intragastric intubation at dosage levels of 10, 100, or 1,000 mg/kg/day. Treatment was carried out once daily for 28 consecutive days. Similarly, control animals received corn oil (5 mL/kg/day). At 1,000 mg/kg/day specific changes in general health, body weight gains, food consumption, biochemical parameters, organ weights, macroscopic and microscopic pathology were recorded. Statistically significant observations noted at the high dose level of 1,000 mg/kg/day included: Lower food consumption and bodyweight gains in males; higher glutamic-pyruvic transaminase levels in males and females; higher blood urea nitrogen levels in females; and higher adjusted liver weights in females, and minimal centrilobular hepatocyte enlargement in males and females.

17. *90–Day oral toxicity in dogs*. In a 90–day oral toxicity study in dogs, a dose level of 30 mg/kg/day was determined to be the NOAEL. *N*-(n-octyl)-2-pyrrolidone was administered orally via capsule at dosage levels of 30, 90, and 240 mg/kg/day. All animals were observed daily for clinical signs of toxicity. After treatment, all surviving animals were subjected to complete necropsy with histological examination. Dose related neurological signs and body weight loss were observed at 90 and 240 mg/kg/day levels. Also at 90 and 240 mg/kg/day, changes in clinical pathological parameters were observed and were dose-related. In addition, dose-related increases in both absolute and relative liver weights were observed in all groups but was significant in only 90 and 240 mg/kg/day groups. One female death occurred on day 42 in the 240 mg/kg/day group.

18. *90–Day dietary toxicity in rats*. Based on the results of a 90–day feeding study in rats, 600 parts per million (ppm) was considered a NOAEL following dietary administration of *N*-(n-octyl)-2-pyrrolidone for 90 days. *N*-(n-octyl)-2-pyrrolidone was administered orally via diet to rats at dosage levels of 60, 600, and 10,000 ppm. All animals were observed daily for clinical signs of toxicity. After treatment, all surviving animals were subjected to complete necropsy with histological examination. Reduced weight gain, increased absolute and relative liver weights and mild hepatocyte hypertrophy were observed at 10,000 ppm. No treatment-related effects were observed at 60 and 600 ppm.

19. *Endocrine disruption*. *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone are not expected to be endocrine disrupters. They do not share structural similarity with currently known or suspected chemicals or chemical classes being studied for this effect.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Residue data are generally not required for inert ingredient exemptions from a tolerance. International Specialty Products has exposure data on 4 representative crops to support the listing of *N*-(n-octyl)-2-pyrroidone and *N*-(n-dodecyl)-2-pyrrolidone as an inert ingredient exempted from the requirements of a tolerance when used in accordance with good agricultural practices at levels not to exceed 1% in the final solution for preharvest and postharvest application, and application to animals. A dietary residue exposure system (DRES) analysis was run using a model based on Kenaga and Hoerger's ''Maximum Expected Residues on Vegetation.'' The four representative crops chosen for the analysis were: Wheat, lettuce, apples, and sugar beets. The reference dose used by EPA, was derived from the NOAEL obtained from an animal study in dogs, the most sensitive species in chronic studies with these materials. For *N*-(n-octyl)-2-pyrrolidone the NOAEL was 30 mg/kg bwt/day in the 90–day dog study. A 250–fold safety factor results in a reference dose of 0.12 mg/kg bwt/day. This reference dose (RfD) can then be compared to the dietary exposure yielding a ''percent of dose utilized'' estimate. An application rate of 0.25 lb (113 grams) *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone/acre of crop was used for the analysis. Apples, under the category of ''fruit-cherries, peaches'' results in an estimated residue of 1.75 ppm. Lettuce (head and leaf), under the category ''leaves and leafy crops'' results in an estimated residue of 31 ppm. Wheat, under the category of ''forage-alfalfa, clover'' results in an estimated residue of 14 ppm. Sugar beets (root crop) is not estimated in the model, but a default value of 5 ppm is assumed. This is a conservative estimate given that the pesticide formulation does not physically touch the crop.

Using these input parameters, a residue file was assembled which lists the chronic reference dose and all of the relevant commodities that are included in the consumption data base. The exposure analysis shows that, for the U.S. population (general population, 48 contiguous states, all seasons), the listed crops utilize only 25% of the reference dose. This analysis shows there is a substantial margin of safety for the use of *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone on these crops at 0.25 lb/acre.

ii. *Drinking water*. Based on its very low application rate, as well as the environmental fate studies, *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone would not be expected to persist in the environment, nor contaminate drinking water supplies.

