overall U.S. population, using mean field trial values, processing factors and projected peak percent crop treated values. The percent of the acute population adjusted dose (aPAD) (7.3%) for the overall U.S. population shows that an adequate margin of safety exists. Using only PHED data levels A and B (those with a high level of confidence), MOEs for occupational exposure are 650 for mixer/loaders and 1,351 for air blast applicators (worst-case). Based on the completeness and reliability of the toxicity data and the conservative exposure assessments, there is a reasonable certainty that no harm will result from the aggregate exposure of residues of indoxacarb including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children*. Chronic dietary exposure of the most highly exposed subgroup in the population, children age 1–6 years old, is 0.000238 mg/kg/day or 1.2% of the RfD. For infants (non-nursing, 1 year old), the exposure accounts for 0.3% of the RfD. For acute exposure at the 99.9th percentile (based on a Tier 3 assessment) the exposure was 0.013973 mg/kg/day (11.6% aPAD) for children 1–6 years old and 0.026036 mg/kg/day (21.7% aPAD) for non-nursing infants. There are residential uses of indoxacarb pending, but exposure is calculated to be extremely minimal. The estimated levels of indoxacarb in drinking water are well below the below the DWLOC. Based on the completeness and reliability of the toxicity data, the lack of toxicological endpoints of special concern, the lack of any indication that children are more sensitive than adults to indoxacarb, and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure of residues of indoxacarb, including all anticipated dietary exposure and all other non-occupational exposures. Accordingly, there is no need to apply an additional safety factor for infants and children.

F. International Tolerances

To date, no international tolerances exist for indoxacarb.

[FR Doc. E4–550 Filed 3–16–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0011; FRL–7343–5]

Ammonium Nonanoate; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of the pesticide chemical ammonium nonanoate in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2004–0011, must be received on or before April 16, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8380; e-mail address: *gandhi.bipin@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0011. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket.

Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0011. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0011. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0011.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2004–0011. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number

assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 4, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Falcon Lab LCC

PP 3E6789

EPA has received a pesticide petition (PP 3E6789) from Falcon Lab LLC, 1103 Norbee Drive, Wilmington, DE 19803 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for ammonium nonanoate in or on all raw agricultural commodity. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. In solution, ammonium nonanoate (CAS No. 112–05–0) is ionized and occurs as the straight chain C-9 nonanoic acid and the ammonium ion. Nonanoic acid is metabolized by beta-oxidation and by respiration through the citric acid cycle, converted to carbon dioxide and water. Suryanarayanan and McConnell (Ref. 1) showed the tracer in nonanoic acid-1-C14 was 98% assimilated into metabolites by beta-oxidation to acetyl CoA and utilized via the glyoxylate cycle in wheat stem rust uredospores.

2. *Analytical method*. In the **Federal Register** of February 19, 2003 (68 FR 7931) (FRL–7278–7), it is indicated that the analytical method for nonanoic acid is being made available to anyone interested in pesticide enforcement when requested, from Norm Cook, Antimicrobials Division (7510C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. Office location and telephone number: 1921 Jefferson Davis Highway, 3rd Floor, Arlington, VA 22202, (703) 308–8253.

3. *Magnitude of residues*. Nonanoic acid is a naturally occurring component of fatty acids in plants (68 FR 7931). Lowfat chedder cheese contained small amounts of nonanoic acid (Ref. 2). Nonanoic acid is naturally present at levels up to 224 parts per billion (ppb) in apples, 385 parts per million (ppm) in the skin of grapes, and 143 ppm in grape pulp. It is present in a number of other foods as well. An average serving of grapes containing 385 ppm of nonanoic acid in the grape skins would result in exposure to nonanoic acid to an average consumer of 164 µg/kg/day (68 FR 7931).

Nonanoic acid may be safely used as synthetic food flavoring substances and adjuvants in food in the minimum quantity required to reproduce the intended effect (21 CFR 172.515). Nonanoic acid may be used in an aliphatic acid mixture for washing or to assist in the peeling of fruits and vegetables. The aliphatic acid mixture may be used at a level not to exceed 1% in the lye peeling solution (21 CFR 173.315), (68 FR 7931).

