatty acids (EPA 2004), the Agency states "glycerol fatty acids are metabolized to free fatty acids and glycerol….These breakdown products are indistinguishable from the natural background of these same compounds in living systems."

There are numerous other examples where the Agency has made the same determination. In its decision to register ammonium nonanoate (EPA, 2006), the Agency reconfirmed that the C9 is naturally occurring and of no toxicological concern outside of skin and eye irritation when undiluted. EPA confirmed that the basis is that this salt of the C9 fatty acid converts to the free fatty acid and that, as such, it is of no toxicological concern. Further, the Agency has identified that "Edible fats and oils means all edible (food or feed) fats and oils, derived from either plants or animals, whether or not commonly consumed" are minimal risk (40 CFR 180.950(c)); inasmuch as the C8, C9, and C10 fatty acids are of plant and animal origin, fall within the definition of fats and oils (as defined by the Institute of Medicine, 2002), and are commonly consumed, these three fatty acids also should be considered as minimal risk for the proposed uses. EPA also has specifically listed soap salts of the free fatty acids as minimal risk under 40 CFR 180.950(e).

Data from published literature can be used to address the toxicological profile of these compounds. The long history of safe use of these and related fatty acids, along with their natural occurrence, demonstrates that no substantial risks to human health are expected from the proposed uses of the C8-10 fatty acids. As such, a waiver from the need to conduct specific studies is requested.

ACUTE TOXICITY PROFILE OF THE INDIVIDUAL ACTIVE INGREDIENTS

OPPTS 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600

The C8-C10 n-carboxylic acids are of low toxicity and are not sensitizers. Based on the public literature and on expected response associated with pH, the pure acid forms can be slight to moderate skin irritants and severe eye irritants.

	C8 Octanoic Acid	C9 Nonanoic acid	C10 Decanoic Acid
Acute oral LD50 mg/kg	10,080	> 3000	> 3000
Acute dermal LD50 mg/kg	> 5000	> 5000 (rabbit)	> 5000
Acute Inhalation LC50 mg/L	> 2	> 2	> 2
Skin Irritation	Slight irritant	Moderate Irritant	Slight irritant
Eye Irritation	Severe irritant	Severe irritant	Severe irritant
Dermal sensitization	Not a sensitizer	Not a sensitizer	Not a sensitizer

GENOTOXICITY PROFILE (OPPTS 870.5100, 870.5300, 870.5550, 870.5375)

WHO 1998 concludes that these saturated n-carboxylic acids are consistently negative in *in vitro* studies. Results listed for octanoic and decanoic acids show negative results in Ames assays, UDS in rat hepatocyte assays, and others. HPV 2005 reports negative results for octanoic (as octanol) and nonanoic (as nonanol and as nonanoic) in the Ames reverse mutation assay and UDS in rat hepatocytes assay, for nonanoic (as nonanol) in the mouse lymphoma forward mutation assay, sister chromatid exchange assay, chromosomal aberrations assay, cytogenetic assays in rat hepatocytes (micronuclei and mitotic index, and UDS in both rat and human hepatocytes.

There is no evidence that any of the C8-C10 fatty acids are genotoxic.

The free fatty acids, which occur naturally in living systems, are not genotoxic in living systems. Additional testing would not be of value to EPA in its evaluation of risks.

SUBCHRONIC TOXICITY PROFILE (OPPTS 880.3100)

WHO 1998 reports that the NOEL for decanoic acid fed to rats in the diet for 150 days is > 5000 mg/kg bw, the only tested dose. Limited other data reported by HERA 2002, ECB 2000a, b, c, and HPV 2005 supports that there is no adverse toxicological effect at limit dose levels (1 g/kg bw). Repeat dose dermal toxicity studies with the acid form do show local irritation and similar effects at the skin surface, associated strictly with the known irritant effects, but no evidence of any systemic activity has been reported. In its decisions on free fatty acids and related compounds, EPA has concurred with these conclusion (EPA 1992, 2002, 2003, 2004, 2006).

The long history of safe use as food and feed additives, along with the natural occurrence of these fatty acids in animal systems, supports that there will be no adverse toxicological effects. Additional testing would not be of value to EPA in its evaluation of risks.

DEVELOPMENTAL TOXICITY (OPPTS 870.3700)

HPV 2005 reports on published results of the Chernoff/Kalock assay in Sprague-Dawley rats with octanoic acid, in which there were no fetal effects in the absence of maternal toxicity, with the Maternal LOAEL at 1125 mg/kg bw and fetal NOEL at 1125 mg/kg bw. A teratology study with nonanoic acid conducted in Sprague-Dawley rats at a single dose of 1500 mg/kg bw/day by gavage resulted in no maternal or fetal effects; the NOEL for both maternal toxicity and fetotoxicity is 1500 mg/kg bw/day, the only dose tested. A study with octanoic acid, with a single gavage dose at day 20 of gestation at 2700 mg/kg bw resulted in severe maternal toxicity and no fetotoxicity; this published study is of limited utility because of lack of adequate documentation.

Overall, none of the C8-C10 fatty acids is considered to be a developmental toxicant. The long history of safe use as food and feed additives, along with the natural occurrence of these fatty acids in animal systems, supports that there will be no adverse toxicological effects. In its decisions on free fatty acids and related compounds, EPA has concurred with this conclusion (EPA 1992, 2002, 2003, 2004, 2006). Additional testing would not be of value to EPA in its evaluation of risks.

REPRODUCTIVE TOXICITY (OPPTS 870.3800)

HERA 2002 summarizes a published 3-generation reproduction study in mice fed a diet containing 8.6% of a crude oil composed of 76% decanoic acid. There were no reproductive effects, nor was there any evidence of any other long-term effects.

HERA notes that fats and oils commonly are used as controls and as vehicles in animal toxicity studies. As such, no adverse effects are expected from these compounds.

The long history of safe use as food and feed additives, along with the natural occurrence of these fatty acids in animal systems, supports that there will be no adverse toxicological effects. In its decisions on free fatty acids and related compounds, EPA has concurred with this conclusion (EPA 1992, 2002, 2003, 2004, 2006). Additional testing would not be of value to EPA in its evaluation of risks.

CHRONIC TOXICITY AND CARCINOGENICITY (OPPTS 870.4300)

No specific studies have been reported to evaluate chronic toxicity and carcinogenicity of the C8-C10 fatty acids. However, the long history of safe use as food and feed additives, along with the natural occurrence of these fatty acids in animal systems, supports that there will be no adverse toxicological effects. In its decisions on free fatty acids and related compounds, EPA has concurred with this conclusion (EPA 1992, 2002, 2003, 2004, 2006). Additional testing would not be of value to EPA in its evaluation of risks.

METABOLISM AND TOXICOKINETICS (OPPTS 870.7485)

HSDB 2007a reports that "caprylic acid administered to rats is readily metabolized by the liver and many other tissues, forming carbon dioxide and two-carbon fragments, which are incorporated into long-chain fatty acids, as well as other water-soluble products." Also reported is a published study on the phamacokinetics of octanoic acid in female rats. There was dose-dependent decrease in total body clearance, possibly suggesting a saturation effect. Octanoic acid was not excreted in the urine and did not evidence enterophepatic recirculation. HERA 2002 reports on a study evaluating metabolism of fatty acids, where the C10 component was rapidly metabolized and excreted primarily as CO2. In its decisions on free fatty acids and related compounds, EPA has concurred with this conclusion (EPA 1992, 2002, 2003, 2004, 2006).

The C8-C10 fatty acids are rapidly metabolized and excreted or recombined to form longer chain fatty acids and related compounds, all of which are essential for energy production in man and animals.

IMMUNOTOXICITY (OPPTS 880.3550)

Because the C8-C10 n-carboxylic acids are normal and essential constituents of plants and animals and normal components of the diet, it is highly unlikely that any of these would be immunotoxic. A waiver from the requirement to conduct a study is requested.

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EXHIBIT B

Study Title

C8, C9, and C10 n-Carboxylic Acids
Summary of Environmental Toxicology
And Waiver Request

Data Requirement

US-EPA Guideline Number OPPTS 850 Series

Author

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Sponsor

Stratacor, Inc.
1315 So. 46th Street, Bldg. 154
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Study Completion Date

December 21, 2007

Report Number

SI-2007ET

Total pages: 10

Statement of Data Confidentiality

No information is claimed confidential on the basis of its falling with in the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company: Stratacor, Inc.

Submitter Elizabeth Anne Brown, Ph.D.

Title: Steptoe & Johnson, LLP, agent for Stratacor Inc.

Signed: Elizabeth Anne Brown

Date: December 21, 2007

Good Laboratory Practices Statement

The following discussion and presentation of information is not subject to the principles of 40 CFR 160, GOOD LABORATORY PRACTICE STANDARDS (FIFRA), as promulgated in the United States Federal Register, 54, No. 158, 34067-34704, 17 August 1989.

Author/
Submitter: Elizabeth Anne Brown
Elizabeth Anne Brown, Ph.D.
Date: 12/21/2007

Sponsor: William G. Reifenrath
William Reifenrath
Stratacor, Inc.
Date: 12/21/2007

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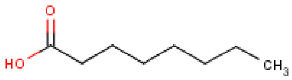
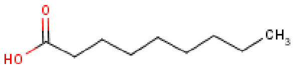
INTRODUCTION

The C8, C9, and C10 n-carboxylic acids (fatty acids) are naturally occuring, well-understood compounds that are essential components of energy production in vertebrate systems. The compounds are closely associated, readily interconverted in energy production, metabolized similarly, and have similar toxicological profiles. Because of the natural and normal metabolism of these compounds and their close chemical structures, they can be considered together.

As concluded by EPA in its decision on C8-12 fatty acid monoesters, "…vertebrate systems are capable of metabolizing each of the acids in the range of C8 to C18 with equal facility. In fact, oxidation of fatty acids is a primary source of energy in vertebrate systems. Fatty acids are supplied in the diet in the form of triacylglycerols (fats) which are hydrolyzed by pancreatic lipase enzymes to form free fatty acids…" EPA concluded that there are no known adverse toxicological effects from the fatty acids which include the C8-C10 forms. (69 FR 34937, June 23, 2004).

The following are the specific compounds of interest:

Basic ID	C8 Octanoic Acid	C9 Nonanoic acid	C10 Decanoic Acid
CAS RN	124-07-2	112-05-0	334-48-5
Other names	Caprylic Acid n-Octoic acid	Pelargonic acid	Capric acid 1-nonanecarboxylic acid
EPA PC	128919	217500	128955
Structure			
Molecular formula	$C_8H_{16}O_2$ (C8-H16-O2)	C9-H18-O2	C10-H20-O2

ChemID Plus also lists CAS 68937-75-7 for Fatty Acids, C8-10; no specific information has been located for the group CAS RN.

These C8-10 fatty acids are saturated and are considered to be mid-chain in length, compared to the longer C12-18 fatty acids. However, all these fatty acids are well-known and understood and all are metabolized by oxidation for production of energy in animals and humans. These fatty acids are not considered to be mutagenic, genotoxic, or carcinogenic, nor are they reproductive or developmental toxicants. These is consistent with their natural, endogenous occurrence, as well as long history of safe use as food and feed additives.

Data from published literature can be used to address the environmental toxicology profile of these compounds. The long history of safe use of these and related fatty acids, along with their natural occurrence in plants and animals, demonstrates that no substantial risks to nontarget organisms are expected from the proposed uses of the C8-10 fatty acids. Further, the proposed use of these actives as a component of Bio-Logic Fly Repellent Oil or similar products intended for use as insect repellents on animals is unlikely to result in exposure to the environment or nontarget organisms. As such, a waiver from the need to conduct specific studies is requested.

AVIAN TOXICITY

OPPTS 850.2100 ACUTE AVIAN TOXICITY

OPPTS 850.2200 AVIAN DIETARY TOXICITY

No published literature on the effects of the C8-C10 fatty acids to avian species has been identified. EPA 1992 reports that soap salts (potassium and ammonium salts of C12-C18 fatty acids) are relatively non-toxic to birds on an acute basis (LD50 >2000 mg/kg) and practically non-toxic on a dietary basis (LC50 > 5000 ppm). The lack of acute toxicity of these compounds to mammals (WHO 1998), their widespread natural occurrence and essentiality for vetebrates including birds, do not suggest any potential hazard to birds; the conclusions on the soap salts are applicable to the C8-C10 fatty acids as well. That position has been confirmed by prior EPA decisions (EPA 1992, 2003a, 2003b, 2004, 2006).

Further, the proposed use of these actives as a component of Bio-Logic Fly Repellent Oil or similar products intended for use as insect repellents on animals is unlikely to result in exposure to the environment or nontarget organisms. Additional testing would not be of value to EPA in its evaluation of risks. A waiver from conducting additional studies is requested.

AQUATIC SPECIES TOXICITY PROFILE

OPPTS 850.1075 ACUTE TOXICITY TO FISH

OPPTS 850.1010 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Available information confirms that C8-C10 fatty acids have very little toxicity to aquatic species (fish and invertebrates)

HPV 2005 reports on results of available data or ECOSAR calculations to estimate the potential toxicity of C8 and C9 fatty acids to aquatic species. The following is a summary of the results.

<u>C8</u>:

- P. reticulata (14-day semi-static assay), using octanal (C8 aldehyde). LC50 = 7.89 mg/L (published study)
- Pimephales promelas (juvenile fathead minnows, continuous flow-through system), using 1-octanol. 96-hr LC50 = 13.5 mg/L (published study)
- ECOSAR calculated 96-hr LC50 for fish = 6.7 mg/L (octanol)
- ECOSAR calculated 48-hr LC50 for Daphnia magna = 167 mg/L (octanoic acid)

<u>C9</u>:

- Pimephales promelas (juvenile fathead minnows, continuous flow-through system), using 1-nonanol. 96-hr LC50 = 5.52 mg/L (published study)
- ECOSAR calculated LC50 for fish = 4.8 mg/L (nonanol)
- ECOSAR calculated 48-hr LC50 for Daphnia magna = 64 mg/L (nonanoic acid)

C10:

While HERA 2003 focuses mainly on salts of longer chain fatty acids, it does include information on C10. An exhaustive literature search was performed to identify available information, which is excerpted below.