2. *Non-dietary exposure*. *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone are used in household and institutional cleaners, specifically hard-surface cleaners. Annual volumes to this market segment approach 150,000 pounds each.

D. Cumulative Effects

There are no cumulative effects expected since *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone rapidly degrade and the very low use rate is not conducive to build-up in the environment.

E. Safety Determination

1. *U.S. population*. As per the details in the dietary residue exposure system analysis, even the most sensitive population, children, 1 to 6 years old, still would be expected to consume slightly more than 1% of the RfD, for the 4 representative crops analyzed.

2. *Infants and children*. No developmental, embryotoxic, or teratogenic effects have been associated with *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone.

F. International Tolerances

The applicant is not aware of any international tolerance or CODEX of maximum residue limits (MRLs) for *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone on any crop or livestock commodities.

[FR Doc. 00–22013 Filed 8–29–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–960; FRL–6737–4]

Notice of Filing Pesticide Petitions to Establish Exemptions from the Requirement of Tolerances for Certain Pesticide Chemicals 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 certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–960, must be

received on or before September 27, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–960 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: For MinerALL, contact Andrew C. Bryceland, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6928; e-mail address: bryceland.andrew@epa.gov.

For section II Platte Chemical Company, Inc., 2, 6-diisopropylnapthalene (2, 6-DIPN), contact Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9525; e-mail address: benmhend.driss@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–960. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–960 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp–docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–960. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain data or information regarding the elements set forth in 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 these petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated:August 21, 2000.

Kathleen Knox, Acting

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

I. Ironwood Clay Company

PP–0F6148

EPA has received a pesticide petition (PP–0F6148) from Ironwood Clay Company, Inc., c/o Plant Sciences Inc., 342 Green Valley Road, Watsonville, CA 95076–1305, proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide Oceanic Clay. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, [Ironwood Clay Company] has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by [Ironwood Clay Company] and EPA has not fully evaluated the merits of the pesticide petition. 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.

A. Product Name and Proposed Use Practices

Oceanic Clay (tradename: MinerALL) is proposed for use as a crop protectant and growth stimulant on agricultural crops. For growing plants, MinerALL works as a crop protectant by forming a barrier on the plant surface. The barrier protects the plant from insects, heat, and stress, as well as creates an inhospitable environment for plant diseases such as powdery mildew, *Botrytis*, and *Fusarium*. The minerals, trace and rare earth elements in MinerALL provide nutrients to plants and beneficial microorganisms. Overall, Oceanic Clay can be classified as having a non-toxic mode of action.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*. Oceanic Clay is a naturally-occurring, pure clay complex composed of minerals, ions, and elements, including trace and rare earth elements.

2. *Magnitude of residue at the time of harvest and method used to determine the residue*. Residues of Oceanic Clay are not expected at the time of harvest, and as such, an analytical method for residues is not applicable.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed*. An analytical method for residues is not applicable. Oceanic Clay is applied to growing crops that are washed as part of the postharvest and packaging process. As products containing Oceanic Clay leave a visible white film on treated surfaces, for cosmetic reasons treated produce would be washed before reaching the marketplace. Residues of Oceanic Clay are not expected on raw agricultural commodities (RAC) and there are no known toxicological effects related to dietary exposure to Oceanic Clay.

C. Mammalian Toxicological Profile

Oceanic Clay has been evaluated for acute toxicity through the oral, inhalation, dermal, and ocular routes of exposure. The results of the studies have all indicated toxicity category IV, which poses no significant human health risks.

The acute oral toxicity of Oceanic Clay in rats is greater than 5,000 milligrams per kilograms (mg/kg) (toxicity category IV), and no toxicity or clinical abnormalities were observed throughout the study period. Acute inhalation in rats is greater than 2.47 mg/L (toxicity category IV), and no toxicity or clinical abnormalities were observed in test animals throughout the study. Eye irritation in rabbits was not observed at a dose of 0.1 mL (toxicity category IV), and no toxicity or clinical abnormalities were observed throughout the study period. Skin irritation in rabbits was not observed at a dose of 0.5 mL (toxicity category IV), and no toxicity or clinical abnormalities were observed throughout the study period. No dermal sensitization was observed in guinea pigs (toxicity category IV), and no toxicity or clinical abnormalities were observed throughout the study period. In addition, clinical studies have been conducted for evaluating safety of cosmetic use of the ingredient, primarily in facial products. In a dermal patch test of 35 participants, the ingredient was rated slightly irritating and non-allergenic. In a facial application test of 40 participants, no irritation was observed. No incidents of hypersensitivity have been reported by researchers, manufacturers or users.