B. Toxicological Profile

1. *Acute toxicity*. Undiluted nonanoic acid administered orally to rats at a dose of 3,200 milligrams/kilogram (mg/kg) did not cause death which indicated a lethal dose LD_{50} 3,200 mg/kg; however, deaths did occur at this dose level when the chemical was administered intraperitoneally (IP) for an IP LDL0 = 3,200 mg/kg. More recently, nonanoic acid of unspecified source administered orally to rats and mice had an LD_{50} 5,000 mg/kg for both rat and mouse. For male rats, the oral LD_{50} >9,000 mg/kg.

Nonanoic acid, as undiluted material, administered to mice by the intravenous route (IV) had an IV LD_{50} = 224 mg/kg. A 10% solution of nonanoic acid in corn oil failed to kill mice at a dose of 3,200 mg/kg when given orally (mouse oral LDL_{50} 3,200 mg/kg), but caused death at a dose of 1,600 mg/kg by the intraperitoneal route (mouse IP LDL0 = 1,600 mg/kg). Symptoms in mice included labored respiration and roughing of the coat and death was observed as soon as 4 days after treatment.

The dermal LD_{50} for undiluted nonanoic acid in rabbits has been reported to be LD_{50} 5,000 mg/kg. Nonanoic acid from an unspecified source caused a dermal LD_{50} 2,000 mg/kg on rats.

Application of nonanoic acid to intact and abraded skin of rabbits had an LD_{50} 9,000 mg/kg, and caused moderate to severe irritation.

These data indicate nonanoic acid has low acute toxicity by intraperitoneal, oral or dermal routes. Intravenous exposure to ammonium nonanoate (nonanoic acid) is irrelevant to its use as an inert ingredient pesticide products. Intraperitoneal nonanoic acid may occur via skin wounds, but the relatively low acute toxicity would be of low risk. Oral and dermal exposure to nonanoic acid are of very low risk.

Nonanoic acid was delivered at 0.46 mg/liter (mg/L) as an aerosol for 4 hours (h) to 10 rats without any mortality; however, at 3.8 mg/L, 80% mortality occurred. Relatively low degree of toxicity occurred following inhalation of the aerosol. Respiratory irritation was observed at both dose levels.

Acute toxicity to other environmental species has been determined for a fatty acid similar to nonanoic acid. Fatty acid sodium salts were found to be less toxic than the parent acids, and toxicities of both increased with chain length (between 6 and 12 carbons). For capric acid (decanoic acid) C-10 in fresh water, the 48 hr lethal concentration $(LC)_{50}$ for red killifish (*Oryzias latipes*) and

gammarus (*Hyale plumulosa*) were 20 and 41 mg/L, respectively. Sodium caprate was less toxic than the acid to killifish (54 mg/L). Based on these data, nonanoic acid in the ammonium salt form (ammonium nonanoate) would be expected to be no more than slightly toxic to aquatic fauna.

Toxicity to algae may be estimated by comparison with data for soaps in general. For example, an LC_{50} range of 180–320 mg/L has been reported for *Chlorella vulgaris*. Therefore, nonanoic acid as the potassium or sodium salt would not be expected to be significantly toxic to algae at these low concentrations of approximately 0.032% w/w (320 ppm).

Toxicity to fish, fathead minnow (*Pimephales promelas*), for 96 hr exposure was reported to be LC_{50} = 104 ppm.

Fatty acids are toxic to aquatic invertebrates, but only slightly toxic to cold and warm water fish species (RED: Soap Salts; EPA–738–R–92–015). However, fatty acids are rapidly destroyed by microbial action and sorption or formation of insoluble salts of calcium or magnesium in soil and water. The proposed uses for nonanoic acid (ammonium nonanoate) as an inert would not be applied near water or on drainage ditches or onto marsh, ponds, lakes, streams or rivers.