"No salt data were found for algae for C10 chain length although one value was found for decanoic acid. A single value only was found for fish and invertebrates (96hour *Oryzias latipes* and 24hour *Daphnia magna* respectively). These values indicated similar toxicity to both species. However, the *D.magna* value was observed at 24 hour and would be expected to be less at 48 hours.

"No terrestrial salt data for the fatty acid salt could be found. However, several data were found for decanoic acid. A 14 day study with *Lycopersicon esculentum* (tomato), reported values of >0.05M for leaf and stem injury and bud mortality (Tucker and Maw,1975). This value equates to a concentration of 8615mg/kg. One further study reported a 1 hour ED95 of 195 mg/kg decanoic acid to *Panagrellus redivius* (nematode) (Kwok *et. al.*,1992). From evidence of aquatic toxicity (Table 19), these data can be considered worst case for the equivalent salt.

"A number of studies were found for toxicity to various species of microorganisms for decanoic acid (Appendix III). Values range from a value of 43mg/l for the EC50 of the inhibition of the rate of duplication after 60 minute (*Bacillus subtilis*) (Freese *et.al.*,1971) to a value of 1016 for the 24 hour EC50 for the inhibition of acetoclastic methanogenic activity in Methanothrix (sp) (Koster and Cramer,1987). One value was found for the Potassium salt of C10 measuring EC50 using microcalorimetry. The reported EC50 value of 2377mg/l was for a range of anaerobic microorganisms (Beaubien *et. al.*,1987). The accuracy of this value has not been determined but does fit in with the overall trend that fatty acids are more toxic than the equivalent salt.

"An overview of the data for the C10 fatty acid salt is provided below.

Table 22. Lowest acute ecotoxicological data for C10-Fatty acid salts

Species	Test method	EC/LC50 (mg/L)		Reliability
Aquatic Invertebrates [16]	*D.magna*	24hr	65	2
Fish [5]	*O.latipes*	96hr days	54	2
Plants [19]	*L. esculentum*	(Fatty acid value) 48h leaf, stem injury, bud mort.	8615mg/kg	4
Terrestrial invertebrate [41]	*P. redivius*	(Fatty acid value) 1 hr immobility	ED95: 195mg/kg	4
Microorganisms [42]	*Anaerobic micro.*	Reduction in heat flux	2377	4

(end quote)

In Appendix III to HERA 2003, the following more detailed information is provided specific to aquatic organisms:

C10

Test Substance	Species	Test Method/ Endpoint	Duration (h)		Concentration (mg/l)	Secondary ref	Primary ref
Decanoic acid	ALGAE	Nitzschia closterium (marine diatom)	cell growth / EC50	72	0.3	3	34
Decanoic acid sodium salt	INVERT	Daphnia magna	Intoxication / EC50	24	65	2	16
Decanoic acid	INVERT	Artemia salina	EC50	16	36	3	23
Decanoic acid	INVERT	Daphnia magna	EC50	24	65	3	16
Decanoic acid	INVERT	Hyale plumulosa	EC50	48	41	3	5
Sodium caprate	FISH	Oryzias latipes	LC50	96	54	3	5
Decanoic acid	FISH	Leuciscus idus	DIN 38412 / LC50	48	95	3	Henkel unpublished data
Decanoic acid	FISH	Leuciscus idus	DIN 38412 / LC0	48	30	3	Henkel unpublished data
Decanoic acid	FISH	Leuciscus idus	DIN 38412 / LC100	48	300	3	Henkel unpublished data
Decanoic acid	FISH	Oryzias latipes	LC50	96	20	3	5

Fatty acids are readily biodgradable and rapidly metabolized by soil microorganisms (half-life <1 day). The proposed product is not intended for direct application to aquatic sites; thus, indirect or direct exposure to aquatic organisms is unlikely.

On the basis of the above information, the long history of safe use as food and feed additives, along with the natural occurrence of these fatty acids in animal and plant systems, supports that there will be no adverse toxicological effects. That position has been confirmed by prior EPA decisions (EPA 1992, 2003a, 2003b, 2004, 2006). Further, the proposed use of these actives as a component of Bio-Logic Fly Repellent Oil or similar products intended for use as insect repellents on animals is unlikely to result in exposure to the environment or nontarget organisms. Additional testing would not be of value to EPA in its evaluation of risks. A waiver from conducting additional studies is requested.

TERRESTRIAL PLANTS

OPPTS 850.4100 SEEDLING EMERGENCE

OPPTS 850.4150 VEGETATIVE VIGOR

Available information confirms that C8-C10 fatty acids have very little toxicity to terrestrial or to aquatic plants. In fact, these fatty acids are normal constituents of many plants.

HPV 2005 reports on results of available data or ECOSAR calculations to estimate the potential toxicity of C8 and C9 fatty acids to aquatic species. The following is a summary of the results.

C8:

- ECOSAR calculated 96-hr LC50 for green algae = 110 mg/L (octanoic acid)

C9:

- ECOSAR calculated 96-hr LC50 for green algae = 44 mg/L (nonanoic acid)

C10:

While HERA 2003 focuses mainly on salts of longer chain fatty acids, it does include information on C10. An exhaustive literature search was performed to identify available information, which is excerpted below.

C10

Test Substance	Species	Test Method/ Endpoint		Duration	Concentration (mg/l)	Secondary ref	Primary ref
Decanoic acid	PLANT	Lycopersicon esculentum (tomato)	Leaf injury	14 days	>0.05M	2	19
Decanoic acid	PLANT	Lycopersicon esculentum (tomato)	Stem injury	14 days	>0.05M	2	19
Decanoic acid	PLANT	Lycopersicon esculentum (tomato)	Bud mortality	14 days	>0.05M	2	19
Decanoic acid	INVERT	Panagrellus redivius (nematode)	Immobility / EC95	1hr	195	3	41

Fatty acids are readily biodgradable and rapidly metabolized by soil microorganisms (half-life <1 day). The proposed product is not intended for direct application to terrestrial sites; thus, indirect or direct exposure to nontarget plants is unlikely.

On the basis of the above information, the long history of safe use as food and feed additives, along with the natural occurrence of these fatty acids in animal and plant systems, supports that there will be no adverse toxicological effects. That position has been confirmed by prior EPA decisions (EPA 1992, 2003a, 2003b, 2004, 2006). Further, the proposed use of these actives as a component of Bio-Logic Fly Repellent Oil or similar products intended for use as insect repellents on animals is unlikely to result in exposure to the environment or nontarget organisms. Additional testing would not be of value to EPA in its evaluation of risks. A waiver from conducting additional studies is requested.

NONTARGET INSECTS

OPPTS 850.4350 HONEYBEE TOXICITY

No data are available to identify the potential contact toxicity to honey bees. However, the proposed use of the C8-C10 fatty acids as repellents applied to livestock is unlikely to result in exposure to honey bees. Further, the long history of safe use as food and feed additives, along with the natural occurrence of these fatty acids in animal systems, supports that there will be no adverse toxicological effects. That position has been confirmed by prior EPA decisions (EPA 1992, 2003a, 2003b, 2004, 2006). Further, the proposed use of these actives as a component of C8910 or similar products intended for use as insect repellents on animals is unlikely to result in exposure to the environment or nontarget organisms. Additional testing would not be of value to EPA in its evaluation of risks. A waiver from conducting additional studies is requested.

References

CHEMID PLUS at National Library of Medicine

EPA. 1992. Reregistration Eligibility Decision for Soap Salts. September 1992. http://www.epa.gov/oppsrrd1/REDs/old_reds/soap_salts.pdf (viewed on 6/5/2007)

EPA. 2003a. Salts of Fatty Acids: Recommendations for Tolerance Reassessment. Memorandum from K. Boyle to S. Lewis (September 27, 2003), with attached assessment document for tolerance reassessment, memorandum from D. Smegal to K. Boyle, September 25, 2003. (www.regulations.gov, EPA-HQ-OPP-2005-0487-0003)

EPA. 2003b. Science review in support of the registration of the technical grade active ingredient (TGAI) Product VMX-42 Technology Propylene glycol monocaprylate. Memorandum from R. Jone to C. Frazer, April 8, 2003. (www.regulations.gov, EPA-HQ-OPP-2003-0379-0002)

EPA. 2004. Tolerance Reassessment Decision for glycerol and the glycerol esters of fatty acids. Memorandum from B. Shackleford to P. Caulkins, May 18, 2004. (www.regulations.gov, EPA-HQ-OPP-2005-0487-0008)

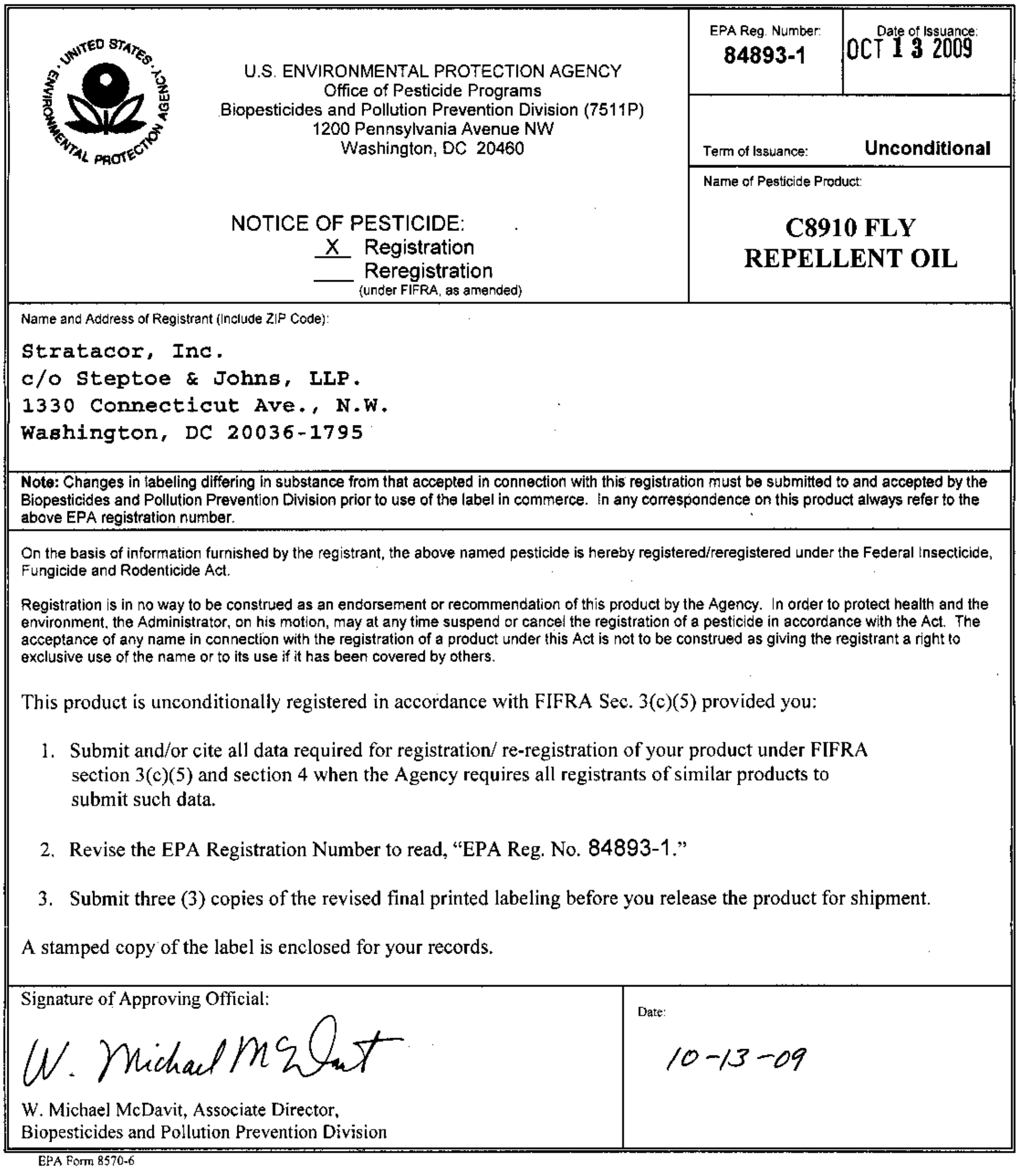
EPA. 2006. Ammonium nonanoate (031802) Fact Sheet and technical document. http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_031802.htm (viewed on 10/11/2007)

HERA 2003. Fatty Acid Salts. Environmental Risk Assessment. Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products. 61 pages http://www.heraproject.com/files/5-E-04-%20HERA%20Fatty%20acid%20salts%20Env%20web%20wd.pdf (viewed on 5/14/2007)

HPV 2005: Flavor and Fragrance High Production Volume Consortia. February 2005. C7-C9 Aliphatic Aldehydes and Carboxylic Acids Grouping. HPV Challenge Program Robust Summaries and Test Plan. http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm (viewed on 5/14/2007)

WHO. 1998. Saturated aliphatic acyclic linear primary alcohols, aldehydes, and acids. WHO Food Additives Series 40, Monograph 906. JEFCA. http://www.inchem.org/documents/jecfa/jecmono/v040je10.htm (viewed on 5/14/2007)

EXHIBIT C



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number: **84893-1**

Date of Issuance: OCT 13 2009

Term of Issuance: **Unconditional**

Name of Pesticide Product: **C8910 FLY REPELLENT OIL**

NOTICE OF PESTICIDE:
☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Stratacor, Inc.
c/o Steptoe & Johns, LLP.
1330 Connecticut Ave., N.W.
Washington, DC 20036-1795

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c)(5) provided you:

1. Submit and/or cite all data required for registration/ re-registration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Revise the EPA Registration Number to read, "EPA Reg. No. 84893-1."
3. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

W. Michael McDavit

W. Michael McDavit, Associate Director,
Biopesticides and Pollution Prevention Division

Date: 10-13-09

EPA Form 8570-6

MASTER LABEL Occtober 5, 2009

C8910 FLY REPELLENT OIL

For Livestock: Beef and Dairy Cattle and For Horses

To Repel Stable Flies, Horn Flies, House Flies, Ticks, Cattle Lice

Active Ingredients:	
Octanoic Acid	5.0%
Nonanoic Acid	5.0%
Decanoic Acid	5.0%
Other ingredients	85.0%
TOTAL	100.0%

CAUTION

KEEP OUT OF REACH OF CHILDREN

EPA Reg No. 84893-1
EPA Establishment No. xxxx-xxx
Lot Number:

Manufactured for:
Stratacor, Inc.
1315 S. 46th Street, Bldg 154
Richmond, CA 98404 USA

U.S. Patent Nos. 6306415, 6444216, 6953814
European Patent No. 1018873
Australian Patent No. 746766
Canadian Patent Pending

Net Contents: 16 Fl.Oz.