A waiver is being requested for acute dermal toxicity and genotoxicity data requirements, based on the fact that the active ingredient is known to be non-toxic and non-irritating to mammals. The ingredient is available commercially as a facial/cosmetic product for dermal application and it has been evaluated for dermal effects through various studies including clinical trials. Oceanic Clay is not related to any known mutagen and does not belong to a chemical class of compounds containing known mutagens. Finally, the ingredient has never been reported as causing any type of adverse effect to humans, in published literature or through commercial use.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Dietary exposure from use of Oceanic Clay, as proposed, would be expected to be minimal. Oceanic Clay is applied to growing crops that are washed as part of the postharvest and packaging process. As products containing Oceanic Clay leave a visible white film on treated surfaces, for cosmetic reasons treated produce would be washed before reaching the marketplace. Residues of Oceanic Clay are not expected on RAC and there are no known toxicological

effects related to dietary exposure to Oceanic Clay.

ii. *Drinking water*. Exposure to humans from residues of Oceanic Clay in consumed drinking water would be unlikely and there are no known toxicological effects related to exposure to Oceanic Clay.

2. *Non-dietary exposure*. The potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites are commercial, agricultural and horticultural settings. However, non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern. Person protective equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in commercial, agricultural and horticultural settings.

E. Cumulative Exposure

It is not expected that, when used as proposed, Oceanic Clay would result in residues that would remain in human food items. Oceanic Clay has a non-toxic mode of action and therefore has no common mechanism of toxicity with other substances.

F. Safety Determination

1. *U.S. population*. There have been no reports of toxins or secondary metabolites associated with Oceanic Clay, and acute toxicity studies have shown that Oceanic Clay is non-toxic, non-irritating and non-sensitizing when applied to test animals. Residues of Oceanic Clay are not expected on agricultural commodities, and there are no known toxicological effects related to exposure to Oceanic Clay.

2. *Infants and children*. As mentioned above, residues of Oceanic Clay are not expected on agricultural commodities, and there are no known toxicological effects related to dietary exposure to Oceanic Clay. There is a reasonable certainty of no harm for infants and children from exposure to Oceanic Clay from the proposed uses.

G. Effects on the Immune and Endocrine Systems

Oceanic Clay is a naturally-occurring clay. To date there is no evidence to suggest that Oceanic Clay functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Existing Tolerances

There is no U.S. EPA Tolerance.

I. International Tolerances

A Codex Alimentarium Commission maximum residue level (MRL) is not required for Oceanic Clay.

II. Platte Chemical Company, Inc.

PP–8G5008

EPA has received a pesticide petition (PP–8G05008) from Platte Chemical Company, Inc., 419, 18th Street, P.O. Box 1286, Greely, CO 80632 proposing, pursuant to section 408(d) of the (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish temporary exemption from the requirement of a tolerance for the biochemical pesticide 2, 6–diisopropylnapthalene (2,6–DIPN).

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Platte Chemical Company, Inc., has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Platte Chemical Company, Inc. and EPA has not fully evaluated the merits of the pesticide petition. 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.

In the **Federal Register** of September 22, 1999 (64 FR 51245) (FRL–6381–7), EPA issued a rule pursuant to section 408 of the (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) establishing a temporary exemption from the requirement of a tolerance for residues of 2,6–DIPN. The temporary exemption from the requirement of a tolerance will expire on September 22, 2000. This request for temporary exemption from the requirement of a tolerance is associated with an experimental use permit (EUP No. 34704 EUP–13). 2,6–DIPN is a potato sprout inhibitor and the purpose of the experimental program is to test the efficacy of the active ingredient.