Nonanoic acids are relatively non-toxic to waterfowl and upland game birds (RED: Soap Salts; EPA–738–R–92–015).

As a result of a number of acute toxicity studies, technical nonanoic acid is placed in the following Toxicity Categories: Primary eye irritation (Toxicity Category II); acute dermal and inhalation toxicity (Toxicity Category III); acute oral toxicity (Toxicity Category IV). Sensitization test results showed that nonanoic acid cannot be considered a dermal sensitizer (68 FR 7931).

2. *Genotoxicity*. It was reported that the Ames Test (Salmonella/reverse mutation assay) showed nonanoic acid to be non-mutgenic. Similarly, an *in vivo* cytogenetics study using micronucleus assay gave a negative result. In a mouse lymphoma forward mutation study, nonanoic acid appears to induce a weak mutagenic response at or higher than 50 milligrams/milliliter (mg/mL) level. This was observed in the presence of increasing toxicity, and may be an indication of gross chromosomal changes or damage and not actual mutational changes within the thymidine kinese gene locus (68 FR 7931).

A dermal carcinogenicity study was performed on the shaved skin area of 50 mice and treated twice-weekly with 50 mg doses of undiluted nonanoic acid for 80 weeks. No evidence of severe dermal irritation or systemic toxicity was seen. Histopathology revealed no tumors of the skin or the internal organs (68 FR 7931).

3. *Reproductive and developmental toxicity*. Development toxicity was conducted on a group of 22 pregnant Crl: COBS CD(SD)BR rats. These rats were treated with nonanoic acid in corn oil at a dose of 1,500 mg/kg on gestation days 6 through 15 (both days inclusive). Maternal body weight was not significantly affected during the treatment. Only 1 out of 22 animals showed signs of clinical toxicity. No significant histopathology signs were observed in the maternal animals. Nonanoic acid treatment did not have any significant effect on cesarean section observations. Four fetuses in one litter showed a higher incidence of cleft palate compared to the control mean. For maternal toxicity, EPA determined the no observed adverse effect level (NOAEL) to be greater than 1,500 mg/kg/day. Because fetal effects were observed at 1,500 mg/kg/day, the NOAEL for developmental toxicity was not determined. EPA has determined that this dose is in excess of the Agency's limit dose for toxic effects. The type and level of exposure expected from the active ingredient use of this chemical is much lower than the dose level shown in the study (68 FR 7931).

Nonanoic acid was weakly positive for inducing mutations in mouse lymphoma cells. Mutations were induced with nonanoic acid at greater than or equal to 50 µg/mL. Since the mutations were observed with severe cytotoxicity and small colony development, the observed mutations may have been an aberration caused by cell damage and not actual mutational changes (61 FR 5716) (February 14, 1996) (FRL–5348–9).

Nonanoic acid as single oral doses of 1,250, 2,500 and 5,000 mg/kg to ICR mice followed by bone marrow harvest at 24, 48 and 72 hr after treatment, did not significantly increase micronucleated polychromatic erythrocytes which indicated a negative micronucleus assay test (61 FR 5716).

4. *Subchronic toxicity*.In an oral toxicity study (conducted for 14 days), no systemic toxicity was observed with either sex (animal species unspecified) even at the highest nonanoic acid dose tested, 20,000 ppm (1,834 mg/kg/day). In addition, nonanoic acid showed no adverse effects on survival, clinical signs, body weight gain, food consumption, hematology, clinical chemistry or gross pathology. For each dose, three animals per sex were tested. However, the study did not report organ weights and histopathology. This was considered a deficiency in this study. Nevertheless, the Agency determined that because no toxic effects were observed at a very high level dose approaching 2,000 mg/kg, a 90–day oral study was not necessary (68 FR 7931).