ACCEPTED

OCT 13 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 84893-1

EXHIBIT D

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: October 8, 2009

SUBJECT: Tolerance Exemption Petition for the Active Ingredients C_8-C_{10} n-carboxylic acids (octanoic acid, nonanoic acid, and decanoic acid)

Decision Number:	388782
Petition Number:	8F7317
DP Number:	349189
EPA File Symbol Number:	84893-R
Chemical Class:	Biochemical
PC Codes:	128919, 217500, & 128955
Tolerance Exemptions:	Octanoic acid (Pending) Decanoic acid (40 CFR 180.1225); Pelargonic (Nonanoic) acid (40 CFR 180.1159);
MRID Number:	47327201; 473272-03 to -09; 473272-10 to -13

FROM: Driss Benmhend, Biologist / Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Russell S. Jones, Ph.D., Senior Biologist /s/ 11/5/2009
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

Manying Xue, Chemist /s/ Manying Xue
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

On behalf of Stratacor, Inc., Steptoe & Johnson LLP has submitted an application for registration of the end use product, C8910 Fly Repellent Oil (EPA Symbol No.: 84893-R), containing 5.0% octanoic acid, 5.0% nonanoic acid, and 5.0% decanoic acid as Active Ingredients. In addition, the registrant has requested an exemption from the requirement of a tolerance for the product use on livestock. The end use product C8910 Fly Repellent Oil is proposed to repel flies, ticks, and lice on cattle and horses.

CONCLUSIONS

The petition for a tolerance exemption for free fatty acids with aliphatic carbon chain lengths between C_8-C_{10} is not needed for the proposed food use on the commodities beef and dairy cattle, and horses when applied on livestock animals as an insect repellent. The Agency reviewed the existing exemptions for fatty acids and concluded that C_8-C_{10} free fatty acids can be included under one or more of the following currently established exemptions:

40 CFR 180.950 (c): The Agency states that edible fats and oils derived from either plants or animals are of minimal risk, and exempt from the requirement of a tolerance Since the $\mathbf{C_8}$-$\mathbf{C_{10}}$ fatty acids are of plant and animal origin, and are commonly consumed, these three fatty acids should be considered as minimal risk for the proposed use.

40 CFR 180.1159: An exemption from the requirement of a tolerance is established for residues of pelargonic acid (**nonanoic acid** or C_9) in or on all raw agricultural commodities and in processed commodities when used as a plant growth regulator on plants, seeds, or cuttings and on all food commodities after harvest in accordance with good agricultural practices.

40 CFR 180.1225: An exemption from the requirement of a tolerance is established for residues of decanoic acid ($\mathbf{C_{10}}$) in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of decanoic acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of decanoic acid (up to 170 ppm per application) on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants.

40 CFR 180.940: C_8 is exempt from the requirement of tolerance exemption when used as a sanitizing solution, and as an inert 40 CFR 180.910.

Based on previously reviewed information and data submitted in support of the existing tolerance exemptions for free fatty acids with aliphatic carbon chain lengths between $\mathbf{C_8}$-$\mathbf{C_{18}}$, the Agency concludes that the use of C_8-C_{10} as insect repellents, on the food commodities beef and dairy cattle, and horses is covered under the currently established tolerance exemptions cited above, and that establishment of an additional tolerance exemption is unnecessary.

EXHIBIT E

Final Report

Field Trial to Determine the Efficacy of Two Stratacor Experimental Dust Bag Formulations for Controlling Horn Flies, *Haematobia irritans,* Infesting Cattle

Data Requirement:

Confirmation of Efficacy vs Horn Fly

Study Director:
Elmer Ahrens

Study Completion Date:
September 4, 2010
Performing Laboratory:

Ahrens Research and Consulting
Tel.: (830) 889-6552

Study Location:
Montalvo Ranch, Starr County, Texas (60 miles NW of McAllen, Texas)

Sponsor:
Stratacor, Inc.,1315 South 46th Street, Richmond, CA 94804

Total Number of Pages: 10

Pages 45 through 53 of Appendix E CBI Deleted

EXHIBIT F

Study Title

C8910C8910 Fly Repellent Oil
Summary of Efficacy Data Against Pests of Livestock

Data Requirement

(None)

Author

William G. Reifenrath
Stratacor, Inc.
1315 So. 46th Street, Bldg. 154
Richmond, CA 94804

Sponsor

Stratacor, Inc.
1315 So. 46th Street, Bldg. 154
Richmond, CA 94804

Performing Laboratories

University of California-Riverside
Department of Entomology
Riverside CA 92521

University of Nebraska
West Central Research and Extension Center
North Platte, Nebraska 69101

USDA/ARS
Livestock Insects Research Lab
Kerrville, Texas 78029

Stratacor, Inc.
1315 So. 46th Street, Bldg. 154
Richmond, CA 94804

Study Completion Date

December 27, 2007

Report Number

SI-2007-E

Total pages: 34

Table of Contents

APPENDIX B. Field Tests of C8910 Fly Repellent Oil on Live Cattle and Horses Against Stable Flies

APPENDIX C. Field Tests of C8910 Fly Repellent Oil on Dairy Heifers against Stable Flies

Pages 56 through 94 of Appendix F CBI Deleted

EXHIBIT G

STRATACOR, INC.
1315 South 46th St., Bldg. 154
Richmond, CA 94804

Material Safety Data Sheet

PHONE: (510) 965-1545 Prepared March 20, 2006
(415) 892-7630 (after hours) Revised October 10, 2009

SECTION I – IDENTIFICATION

DO NOT GET IN EYES. KEEP CONTAINER CLOSED. USE ADEQUATE VENTILLATION. WASH THOROUGHLY AFTER HANDLING.

PRODUCT: STRATACOR FLY REPELLENT OIL

CHEMICAL: MIXTURE OF OCTANOIC ACID (CAS NO. 124-07-2), NONANOIC ACID (CAS NO. 112-05-0), AND DECANOIC ACID (CAS NO. 334-48-5) IN MINERAL OIL, CAS NO. 8042-47-5)

SECTION II- INGREDIENT HAZARD CLASSIFICATION

COMPONENT	PEL/TLV	HAZARD
Octanoic Acid	None/None	Corrosive
Nonanoic Acid	None/None	Corrosive
Decanoic Acid	None/None	Corrosive

Octanoic Acid, Nonanoic Acid and Decanoic Acid were given GRAS status by FEMA (1965) and are approved by the FDA for food use (21CFR 182.3025, 21 CFR 172.515, and CFR 121.1070 respectively).

Mineral Oil:

Mineral oil is included in the US EPA List 4A Minimal Risk Inerts, Appendix B, PR Notice 2000-6.

Mineral oil is not an eye or skin irritant and no harmful effects reported for breathing (inhalation) or swallowing (ingestion). No evidence of cancer has been demonstrated in several animal studies. The dermal LD50 is greater than 2000 mg/kg and the oral LD_{50} (rat) is greater than 5000 mg/kg.

SECTION III- HAZARDS IDENTIFICATION

Stratacor Fly Repellent Oil is an experimental material, whose toxicology has not been fully studied. Based on acute toxicology studies of this material and the extensive toxicology literature of it components, the following guidance is given.

SKIN CONTACT: It is not considered hazardous under normal conditions of use, but may cause moderate irritation

The single dose acute dermal LD_{50} of Stratacor Fly Repellent Oil is greater than 5,000 mg/kg of body weight in male and female rats.

A radiotracer study of fatty acid skin absorption was conducted following application of Stratacor Fly Repellent Oil to moistened excised pig skin, a good model for human skin. Absorption into and through the skin (percent of the applied dose) was 23-24% for octanoic acid and 31-34% for decanoic acid. The value for nonanoic acid is expected to be intermediate between these two values. These studies indicated human exposure by this route will be substantial for the fatty acids, comparable to that of N,N-diethyl-m-toluamide (DEET, the leading insect repellent). However, absorbed fatty acids do not represent a hazard, as they are rapidly metabolized by normal human metabolism to provide energy.

Based on a rabbit Draize test, Stratacor Fly Repellent Oil was found to be a moderate skin irritant. This grade of irritation is typical of topical insect repellents intended for human use.

Based on a dermal sensitization study in guinea pigs (Buehler method), Stratacor Fly Repellent Oil is not considered to be a contact sensitizer.

Stratacor Fly Repellent Oil has been repeatedly applied to the skin of horses and cattle, animals whose skin is more sensitive (permeable) than human skin; no reports of skin irritation under controlled experimental conditions have been received as of this date of revision.

EYE CONTACT: May cause irritation

In the rabbit Draize test, Stratacor Fly Repellent Oil was found to be a mild eye irritant, typical of topical insect repellents intended for human use.

VAPOR INHALATION: Not considered hazardous under normal conditions of use, but may cause transient irritation of respiratory passages. Based on an acute inhalation toxicity study (limit test) in rats, the single exposure acute inhalation LC_{50} of Stratacor Fly Repellent Oil is greater than 2.15 mg/L in male and female rats.

AEROSOL INHALATION: Not considered hazardous under normal conditions of use, but may cause transient irritation of respiratory passages.

INGESTION: May be harmful if swallowed in large quantities. The acute oral LD_{50} of Stratacor Fly Repellent Oil is greater than 5,000 mg/kg of body weight in female rats.

SECTION IV- FIRST AID MEASURES

SKIN CONTACT: Flush skin with plenty of water.

EYE CONTACT: Flush eyes with plenty of water. Do not rub eyes.

INHALATION: Immediately remove exposed person to fresh air. If breathing has stopped, give artificial respiration, preferably, mouth to mouth. Get medical attention immediately.

INGESTION: Do not induce vomiting. If exposed person is conscious and able to swallow, promptly give drinking water to dilute. Do not give sodium bicarbonate, fruit juices, or vinegar. Never give anything by mouth if victim is unconscious or having convulsions. Call a physician or poison control center immediately.

SECTION V-PHYSICAL/CHEMICAL CHARACTERISTICS

Appearance, color and odor: a clear liquid with a coconut-like odor

Solubility in water: insoluble.

Evaporation rate: Initially, fatty acids at approximately 20 ug/cm^2-h @ 32^oC. The evaporation rate will increase with temperature, and decrease with time.

Melting point: none (liquid at 4^oC and room temperature). May solidify at -20^oC.

Boiling point: $260-428^oC$ (mineral oil)

SECTION VI – REACTIVITY

Stability: Generally stable

Hazardous Polymerization: Not likely

Conditions and Materials to Avoid: Keep away from heat and flames. Avoid contact with oxidizing materials and basic chemicals

Hazardous Decomposition Products: Decomposition may produce carbon monoxide and carbon dioxide

SECTION VII – ENVIRONMENTAL PROTECTION

Avoid uncontrolled release of this material, such as breakage of bagged material or spills of bulk material. Dispose in accordance with Federal, State, and Local regulations.

SECTION VIII – EMPLOYEE PROTECTION

Control Measures: Handle in the presence of adequate ventilation

Respiratory Protection: Recommended exposure limits (i.e. OSHA-PEL and ACGIH-TLV) have not been established for this material. Whether there is a need for respiratory protection under your conditions of handling of this material should be evaluated by a qualified health specialist.

Eye Protection: Wear protective shield (safety glasses) when exposed to aerosol

Protective Gloves: Optional

Other Protective Clothing and Equipment: Optional

Work/Hygienic Practices: Avoid creating and breathing aerosols.

SECTION IX – HANDLING AND STORAGE

Store in cool, dry, well-ventilated areas away from sunlight. For spills, use oil sorbent materials and place into closable container for disposal.

The information presented herein is believed to be factual as it has been derived from the works and opinions of persons believed to be qualified experts; however, nothing contained in this information is to be taken as a warranty or representation for which Stratacor Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.

EXHIBIT H

MSDS FOR NONANOIC ACID

Emery Oleochemicals LLC
Material Safety Data Sheet

EMERY 1202 PELARGONIC ACID

Date of printing : 9/22/2010.
Date of revision : 9/22/2010.
SDS No. : RS000000010430

1 . Product and company identification

Product name : EMERY 1202 PELARGONIC ACID
For industrial use only. Not for feed use.

Supplier
Emery Oleochemicals LLC
4900 Este Avenue
Cincinnati, OH 45232-1446
Phone: +1-800-543-7370
Fax-no.: +1-513-246-3332
Plant 24 Hr Phone: +1-513-762-2635

Material uses : Industrial applications: Various
Responsible name : **Emery Oleochemicals Product Safety & Regulations**
In case of emergency +1-800-424-9300 or +1-703-527-3887
Product type : Liquid. [Clear.]

2 . Hazards identification

Physical state : Liquid. [Clear.]
Odor : Characteristic.
OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Emergency overview : WARNING!

CAUSES RESPIRATORY TRACT, EYE AND SKIN IRRITATION.

Irritating to eyes, respiratory system and skin. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use only with adequate ventilation. Keep container tightly closed and sealed until ready for use. Wash thoroughly after handling.

Routes of entry : Dermal contact. Inhalation.

