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SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and the Fact Sheet are available from the EPA home page at the **Federal Register** Environmental Sub-Set entry for this document under "Laws and Regulations" (<http://www.epa.gov/fedrgstr/>).

EPA issued a notice, published the **Federal Register** of February 25, 1998 (63 FR 9517)(FRL-5773-7), which announced that Ecogen Inc., 2005 Cabot Blvd., West, P.O. Box 3023 Langhorne, PA 19047-3023, had submitted an application to conditionally register the pesticide product BTI Technical Powder Bioinsecticide (EPA File Symbol 55638-UR) containing the active ingredient *Bacillus thuringiensis* subspecies *israelensis* strain EG2215 at 20%, an active ingredient not included in any previously registered pesticide product.

The application was approved on September 30, 1998, as BTI Technical Powder Bioinsecticide, a manufacturing use product for formulation into end-use products to control mosquitoes (EPA Registration Number 55638-41).

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for a new active ingredient where certain data are lacking, on condition that such data are received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that use of the pesticide during the conditional registration period will not cause unreasonable adverse effects; and that use of the pesticide is in the public interest. The Agency has considered the available data on the risks associated with the proposed use of *Bacillus thuringiensis* subspecies *israelensis* strain EG2215, and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of *Bacillus thuringiensis* subspecies *israelensis* strain EG2215 during the period of conditional registration will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is, in the public interest.

Consistent with section 3(c)(7)(C), the Agency has determined that this

conditional registration is in the public interest. Use of the pesticides are of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

The studies listed below must be completed within 6 months of the date of the conditional registration:

1. A *Daphnia* Study.
2. An Interperitoneal Injection Study.
3. Mosquito Bioassay to Verify the Potency of the Toxin.
4. An Eye/Dermal Irritation Study.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(C). If these conditions are not complied with, the registration will be cancelled in accordance with FIFRA section 6(e).

More detailed information on this conditional registration is contained in an EPA Pesticide Fact Sheet on *Bacillus thuringiensis* subspecies *israelensis* strain EG2215.

A paper copy of this fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, CM #2, Arlington, VA 22202 (703-305-5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: October 20, 1998.

Janet L. Andersen,

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

[FR Doc. 98-31547 Filed 11-24-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-841; FRL 6039-7]

Notice of Filing of Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition (PP) 8G5008 for an exemption from the requirement of a temporary tolerance for residues of the biopesticide, 2,6-diisopropyl-naphthalene (2,6-DIPN) when used to inhibit sprouting in potatoes held in storage.

DATES: Comments, identified by the docket control number (PF-841), must be received on or before December 28, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Rita Kumar, PM 90, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail: Rm. 902W5, CM#2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 308-8291; e-mail: kumar.rita@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition 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 this petition contains 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 the petition. This petition was submitted to support an application for an experimental use permit (EUP) to treat potatoes in closed storage facilities, to evaluate the control of sprouting. A notice of receipt for this EUP is being published elsewhere in this issue of the **Federal Register**. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number (PF-841) (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number (PF-841) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: November 4, 1998.

Janet L. Andersen,

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

Summary of the Petition

Petitioners summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summary verbatim with minor non-substantive editorial changes. 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.

Platte Chemical Company

PP 8G5008

EPA has received a pesticide petition (PP) 8G5008 from Platte Chemical Company, 419, 18th Street, Greeley, CO 80632, proposing pursuant to section 408(d) of the (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a temporary tolerance for residues of 2,6-DIPN in or on the raw agriculture commodity potatoes.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Platte Chemical Company has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Platte Chemical Company and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

A. Proposed Use Practices

The proposed experimental program will be conducted in potato storage facilities located in Idaho, Maine, Minnesota, North Dakota, Oregon, Washington, and Wisconsin. Stored potatoes will be treated in one or two facilities in each state. The proposed experimental program would utilize 1,500 pounds of active ingredient on

approximately 90 million pounds of stored potatoes during 1998 and 1999. The active ingredient, 2,6-DIPN, is a plant growth regulator that will be applied as an aerosol at a rate of one pound active ingredient per 60,120 pounds of potatoes, to achieve an initial residue of 16.6 parts per million (ppm). A maximum of 3 applications may be made while the potatoes are held in storage.

B. Product Identity/Chemistry

1. *Identity of the biopesticide.* EPA has classified DIPN as a biochemical pesticide. The formulated end product, Amplify Sprout Inhibitor, contains 100% DIPN as the active ingredient which is an odorless liquid.

C. Residue Chemistry

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. Potatoes were treated using a small chamber system that reproduced a commercial environment, including temperatures and humidity. The 2,6-DIPN was applied to the chambers using a fogging device that reproduced a commercial operation, but on a small scale. When treated up to 3 times during storage at a rate of 1.2 pounds active ingredient per 60,120 pounds of potatoes and sampled 0 days after treatment (DAT) to 180 DAT, residues in the peel ranged from 0.15 ppm to 4.05 ppm. Residues for whole potatoes ranged from 0.03 ppm to 2.43 ppm.

The 2,6-DIPN residues for potato peel were as follows: Potatoes treated 1 time at 1.2 pounds active ingredient per 60,120 pounds of potato had residues of 2.82 ppm, 3.39 ppm, and 4.05 ppm at 0 DAT; 1.01 ppm, 2.59 ppm, and 2.77 ppm at 30 DAT; 0.33 ppm, 0.46 ppm, and 0.76 ppm at 90 DAT; and 0.15 ppm, 0.24 ppm, and 0.24 ppm at 180 DAT.

Potatoes were treated 3 times at 1.2 pounds active ingredient per 60,120 pounds of potato per treatment at 0 day and at 60 days, and 120 days after the first treatment.