A. Product Name and Proposed Use Practices

The end use product, Amplify® sprout inhibitor, contains 99.7% 2,6–DIPN. The experimental program will be conducted in potato storage facilities located in Idaho, Maine, Minnesota, North Dakota, Oregon, South Dakota, Washington, and Wisconsin. According to the National Agricultural Statistics Service, approximately 359 cut weight (cwt; 1 cwt equals approximately 100 pounds) of potatoes are grown per acre in the United States. The EUP program will utilize 2,500 pounds of active ingredient on approximately 150 million pounds of stored potatoes during 2000 and 2001. This represents approximately 4,180 acres of potatoes. 2,6–DIPN is a plant growth regulator that is applied as an aerosol at the rate of one pound active ingredient per 600 cwt of potatoes, to achieve a rate of 16.6 parts per million (ppm). Only one application may be made while the potatoes are held in storage.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*. EPA has classified 2,6–DIPN as a biochemical pesticide (June 5, 1995, EPA letter from William Schneider to Fred Betz). The formulated end product, Amplify® sprout inhibitor, contains 99.7% 2,6–DIPN as the active ingredient. In order to determine the magnitude of 2,6–DIPN residues, Platte conducted studies in/on potatoes and the effect of processing (i.e., washing and cooking) on 2,6–DIPN residues. According to the 2,6–DIPN label, one application of 16.6 ppm should be applied.

2. *Magnitude of residue*—at the time of harvest and the method used to determine the residue. a. *2,6–DIPN magnitude of residues in/on potatoes postharvest storage*. Platte conducted studies to determine 2,6–DIPN residues in whole potatoes and peels at various times, up to 180 days, following 1 to 3 treatments at the maximum application rate. A gas chromatography method was used to measure residues of 2,6–DIPN. Under the EUP, potatoes can only be treated once with Amplify®. Treated potatoes must be held for a minimum of 30 days before being released for processing. Potatoes were treated using a small chamber system that reproduced a commercial operation, but on a small scale. Use of the small chamber system produces realistic but worst-case residue values compared to a full-scale commercial operation characterized by use conditions and practices that would tend to reduce residues to a greater extent than the chamber system. When treated once during storage at a rate of 1.2 pounds active ingredient per 600 cwt. of potatoes, and sampled 30 days after treatment (DAT), residues for whole potatoes were 0.22 ppm, 0.28 ppm, and 0.41 ppm. Under these same conditions, residues in/on the peel were 1.01 ppm, 2.59 ppm, and 2.77 ppm.

b. *2,6–DIPN magnitude of residues in/on processing potatoes*. A magnitude of the residue study was conducted to determine the effect of processing (i.e., baking, boiling, and frying) on whole red and Russet potatoes. Potatoes were treated with a thermal fog of 2,6–DIPN,

in accordance with standard agronomic practices. Two application scenarios were studied: one 20 ppm active ingredient application and 3 applications of 20 ppm active ingredient, totaling 60 ppm active ingredient. A liquid chromatography method was used to analyze residues of 2,6–DIPN in/on the potatoes.

2,6–DIPN residues for whole potatoes were as follows: Whole potatoes treated once (20 ppm) at 0 DAT had residues of 0.17 ppm, 0.26 ppm, 0.27 ppm, 0.15 ppm, 0.21 ppm, and 0.14 ppm. Potatoes treated once (20 ppm) at 3 DAT had residues of 0.14 ppm, 0.08 ppm, 0.18 ppm, 0.09 ppm, 0.25 ppm, and 0.14 ppm. Potatoes treated 3 times (60 ppm) at 0 DAT had residues of 0.97 ppm, 1.14 ppm, 0.59 ppm, 1.70 ppm, 2.10 ppm, and 1.44 ppm. Potatoes treated 3 times (60 ppm) at 3 DAT had residues of 0.58 ppm, 0.72 ppm, 0.75 ppm, 1.13 ppm, 0.57 ppm, and 0.48 ppm.

For whole potatoes baked in aluminum foil, 2,6–DIPN residues were as follows: Potatoes treated once (20 ppm) had residues of 0.08 ppm, and <0.02 ppm. Potatoes treated 3 times (60 ppm) had residues of 0.50 ppm, 0.07 ppm, and 0.24 ppm.

For whole potatoes baked without aluminum foil, 2,6–DIPN residues were as follows: Potatoes treated once (20 ppm) had residues of 0.32 ppm, 0.26 ppm, and 0.13 ppm. Potatoes treated 3 times (60 ppm) had residues of 0.73 ppm, <0.02 ppm, and 0.46 ppm.