Potential acute health effects
Inhalation : Irritating to respiratory system.
Ingestion : No known significant effects or critical hazards.
Skin : Irritating to skin.
Eyes : Irritating to eyes.

Potential chronic health effects
Chronic effects : No known significant effects or critical hazards.

Over-exposure signs/symptoms
Inhalation : Adverse symptoms may include the following:
respiratory tract irritation
coughing
Ingestion : No specific data.
Skin : Adverse symptoms may include the following:
irritation
redness
Eyes : Adverse symptoms may include the following:
pain or irritation
watering
redness

2 . Hazards identification

See toxicological information (section 11)

3 . Composition/information on ingredients

General chemical description

Pelargonic Acid

Name	CAS number	%
Pelargonic acid (C9)	112-05-0	94
Caprylic Acid (C8)	124-07-2	4
Capric acid (C10)	334-48-5	2

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4 . First aid measures

Eye contact	: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention immediately.
Skin contact	: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention immediately.
Inhalation	: Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.
Ingestion	: Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.
Protection of first-aiders	: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.
Notes to physician	: No specific treatment. Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

5 . Fire-fighting measures

Does the product burn?	: Non-flammable.
Flammability of the product	: In a fire or if heated, a pressure increase will occur and the container may burst.
Extinguishing media	
Suitable	: Use an extinguishing agent suitable for the surrounding fire.
Not suitable	: None known.
Special exposure hazards	: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Hazardous thermal decomposition products	: Decomposition products may include the following materials: carbon dioxide carbon monoxide
Special protective equipment for fire-fighters	: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6 . Accidental release measures

Personal precautions : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see section 8).

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods for cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see section 1 for emergency contact information and section 13 for waste disposal.

7 . Handling and storage

Handling : Put on appropriate personal protective equipment (see section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Storage : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

8 . Exposure controls/personal protection

Consult local authorities for acceptable exposure limits.

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

Engineering measures : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal protection

8 . Exposure controls/personal protection

Respiratory	: Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
Hands	: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
Eyes	: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.
Skin	: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Environmental exposure controls	: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9 . Physical and chemical properties

Physical state	: Liquid. [Clear.]
Flash point	: Open cup: 140.6°C (285.1°F) [Cleveland Open]
Color	: Yellowish.
Odor	: Characteristic.
Boiling/condensation point	: 230 to 237°C (446 to 458.6°F)
Density	: 0.904 g/cm^3 [25°C (77°F)]
Solubility	: Very slightly soluble in the following materials: cold water and hot water.

10 . Stability and reactivity

Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Hazardous polymerization	: Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid	: No specific data.
Materials to avoid	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11 . Toxicological information

Acute toxicity

Product/ingredient name	**Result**	**Species**	**Dose**
EMERY 1202	LD50 Oral	Rat	>5000 mg/kg

12 . Ecological information

Environmental effects : No known significant effects or critical hazards.

13 . Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Refer to Section 7: HANDLING AND STORAGE and Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION for additional handling information and protection of employees.

14 . Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
DOT Classification	Not regulated.	-	-	-		-
IMDG Class	Not regulated.	-	-	-		-
IATA-DGR Class	Not regulated.	-	-	-		-

PG* : Packing group

15 . Regulatory information

United States inventory (TSCA 8b) : All components are listed or exempted.

HCS Classification : Irritating material

U.S. Federal regulations : **SARA 302/304/311/312 extremely hazardous substances**: No products were found.
SARA 302/304 emergency planning and notification: No products were found.
SARA 302/304/311/312 hazardous chemicals: Nonanoic acid; octanoic acid; capric acid
SARA 311/312 MSDS distribution - chemical inventory - hazard identification: Nonanoic acid: Immediate (acute) health hazard; octanoic acid: Immediate (acute) health hazard, Delayed (chronic) health hazard; capric acid: Immediate (acute) health hazard, Delayed (chronic) health hazard

SARA 313 : No products were found.

California Prop. 65 : No products were found.

CERCLA: Hazardous substances. : No products were found.

16 . Other information

Label requirements : CAUSES RESPIRATORY TRACT, EYE AND SKIN IRRITATION.

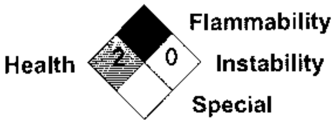
Hazardous Material Information System (U.S.A.) :

Health	2
Flammability	1
Physical hazards	0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.) :



Date of printing : **9/22/2010.**

<u>Notice to reader</u>

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

EXHIBIT I

NONANOIC ACID

CASRN: 112-05-0

For other data, click on the Table of Contents

Human Health Effects:

Human Toxicity Excerpts:

A 12% SOLN OF NONANOIC ACID IN PETROLATUM PRODUCED NO IRRITATION ON HUMAN SKIN AFTER A 48-HR CLOSED PATCH TEST. ... NO SENSITIZATION REACTIONS WERE PRODUCED IN 25 VOLUNTEERS AFTER PATCH TESTING WITH NONANOIC ACID (12% IN PETROLATUM).
`[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994., p. 3559]**PEER REVIEWED**`

VARIOUS CONCN OF NONANOIC ACID IN 1-PROPANOL WERE APPLIED TO 116 HEALTHY VOLUNTEERS AND 75 DERMATITIS PATIENTS AS A POSITIVE CONTROL FOR PATCH TESTING. A DOSE OF 20% PRODUCED SKIN REACTIONS IN 90.1-93.9% OF SUBJECTS. LESIONS CONSISTED OF ERYTHEMA AT 48 HR & PIGMENTATION @ 96 HR.
`[WAHLBERG JE, MAIBACH HI; CONTACT DERMATITIS 6 (2): 128 (1980)]**PEER REVIEWED**`

Human Toxicity Values:

LD50 Rat oral 15 g/kg
`[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994., p. 3559]**PEER REVIEWED**`

Probable Routes of Human Exposure:

NIOSH (NOES Survey 1981-1983) has statistically estimated that 46,467 workers (1,484 of these are female) are potentially exposed to nonanoic acid in the US(1). Occupational exposure to nonanoic acid may occur through dermal contact with this compound at workplaces where nonanoic acid is produced or used(SRC). The general population will be exposed to nonanoic acid via inhalation of ambient air, ingestion of food and drinking water, and dermal contact with food and other products containing nonanoic acid(SRC).
`[(1) NIOSH; National Occupational Exposure Survey (NOES) (1983)]**PEER REVIEWED**`

Emergency Medical Treatment:

Emergency Medical Treatment:

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The following Overview, *** GENERAL OR UNKNOWN CHEMICAL ***, is relevant for this HSDB record chemical.

Life Support:

- o This overview assumes that basic life support measures have been instituted.

Clinical Effects:

0.2.1 SUMMARY OF EXPOSURE

0.2.1.1 ACUTE EXPOSURE

A) A SPECIFIC REVIEW on the clinical effects and treatment of individuals exposed to this agent HAS NOT YET BEEN PREPARED. The following pertains to the GENERAL EVALUATION and TREATMENT of individuals exposed to potentially toxic chemicals.

B) GENERAL EVALUATION -

1) Exposed individuals should have a careful, thorough medical history and physical examination performed, looking for any abnormalities. Exposure to chemicals with a strong odor often results in such nonspecific symptoms as headache, dizziness, weakness, and nausea.

C) IRRITATION -

1) Many chemicals cause irritation of the eyes, skin, and respiratory tract. In severe cases respiratory tract irritation can progress to ARDS/acute lung injury, which may be delayed in onset for up to 24 to 72 hours in some cases.

2) Irritation or burns of the esophagus or gastrointestinal tract are also possible if caustic or irritant chemicals are ingested.

D) HYPERSENSITIVITY -

1) A number of chemical agents produce an allergic hypersensitivity dermatitis or asthma with bronchospasm and wheezing with chronic exposure.

Laboratory:

- A) A number of chemicals produce abnormalities of the hematopoietic system, liver, and kidneys. Monitoring complete blood count, urinalysis, and liver and kidney function tests is suggested for patients with significant exposure.
- B) If respiratory tract irritation or respiratory depression is evident, monitor arterial blood gases, chest x-ray, and pulmonary function tests.

Treatment Overview:

0.4.2 ORAL EXPOSURE

- A) GASTRIC LAVAGE
  - 1) Significant esophageal or gastrointestinal tract irritation or burns may occur following ingestion. The possible benefit of early removal of some ingested material by cautious gastric lavage must be weighed against potential complications of bleeding or perforation.
  - 2) GASTRIC LAVAGE: Consider after ingestion of a potentially life-threatening amount of poison if it can be performed soon after ingestion (generally within 1 hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first.
    - a) CONTRAINDICATIONS: Loss of airway protective reflexes or decreased level of consciousness in unintubated patients; following ingestion of corrosives; hydrocarbons (high aspiration potential); patients at risk of hemorrhage or gastrointestinal perforation; and trivial or non-toxic ingestion.
- B) ACTIVATED CHARCOAL
  - 1) Activated charcoal binds most toxic agents and can decrease their systemic absorption if administered soon after ingestion. In general, metals and acids are poorly bound and patients ingesting these materials will not likely benefit from activated charcoal administration.
    - a) Activated charcoal should not be given to patients ingesting strong acidic or basic caustic chemicals. Activated charcoal is also of unproven value in patients ingesting irritant chemicals, where it may obscure endoscopic findings when the procedure is justified.
  - 2) ACTIVATED CHARCOAL: Administer charcoal as a slurry (240 mL water/30 g charcoal). Usual dose: 25 to 100 g in adults/adolescents, 25 to 50 g in children (1 to 12 years), and 1 g/kg in infants less than 1 year old.
- C) DILUTION -
  - 1) Immediate dilution with milk or water may be of benefit in caustic or irritant chemical ingestions.
  - 2) DILUTION: Immediately dilute with 4 to 8 ounces (120 to 240 mL) of water or milk (not to exceed 4 ounces/120 mL in a child).
- D) IRRITATION -
  - 1) Observe patients with ingestion carefully for the possible development of esophageal or gastrointestinal tract irritation or burns. If signs or symptoms of

esophageal irritation or burns are present, consider endoscopy to determine the extent of injury.

- E) OBSERVATION CRITERIA -
  - 1) Carefully observe patients with ingestion exposure for the development of any systemic signs or symptoms and administer symptomatic treatment as necessary.
  - 2) Patients symptomatic following exposure should be observed in a controlled setting until all signs and symptoms have fully resolved.

0.4.3 INHALATION EXPOSURE

- A) DECONTAMINATION -
  - 1) INHALATION: Move patient to fresh air. Monitor for respiratory distress. If cough or difficulty breathing develops, evaluate for respiratory tract irritation, bronchitis, or pneumonitis. Administer oxygen and assist ventilation as required. Treat bronchospasm with inhaled beta2 agonist and oral or parenteral corticosteroids.
- B) IRRITATION -
  - 1) Respiratory tract irritation, if severe, can progress to pulmonary edema which may be delayed in onset up to 24 to 72 hours after exposure in some cases.
- C) ACUTE LUNG INJURY -
  - 1) ACUTE LUNG INJURY: Maintain ventilation and oxygenation and evaluate with frequent arterial blood gas or pulse oximetry monitoring. Early use of PEEP and mechanical ventilation may be needed.
- D) BRONCHOSPASM -
  - 1) If bronchospasm and wheezing occur, consider treatment with inhaled sympathomimetic agents.
- E) OBSERVATION CRITERIA -
  - 1) Carefully observe patients with inhalation exposure for the development of any systemic signs or symptoms and administer symptomatic treatment as necessary.
  - 2) Patients symptomatic following exposure should be observed in a controlled setting until all signs and symptoms have fully resolved.

0.4.4 EYE EXPOSURE

- A) DECONTAMINATION: Irrigate exposed eyes with copious amounts of room temperature water for at least 15 minutes. If irritation, pain, swelling, lacrimation, or photophobia persist, the patient should be seen in a health care facility.

0.4.5 DERMAL EXPOSURE

- A) OVERVIEW
  - 1) DERMAL DECONTAMINATION -
    - a) DECONTAMINATION: Remove contaminated clothing and wash exposed area thoroughly with soap and water. A physician may need to examine the area if irritation or pain persists.
  - 2) PESTICIDES -
    - a) DECONTAMINATION: Remove contaminated clothing and jewelry. Wash the skin, including hair and nails, vigorously; do repeated soap washings. Discard contaminated clothing.
  - 3) IRRITATION -

a) Treat dermal irritation or burns with standard topical therapy. Patients developing dermal hypersensitivity reactions may require treatment with systemic or topical corticosteroids or antihistamines.

4) DERMAL ABSORPTION -

a) Some chemicals can produce systemic poisoning by absorption through intact skin. Carefully observe patients with dermal exposure for the development of any systemic signs or symptoms and administer symptomatic treatment as necessary.

Range of Toxicity:

A) No specific range of toxicity can be established for the broad field of chemicals in general.