The 2,6-DIPN residues in peels were 2.18 ppm, 2.55 ppm, and 3.52 ppm at 0 DAT; 1.30 ppm, 1.82 ppm, and 2.59 ppm at 30 DAT; 2.43 ppm, 2.71 ppm, and 4.51 ppm at 60 DAT; 0.86 ppm, 1.32 ppm, and 1.83 ppm at 90 DAT; 2.41 ppm, 3.79 ppm, and 3.49 ppm at 120 DAT; and 0.74 ppm, 0.86 ppm, and 0.91 ppm at 180 DAT.

The 2,6-DIPN residues for whole potatoes were as follows: Potatoes treated 1 time at 1.2 pounds active

ingredient per 60,120 pounds of potato had residues of 0.82 ppm, 1.18 ppm, and 1.27 ppm at 0 DAT; 0.22 ppm, 0.28 ppm, and 0.41 ppm at 30 DAT; 0.10 ppm, 0.11 ppm, and 0.04 ppm at 90 DAT; and 0.03 ppm, 0.03 ppm, and 0.05 ppm at 180 DAT.

Potatoes treated 3 times at day 0, 60, and 120, as described above, had 2,6-DIPN residues of 0.83 ppm, 1.28 ppm, and 1.39 ppm at 0 DAT; 0.25 ppm, 0.30 ppm, 0.37 ppm at 30 DAT; 0.80 ppm, 1.07 ppm, and 2.43 ppm at 60 DAT; 0.28 ppm, 0.42 ppm, and 0.62 ppm at 90 DAT; 1.16 ppm, 1.79 ppm, and 1.86 ppm at 120 DAT; and 0.13 ppm, 0.17 ppm, and 0.24 ppm at 180 DAT.

Magnitude of residue at the time of harvest and method used to determine the residue. A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed. Since the petitioner has requested a tolerance exemption, an analytical method to detect residues is not required.

D. Toxicology Profile

1. *Acute toxicity.* Technical 2,6-DIPN exhibits low acute toxicity. It is a toxicity category IV biopesticide. The rat oral LD₅₀ is greater than 5,000 milligram/kilogram (mg/kg), the rabbit dermal LD₅₀ is greater than 5,000 mg/kg, and the rat inhalation LC₅₀ is greater than 2.60 milligram/Liter (mg/L) 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, and shows minimal ocular irritation 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. *Other tests.* No additional mammalian toxicology testing has been conducted. Platte requested a waiver from the requirement to submit further mammalian toxicology studies on the basis of the favorable toxicological profile for 2,6-DIPN, the low residues observed in treated potatoes, the specific plant growth regulator mode of action, and the confined nature of the proposed use. No data were 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 6 years.

E. Aggregate Exposure

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information about exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure from food and drinking water.* Any dietary exposure resulting from applications made under an experimental use permit (EUP) would be through potato consumption and animal products in which animals are fed potato feed stocks. Residues in treated potatoes have been shown to be low. Residues would be expected to continue to decline after potatoes are removed from storage and before consumption. Cooking and/or processing would be expected to further lower the residue level in consumed potatoes or potato products. Since 2,6-DIPN would only be used in commercial storage warehouses, there is little if any potential for drinking water exposure. There are no other established U.S. tolerances or exemptions from tolerances for 2,6-DIPN food or feed crops in the United States. The Agency has classified 2,6-DIPN as a biochemical pesticide.

2. *Non-dietary exposure.* The EUP would only cover use for direct application to potatoes when stored in commercial warehouses. There are currently no other registered uses of 2,6-DIPN. Non-dietary exposure to 2,6-DIPN via lawn care, topical treatments, etc., will not occur. Thus, the potential for non-occupational exposure to the general population is virtually non-existent.

F. Cumulative Exposure

EPA also is required to consider the potential for cumulative effects of 2,6-DIPN and other substances that have a common mechanism of toxicity. Consideration of a common mode of toxicity is not appropriate, given that there is no indication of mammalian toxicity of 2,6-DIPN and no information that indicates toxic effects, if any, would be cumulative with any other compounds. Since, 2,6-DIPN does not exhibit a toxic mode of action in the target plant, it is appropriate to consider only the potential risks of 2,6-DIPN in this exposure assessment.

G. Endocrine Effects

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. Safety Determinations

1. *U.S. population in general and infants and children.* Since there are no anticipated residues in drinking water or from other non-occupational sources, and no reliable information exists on cumulative effects due to a common mechanism of toxicity, the aggregate exposure to 2,6-DIPN is adequately represented by the dietary route. The lack of toxicity of 2,6-DIPN has been demonstrated by the results of acute toxicity testing in mammals in which 2,6-DIPN caused no adverse effects when dosed orally, dermally, and via inhalation at the limit dose for each study. Anticipated residues in consumed potatoes are low. Moreover, 2,6-DIPN exhibits close similarity to other plant-based, naturally occurring methyl and isopropyl naphthalenes. Thus, the dietary exposure to 2,6-DIPN should pose negligible risks to human health. Based on the lack of toxicity and low exposure, there is a reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to 2,6-DIPN residues. Exempting 2,6-DIPN from the requirement of a tolerance should pose no significant risk to humans or the environment.

I. Analytical Method

An analytical method for residues is not applicable, as this proposes an exemption from the requirement of a tolerance.

J. Existing Tolerances

No codex maximum residue levels are established for residues of 2,6-DIPN in or on any food or feed crop.

[FR Doc. 98-31248 Filed 11-24-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[OPP-50848; FRL-6043-4]

Experimental Use Permit; Notice of Receipt of Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application [34704-EUP-RG] from