Nonanoic acid at 80, 40, 20 and 10% applied as a 15 micro-liter aliquot to patches placed on the lower back of 152 women for 47 hr and evaluated at 48 and 96 hr indicated erythema (redness) decreased with time for all concentrations, but the higher concentrations increased surface changes with time (Ref. 3). Reiche *et al.* suggested nonanoic acid was an irritant rather than an allergen regardless of the increase in skin reaction over patch test exposure time. The skin reaction to 10% nonanoic acid for 47 hr was considered to be mild by the National Institute of Occupational Safety and Health (NIOSH).

Solutions of nonanoic acid at 0.5 M or 1.0 M in propanol (approximately 10 to 20% w/w) caused skin irritation when applied under occlusive patches in 25 human volunteers. A 20% nonanoic acid solution in propanol and applied as a patch test produced skin reactions in 94% of 116 healthy male volunteers. The lesions consisted of mainly erythema (redness) at 48 hr and pigmentation at 96 hr (Ref. 4).

Forty two nonatopic healthy male subjects of 18 to 47 years of age had 3 to 10 patch tests on the volar area of the forearm applied with 8 mm Finn Chambers which were assessed by two independent readers at 48 hr post application. A six point grading scale from no visible reaction to intense erythema with bulbous formation indicated chemical concentrations which produced patch test reactions of less than or equal to 2+ in at least 75% of the subjects as follows: 0.5% Benzalkonium-chloride, 5% sodium lauryl sulfate, 0.8% croton-oil, 0.02 dithranol, 80% nonanoic acid (propanol solution), 100% propylene glycol and 2% sodium hydroxide (Ref. 5).

One hundred hospitalized patients with different types of skin disease were patch tested with nonanoic acid with a 48 hr contact period followed by evaluation at 1 and 72 hr after patch removal. The nonanoic acid concentration to produce a discernible irritation reaction in 50% of the population (ID50) was calculated by conventional probit analysis. The calculated ID50 for males and females was 5.3 and 6.4%, respectively, nonanoic acid concentration. Three of 100 patients reacted to 1% nonanoic

acid and all reacted to 20 to 39.3% nonanoic acid (Ref. 6). NIOSH reported an 80 and 20% nonanoic acid solution with 48 and 24 hr human skin contact, respectively, caused moderate skin irritation.

Sensitization reactions were not observed in 25 human volunteers after patch testing with 12% nonanoic acid solution in petroleum ether.

Nonanoic acid is a non-sensitizing irritant which means it does not cause allergic reactions in most humans. Nonanoic acid is lipophilic and non-sensitizing.

Nonanoic acid at a dose of 500 mg/kg in contact with rabbit skin for 24 hr was a moderate irritant. Nonanoic acid in an undiluted form produced severe skin irritation in guinea pigs when applied to the skin.

A 28–day dermal toxicity study conducted on rabbits was submitted to EPA under TSCA section 8(e). Five male and five female New Zealand white rabbits were dermally treated with nonanoic acid present in mineral oil. In all, 10 applications were made (5 per week) at a dose level of 500 mg/kg/day (25% w/w). A 2–week recovery period was allowed for selected rabbits. During the first and second week of treatment slight body weight loss and decreased food consumption were observed. One female rabbit showed ocular discharge and hypoactivity during the second week of treatment. All rabbits dermally treated with nonanoic acid by day 14 showed signs of severe erythema and moderate edema. Dermal reactions consisting of moderate desquamation, moderate fissuring, eschar, exfoliation and necrosis were also observed at day 14. By day 29, all dermal reactions had reversed. It was evident that at the treatment level of 500 mg/kg/day of nonanoic acid, significant dermal signs of toxicity were observed but no significant systemic reaction (68 FR 7931). There is additional information on the previous study with 10 New Zealand rabbits which showed that mortality did not occur and microscopic effects on kidneys, liver, lungs, heart and brains were not observed. Slight to severe skin irritation occurred in the first week and progressed to necrosis in the second week. Skin irritation on four rabbits subsided during 2 weeks of recovery after treatments ended. NIOSH characterized the effect on rabbit skin, in the previous study, as moderate.