[Rumack BH POISINDEX(R) Information System Micromedex, Inc., Englewood, CO, 2006; CCIS Volume 130, edition expires Nov, 2006. Hall AH & Rumack BH (Eds): TOMES(R) Information System Micromedex, Inc., Englewood, CO, 2006; CCIS Volume 130, edition expires Nov, 2006., p.]**PEER REVIEWED**

Animal Toxicity Studies:

Non-Human Toxicity Excerpts:

NO SYMPTOMS OF TOXICITY COULD BE PRODUCED BY INHALATION OF CONCN VAPORS IN RATS.
[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994., p. 3558]**PEER REVIEWED**

NONANOIC ACID, FED FOR 4 WK @ 4.17% IN DIET, DEPRESSED RATE OF GROWTH ONLY IN VITAMIN B12-DEFICIENT RATS. 5% IN DIET WAS FAIRLY WELL UTILIZED BY GROWING CHICKS.
[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994., p. 3559]**PEER REVIEWED**

NONANOIC ACID DECR THE CONTRACTILE FORCE OF ISOMETRICALLY ACTING RAT PAPILLARY MUSCLES, WITH THE EFFECT DEPENDING ON BOTH CONCN (0.1-1 MMOL) AND TIME OF EXPOSURE (2-12 MIN). THE POSTEXTRASYSTOLIC POTENTIATION AND THE TIME TO REACH A NEW STEADY STATE LEVEL OF CONTRACTION FOLLOWING A PAIRED PULSE STIMULATION WERE INCR BY NONANOIC ACID.
[CAFFIER G, PFEIFFER C; ACTA BIOL MED GER 36 (7-8): 1077 (1977)]**PEER REVIEWED**

...(0.5 OR 1.0 MOLAR IN PROPANOL) CAUSED IRRITATION /IN HUMANS/ WHEN APPLIED UNDER OCCLUSIVE PATCHES.
[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and

Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994., p. 3559]**PEER REVIEWED**

Non-Human Toxicity Values:

LD50 Mouse iv 224 + or - 4.6 mg/kg
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1214]**PEER REVIEWED**

TSCA Test Submissions:

Nonanoic acid (CAS # **112-05-0)** was evaluated for subchronic dermal toxicity and irritation in New Zealand White rabbits (5/sex/group) exposed to 500 mg/kg/day (25% w/w in mineral oil) for 5 days/week for 2 weeks. Half of the animals (3 males, 2 females) received applications upon abraded skin and half (3 females, 2 males) received applications on intact skin. Applications remained uncovered. An additional control group of 10 rabbits was treated dermally with 2 g/kg/day mineral oil. There were no mortalities throughout treatment or 2-week recovery (4 rabbits). All treated animals showed slight weight losses in the second week and food consumption was diminished in 2nd and 3rd weeks of study. Severe erythema, slight to severe edema characterized signs of irritation at the sites of application with necrosis and eschar appearing in all animals in the second week. Atonia, desquamation, fissuring and exfoliation of eschar tissue were noted as well. Treatment-related weight loss and signs of dermal irritation resolved in animals held for 2-week recovery. Upon necropsy of 6 animals (3/abraded and 3/intact) at 2 weeks, no treatment- related gross pathology was identified other than morphological changes of treated dermis. Microscopic examination revealed generally localized necrosis accompanied by epidermal hyperplasia, hyperkeratosis, and occasional diffuse and perifollicular dermal inflammation at both abraded and intact application sites. Treated rabbits held for recovery was reepithelialized and continuous with normal follicular structure and population, and with persisting mild to moderate epidermal hyperplasia and hyperkeratosis. Microscopic examination of select visceral organs from 6 rabbits at 2 weeks and 4 recovered rabbits at 4 weeks failed to expose a systemic effect of treatment.
[RHONE-POULENC INC; A 28-Day Dermal Toxicity Study in Rabbits; 9/30/81; EPA Doc No. 88-920010172; Fiche No. OTS0546557]**UNREVIEWED**

Nonanoic acid (CAS # **112-05-0)** was evaluated for developmental and maternal toxicity in 22 pregnant Crl:COBS, CDBR rats administered doses of 1500 mg/kg bw by oral intubation on gestational days 6 through 15. A control group of 22 female rats received gavage doses of corn oil (vehicle). On Day 20, all rats were sacrificed for Caesarian delivery and determination of fetal/embryotoxicity and teratogenic effects, as well as fertility indices and maternal toxicity. No excess mortality, retarded bodyweight gains, decreased food consumption or other clinical signs of maternal toxicity were observed relative to control. Likewise, gross pathology upon terminal sacrifice identified no treatment-related effects in the pregnant dams. Pregnancy rates, mean number of corpora lutea, implantations, and mean implantation efficiency (implantations per corpora lutea) were comparable to controls, as were gravid and nongravid uterine weights, and mean ovarian, uterine, and litter data. Embryotoxic effects (number of resorptions, number of

fetuses, fetal viability, mean fetal bodyweight, mean fetal length) were not observed. Gross pathology and skeletal examinations produced no statistically significant evidence of fetotoxicity or teratogenicity in a viable fetal population similar to that in the control group. Of 80 fetuses from 22 litters of the treated rats, there were 2 instances of cleft palate, 2 fetuses with small tongue, and a single incidence hydroureter that were not seen in control fetuses. Skeletal anomalies were likewise not statistically linked to treatment and the number of variant fetuses (2) were equal to variant controls.
[RHONE-POULENC INC; Teratology Screen in Rats, Project No. 299-534; 7/28/83; EPA Doc No. 88-920009562; Fiche No. OTS0571218]**UNREVIEWED**

Metabolism/Pharmacokinetics:

Metabolism/Metabolites:

INFUSION OF AN EMULSION CONTAINING 20% TRINONANOATE, 0.9% SODIUM CHLORIDE, & 1% SOYBEAN LECITHINS INTO DOGS RESULTED IN OXIDN OF NONANOIC ACID.
[BACH A ET AL; NUTR METAB 14 (4): 203 (1972)]**PEER REVIEWED**

NONANOIC ACID IS METABOLIZED BY THE LIVER TO PRODUCE KETONE BODIES. METABOLISM OCCURS VIA BETA-OXIDATION, AND NO EVIDENCE WAS FOUND IN RATS OF CHAIN ELONGATION OR TISSUE STORAGE OF THE ACID. METAB OF THE TERMINAL PROPIONIC ACID RESIDUE RESULTS IN INCREASED GLUCOSE AND GLYCOGEN SYNTHESIS.
[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994., p. 3560]**PEER REVIEWED**

Pharmacology:

Environmental Fate & Exposure:

Environmental Fate/Exposure Summary:

Nonanoic acid may be released into the environment in various waste streams from its production and use in organic syntheses, lacquers, plastics, in the production of hydrotropic salts, pharmaceuticals, synthetic flavors and odors, esters for turbojet lubricants, as a flotation agent, vinyl plasticizer, and as a gasoline additive. If released to the atmosphere, nonanoic acid is expected to exist solely as a vapor in the ambient atmosphere based on a measured vapor pressure of 1.6X10-3 mm Hg. Vapor-phase nonanoic acid will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals with an estimated half-life of 1.6 days. If released to soil, nonanoic acid is expected to have low mobility based on an estimated Koc of 1700. Volatilization of nonanoic acid from dry soil surfaces is not expected to occur based on its measured vapor pressure. An estimated Henry's Law constant of 1.6X10-6 atm-cu m/mole indicates that volatilization from wet soil surfaces may be important. Limited biodegradation data suggest that nonanoic acid has the potential to biodegrade in both soil and water under aerobic conditions. If released into water, nonanoic acid is expected to adsorb to suspended solids and sediment in the water column based on its estimated Koc. Nonanoic acid's pKa of 4.95 indicates that it will exist predominately in the ionized form at environmental pHs. Volatilization of nonanoic acid from water surfaces is not expected to be an important fate process based on this compound's pKa and its estimated Henry's Law constant. The potential for bioconcentration of nonanoic acid in aquatic organisms is high based on an estimated BCF of 230. Hydrolysis is not expected to be an important process due to the lack of hydrolyzable functional groups. Occupational exposure to nonanoic acid may occur through dermal contact with this compound at workplaces where nonanoic acid is produced or used. The general population will be exposed to nonanoic acid via inhalation of ambient air, ingestion of food and drinking water, and dermal contact with food and other products containing nonanoic acid. (SRC) **PEER REVIEWED**

Probable Routes of Human Exposure:

NIOSH (NOES Survey 1981-1983) has statistically estimated that 46,467 workers (1,484 of these are female) are potentially exposed to nonanoic acid in the US(1). Occupational exposure to nonanoic acid may occur through dermal contact with this compound at workplaces where nonanoic acid is produced or used(SRC). The general population will be exposed to nonanoic acid via inhalation of ambient air, ingestion of food and drinking water, and dermal contact with food and other products containing nonanoic acid(SRC). [(1) NIOSH; National Occupational Exposure Survey (NOES) (1983)]**PEER REVIEWED**

Natural Pollution Sources:

...AS AN ESTER IN OIL OF PELARGONIUM. [The Merck Index. 9th ed. Rahway, New Jersey: Merck & Co., Inc., 1976., p. 916]**PEER REVIEWED**..IN SEVERAL ESSENTIAL OILS, EITHER FREE OR ESTERIFIED: ROSE, GERANIUM, ORRIS, LITSEA CUBEBA, ARTEMISIA ARBORESCENS L, HOPS, CHAMAECYPARIS PISIFERA ENDL, EREMOCITRUS GLAUCA L, FRENCH LAVENDER, AND IN OAK MUSK. [Fenaroli's Handbook of Flavor Ingredients. Volume 2. Edited, translated, and revised by T.E. Furia and N. Bellanca. 2nd ed. Cleveland: The Chemical Rubber Co., 1975., p. 433]**PEER REVIEWED**

Nonanoic acid was identified as a volatile constituent of the kiwi fruit flower(1). [(1) Tatsuka K et al; J Agric Food Chem 38: 2176-80 (1993)]**PEER REVIEWED**

Artificial Pollution Sources:

Nonanoic acid's production and use in organic syntheses, lacquers, plastics, in the production of hydrotropic salts, pharmaceuticals, synthetic flavors and odors, esters for turbojet lubricants, as a flotation agent, vinyl plasticizer, and as a gasoline additive(1) may result in its release to the environment through various waste streams(SRC).

[(1) Lewis RJ Jr; Hawley's Condensed Chemical Dictionary 12th ed NY, NY: Van Nostrand Reinhold Co p. 877 (1993)]**QC REVIEWED**

Environmental Fate:

TERRESTRIAL FATE: Based on a recommended classification scheme(1), an estimated Koc value of 1700(SRC), determined from a measured log Kow of 3.42(2) and a recommended regression-derived equation(3), indicates that nonanoic acid is expected to have low mobility in soil(SRC). Volatilization of nonanoic acid may be important from moist soil surfaces(SRC) given an estimated Henry's Law constant of 1.6X10-6 atm-cu m/mole(SRC) from its experimental values for vapor pressure, 1.6X10-3 mm Hg(4), and water solubility, 210 mg/l(5). Nonanoic acid is not expected to volatilize from dry soil surfaces based on its measured vapor pressure(4). Biodegradation of nonanoic acid in studies using sewage and sludge inoculum(6,7) indicate that biodegradation in soil may be important(SRC).
[(1) Swann RL et al; Res Rev 85: 23 (1983) (2) Sangster J; LOGKOW Databank, Sangster Res Lab, Montreal Quebec, Canada (1994) (3) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington DC: Amer Chem Soc pp. 4-9 (1990) (4) Daubert TE, Danner RP; Physical and thermodynamic properties of pure chemicals: data compilation. Design Inst Phys Prop Data, Amer Inst Chem Eng., Washington, DC: Taylor & Francis, Vol 4 (1995) (5) Yalkowsky SH, Dannenfelser RM; Aquasol Database of Aqueous Solubility. Ver 5. College of Pharmacy, Univ of Ariz - Tucson, AZ. PC Ver (1992) (6) Yonezawa Y et al; Kogai Shigen Kenkyusho Iho 12: 85-91 (1982) (7) Heukelekian H, Rand MC; J Water Pollut Contr Assoc 27: 1040-53 (1955)]**PEER REVIEWED**

AQUATIC FATE: Based on a recommended classification scheme(1), an estimated Koc value of 1700(SRC), determined from a measured log Kow of 3.42(2) and a recommended regression-derived equation(3), indicates that nonanoic acid is expected to adsorb to suspended solids and sediment in water(SRC). Nonanoic acid may volatilize from water surfaces(3,SRC) based on an estimated Henry's Law constant of 1.6X10-6 atm-cu m/mole(SRC) from its experimental values for vapor pressure, 1.6X10-3 mm Hg(4), and water solubility, 210 mg/l(5). Estimated volatilization half-lives for a model river and model lake are 29 and 210 days, respectively(3,SRC). Nonanoic acid's pKa of 4.95 at 25 deg C(6) indicates that nonanoic acid will exist predominately in the ionized form under environmental pHs(SRC). Volatilization of the ionized form from water surfaces is not expected to be an important fate process(SRC). According to a classification scheme(7), an estimated BCF value of 230(3,SRC), from a measured log Kow(2), suggests that bioconcentration in aquatic organisms is high(SRC). A total organic carbon removal ratio of 99% was observed for nonanoic acid using a non-acclimated activated sludge and an initial nonanoic acid concn of 100 mg total organic carbon/l(8). A BOD of 0.59 (g/g) was observed for nonanoic acid after 5 days incubation using a sewage inoculum(9).
[(1) Swann RL et al; Res Rev 85: 23 (1983) (2) Sangster J; LOGKOW Databank, Sangster Res Lab, Montreal Quebec, Canada (1994) (3) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington DC: Amer Chem Soc pp. 4-9, 5-4, 5-10, 15-1 to 15-29 (1990) (4) Daubert TE, Danner RP; Physical and thermodynamic properties of pure chemicals: data compilation. Design Inst Phys Prop Data, Amer Inst Chem Eng.,

Washington, DC: Taylor & Francis, Vol 4 (1995) (5) Yalkowsky SH, Dannenfelser RM; Aquasol Database of Aqueous Solubility. Version 5. College of Pharmacy, Univ of Ariz - Tucson, AZ. PC Version. (1992) (6) Dean JA; Handbook of Organic Chemistry, NY, NY: McGraw-Hill, Inc p. 8-45 (1987) (7) Franke C et al; Chemosphere 29: 1501-14 (1994) (8) Yonezawa Y et al; Kogai Shigen Kenkyusho Iho 12: 85-91 (1982) (9) Heukelekian H, Rand MC; J Water Pollut Contr Assoc 27: 1040-53 (1955)]**PEER REVIEWED**

ATMOSPHERIC FATE: According to a model of gas/particle partitioning of semivolatile organic compounds in the atmosphere(1), nonanoic acid, which has a measured vapor pressure of 1.6X10-3 mm Hg at 25 deg C(2), is expected to exist solely as a vapor in the ambient atmosphere. Vapor-phase nonanoic acid is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals(SRC); the half-life for this reaction in air is estimated to be about 1.6 days(3,SRC).
[(1) Bidleman TF; Environ Sci Technol 22: 361-367 (1988) (2) Daubert TE, Danner RP; Physical and thermodynamic properties of pure chemicals: data compilation. Design Inst Phys Prop Data, Amer Inst Chem Eng., Washington, DC: Taylor & Francis, Vol 4 (1995) (3) Meylan WM, Howard PH; Chemosphere 26: 2293-99 (1993)]**PEER REVIEWED**