For French fried potatoes, 2,6–DIPN residues were as follows: Potatoes treated once (20 ppm) had residues of 0.07 ppm, 0.04 ppm, and 0.03 ppm. Potatoes treated 3 times (60 ppm) had residues of 0.11 ppm, 0.06 ppm, and 0.11 ppm.

c. *2,6–DIPN determination of residues in/on whole potatoes and potato fractions (flesh and peel).* A study was conducted to determine the residues in/on whole potatoes and the potato fractions (flesh and peel). A liquid chromatography method was used to analyze residues of 2,6–DIPN.

2, 6–DIPN residues for whole potatoes were as follows: Whole potatoes treated once (20 ppm) at 0 DAT had residues of 0.12 ppm, 0.16 ppm, and 0.11 ppm. Potato peels treated once (20 ppm) at 0 DAT had residues of 1.76 ppm, 1.56 ppm, and 1.46 ppm. Potato flesh samples treated once (20 ppm) at 0 DAT had no detectable residues above the limit of quantification (LOQ) of 0.02 ppm. Peeled potato samples from 0, 30, and 90 DAT were analyzed for residues; however, no residues above the LOQ of 0.02 ppm were detected.

Residue levels in whole potatoes that have been treated with 2,6–DIPN at the proposed application rate range from 0.22 ppm to 0.41 ppm at 30 DAT. The average residue value is 0.30 ppm. As stated earlier, the small chamber system used to treat potatoes in this study represents a worst-case scenario.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* Residues are expected to decline from the time potatoes are removed from storage to the time of consumption. In addition, processing studies demonstrate that washing and cooking substantially reduce residues. Results from peeling studies show that quantifiable residues are not expected in the potato flesh. Because of the relatively low residues observed and the impact of processing, dietary exposure to 2,6–DIPN is expected to be minimal.

C. Mammalian Toxicological Profile

1. *Acute toxicity.* Technical 2,6–DIPN exhibits low acute toxicity. It is a toxicity category III (based on eye irritation) biopesticide. The rat oral LD_{50} is greater than 5,000 mg/kg (toxicity category IV), the rabbit dermal LD_{50} is greater than 5,000 mg/kg (toxicity category IV), and the rat inhalation LD_{50} is greater than 2.60 mg/L (toxicity category IV) at the maximum attainable condition. In addition, 2,6–DIPN is not a skin sensitizer in guinea pigs, shows no dermal irritation at 72 hours in rabbits (toxicity category IV), and shows minimal ocular irritation (toxicity category III) in rabbits. The end use formulation is the same as the technical formulation, it contains no intentionally added inert ingredients.

2. *Genotoxicity.* Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vivo*/*in vitro* unscheduled DNA synthesis in rat primary hepatocyte cultures at 2 time points, and an *in vivo* mouse micronucleus assay have been conducted for 2,6–DIPN. These studies show a lack of genotoxicity for 2,6–DIPN.

3. *90–Day subchronic toxicity study in rats.* 2,6–DIPN was administered in the diet to rats (10 animals/sex/group) at doses of 0, 750, 1,500, or 3,000 ppm (or approximately 0, 37.5, 75, and 150 mg/kg/day for 14 weeks. The no-observed adverse effect level (NOAEL) for this study is 1,500 ppm (75 mg/kg/day) in male and female rats was based on hepatocytic hypertrophy in the liver, tubular nephrosis in the kidney, and cortical cell atrophy in the adrenal gland at 3,000 ppm. A conservative NOAEL is 750 ppm (37.5 mg/kg/day) based on pupil constriction, minimal clinical pathology changes, and changes in organ weights (with no correlating histopathology findings) at 1,500 ppm.

4. *Developmental toxicity in rats.* 2,6–DIPN was administered to pregnant rats at doses of 0, 50, 150, and 500 mg/kg/day from days 6–19 of gestation. The maternal toxicity NOAEL was 50 mg/kg/day based on decreased body weight (bwt) and feed consumption. The NOAEL for prenatal development toxicity was considered to be 150 mg/kg/day based on decreased fetal body weight. There is no evidence of teratogenicity or of increased fetal susceptibility to 2,6–DIPN.

5. *Metabolism.* The metabolism of 2,6–DIPN and di-isopropylnapthalenes have been investigated, and several references to this work have been found in the published literature. In one study, rats were given a single dose or a daily oral dose for 1 month. Tissues were evaluated from animals sacrificed at 0, 2, 4, 24, and 48 hours following the single dose, and 2, 4, and 24 hours, and 7 and 30 days following the repeated dose administration. DIPNs were found predominantly in body fat and subcutaneous fat 2 hours after the dose, with amounts increasing at 24 hours after the dose, and only slightly dropping at 48 hours.