Severe irritation was produced by the application of 91 mg of nonanoic acid to the rabbit eye. This same study was reported for nonanoic acid as severely irritating to rabbit eyes and aerosols are also an eye irritant. NIOSH reported two eye irritation studies which showed 91 mg of nonanoic acid caused severe rabbit eye injury as reported above and published in 1964, but another study, published in 1999, with a 100 uL (0.1 mL = approx one drop) dose or droplet to the rabbit eye caused only mild injury. Since the source of nonanoic acid is unknown in the 1999 study, it is impossible to compare the actual dose; however, since nonanoic acid has a density less than water, the doses used in these studies would appear similar. Therefore, these results would appear inconclusive for eye irritation or indicate a rather large range of experimental error.

Rats exposed to atmospheric concentrations of 840 mg/cubic-meter (125 ppm) nonanoic acid for a period of 6 hr showed no symptoms of toxicity. However, in another study, test animals (species not specified) subjected to an atmospheric concentration of 3.75 mg/L (1,150 ppm) nonanoic acid for a period of 6 hr developed clinical signs of nasal discharge, blinking, and labored breathing. Inhalation exposure indicated nonanoic acid was a respiratory irritant.

5. *Chronic toxicity*. Oral exposure of 8 male rats to nonanoic acid at 4.17% in the diet (approximately 2,100 g/kg/day) for 4 weeks had no effect on survival. A slight 4% decrease in mean growth was observed, but not statistically significant.

A study on chronic toxicity/carcinogenicity in mice was conducted for 80 weeks. A dose of 50 mg of nonanoic acid was dermally applied to each shaved mouse twice/day for 80 weeks. Histopathology showed no non-neoplastic or neoplastic lesions on skins and internal organs of mice. The Agency concluded that this study although not exactly conducted according to guideline, adequately assesses the chronic toxicity and the carcinogenic potential of nonanoic acid via the dermal route (68 FR 7931).

6. *Animal metabolism*. Mammals, birds and invertebrates consume fatty acids as a normal constituent of their daily diet (RED: Soap Salts; EPA–738–R–92–015) and would metabolize nonanoic acid via normal respiration, the same as plants.

7. *Metabolite toxicology*. Nonanoic acid, as a straight chain carbon molecule, would be metabolized by beta-oxidation to form acetate molecules which enter the citric acid cycle and are metabolized to carbon dioxide, water and energy. None of the metabolites would be considered to have any toxicological risk.

8. *Endocrine disruption*. Straight chain carbon molecules, as in the C9 carbon chain of nonanoic acid would be unlikely to cause a risk of endocrine disruption. Nonanoic acid occurs naturally in plants and animals.

C. Aggregate Exposure

1. *Dietary exposure*. The Food and Drug Administration has cleared nonanoic acid as a synthetic food flavoring agent (21 CFR 172.515), as an adjuvant, production aid and sanitizer to be used in contact with food (21 CFR 178.1010(b)) and in washing or to assist in lye peeling of fruits and vegetables (up to 1%) (21 CFR 173.315). Nonanoic acid is also exempt from the requirement of a tolerance when used in or on all food commodities, as a plant regulator on plants, seeds, or cuttings after harvest in accordance with Good Agricultural Practices (GAP). It is also exempt from a tolerance when used as a herbicide on all plant food commodity provided that allocations are not made directly to the food commodity except when used as a harvest aid or desiccant to any root or tuber vegetable, bulb, or cotton (40 CFR 180.1159), (68 FR 7931). Applications of ammonium nonanoate (dissociated into nonanoic acid), as an inert ingredient additive, would potentially contact all plant parts of food crops.