Environmental Biodegradation:

A total organic carbon removal ratio of 99% was observed for nonanoic acid using a non-acclimated activated sludge and an initial nonanoic acid concn of 100 mg total organic carbon/l(1). A BOD of 0.59 (g/g) was observed for nonanoic acid after 5 days incubation using a sewage inoculum(2). A 75% decrease in the initial nonanoic acid concn of 1.6 mg/l was observed after 21 days incubation in an aerobic mixed bacterial culture obtained from trench leachate at a low-level radioactive waste disposal site in West Valley, NY(3). An increase of 52% in the nonanoic acid concn of 4.2 mg/l in anaerobic bacterial cultures obtained from trench leachate was attributed to the breakdown of complex compounds(3).
[(1) Yonezawa Y et al; Kogai Shigen Kenkyusho Iho 12: 85-91 (1982) (2) Heukelekian H, Rand MC; J Water Pollut Contr Assoc 27: 1040-53 (1955) (3) Francis AJ; Environmental Migration of Long-lived Radionuclides, Vienna, Austria: Inter Atomic Energy Agency IAEA-SM-257/72 pp. 415-29 (1982)]**PEER REVIEWED**

Environmental Abiotic Degradation:

The rate constant for the vapor-phase reaction of nonanoic acid with photochemically-produced hydroxyl radicals has been estimated as 9.8X10-12 cu cm/molecule-sec at 25 deg C(SRC) using a structure estimation method(1,SRC). This corresponds to an atmospheric half-life of about 1.6 days at an atmospheric concn of 5X10+5 hydroxyl radicals per cu cm(1,SRC). Nonanoic acid is not expected to undergo hydrolysis in the environment(SRC) due to the lack of functional groups to hydrolyze(2).
[(1) Meylan WM, Howard PH; Chemosphere 26: 2293-99 (1993) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington DC: Amer Chem Soc pp. 7-4, 7-5 (1990)]**PEER REVIEWED**

Environmental Bioconcentration:

An estimated BCF value of 230 was calculated for nonanoic acid(SRC), using a measured log Kow of 3.42(1) and a recommended regression-derived equation(2). According to a classification scheme(3), this BCF value suggests that bioconcentration in aquatic organisms is high(SRC).
[(1) Sangster J; LOGKOW Databank, Sangster Res Lab, Montreal Quebec, Canada (1994) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington DC: Amer Chem Soc pp. 5-4, 5-10 (1990) (3) Franke C et al; Chemosphere 29: 1501-14 (1994)]**PEER REVIEWED**

Soil Adsorption/Mobility:

The Koc of nonanoic acid is estimated as approximately 1700(SRC), using a measured log Kow of 3.42(1) and a regression-derived equation(2,SRC). According to a recommended classification scheme(3), this estimated Koc value suggests that nonanoic acid is expected to have low mobility in soil(SRC).
[(1) Sangster J; LOGKOW Databank, Sangster Res Lab, Montreal Quebec, Canada (1994) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington DC: Amer Chem Soc pp. 4-9 (1990) (3) Swann RL et al; Res Rev 85: 23 (1983)]**PEER REVIEWED**

Volatilization from Water/Soil:

The Henry's Law constant for nonanoic acid is estimated as 1.6X10-6 atm-cu m/mole(SRC) from its experimental values for vapor pressure, 1.6X10-3 mm Hg(1), and water solubility, 210 mg/l(2). This value indicates that nonanoic acid will volatilize slowly from water surfaces(3,SRC). Based on this Henry's Law constant, the estimated volatilization half-life from a model river (1 m deep, flowing 1 m/sec, wind velocity of 3 m/sec) is estimated as approximately 29 days(3,SRC). The estimated volatilization half-life from a model lake (1 m deep, flowing 0.05 m/sec, wind velocity of 0.5 m/sec) is estimated as approximately 210 days(3,SRC). Nonanoic acid's pKa of 4.95 at 25 deg C(4) indicates that nonanoic acid will exist predominately in the ionized form under environmental pHs(SRC). Volatilization of the ionized form from water surfaces is not expected to be an important fate process(SRC). Nonanoic acid's Henry's Law constant(1,2,SRC) indicates that volatilization from moist soil surfaces may occur(SRC). Nonanoic acid is not expected to volatilize from dry soil surfaces(SRC) based on a measured vapor pressure of 1.6X10-3 mm Hg(1).
[(1) Daubert TE, Danner RP; Physical and thermodynamic properties of pure chemicals: data compilation. Design Inst Phys Prop Data, Amer Inst Chem Eng., Washington, DC: Taylor & Francis, Vol 4 (1995) (2) Yalkowsky SH, Dannenfelser RM; Aquasol Database of Aqueous Solubility. Version 5. College of Pharmacy, Univ of Ariz - Tucson, AZ. PC Version. (1992) (3) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington DC: Amer Chem Soc pp. 15-1 to 15-29 (1990) (4) Dean JA; Handbook of Organic Chemistry, NY,NY: McGraw-Hill, Inc p. 8-45 (1987)]**PEER REVIEWED**

Environmental Water Concentrations:

DRINKING WATER: Nonanoic acid was quantitatively detected in drinking water in: Cincinnati, OH in Oct 1978; New Orleans, LA in Jan 1976; Philadelphia, PA in Feb 1976; Ottumwa, IA in Sept 1976; and Seattle, WA in Nov 1976(1). Nonanoic acid was detected in treated water samples taken from sampling taps in treatment works at an unspecified concn(2).
[(1) Lucas SV; GC/MS Analysis of Organics in Drinking Water Concentrates and Advanced Waste Treatment Concentrates: Vol 1 Analysis Results for 17 Drinking Water, 16 Advanced Waste Treatment and 3 Process Blank Concentrates USEPA-600/1-84-020A (NTIS PB85-128221) Columbus, OH: Columbus Labs Health Eff Res Lab (1984) (2) Fielding M et al; Organic Micropollutants in Drinking Water, TR-159, Medmenham, Eng Water Res Cent (1981)]**PEER REVIEWED**

SURFACE WATER: Nonanoic acid was detected at a concn of 0.01 ppb in a water sample from the Inner Harbor Navigation Canal, Lake Pontchartain, New Orleans, LA collected at a depth of 10 m on the flood tide on June 23, 1980(1).
[(1) McFall AJ et al; Chemosphere 14: 1253-65 (1985)]**PEER REVIEWED**

RAIN/SNOW: Nonanoic acid was detected in rainwater samples collected in a suburb of Hannover, Germany at an unspecified concn(1). Rain and snow samples collected from nine different locations in southern CA between 1982 and 1984 contained nonanoic acid at concns ranging from 0.007 to 0.14 uM(2). Rainwater samples collected in west Los Angeles between 1982 and 1983 contained nonanoic acid at concns ranging from 0.01 to 0.13 uM(2).
[(1) Winkeler HD et al; Vom Wasser 70: 107-17 (1988) (2) Kawamura K et al; Atmos Environ 30: 1035-52 (1996)]**PEER REVIEWED**

Effluent Concentrations:

Nonanoic acid was detected in aqueous industrial effluent extracts collected between Nov 1979-81 in the following industrial categories (concentration in one effluent extract): ore mining (12 ng/ul); auto and other laundries (34 ng/ul); porcelain/enameling (28 ng/ul); electronics (3084 ng/ul); mechanical products (1954 ng/ul); and publicly owned treatment works at an unknown concn(1). Nonanoic acid was identified in the acidic fraction of sewage and sludge from the Iona Island Sewage Treatment Plant, British Columbia(2). The acidic fraction of oil shale retort water from the Kerosene Creek seam of the Rundle deposit, Queensland, Australia, was found to contain nonanoic acid at a concn of 200 mg/l(3). A grab sample, obtained in April 1980, of the final effluent from the Addison, IL Publicly Owned Treatment Works was found to contain nonanoic acid at an unreported concn(4). Groundwater samples contaminated by industrial pollution near Barcelona, Spain were found to contain nonanoic acid at concns ranging from <5 to 75 ng/l(5). Nonanoic acid was detected in trench leachate from a low-level radioactive waste disposal site in West Valley, NY at an average concn of 4.5 mg/l(6). Nonanoic acid was detected in process retort water from the Occidental Oil Shale, Inc facility in Logan Wash, CO at a concn of 81 mg/l(7).
[(1) Bursey JT, Pellizzari ED; Analysis of Industrial Wastewater for Organic Pollutants in Consent Degree Survey, Contract No. 68-03-2867, Athens, GA: USEPA Environ Res Lab (1982) (2) Rogers IH et al; Water Pollut Res J Canada 21: 187-204 (1986) (3) Dobson KR et al; Water Res J

19: 849-56 (1985) (4) Ellis DD et al; Arch Environ Contam Toxicol 11: 373-82 (1982) (5) Guardiola J et al; Water Supply 7: 11-16 (1989) (6) Francis AJ et al; Nuclear Tech 50: 158-63 (1980) (7) Leenheer JA et al; Environ Sci Technol 16: 714-23 (1982)]**PEER REVIEWED**

Nonanoic acid was detected in: process water from in situ coal gasification in Gillette, WY at a concn of 5 ppm; retort water from in situ oil shale processing in Rock Springs, WY at a concn of 493 ppm; and boiler blowdown water from in situ shale oil processing in DeBeque, CO at a concn of 132 ppm(1). Nonanoic acid was identified as a byproduct of chlorine dioxide disinfection of drinking water at a pilot plant in Evansville, IN(2). Fine aerosol emission rates of nonanoic acid from heavy-duty diesel trucks, noncatalyst-equipped, and catalyst-equipped automobiles were 146.9, 8.6, and 196.2 ug/km, respectively(3). Nonanoic acid was detected in road dust particles collected from paved streets in a residential area of Pasadena, CA in May 1988 at a concn of 135.4 ug/g of particle sample; brake lining particles at a concn of 87.4 ug/g of particle sample; and tire wear particles at a concn of 90.9 ug/g of particle sample(4). Nonanoic acid was identified as a fine particle released from a natural gas-fired space heater and water heater; emission rates were 225.2 pg/kJ and 482.6 pg/kJ for the first series of filters and backup filters within the samplers, respectively(5).
[(1) Pellizzari ED et al; Identification of organic components in aqueous effluents from energy-related processes. ASTM Spec Tech Publ. STP 686 pp. 256-73 (1979) (2) Richardson SD et al; Environ Sci Technol 28: 592-99 (1994) (3) Rogge WF et al; Environ Sci Technol 27: 636-51 (1993) (4) Rogge WF et al; Environ Sci Technol 27: 1892-904 (1993) (5) Rogge WF et al; Environ Sci Technol 27: 2736-44 (1993)]**PEER REVIEWED**

Sediment/Soil Concentrations:

Nonanoic acid was detected but not quantitated in sediment samples collected from Dokai Bay, Japan on Sept 28 1990(1).
[(1) Terashi A et al; Bull Environ Contam Toxicol 50: 348-55 (1993)]**PEER REVIEWED**

Atmospheric Concentrations:

Nonanoic acid was identified in air samples collected along the Niagara River in Sept 1982 at an unreported concn(1). The average ambient annual concn of nonanoic acid in fine particles collected from West Los Angeles, downtown Los Angeles, Pasadena, Rubidoux, and San Nicolas Island, CA in 1982 was 3.3, 6.6, 5.3, 9.9, and 0.24 ng/cu m, respectively(2). Nonanoic acid was detected in emissions from a municipal waste incineration plant at an unspecified concn(3). Nonanoic acid was detected at an unreported concn in forest air samples collected in a spruce forest in Eggegebirge, North-Rhine Westphalia(4). Air samples collected in Los Angeles between July and Sept 1984 contained 0.0009 to 0.011 ppb nonanoic acid(5). Nonanoic acid was detected in exhaust from a gasoline engine at a concn of 0.052 ppb(5). Remote aerosol samples collected from the North Pacific Ocean, heavily vegetated areas of American Samoa, and the Marshall Islands contained a nonanoic acid concn of 0.031, 4.91, and 0.060 mg/cu m, respectively(6).