Significant distribution of DIPNs to liver, heart, kidney, and brain was seen at 2 hours; material in these compartments was eliminated by 48 hours following the single dose. Following repeated doses, the amount of DIPNs distributed in tissues 2 hours after the last dose was lower than or equivalent to that seen following a single dose. The amount in body and subcutaneous fat 2 hours following the last dose, although approximately 2–fold higher than that seen following a single dose, diminished markedly by 30 days post-exposure. The half-life in fat was approximately 7 days. Thus, DIPNs showed a relatively low potential for persistent bioaccumulation.

Another study investigated the urinary metabolites of 2,6–DIPN following a single oral dose. Approximately 23% of the dose was excreted in the urine by 24 hours post-dosing.

Other tests. Naphthalene is associated with pulmonary necrosis (following intraperitoneal administration) and carcinogenesis in mice. A study has been reported in the public literature that compared the potential of napthalene, 2-methylnapthalene, 2-isopropylnaphthalene, and 2,6–DIPN to produce pulmonary damage in mice. The study's data suggest that 2,6–DIPN is very unlikely to share the pulmonary toxicity characteristic of napthalene.

No data have been found in the literature that would indicate 2,6–DIPN has any adverse effect on mammals. No incidents of hypersensitivity or any other adverse effects have been observed in individuals handling the material over the past 8 years.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Potential dietary exposure resulting from applications made under an experimental use permit (EUP) would be through the consumption of potato products and animal products from livestock-fed potato feed items. The registrant has made arrangements with processors of 2,6–DIPN-treated potatoes to prohibit feeding treated culls and potato waste to livestock. Thus, potential dietary exposure would result from consumption of treated potatoes only.

2,6–DIPN is not approved for use on any food other than potatoes that are associated with Platte's EUP. Thus, there will be no exposure of 2,6–DIPN from food other than treated potatoes.

a. *Acute dietary exposure*. Exposure to chemicals that have the potential to elicit a toxic response after a relatively short period of exposure (acute toxicant) is calculated using a distribution of exposure estimated from the entire consumption database. The exposure algorithm uses the basic relationship, that exposure is the product of the amount of food consumed and the magnitude of the residue in/on that food. Residues that are observed in/on crops are found to occur as a distribution. Likewise, food consumption patterns are best described by a consumption distribution. The most realistic calculation of acute dietary exposure, therefore, is to multiply the distribution of residues and the distribution of consumption.

For the acute analysis presented here, the Monte Carlo approach was used to estimate dietary exposure from potential residues of 2,6–DIPN in all potatoes. In the Monte Carlo model, the distribution of the residue data (0.22 ppm to 0.41 ppm) was used in conjunction with individual consumption data for each food. The residue distribution was multiplied by the processing factors (PF) determined from 2,6–DIPN processing studies on baked (PF=0.54), boiled (PF=0.33), fried (PF=0.17), and peeled potatoes (PF=0.15). In addition, it was assumed that 100% of the potatoes consumed would be treated with 2,6–DIPN at the proposed label use rate. That is, no adjustments were made for the percentage of all potatoes that would be stored and treated with 2,6–DIPN.

The acute exposure estimate at the 99.9th percentile of exposure for the overall U.S. population was 0.001770 mg/kg bwt/day. When compared to a maternal toxicity NOAEL of 50 mg/kg bwt/day from a developmental toxicity study in rats, the margin of exposure (MOE) at the 99.9th percentile of exposure is 28,246. For women of child-bearing age, the acute exposure estimate at the 99.9th percentile of exposure was 0.001070 mg/kg bwt/day (MOE=46,730). The population subgroup with the highest predicted level of acute exposure was children 1 to 6 years of age. Acute exposure for children 1 to 6 years of age was 0.003318 mg/kg bwt/day (MOE=15,070). Because the predicted exposures, expressed as MOEs, are well above 100, there is reasonable certainty that no acute effects would result from dietary exposure to 2,6–DIPN.