A calculation of the dietary exposure is complicated by the exemption from tolerance for nonanoic acid and particularly for the 21 CFR 172.515 rule which allows direct addition of nonanoic acid into food at the minimum quantity required to produce the desired effect. However, in the aggregate, the daily consumption of nonanoic acid is probably less than 1 mg/kg/day. The worst case scenarios presented indicate nonanoic acid exposure as tens of µg/kg/day. Based on cited public data in this document, the no effect level for mice and rats for ingested nonanoic acid is 3,000 mg/kg/day and the estimated maximum human dietary exposure is 0.030 mg/kg/day; therefore, a 10,000 fold safety factor or greater is estimated for nonanoic acid in food. However, since nonanoic acid is rapidly metabolized in the human digestive system, the estimated safety factor is a temporal and minimal estimate. The petitioner believes that the surfactant properties of ammonium nonanoate (nonanoic acid) should enhance the efficacy of pesticides with a concomitant reduction of pesticide rates and reduce dietary exposure to pesticides.

i. *Food*. For nonanoic acid as a sanitizer use, a worst case dietary exposure estimate has been calculated, assuming that all food consumed by an adult or child has contacted a sanitized surface using pelargonic acid (nonanoic acid), that a 1 mg square centimeter (sq

cm) sanitizer residue remains on the surface, and that 100% of the residue (170 ppm) is transferred to the food from the surface. Using these assumptions, in which all food contacts 4,000 sq cm of sanitized non-porous food-contact surfaces a worst case dietary exposure of 680 µg/day is calculated. For a 70 kg adult this becomes 9.7 µg/kg/day and for a 15 kg child, exposure is calculated as 45 µg/kg/day (68 FR 7931).

For a typical use as an inert ingredient, nonanoic acid as ammonium nonanoate at a concentration of 0.5% w/w in the dilute spray solution applied in 20 gal/acre spray volume would apply approximately 8.7 mg/sq ft of ammonium nonanoate of which 7.8 mg is nonanoic acid. If we assume 8 cucumbers of 4.0 lb total weight completely covered the 1 sq ft area, the consumption of one-half of one cucumber (0.25 lb raw cucumber) would result in an exposure to 0.5 mg nonanoic acid. Therefore, the calculated exposure to a typical 70 kg adult would be 7 µg/kg/day; and for a child of 15 kg, the exposure would be 33 µg/kg/day nonanoic acid. The calculated human exposure would be the same for one cucumber or more per sq ft because the application is uniformly applied to the soil surface area or crop laying on the soil surface. The actual exposure in the cucumber example should be less than calculated because the consumption was assumed to occur on the day of application without cucumber washing or preparation and without consideration of normal interception of some of the spray application by plant foliage.

Some pesticide applications are directed sprays which would reduce potential contact with the edible plant parts. Translocation of nonanoic acid is unlikely to occur since its mode of action is a physical reaction with cell membranes as a lipophilic chemical. The petitioner believes that ammonium nonanoate would be a more acceptable adjuvant alternative to many surfactants in use today.

ii. *Drinking water*. Nonanoic acid, as an inert ingredient in pesticide formulations should not be applied near or on potable water. The rapid dissipation of nonanoic acid in soil, with an estimated soil half-life of 1–day for fatty acids, should mitigate any potential for water contamination by run-off from treated fields. Drainage ditches and lakes, ponds, streams and rivers will be prohibited from nonanoic acid application. KX-6116 as a sanitizer contained nonanoic acid as its active component and low concentrations of nonanoic acid could be expected to be introduced into drinking water. However, EPA concluded exposure through drinking water was expected to be low and not of significance (68 FR 7931). The petitioner believes that ammonium nonanoate (nonanoic acid) as an inert ingredient is not expected to be applied near drinking water sources. Rapid metabolism of nonanoic acid in 1 to 9 days in soil should prevent potential contamination of surface water or ground water (68 FR 7931). The soil half-life of fatty acids was estimated to be less than 1–day (RED: Soap Salts; EPA–738–R–92–015).

The nonanoic acid log octanol/water partition coefficient is 3.42 which indicated the hydrophobic molecule, nonanoic acid, would have a very strong affinity to the organic matter in soil and would not leach into ground water. Microbial degradation in soil, which proceeds at a half-life rate of 1–day for fatty acids, would probably rapidly eliminate the strongly adsorbed nonanoic acid from soil. These factors would probably assure nonanoic acid would not occur in ground water. The salts of nonanoic acid would dissociate into the ionic forms of nonanoic acid and the free salt in soil and although ammonium nonanoate is water soluble, it would be bound to soil organic matter in the dissociated form. Soils contain abundant magnesium and calcium ions which would form insoluble salts of nonanoic acid and contribute to protection of ground water.

2. *Non-dietary exposure*. Applicator exposure to nonanoic acid as an inert ingredient is not expected to exceed the currently approved uses. The use of ammonium nonanoate (nonanoic acid) with herbicides should increase the rate of plant tissue necrosis and should reduce the potential risk to adults or children who contact sprayed plant parts, because the rapidly desiccated plant cells should retain nonanoic acid, as an inert ingredient, and the herbicide active ingredient bound to collapsed cell tissues. Off-target movement of the inert ingredient additive, nonanoic acid, as ammonium nonanoate, should not be expected to exceed the potential off-target movement of the pesticide active ingredient.

Fatty acids and their salts are a potential risk for eye injury; therefore, eye protection would be recommended when handling ammonium nonanoate. The solid form of 100% ammonium nonanoate crystals could have a reduced risk to eyes compared to the 40% liquid concentrate because accidental facial exposure by splashing would be eliminated. Also 100% crystalline ammonium nonanoate would have less eye exposure risk compared to other typical liquid surfactants.

Nonanoic acid is slightly volatile and is a component of the odor of milk, cheese, fats and soap. However, the estimated half-life in the atmosphere for nonanoic acid is 1.6 days. Therefore, inhalation exposure would be minimal for most occupations. Workers in the aforementioned industries of cheese and soap, etc. have not been seriously afflicted by long-term exposure to environments with nonanoic acid in the work environment.

D. Cumulative Effects

EPA concluded that pelargonic acid (nonanoic acid) is sufficiently non-toxic that EPA can determine that it does not share a common mechanism of toxicity with other substances (68 FR 7931). The rapid dissipation of nonanoic acid in the environment, i.e. soil half-life of 1–day and atmospheric half-life of 1.6 days, and normal metabolism of nonanoic acid by humans would probably prevent an accumulation of residual levels in the environment to trigger any cumulative effects. The mechanism of action of nonanoic acid and some other fatty acids on plants is a physical effect on plant cell walls which affects cell wall integrity and would be less likely to have a cumulative effect as compared to compounds with a mode of action that affects metabolic or regulatory functions in organisms.

E. Safety Determination

1. *U.S. population*. Ammonium nonanoate forms nonanoic acid in solution and nonanoic acid occurs naturally in laundry and hygienic soaps as sodium or potassium nonanoate. Therefore, the toxicological properties of the ionized form, nonanoic acid are reviewed for the toxicological profile. Nonanoic acid is used as a antimicrobial agent or sanitizer for food contact surfaces. It is also used in lithographic plate developer solutions. The three uses described above involve disposal via public sewer systems, which indicates the low risk concern associated with nonanoic acid in the environment. Nonanoic acid is also used as a herbicide with directed and shielded applications on all food crops and is exempt from tolerance. However, the directed and shielded application would be expected to prevent contact with the edible plant parts. Nonanoic acid is exempt from a tolerance when applied to root or tuber vegetable, bulb or cotton as a desiccant or harvest aid.

The proposed use, in this notice of filing for ammonium nonanoate (nonanoic acid) as an inert ingredient,

would be for applications to agricultural commodities at rates less than those used as an herbicide or crop desiccant.

Based on the following five considerations, EPA concluded that nonanoic acid is unlikely to pose a risk under all reasonable exposure scenarios:

i. Fatty acids such as nonanoic acid are processed by known metabolic pathways within the body and contribute to normal physiological function.

ii. Nonanoic acid is naturally present at levels up to 224 ppb in apples, 385 ppm in the skin of grapes, and 143 ppm in grape pulp. It is present in a number of other foods as well. An average serving of grapes containing 385 ppm of nonanoic acid in the grape skins would result in exposure to nonanoic acid to an average consumer of 164 µg/kg/day. In comparison, a worst case estimate of dietary exposure to nonanoic acid as a result of its use as sanitizer is 9.7 µg/kg/day for a 70 kg adult and 45 µg/kg/day for a 15 kg child.

iii. The Food and Drug Administration has cleared nonanoic acid as a synthetic food flavoring agent and adjuvant (21 CFR 172.515), as an adjuvant, production aid and sanitizer to be used in contact with food (21 CFR 178.1010(b)) and in washing or to assist in lye peeling of fruits and vegetables (up to 1% nonanoic acid) (21 CFR 173.315). Nonanoic acid is also exempt from the requirement of a tolerance when used in or on all food commodities, as a plant regulator on plants, seeds, or cuttings after harvest in accordance with GAP. It is also exempt from a tolerance when used as a herbicide on all plant food commodities provided that allocations are not made directly to the food commodity except when used as a harvest aid or desiccant to any root or tuber vegetable, bulb, or cotton (40 CFR 180.1159).

iv. Dietary toxicity testing evidenced adverse reactions only at doses that were at or above limit doses. Dermal toxicity testing showed no significant systemic reaction.

v. The estimated exposures to nonanoic acid and other fatty acids from direct or indirect addition to food as well as sanitizer uses are well below the doses administered in animal studies that are required to elicit an adverse effect. Accordingly, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to nonanoic acid (68 FR 7931).

Nonanoic acid has an estimated 1–day half-life in soil (RED: Soap Salts; EPA–738–R–92–015) and the estimated half-life in the atmosphere is about 1.6 days. Volatilization half-life of nonanoic acid from a river was estimated to be 29 days from a model river and 210 days from a model lake. Nonanoic acid is also inactivated in water by the formation of calcium and magnesium salts which are insoluble precipitates and non-reactive. In summary, nonanoic acid is highly unlikely to accumulate in the environment due to rapid metabolism in soils and neutralization as insoluble salts.

2. *Infants and children.* As previously discussed the dietary safety factor for nonanoic acid is approximately 10,000 fold; therefore, risk to children and infants, with primary exposure thru ingestion, would be of minimal concern.

Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. Based on the numerous considerations, EPA concluded that pelargonic acid was sufficiently non-toxic that a margin of safety analysis was not appropriate. For the same reasons, EPA has not applied an additional margin of safety for the protection of infants and children (68 FR 7931).

F. International Tolerances

Codex maximum residue levels have not been established for nonanoic acid (68 FR 7931).

G. References

1. Suryanarayanan, S. and W. B. McConnell. 1964. The metabolism of pelargonate-1-C14 by wheat stem rust uredospores. Report: NRC8214. National Research Council of Canada, Saskatoon (Saskatchewan) Prairie Regional Lab., May 8, 1964 (Abstract).

2. Haque, Z. U. and K. J. Aryana. 2002. Volatiles in lowfat chedder cheese containing commercial fat replacers. Food Sci. Tech. Res. 8(2): 188–190 (Abstract).

3. Reiche, L., C. Willis, J. Wilkison, S. Shaw and O. de Lacharriere. 1998. Clinical morphology of sodium lauryl sulfate and nonanoic acid irritant patch test reactions at 48h and 96h in 152 subjects. Contact Dermatitis 39(5): 240–243 (Abstract).

4. Wahlberg, J. E. and H. I. Maibach. 1980. Nonanoic acid irritation - A positive control at routing patch testing? Contact Dermatitis 6(2): 128–130 (Abstract).

5. Willlis, C. M., C. J. M. Stephens and J. D. Wilkinson. 1988. Experimentally-induced irritant contact dermatitis. Determination of optimum irritant concentrations. Contact Dermatitis 18(1): 20–24 (Abstract).

6. Wahlberg, J. E., K. Wrangsjo and A. Hietasalo. 1985. Skin irritancy from nonanoic acid. Contact Dermatitis 13(4): 266–269 (Abstract).

[FR Doc. E4–553 Filed 3–16–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0044; FRL–7347–1]

Buprofezin; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2004–0044, must be received on or before April 16, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)