[(1) Hoff RM, Chan K; Environ Sci Technol 21: 556-61 (1987) (2) Rogge WF et al; Atmos Environ 27A: 1309-30 (1993) (3) Jay K, Stieglitz L; Chemosphere 30: 1249-60 (1995) (4) Helmig D et al; Chemosphere 19: 1399-1412 (1989) (5) Kawamura K et al; Environ Sci Technol 19: 1082-6 (1985) (6) Kawamura K, Gagosian RB; Nature 325: 330-1 (1987)]**PEER REVIEWED**

Food Survey Values:

Nonanoic acid was identified as a volatile component of raw beef(1). Nonanoic acid has been identified as a volatile flavor component of mutton and beef(2). Aerosol emission rates of nonanoic acid from frying hamburger meat was 10.2 mg/kg of meat cooked; emission rates from charbroiling hamburger was 30.6 mg/kg of meat cooked for extra lean hamburger (approx. 10.0% fat) and 47.1 mg/kg of meat cooked for regular hamburger (approx. 21% fat)(3).
[(1) King MF et al; J Agric Food Chem 41: 1974-81 (1993) (2) Shahidi F et al; CRC Crit Rev Food Sci Nature 24: 141-243 (1986) (3) Rogge WF et al; Environ Sci Technol 25: 1112-25 (1991)]**PEER REVIEWED**

Plant Concentrations:

Nonanoic acid was identified as a volatile constituent of the kiwi fruit flower(1). Nonanoic acid was found in fine particulate matter released (by resuspension and agitation of the leaf composites) from green and dead plant leaves at concns of 444.7 and 596.8 ug/g, respectively(2).
[(1) Tatsuka K et al; J Agric Food Chem 38: 2176-80 (1993) (2) Rogge WF et al; Environ Sci Technol 27: 2700-11 (1993)]**PEER REVIEWED**

Fish/Seafood Concentrations:

Nonanoic acid was detected in fresh mussels obtained from the Oarai Coast in Ibaraki, Japan at a concn of 0.08 ug/g wet weight(1).
[(1) Yashuara A; J Chromatogr; 409: 251-8 (1987)]**PEER REVIEWED**

Other Environmental Concentrations:

Dust samples collected from 12 households in three urban areas of central Finland contained nonanoic acid at an unreported concn(1).
[(1) Hirvonen A et al; Indoor Air 4: 255-64 (1994)]**PEER REVIEWED**

Environmental Standards & Regulations:

FDA Requirements:

Nonanoic acid is a food additive permitted for direct addition to food for human consumption as a synthetic flavoring substance and adjuvant in accordance with the following conditions: 1) the quantity added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food, and 2) when intended for use in or on food it is of appropriate food grade

and is prepared and handled as a food ingredient.
[21 CFR 172.515 (4/1/96)]**PEER REVIEWED**

Chemical/Physical Properties:

Molecular Formula:

C9-H18-O2
PEER REVIEWED

Molecular Weight:

158.24
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1214]**PEER REVIEWED**

Color/Form:

COLORLESS, OILY LIQUID @ ORDINARY TEMP; CRYSTALLIZES WHEN COOLED
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1214]**PEER REVIEWED**

YELLOWISH OIL
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 12th ed. New York, NY: Van Nostrand Rheinhold Co., 1993, p. 877]**PEER REVIEWED**

Odor:

FATTY ODOR
[Fenaroli's Handbook of Flavor Ingredients. Volume 2. Edited, translated, and revised by T.E. Furia and N. Bellanca. 2nd ed. Cleveland: The Chemical Rubber Co., 1975., p. 433]**PEER REVIEWED**

COCONUT AROMA
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Volume 2. Boca Raton, Florida: CRC Press, Inc., 1980., p. 293]**PEER REVIEWED**

Slight odor
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 12th ed. New York, NY: Van Nostrand Rheinhold Co., 1993, p. 877]**PEER REVIEWED**

Taste:

UNPLEASANT TASTE
[Fenaroli's Handbook of Flavor Ingredients. Volume 2. Edited,

translated, and revised by T.E. Furia and N. Bellanca. 2nd ed. Cleveland: The Chemical Rubber Co., 1975., p. 433]**PEER REVIEWED**

EXCELLENT COCONUT TASTE
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Volume 2. Boca Raton, Florida: CRC Press, Inc., 1980., p. 293]**PEER REVIEWED**

Boiling Point:

252-253 DEG C @ 760 MM HG
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1214]**PEER REVIEWED**

Melting Point:

12.5 DEG C
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1214]**PEER REVIEWED**

Density/Specific Gravity:

0.9052 g/cu cm at 20 deg C
[Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 76th ed. Boca Raton, FL: CRC Press Inc., 1995-1996., p. 3-224]**PEER REVIEWED**

Dissociation Constants:

pKa = 4.95 at 25 deg C
[Dean, J.A. Handbook of Organic Chemistry. New York, NY: McGraw-Hill Book Co., 1987., p. 8-45]**PEER REVIEWED**

Heat of Combustion:

-5,456.1 kJ/mol
[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present., p. V5 149]**PEER REVIEWED**

Octanol/Water Partition Coefficient:

Log Kow = 3.42
[Sangster J; LOGKOW Databank, Sangster Res Lab, Montreal Quebec, Canada (1994)]**PEER REVIEWED**

Solubilities:

Soluble in alcohol, chloroform, ether
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals,

Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1214]**PEER REVIEWED**

1:8 IN 50% ALCOHOL; 1:3 IN 60% ALCOHOL; INSOL IN WATER; SOL IN MOST ORG SOLVENTS
[Fenaroli's Handbook of Flavor Ingredients. Volume 2. Edited, translated, and revised by T.E. Furia and N. Bellanca. 2nd ed. Cleveland: The Chemical Rubber Co., 1975., p. 433]**PEER REVIEWED**

In water, 2.12X10+2 mg/l at 30 deg C.
[Yalkowsky SH, Dannenfelser RM; Aquasol Database of Aqueous Solubility. Version 5. College of Pharmacy, Univ of Ariz - Tucson, AZ. PC Version (1992)]**PEER REVIEWED**

Spectral Properties:

INDEX OF REFRACTION: 1.4330 @ 20 DEG C/D
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1214]**PEER REVIEWED**

IR: 60 (Sadtler Research Laboratories Prism Collection)
[Weast, R.C. and M.J. Astle. CRC Handbook of Data on Organic Compounds. Volumes I and II. Boca Raton, FL: CRC Press Inc. 1985., p. V2 4]**PEER REVIEWED**

NMR: 9 (Sadtler Research Laboratories Spectral Collection)
[Weast, R.C. and M.J. Astle. CRC Handbook of Data on Organic Compounds. Volumes I and II. Boca Raton, FL: CRC Press Inc. 1985., p. V2 4]**PEER REVIEWED**

MASS: 988 (Atlas of Mass Spectral Data, John Wiley & Sons, New York)
[Weast, R.C. and M.J. Astle. CRC Handbook of Data on Organic Compounds. Volumes I and II. Boca Raton, FL: CRC Press Inc. 1985., p. V2 4]**PEER REVIEWED**

Vapor Pressure:

1.65X10-3 mm Hg at 25 deg C /From experimentally derived coefficients/
[Daubert, T.E., R.P. Danner. Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, D.C.: Taylor and Francis, 1989., p.]**PEER REVIEWED**

Viscosity:

8.08 mPa sec at 20 deg C
[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present., p. V5 149]**PEER REVIEWED**

Other Chemical/Physical Properties:

Boiling point = 255.6 deg C
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 12th ed. New York, NY: Van Nostrand Rheinhold Co., 1993, p. 877]**PEER REVIEWED**

Acid value: 351 mg KOH/g
[Ashford, R.D. Ashford's Dictionary of Industrial Chemicals. London, England: Wavelength Publications Ltd., 1994., p. 665]**PEER REVIEWED**

Specific heat: 2.91 J/g (for the solid); Heat of fusion: 20.3 kJ/mol.
[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present., p. V5 149]**PEER REVIEWED**

Chemical Safety & Handling:

Hazardous Decomposition:

When heated to decomposition it emits acrid smoke and irritating fumes.
[Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 2498]**PEER REVIEWED**

Occupational Exposure Standards:

Manufacturing/Use Information:

Major Uses:

Organic synthesis, lacquers, plastics, production of hydrotropic salts, pharmaceuticals, synthetic flavors and odors, flotation agent, esters for turbojet lubricants, vinyl plasticizer, gasoline additive.
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 12th ed. New York, NY: Van Nostrand Rheinhold Co., 1993, p. 877]**PEER REVIEWED**

CHEM INT FOR NONANOYL CHLORIDE
PEER REVIEWED

CHEM INT FOR SPECIALTY DIESTERS-EG, WITH PROPYLENE GLYCOL
PEER REVIEWED

Manufacturers:

Henkel Corporation, Hq, The Triad, Suite 200, 2200 Renaissance Boulevard, Gulph Mills, PA 19406, (610) 270-8100; The Emery Group, 11501 Northlake Drive, P.O. Box 429557, Cincinnati, OH 45249 (513) 482-3000; Production site: 4900 Este Avenue, Cincinnati, OH 45202.

[SRI. 1996 Directory of Chemical Producers-United States of America. Menlo Park, CA: SRI International, 1996., p. 592]**PEER REVIEWED**

Hoescht Celanese Corp, Hq, Route 202-206 North, P.O. Box 2500, Somerville, NJ 08876, (908) 231-2000; Chemical Group; Commodity Chemicals, 1601 West LBJ Freeway, P.O. Box 819005, Dallas, TX, (214) 277-4000; Production site: P.O. Box 509, Bay City, TX 77414.
[SRI. 1996 Directory of Chemical Producers-United States of America. Menlo Park, CA: SRI International, 1996., p. 592]**PEER REVIEWED**

Methods of Manufacturing:

Prepn from unsaturated hydrocarbons by the oxo process: Hill, U.S. pat 2,815,355 (1957 to Standard Oil of Indiana); from tall oil unsaturated fatty acids: Maggiolo, U.S. pat 2,865,937 (1958 to Welsbach); by oxidation of oleic acid: Mackenzie, Morgan, U.S. pat 2,820,046 (1958 to Celanese); from rice bran oil fatty acid: Mihara et al, U.S. pat 3,060211 (1962 to Toya Koatsu Ind). Purification: Port, Reiser, U.S. pat 2,890,230 (1959 to U.S.D.A.).
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1214]**PEER REVIEWED**

BY OXIDN OF METHYLNONYL KETONE; FROM HEPTYL IODIDE VIA MALONIC ESTER SYNTHESIS.
[Fenaroli's Handbook of Flavor Ingredients. Volume 2. Edited, translated, and revised by T.E. Furia and N. Bellanca. 2nd ed. Cleveland: The Chemical Rubber Co., 1975., p. 433]**PEER REVIEWED**

By oxidation of nonyl alcohol or nonyl aldehyde, the oxidation of oleic acid, especially by ozone.
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 12th ed. New York, NY: Van Nostrand Rheinhold Co., 1993, p. 877]**PEER REVIEWED**

General Manufacturing Information:

NON-ALCOHOLIC BEVERAGES 1.8 PPM; ICE CREAM, ICES, ETC 7.8 PPM; CANDY 6.6 PPM; BAKED GOODS 13 PPM; SHORTENING 10 PPM.
[Fenaroli's Handbook of Flavor Ingredients. Volume 2. Edited, translated, and revised by T.E. Furia and N. Bellanca. 2nd ed. Cleveland: The Chemical Rubber Co., 1975., p. 433]**PEER REVIEWED**

FLAVORS USEFUL IN COCONUT, BERRY.
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Volume 2. Boca Raton, Florida: CRC Press, Inc., 1980., p. 293]**PEER REVIEWED**

PELARGONIC ACID SHOWED STRONG ANTIBACTERIAL ACTIVITY AGAINST STREPTOCOCCUS FAECALIS IN SILKWORM LARVAE.
[IIZUKA T ET AL; J FAC AGRIC, HOKKAIDO UNIV 59 (2): 262 (1979)]**PEER REVIEWED**

PELARGONIC ACID INHIBITED CLEAVAGE OF HEMICENTROTUS PULCHERRIMUS EGGS AT A CONCN OF 200 PPM.
[IWANAMI Y ET AL; CELL STRUCT FUNCT 4 (1): 67 (1979)]**PEER REVIEWED**

PELARGONIC ACID INHIBITED POLLEN GERMINATION (AVG GERMINATION 0-1.1%) AND POLLEN TUBE ELONGATION (AVG TUBE LENGTH 0-0.2 NM) IN CAMELLIA SINENSIS AND MITOTIC DIVISION OF GENERATIVE NUCLEUS IN ORNITHOGALUM VIRENS (AVG MITOSIS 0-40.6%).
[IWANAMI Y, IWADARE T; BOT GAZ (CHICAGO) 140 (1): 1 (1979)]**PEER REVIEWED**

PLAQUE SAMPLES COLLECTED AFTER A NONANOATE-GLUCOSE MOUTH RINSE @ PH 8.0 SHOWED LESS ACID FORMATION AND GLYCOLYSIS. NONANOATE IS EFFECTIVE IN THE PRESENCE OF SUGAR IN INHIBITING GLYCOLYSIS & PREVENTING LOW PH PRODN FROM CARBOHYDRATES WHICH ARE LIKELY TO BE HIGHLY CARIOGENIC.
[HAYES ML; ARCH ORAL BIOL 26 (3): 223 (1981)]**PEER REVIEWED**

FEMA NUMBER 2784
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972., p. 904]**PEER REVIEWED**

COMPOSITIONS CONTAINING PELARGONIC ACID ARE ATTRACTANTS FOR TABAKOSHIBANMUSHI (A PEST INSECT THAT INFESTS STORED FOODS AND TOBACCO).
[TABAKOSHIBANMUSHI ATTRACTANTS; JPN KOKAI TOKKYO KOHO PATENT NO 82 72901 05/07/82 (JAPAN TOBACCO AND SALT PUBLIC CORP)]**PEER REVIEWED**

EXPTL USE: PHARMACEUTICAL PREPN FOR TREATMENT OF ATHLETE'S FOOT CONTAIN NONYLIC ACID 1-20 PARTS. TOPICAL APPLICATION OF THE PREPN TOTALLY CONTROLLED THE INFECTION WITHIN 4 WK.
[ANZAI K; THERAPEUTIC AGENTS FOR ATHLETE'S FOOT; JAPAN KOKAI PATENT NO 77139729 11/21/77]**PEER REVIEWED**

EXPTL USE: BACTERICIDAL AND FUNGICIDAL TOPICAL MEDICATIONS CONTAIN PELARGONIC ACID. THE EFFICACY OF THIS PRODUCT FOR THE TREATMENT OF WOUND INFECTIONS IS DEMONSTRATED.
[TOPICAL MEDICATIONS FOR SKIN DISORDERS; JPN KOKAI TOKKYO KOHO PATENT NO 80162713 12/18/80 (YASUNISHI, KOSAKU)]**PEER REVIEWED**

Formulations/Preparations:

Grade: Technical 99%
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 12th ed. New York, NY: Van Nostrand Rheinhold Co., 1993, p. 877]**PEER REVIEWED**

U. S. Production:

(1980) 9.75X10+9 GRAMS (EST CONSUMPTION)
PEER REVIEWED

(1981) PROBABLY GREATER THAN 6.81X10+6 GRAMS
PEER REVIEWED

Laboratory Methods:

Analytic Laboratory Methods:

SIMULTANEOUS GAS CHROMATOGRAPHIC SEPARATION OF A MIXT OF FATTY ACIDS, PHENOLS AND INDOLES INCL NONANOIC ACID IN CIGARETTE SMOKE IS DESCRIBED.
[HOSHIKA Y; J CHROMATOGR 144 (2): 181 (1977)]**PEER REVIEWED**

Special References:

Special Reports:

OPDYKE DL J; MONOGRAPHS ON FRAGRANCE RAW MATERIALS. PELARGONIC ACID; FOOD COSMET TOXICOL 16 (SUPPL 1): 839 (1978). A REVIEW WITH 44 REF ON PELARGONIC ACID INCL TOXICITY, IRRITATION, SENSITIZATION, METAB, ANTITUMOR ACTIVITY, PHARMACOL, AND EFFECT ON ENZYMES.

Synonyms and Identifiers:

Synonyms:

CIRRASOL 185A
PEER REVIEWED

EMFAC 1202
PEER REVIEWED

N-NONANOIC ACID
PEER REVIEWED

NONOIC ACID
PEER REVIEWED

N-NONOIC ACID
PEER REVIEWED

NONYLIC ACID
PEER REVIEWED

N-NONYLIC ACID
PEER REVIEWED

OCTANE-1-CARBOXYLIC ACID
PEER REVIEWED

PELARGIC ACID
PEER REVIEWED

PELARGONIC ACID
PEER REVIEWED

PELARGON (RUSSIAN)
PEER REVIEWED

Formulations/Preparations:

Grade: Technical 99%
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 12th ed. New York, NY: Van Nostrand Rheinhold Co., 1993, p. 877]**PEER REVIEWED**

Administrative Information:

Hazardous Substances Databank Number: 5554

Last Revision Date: 20030214

Last Review Date: Reviewed by SRP on 9/18/1997

Update History:

Complete Update on 02/14/2003, 1 field added/edited/deleted.
Complete Update on 11/08/2002, 1 field added/edited/deleted.
Complete Update on 08/06/2002, 1 field added/edited/deleted.
Complete Update on 01/14/2002, 1 field added/edited/deleted.
Complete Update on 08/09/2001, 1 field added/edited/deleted.
Complete Update on 05/15/2001, 1 field added/edited/deleted.
Complete Update on 06/12/2000, 1 field added/edited/deleted.
Complete Update on 02/08/2000, 1 field added/edited/deleted.
Complete Update on 02/02/2000, 1 field added/edited/deleted.
Complete Update on 09/21/1999, 1 field added/edited/deleted.
Complete Update on 08/27/1999, 1 field added/edited/deleted.
Complete Update on 06/03/1998, 1 field added/edited/deleted.
Complete Update on 03/10/1998, 1 field added/edited/deleted.
Complete Update on 12/15/1997, 32 fields added/edited/deleted.
Field Update on 11/01/1997, 1 field added/edited/deleted.
Complete Update on 04/23/1997, 6 fields added/edited/deleted.

Complete Update on 03/17/1997, 34 fields added/edited/deleted.
Complete Update on 01/30/1996, 1 field added/edited/deleted.
Complete Update on 01/05/1995, 1 field added/edited/deleted.
Complete Update on 04/04/1994, 1 field added/edited/deleted.
Field update on 01/08/1993, 1 field added/edited/deleted.
Complete Update on 10/10/1990, 1 field added/edited/deleted.
Complete Update on 04/16/1990, 1 field added/edited/deleted.
Field update on 12/29/1989, 1 field added/edited/deleted.
Complete Update on 01/16/1985

EXHIBIT J

NONANOIC ACID MONOGRAPH ON FRAGRANCE RAW MATERIAL

PELARGONIC ACID

Synonyms: Nonanoic acid; octane-1-carboxylic acid.
Structure: $CH_3\cdot[CH_2]_7\cdot COOH$.
Description and physical properties: *Merck Index* (1976).
Occurrence: Reported to be found in several essential oils, including those of rose, geranium, orris, *Litsea cubeba*, *Artemisia arborescens* L., hops, *Chamaecyparis pisifera* Endl., *Eremocitrus glauca* L. and French lavender, and in oak moss (*Fenaroli's Handbook of Flavor Ingredients*, 1975).
Preparation: By oxidation of oleic acid (Arctander, 1969).
Uses: In public use since the 1930s.
Concentration in final product (%):

	Soap	*Detergent*	*Creams, lotions*	*Perfume*
Usual	0·01	0·001	0·005	0·04
Maximum	0·1	0·01	0·01	0·2

Analytical data: Gas chromatogram, RIFM no. 76–223; infra-red curve, RIFM no. 76–223.

Status

Pelargonic acid was given GRAS status by FEMA (1965) and is approved by the FDA for food use (21 CFR 172.515). The Council of Europe (1974) included this acid at a level of 20 ppm in the list of artificial flavouring substances that may be added to foodstuffs without hazard to public health. CAS Registry No. 112–05–0.

Biological data

Acute toxicity. A 10% solution in corn oil caused no deaths when given orally to rats in single doses up to 3·2 g/kg (Fassett, 1963). In a 2% emulsion based on cottonseed oil, emulsifiers and buffer, the iv LD_{50} of nonanoic acid in mice was found to be 244 mg/kg; the animals immediately had convulsions and collapsed on their sides and respiration ceased within 2 min, sometimes after hyperpnoea (Orö & Wretlind, 1961). The acute dermal LD_{50} in rabbits exceeded 5 g/kg (Moreno, 1976).

Subacute toxicity. Pelargonic acid, fed at a dietary level of 4·17% to male Wistar rats depressed growth, an effect that was particularly pronounced in vitamin B_{12}-deficient rats (Dryden & Hartman, 1971). Added to the diet of growing chicks at a level of 5%, the acid was relatively digestible and palatable and was fairly well utilized as an energy source (Yoshida, Morimoto & Oda, 1970).

Irritation. Pelargonic acid has been reported to be a strong skin irritant to the guinea-pig (Fassett, 1963), and applied full strength to intact or abraded rabbit skin for 24 hr under occlusion it was moderately irritating (Moreno, 1976). However, when injected (in 0·01 or 0·1 M concentration) intradermally into the guinea-pig, the rabbit and man, the resulting slight induration and mild erythema could not be differentiated from that associated with the olive-oil control (Stillman, Maibach & Shalita, 1975). Tested at 12% in petrolatum, it produced no irritation after a 48-hr closed-patch test on human subjects (Kligman, 1976). When a 0·5 M solution of pelargonic acid in propanol was applied to human skin under occlusive patches daily for 10 days or until erythema was produced, seven of the ten subjects had developed signs of irritancy after 7 days, with the earliest response occurring on day 2. When the concentration of pelargonic acid was increased to 1 M, responses were seen in all ten subjects by day 8.

Sensitization. A maximization test (Kligman, 1966; Kligman & Epstein, 1975) was carried out on 25 volunteers. The material (RIFM no. 76–223) was tested at a concentration of 12% in petrolatum and produced no sensitization reactions (Kligman, 1976).

Metabolism. In fatty acid studies on the perfused rat liver, 5 mM pelargonic acid increased the amount of β-hydroxybutyrate, acetoacetate, glucose and total ketone bodies formed, and the β-hydroxybutyrate/acetoacetate ratio (Krebs & Hems, 1970).

Anti-tumour assay. After administration of Ehrlich ascites carcinoma cells ip to female ddY mice, pelargonic acid, administered ip once daily for 5 days in a dose of 400 mg/kg/day, exhibited no anti-tumour activity and produced a decrease in body weight but no deaths (Nishikawa, Okabe, Yoshimoto, Kurono & Fukuoka, 1976).

Pharmacology. Pelargonic acid, in a 1% emulsion with cottonseed oil, had no direct action on the guinea-pig small intestine, but inhibited contractions elicited by histamine (Orö & Wretlind, 1961). Isolated frog hearts depressed with 10 μM-monoiodoacetic acid displayed positive inotropic effects following pelargonic acid administration (de Boer, Houtsmuller & Vergroesen, 1973).

Pelargonic acid was one of many saturated fatty acids whose ratio to polyunsaturated fatty acids was shown to be lower in red blood cells from patients with acute and chronic blood dyscrasias than in normal human red blood cells (Introzzi, Notario, Di Marco, Doneda & Meduri, 1965).

Effects on enzymes. Nicotinamide adenine dinucleotide (NAD) nucleosidase from bull semen was found to be competitively inhibited with respect to NAD by pelargonic acid (Yuan & Anderson, 1972). The acid also inhibited L-α-glycerophosphate dehydrogenase from rabbit muscle competitively with respect to NAD and non-competitively with respect to the substrate L-α-glycerophosphate (Kim & Anderson, 1969).

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EXHIBIT K

CONFIDENTIAL BUSINESS STATEMENT

The information on page 12 relating to mechanism of action is regarded as business confidential, as the information disclosed is subject matter to a pending patent application and also to a pending grant application to the Foundation for the National Institutes of Health. Pages 45 through 53 of Exhibit E and pages 56 through 94 of Exhibit F are regarded as business confidential, as the information has not been published or the information has not yet been submitted to EPA for registration purposes or has proprietary data on formulation composition.

EXHIBIT L

1103 Norbee Drive, Wilmington, De 19803 www.falconlabllc.com 302-764-0392

To: **Members of the National Organic Standards Board (NOSB)**

From: Robert A. Smiley, Ph. D., C. Edward Beste, Ph. D. and Joan M. Smiley, MBA
Falcon Lab LLC
December 3, 2008

Does the charter of the NOSB regarding the approval of organic materials include economic considerations? We are curious because the impression that we got (and apparently many others that we spoke to) from the Nov. 17 and 18, 2008 NOSB meeting was that you seem to have little or no concern **for economic matters** for organic farmers or organic food consumers.

As the registrant of a BPPD-EPA approved organic herbicide, RACER® (ammonium nonanoate), we wonder why the NOSB fails to consider grower requirements for economically viable production inputs that can be obtained from a reliable and sustainable source. To be profitable, growers must have resources that are not at risk from supply shortages and turbulent international markets.

The recent NOSB meeting conveyed a lack of concern for growers, and instead, over concern for certification requirements and regulations. If "organic agriculture" depends on "trust" as stated by many speakers, the NOSB members showed little "trust" in their deliberations.

Recent substantial earnings decline at the food chain Whole Foods have been attributed to less demand for organic food. This is probably due to both higher costs and lower supplies. This caused Whole Foods to postpone building new stores and may predict future conditions regarding the organic market.

It was obvious that none of the recommended petition rejections at the NOSB meeting addressed the economic aspects of your decisions in the various committee deliberations leading to petition rejections. Here's why our curiosity is also a concern:

> Over the last year, we have received many phone calls and emails from organic farmers from all over the country asking about the status of the soap, ammonium nonanoate, as an organic herbicide. These farmers included orchard owners, vineyard owners, vegetable growers and even hay growers. These were dedicated organic farmers. The lack of adequate weed control methods lowers both yield and quality of their produce, according to their comments. One stated that he was considering giving up organic farming because of that cost alone.
>
> Since we don't currently sell or advertise our ammonium nonanoate product (RACER®), inquiries are most often from word of mouth, presumably from grower observations or discussions at University experiment stations or grower meetings. RACER® herbicide has been tested at many Universities including the following:

Univ. of Delaware, Oklahoma State, Cornell, Penn State, Univ. of Mass. and UC Davis and two USDA sites. USDA's IR-4 has awarded three grants to colleges for the testing of ammonium nonanoate as an herbicide.

During the Crops session, the Committee chairman publicly stated that one of the reasons for rejecting our petition to add synthetically produced ammonium nonanoate as a soap herbicide to the NOP list (even though ammonium nonanoate is widespread in nature) was that lemongrass oil (a natural essential oil herbicide) would take care of the weed problems. Somehow, according to him, this will encourage more research on such types of herbicides. This is a curious conclusion. What was not stated, but is known in the industry, is that lemongrass oil sells for at least $300/gal. in bulk and requires many tens of gallons per acre of dilute spray to be effective. It is also not new. The bioherbicidal use of lemongrass oil was first publicly suggested in 1999. One does not need to be overly skilled at basic math to realize that it is cost prohibitive and does not adequately address the weed problems of organic farmers or it would be widely used now. Other natural herbicides, such as clove oil or eucalyptus oil, are also expensive and not as effective (these require even more per acre). And, if organic farmers suddenly increased the use of essential oil-based or other natural source herbicides, the world supply would be quickly exhausted. According to the law, this is a required consideration by the NOSB but apparently was ignored in November.

<u>Synthetic</u> acetic acid is <u>openly</u> used in organic farming as an herbicide at strengths greater than allowed by OMRI (to be effective) on the pretext that it is vinegar, a fact apparently ignored by at least some certifiers. On the other hand, ammonium nonanoate, is more effective than acetic acid and can be made and sold at competitive prices to herbicides used by conventional farmers (a huge win for organic farmers).

At the risk of being offensive, it appears that the denial of choices for organic growers by the NOSB borders on illegal Restraint of Trade. Legal recourse might be sought by overly frustrated farmers should your practices continue, i.e. woefully inadequate consideration of economic matters to the farmer and consumer. A copy of this letter is being sent to the Administrator of the AMS and the Secretary of Agriculture to make them aware of this possibility.

As discussed at the meeting, organic certification is based on faith and trust; therefore, growers can express their commitment to the ideals of "Organic Ag" by using essential oil based herbicides instead of "synthetic equals" of natural products when the conditions imposed by the NOP are encountered (§205.601). Obviously, Falcon Lab is at a disadvantage in offering a soap-based synthetic product to growers and does not expect faithful growers to divert from the accepted practices of organic production. However, we know that Congressional Law allows "synthetic equals" to be provided for organic production. We believe that Congress gave the NOSB an obligation to provide growers with the tools for organic food production. Shortages of "natural substances" in the world economy can occur and alternatives are essential to maintain the economic viability of organic growers.

RACER® ammonium nonanoate herbicide will be on the market in 2009 and Falcon Lab is requesting the NOSB of the NOP, USDA to reconsider our petition for organic use before the 2009 crop season.