b. *Chronic dietary exposure*. Chronic exposure estimates were calculated for potential residues of 2,6–DIPN in/on all potatoes, including those destined for processing (e.g., frozen, canned). Generally, exposure to chemicals that have the potential to elicit a toxic response after an extended period of exposure (chronic toxicant) is calculated using per-capita mean consumption estimates and an average residue value. As a conservative estimate of potential long-term dietary exposure, it was assumed that 100% of the potatoes consumed would contain 2,6–DIPN residues at 0.30 ppm (average residue). This residue value was multiplied by the processing factors (PF) determined from 2,6–DIPN processing studies on baked (PF=0.54), boiled (PF=0.33), fried (PF=0.17), and peeled potatoes (PF=0.15). Because of its status as a biopesticide, chronic toxicity studies would not normally be required for 2,6–DIPN; however, exposures were compared to a reference dose (RfD) of 0.0375 mg/kg bw/day based on a conservative NOAEL from a subchronic study and an uncertainty factor of 1,000. An additional 10–fold factor was incorporated because of the absence of a chronic toxicity study.

For the overall U.S. population, chronic exposure was estimated to be 0.000095 mg/kg bwt/day or 0.3% of the RfD. Chronic exposure also was calculated for women of child-bearing age. The exposure estimate was 0.000089 mg/kg bwt/day (0.2% of the RfD). For the most highly exposed population subgroup, children 1 to 6 years of age, chronic exposure was estimated to be 0.000175 mg/kg bwt/day or 0.5% of the RfD.

ii. *Drinking water*. There is no established maximum concentration level for 2,6–DIPN in water. Based on the low use rate and an indoor use pattern that is not widespread, residues of 2,6–DIPN in drinking water and exposure from this route is unlikely.

2. *Non-dietary exposure*. 2,6–DIPN is not registered for any use that could result in non-occupational, non-dietary exposure to the general population.

E. Cumulative Exposure

There is no evidence to indicate or suggest that 2,6–DIPN has any toxic effects on mammals that would be cumulative with those of any other chemicals. For the purposes of this exemption from tolerance, therefore, Platte assumes that 2,6–DIPN does not have a common mechanism of toxicity with other substances.

F. Safety Determination

A dietary exposure assessment for 2,6–DIPN was conducted using Novigen Sciences' dietary exposure evaluation model (DEEM^{tm}). Versions 6.73 (Acute Module) and 6.74 (Chronic Module). Dietary exposure to 2,6–DIPN was only based upon potatoes, including fresh potatoes. However, the Amplify® label restricts application of the product to potatoes used only for processing. Therefore, the following is an extremely conservative assessment of the dietary exposure.

1. *U.S. population*. The acute exposure estimate at the 99.9th percentile of exposure for the overall U.S. population was 0.001770 mg/kg bwt/day. When compared to a maternal toxicity NOAEL of 50 mg/kg bwt/day from a developmental toxicity study in rats, the MOE at the 99.9th percentile of exposure is 28,246. For women of child-bearing age, the acute exposure estimate at the 99.9th percentile of exposure was 0.001070 mg/kg bwt/day (MOE = 46730). For the overall U.S. population, chronic exposure was estimated to be 0.000095 mg/kg bwt/day or 0.3% of the RfD. Chronic exposure also was calculated for women of child-bearing age. The exposure estimate was 0.000089 mg/kg bwt/day (0.2% of the RfD) for women of child-bearing age.

2. *Infants and children*. Acute exposure for infants and children 1 to 6 years of age were 0.002794 mg/kg bwt/day (MOE = 17,898) and 0.003318 mg/kg bwt/day (MOE = 15,070), respectively. For the most highly exposed population subgroup, children 1 to 6 years of age, chronic exposure was estimated to be 0.000175 mg/kg bwt/day or 0.5% of the RfD. Chronic exposure also was calculated for infants. The exposure estimate was 0.000107 mg/kg bwt/day (0.3 percnt of the RfD) for infants.

G. Effects on the Immune and Endocrine Systems

Platte has no information to suggest that 2,6–DIPN will adversely affect the immune or endocrine systems. The Agency is not requiring information on endocrine effects of this biochemical pesticide at this time.

H. Existing Tolerances/International Tolerances

No Codex maximum residue levels (MRLs) are established for residues of 2,6–DIPN in/on any food or feed crop.

[FR Doc 00–22166 Filed 8–29–00; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–967; FRL–6739–4]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals 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 certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–967, must be received on or before September 24, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–967 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Fungicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–967. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–967 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–967. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI,