

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 ethephon (2-chloroethyl)phosphonic acid and cyclanilide 1-(2,4-dichlorophenylaminocarbonyl)-cyclopropane carboxylic acid, 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 ethephon (2-chloroethyl)phosphonic acid and cyclanilide 1-(2,4-dichlorophenylaminocarbonyl)-cyclopropane carboxylic acid 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.

These products are conditionally registered in accordance with FIFRA section 3(c)(7)(C). If the conditions are not complied with the registrations will be subject to cancellation in accordance with FIFRA section 6(e).

Consistent with section 3(c)(7)(C), the Agency has determined that these conditional registrations are 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.

More detailed information on these conditional registrations is contained in an EPA Pesticide Fact Sheet on cyclanilide 1-(2,4-dichlorophenylaminocarbonyl)-cyclopropane carboxylic acid.

A 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 (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: June 25, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[PF-749; FRL-5728-9]

Notice of Filing of Pesticide Petitions

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 the docket control number PF-749, must be received on or before August 4, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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: Regulatory Action Leader Edward Allen, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 5th floor CS #1, 2800 Crystal Drive, Arlington, VA 22202. Telephone No. (703) 308-8699. e-mail: allen.edward@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-749] (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. 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-749] 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: June 26, 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.

1. Auxein Corporation

PP 7G4838

EPA has received a pesticide petition (7G4838) from Auxein Corporation, 3900 Collins Road, P. O. Box 27519, Lansing, MI, proposing pursuant to section 408 (d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a (d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of GABA in or on snap beans, peanuts, cotton, potatoes, tomatoes, lettuce, green peppers, spinach, broccoli, cauliflower, and cabbage. Pursuant to the section 408(d)(2)(A)(I) of the FFDCA, as amended, Auxein Corporation has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Auxein Corporation 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 the states of Alabama, Arizona, California, Florida, Georgia, Idaho, Maine, Michigan, Minnesota, Mississippi, North Carolina, North Dakota, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Washington, and Wisconsin. Crops to be treated are snap beans, peanuts, cotton, potatoes, tomatoes, lettuce, green peppers, spinach, broccoli, cauliflower, and cabbage. Depending on the crop, application is made at first bloom, first bud or at the 5-6 leaf stage. Subsequent applications, for a maximum of three (3) applications, are at 1- to 3-week intervals. The rate range is 0.125 - 0.75 pounds of formulated product /acre per treatment not to exceed a maximum of 1.5 lbs/A per growing season. The proposed EUP program would utilize 462 pounds of active ingredients (231 pounds of gamma aminobutyric acid and 231 pounds of L-glutamic acid) in 793 pounds of formulated product. A total of 822 pounds of formulated product will be shipped. A maximum of 790 acres will be treated under this EUP. The formulated product, AuxiGro™ Plant Growth Enhancer, increases plant growth, yield and fruit quality.

B. Product Identity/Chemistry

AuxiGro WP is an off-white colored, wettable powder. AuxiGro contains two active ingredients: 36.5% L-glutamic acid, a key amino acid, and 29.2% gamma aminobutyric acid (GABA), a non-protein amino acid. GABA is a white, crystalline powder with a pH of 6.5 to 7.5. The pH of a 1% solution of AuxiGro is 4.4. The bulk density of the end-use formula is 0.52 g/ml. GABA is ubiquitous in nature and has been found in microorganisms, lower and higher plants, fish, birds, insects and mammals.

C. Toxicological Profile

GABA is a ubiquitous non-protein amino acid present in all living things. It is an inhibitory neurotransmitter in many brain regions and central nervous systems of mammals. Due to GABA's role in the nervous system, it has been administered to humans with the aim of improving central GABA-mediated transmission and to control Huntington's disease, Parkinson's disease, schizophrenia and other seizure states. AuxiGro, the end-use formula containing 29.2% GABA, has been studied for acute toxicity. Acute oral toxicity in rats is greater than 5,050 mg/kg. Acute dermal toxicity in rabbits is

greater than 5,050 mg/kg. An eye irritation study using rabbits resulted in redness in one rabbit's unwashed eye, but cleared within 48 hours. Limited signs of dermal irritation cleared within 24 hours. There was no indication of dermal sensitization in a guinea pig dermal sensitization study.

D. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.* Dietary exposure due to topical applications of GABA and glutamic acid is difficult to estimate because both chemicals are ubiquitous in nature; applications associated with the EUP would be minuscule compared to levels found in nature, and both are readily utilized by microorganisms. Furthermore, GABA and glutamic acid are presently available for direct human consumption.

2. *Non-dietary, non-occupational exposure.* Increased non-dietary exposure of GABA and glutamic acid via lawn care, topical insect repellents, etc., is not applicable to this EUP application.

E. Cumulative Exposure

GABA is ubiquitous in nature. Incremental levels of exposure resulting from this EUP program are minuscule when compared to the high levels of GABA found naturally-occurring in food.

F. Endocrine Disruptors

Auxein has no information to suggest that GABA will adversely affect the immune or endocrine systems.

G. Safety Considerations

GABA is available for human consumption as a food additive and pharmaceutical agent. It also occurs naturally in food. Incremental exposure to GABA resulting from this EUP program is minuscule. Considering the negligible contributions to the environment resulting from the application of AuxiGro, the abundance and role of GABA in foods and in the human body, it can be concluded that GABA is safe for the intended use, i.e., without measurable hazard.

H. Analytical Method

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

I. Existing Tolerances

Auxein is not aware of any tolerances or MRLs issued for GABA outside of the United States.

2. Auxein Corporation

PP 7G4839

EPA has received a pesticide petition (7G4839) from Auxein Corporation, 3900 Collins Road, P. O. Box 27519, Lansing, MI, proposing pursuant to section 408 (d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a (d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of glutamic acid in or on snap beans, peanuts, cotton, potatoes, tomatoes, lettuce, green peppers, spinach, broccoli, cauliflower, and cabbage. Pursuant to the section 408 (d) (2) (A) (i) of the FFDCA, as amended, Auxein Corporation has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Auxein Corporation 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 the states of Alabama, Arizona, California, Florida, Georgia, Idaho, Maine, Michigan, Minnesota, Mississippi, North Carolina, North Dakota, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Washington, and Wisconsin. Crops to be treated are snap beans, peanuts, cotton, potatoes, tomatoes, lettuce, green peppers, spinach, broccoli, cauliflower, and cabbage. Depending on the crop, application is made at first bloom, first bud or at the 5-6 leaf stage. Subsequent applications, for a maximum of three (3) applications, are at 1- to 3-week intervals. The rate range is 0.125 - 0.75 pounds of formulated product /acre per treatment not to exceed a maximum of 1.5 lbs/A per growing season. The proposed EUP program would utilize 462 pounds of active ingredients (231 pounds of gamma aminobutyric acid and 231 pounds of L-glutamic acid) in

793 pounds of formulated product. A total of 822 pounds of formulated product will be shipped. A maximum of 790 acres will be treated under this EUP. The formulated product, AuxigroG5™ Plant Growth Enhancer, increases plant growth, yield and fruit quality.

B. Product Identity/Chemistry

Auxigro WP is an off-white colored, wettable powder. Auxigro contains two active ingredients: 36.5% L-glutamic acid, a key amino acid, and 29.2% gamma aminobutyric acid (GABA), a non-protein amino acid. Glutamic acid is a white, practically odorless, free flowing crystalline powder. It is slightly soluble in water, forming acidic solutions. The pH of a 1% solution of Auxigro is 4.4. The bulk density of the end-use formula is 0.52 g/ml. Glutamic acid is ubiquitous in nature and has been found in microorganisms, lower and higher plants, fish, birds, insects and mammals. Glutamate is widely available as a direct food additive and as a pharmaceutical agent. Glutamic acid is presently cleared by EPA for use as an inert ingredient in certain pesticide products.

C. Toxicological Profile

Glutamic acid is an ubiquitous and very abundant amino acid. It is found in virtually all proteins. Glutamic acid is listed as Generally Recognized as Safe the Food and Drug Administration (FDA) and is approved by the EPA as (GRAS) by an inert for seed treatment as a plant nutrient. Condensed, extracted fermentation glutamic acid is approved by the FDA for use in animal feed. Glutamic acid is highly regulated in man and other organisms, the mechanisms of which are well understood. Glutamate has been administered to numerous species in long term dietary studies without adverse effects. Auxigro, the end-use formula, has been studied for acute toxicity. Acute oral toxicity in rats is greater than 5,050 mg/kg. Acute dermal toxicity in rabbits is greater than 5,050 mg/kg. An eye irritation study using rabbits resulted in redness in one rabbit's unwashed eye, but cleared within 48 hours. Limited signs of dermal irritation cleared within 24 hours. There was no indication of dermal sensitization in a guinea pig dermal sensitization study.

D. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The

primary non-food sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.* Dietary exposure due to topical applications of GABA and glutamic acid is difficult to estimate because both chemicals are ubiquitous in nature; applications associated with the EUP would be minuscule compared to levels found in nature, and both are readily utilized by microorganisms. Furthermore, GABA and glutamic acid are presently available for direct human consumption.

2. *Non-dietary, non-occupational exposure.* Increased non-dietary exposure of GABA and glutamic acid via lawn care, topical insect repellents, etc., is not applicable to this EUP application.

E. Cumulative Exposure

Glutamic acid is ubiquitous in nature. Incremental levels of exposure resulting from this EUP program are minuscule when compared to the high levels of glutamic acid found naturally-occurring in food.

F. Endocrine Disruptors

Auxein has no information to suggest that glutamic acid will adversely affect the immune or endocrine systems.

G. Safety Considerations

Glutamic acid is available for human consumption as a food additive and pharmaceutical agent. All food contains relatively high levels of glutamic acid. Incremental exposure resulting from this EUP program is minuscule. Considering the negligible contributions to the environment resulting from the application of Auxigro, the abundance and role of glutamic acid in foods and in the human body, it can be concluded that glutamic is safe for the intended use, i.e., without measurable hazard.

H. Analytical Method

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

I. Existing Tolerances

L-Glutamic acid is presently listed as exempt from tolerances under 40 CFR 180.1001 when used as a plant nutrient for seed treatment.

Auxein is not aware of any tolerances or MRLs issued for glutamic acid outside of the United States.

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