

entry for this document under "Rules and Regulations" (<http://www.epa.gov/fedrgstr/>).

EPA issued a notice, published in the **Federal Register** of September 27, 1995 (60 FR 49838; FRL-4971-4), which announced that Kaken Pharmaceutical Co., Ltd. Agrochemical and Animal Health Products Division, of Japan, represented by Stewart Pesticide Registration Associates, Inc., Suite 603, 1901 North Moore St., Arlington, VA 22209, had submitted applications to register the pesticide products STOPIT Wettable Powder Turf Fungicide and Polyoxin D Zinc Salt Technical (EPA File Symbols 68173-E and 68173-R), containing the new active ingredient polyoxin D zinc salt (1:1), zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1 (2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate at 2.5 and 23.8 percent respectively, an active ingredient not included in any previously registered products.

The applications were approved on August 20, 1997, as STOPIT Wettable Powder Turf Fungicide for use on turf of golf courses, home lawns, parks, and commercial and institutional grounds (EPA Registration Number 68173-2) and Polyoxin D Zinc Salt Technical for formulation into fungicidal end-use products (EPA Registration Number 68173-1).

The Agency has considered all required data on risks associated with the proposed use of polyoxin D zinc salt (1:1), zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1 (2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate, and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the chemical 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 polyoxin D zinc salt (1:1), zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1 (2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

More detailed information on these registrations is contained in an EPA Pesticide Fact Sheet on Polyoxin D zinc salt.

A copy of this fact sheet, which provides a summary description of the

pesticides, 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 (7506C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 1132, 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, D.C. 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: September 9, 1997.

Janet L. Andersen,

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

[FR Doc. 97-24938 Filed 9-18-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-759; FRL-5739-9]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition (PP 7F4826), submitted by Plant Genetic Systems (America), Inc., proposing the establishment of a regulation for an exemption from the requirement of a tolerance for residues of plant-pesticides *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in or on all raw agricultural commodities.

DATES: Comments, identified by the docket control number PF-759, must be received on or before October 20, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following 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. 1132 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: Michael Mendelsohn, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. CS51B6, Westfield Building North Tower, 2800 Crystal Drive, Arlington, VA 22202, (703) 308-8715; e-mail: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: 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 supports granting of the petition. 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-759] (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:
opd-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-759] 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, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 29, 1997.

Janet L. Andersen,

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

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. 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.

Plant Genetic Systems (America), Inc.

PP 7F4826

EPA has received a pesticide petition (PP 7F4826) from Plant Genetic Systems

(America), Inc., proposing the establishment of a regulation for an exemption from the requirement of a tolerance for residues of plant-pesticides *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in or on all raw agricultural commodities.

A. *Bacillus thuringiensis* subsp. *tolworthi* Cry9C protein uses

Corn plants have been protected from lepidopteran insect pests such as European corn borer [*Ostrinia nubilalis* (Huber)], by expressing a Cry9C protein. The Cry9C protein expressed by the corn plants corresponds to the insecticidal moiety of the Cry9C crystal protein of a *Bacillus thuringiensis* subsp. *tolworthi* strain. The Cry9C protein poses no foreseeable risks to non-target organisms, including mammals, birds and non-target insects. Transgenic corn plants, expressing Cry9C protein, represents an excellent addition to growers' options for insect control that reduces or eliminates the need for chemical inputs and fits well within an integrated pest management program.

B. Product Identity/Chemistry

The Cry9C gene, was isolated from the *B.t. tolworthi* strain, truncated and modified before it was stably inserted into corn plants. The tryptic core of the microbially produced Cry9C delta-endotoxin is similar to the Cry9C protein found in event CBH351. The Cry9C protein was produced and purified from a bacterial host, for the purposes of mammalian toxicity studies. Product analysis that compared the Cry9C protein from the two sources included: SDS-PAGE, Western blots, N-terminal amino acid sequencing, glycosylation tests (for possible post-translational modifications) and insect bioassays.

No analytical method is included since this petition requests an exemption from the requirement of a tolerance.

C. Mammalian Toxicological Profile

Bacillus thuringiensis proteins have insecticidal properties and have been used commercially for more than 30 years. This long history of safe use is the primary reason that *Bt* proteins have been chosen as the basis for the first insecticidal plants produced by biotechnology. *Bt* mode-of-action can be divided into a series of critical steps: ingestion by the insect, specific binding to brush border membrane receptors, membrane insertion, and pore formation. *Bt* proteins do not bind or

cause any other effects to mammalian gut membranes thereby displaying human safety properties. The Cry9C protein mode-of-action is apparently similar to that of the well known Cry1A proteins. Although *Bt* strains have been used for decades as sprayable microbial products, no confirmed cases of allergic reactions have been documented, despite dermal, oral and inhalation exposures. A reference to this is made by the EPA in a **Federal Register** notice, dated August 16, 1995 [60 FR 42443].

In addition to the safe history of *Bt* proteins outlined above, several other studies were performed to provide evidence for mammalian safety of the Cry9C protein. An acute toxicological study was performed with mice, which demonstrated that the Cry9C protein had an LD₅₀ > 6,500 mg/kg. A test for in vitro digestibility under simulated gastric conditions showed that the Cry9C protein found in bacteria and the protein produced in plants was stable for 4 hours when exposed to simulated gastric juice. An amino acid sequence homology search performed using three different data banks (against 135,867 sequences) only found homology to other related *Bt* proteins. All other proteins in the data bank have no major stretches of sequence homology, indicating that the sequence homology is not significant. Therefore, no homology with any known allergen or protein toxin could be demonstrated.

The Cry9C protein or metabolites of the protein are not expected to interact with the immune system, the endocrine system or to have any carcinogenic activity since the protein sequence does not match any known allergens, hormones or since proteins, in general, are not known to be carcinogenic.

All living organisms contain DNA and there are no examples of nucleic acids causing any toxicological effects from dietary consumption. The genetic material necessary for the production of the Cry9C protein in plants includes the genetic construct that encodes the Cry9C protein and all other necessary genetic elements for its expression. These elements include: a promotor, polylinker sequences, leader sequences and terminators and none of which are expected to cause any toxicological effects.

Taken together, the data supports the lack of mammalian toxicological effects for the plant-pesticide *Bacillus thuringiensis* subsp. *tolworthi* Cry9C protein and the genetic material necessary for the production of this protein in or on all raw plant agricultural commodities.

D. Aggregate Exposure

Since the Cry9C protein is expressed in plant tissues, dermal or inhalation will be negligible to non-existent. Drinking water is unlikely to be contaminated with Cry9C protein due to the rapid degradation of plant materials in the soil. Processed plant products may allow for low levels of exposure to the Cry9C protein, but the lack of mammalian toxicity and the lack of sequence homology to known toxins or allergens, has already been demonstrated.

E. Cumulative Exposure

The unique mode-of-action of *Bt* proteins in general, coupled with the lack of mammalian toxicity for the Cry9C protein provides no basis for the expectation of cumulative exposure with other compounds.

F. Safety Determination

Bt microbial pesticides containing Cry proteins have been applied for more than 30 years to food and feed crops consumed by the U.S. population. There have been no human safety problems attributed to Cry proteins. The extensive mammalian toxicity studies performed to support the safety of *Bacillus thuringiensis* - containing pesticides clearly demonstrate that the tested isolates are not toxic or pathogenic (McClintock, *et al.*, 1995, *Pestic. Sci.* 45:95-105). The lack of mammalian toxicity or allergenic properties of the Cry9C protein provides support for our request of an exemption from the requirement of a tolerance set forth in this petition. Non-dietary exposure of infants, children or the US population in general, to the Cry9C protein expressed in plant materials, are not expected due to the uses of this product within agricultural settings.

G. Existing Tolerances

No tolerances or tolerance exemptions have been granted for the *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in or on all raw agricultural commodities.

[FR Doc. 97-24940 Filed 9-18-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-5895-2]

Notice of Proposed Assessment of Clean Water Act Class II Administrative Penalty to Arizona Public Service Company and Opportunity To Comment

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed administrative penalty assessment and opportunity to comment.

SUMMARY: EPA is providing notice of a proposed administrative penalty assessment and proposed Consent Agreement for alleged violations of the Clean Water Act. EPA is also providing notice of the opportunity to comment on the proposed penalty assessment.

Under section 309(g) of the Clean Water Act, 33 U.S.C. 1319(g), EPA is authorized to issue orders assessing civil penalties for various violations of the Act after providing the person subject to the penalty notice of the proposed penalty and the opportunity for a hearing, and after providing interested persons public notice of the proposed penalty and a reasonable opportunity to comment on its issuance.

Class II proceedings are conducted under EPA's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation and Suspension of Permits, 40 CFR part 22. The procedures through which the public may comment on a proposed Class II penalty or participate in a Class II proceeding are set forth in the Consolidated Rules. The deadline for submitting public comment of a proposed Class II order is thirty days after publication of this document.

On the date identified below, EPA commenced the following Class II proceeding for the assessment of penalties:

In the matter of Arizona Public Service Company, P.O. Box 52034, Phoenix, AZ; EPA Docket No. CWA-IX-FY97-16; filed on September 11, 1997, with Mr. Steven Armsey, Regional Hearing Clerk, U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, California 94105, (415) 744-1389, proposed penalty of \$42,000 for unpermitted discharges in August 1994, January 1997, February 1997 and March 1997 into the Gila River from their water reclamation supply system pipeline. EPA and Arizona Public Service Company have agreed to a proposed Consent Agreement in which Arizona Public Service Company shall pay a civil penalty of \$42,000.

FOR FURTHER INFORMATION: Persons wishing to receive a copy of EPA's Consolidated Rules, review the complaint or other documents filed in this proceeding, comment upon a proposed assessment, or otherwise participate in the proceeding should contact the Regional Hearing Clerk identified above. The administrative record for this proceeding is located in the EPA Regional Office identified above, and the file will be open for public inspection during normal business hours. All information submitted by the Respondent is available as part of this administrative record, subject to provisions of law restricting public disclosure of confidential information. In order to provide opportunity for public comment, EPA will take no final action in these proceedings prior to thirty (30) days after the date of publication of this document.

Dated: September 11, 1997.

John Ong,

Acting Director, Water Division.

[FR Doc. 97-24946 Filed 9-18-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-5895-4]

EPA's Final Decision To Withdraw Phase I Total Maximum Daily Loads (TMDLs) for Copper in certain New Jersey Waters of New York-New Jersey Harbor

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has determined that certain New Jersey waters of the New York-New Jersey Harbor are not water quality-limited for copper, and therefore, Phase I copper TMDLs are not required for these water segments. The New Jersey Harbor waters for which Phase I Copper TMDLs are being withdrawn are defined as Newark Bay, Hackensack River below the Oradell Dam, Passaic River below the Dundee Dam, Raritan River below the Fieldsville Dam, and Raritan Bay. EPA is hereby issuing public notice of its final decision to withdraw the Phase I TMDLs for copper established by EPA on January 24, 1996.

DATES: September 19, 1997.

ADDRESSES: Copies of the responsiveness summary and relevant supporting documents may be obtained by writing to Mr. Steven Wood, Fate & Effects Team, U.S. Environmental