

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0223; FRL-7315-7]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket identification (ID) number OPP-2003-0223, must be received on or before August 29, 2003.

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

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8263; e-mail address: greenway.denise@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this Action Apply to Me?*

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

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

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

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

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2003-0223. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

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

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

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

materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

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

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

C. How and to Whom Do I Submit Comments?

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

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk

or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0223. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to opp_docket@epa.gov, Attention: Docket ID Number OPP-2003-0223. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

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

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2003-0223.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2003-0223. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

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

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

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

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

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number

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

II. What Action is the Agency Taking?

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

List of Subjects

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

Dated: July 16, 2003.

Janet L. Andersen,

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

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The 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.

I. Valent BioSciences Corporation

PP 3F6586

EPA has received a pesticide petition (PP 3F6586) from Valent BioSciences Corporation, 870 Technology Way, Suite 100, Libertyville, IL. 60048, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide 6-benzyladenine (6-BA) in or on pistachio, and to amend the existing exemption (§180.1150) for apples to expand the uses and increase the application rate.

Valent BioSciences Corporation has submitted the following summary of

information, data, and arguments in support of their pesticide petition. This summary was prepared by Valent BioSciences Corporation 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

6-Benzyladenine is a naturally occurring plant growth regulator used on certain fruit trees and certain ornamental lily tubers. In January 1990, the Agency classified 6-BA as a biochemical pesticide because it resembles natural plant regulators and it displays a nontoxic mode of action. The new use being proposed for 6-BA is as an effective stand-alone fruitlet thinner when applied to apples in the post-bloom period at an application rate not to exceed 182 grams of active ingredient per acre per season (gram per active ingredient per acre per season). 6-Benzyladenine has also been shown to directly increase cell division of treated fruit, resulting in improvements in fruit size over what would be expected from the normal thinning effect. The frequency and timing of application will vary according to the specific growing conditions being treated. The second proposed new use is to reduce alternate bearing in pistachio and thus increase cumulative yield. The proposed maximum application rate for pistachio is 60 grams of active ingredient per acre per season.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* 6-Benzyladenine (*N*-(phenylmethyl)-1H-purin-6-amine) has been tested and residue data generated has been provided to EPA by Valent BioSciences Corporation.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* Trials conducted in various states (New York, Pennsylvania, Virginia, Missouri, Oregon, and Washington) and on various apple cultivars, support the proposed tolerance exemption. This data has been further supported by numerous trials carried out internationally. Residue levels following the maximum number (4) of applications on apple were very close to the limit of quantitation (LOQ) of 5 parts per billion (ppb) at normal

harvest, which averaged 80 days after the last application. Trials indicate rapid degradation of 6-BA residues among all the apple varieties and geographies evaluated.

The analytical methods for detection of 6-BA in apple raw agricultural and processed commodities are comprised of extraction, cleanup on a strong cation exchange (SCX) solid-phase extraction cartridge, derivatization and quantitation by gas chromatography (GC). These were developed by Valent BioSciences Corporation and submitted to EPA, constituting a practical analytical method for detecting and measuring levels of 6-BA in or on commodities, with a LOQ of 0.005 part per million (ppm) that allows for monitoring of food, with the residues at or above the LOQ.

Residue data on 6-BA use on pistachio has been provided to EPA by Valent BioSciences Corporation. Trials were conducted in locations representing the major pistachio production area in the United States. No residues were detected following the maximum number (2) of applications at normal harvest, which averaged 60 days after the last application.

An analytical method based on extraction, clean up and derivatization of 6-BA followed by quantitation by GC was submitted to EPA for residue determination on pistachio. This GC method is adequate for determining residues in or on pistachios with a LOQ of 0.05 ppm.

3. *Why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* Usually, a request for an exemption from the requirement of a tolerance is not accompanied by residue data and an analytical method. Valent BioSciences Corporation has provided this information to the Agency in this case. The information demonstrates that any residue is detected at levels very close to the LOQ. Although a numeric tolerance could be established, it would be very difficult to enforce, as demonstrated by the risk characterization. Valent BioSciences Corporation proposes that the submitted residue data and analytical method support their conclusion that there is a reasonable certainty that no harm to humans or the environment will result from the use of 6-BA on apples and pistachios.

C. Mammalian Toxicological Profile

1. *Acute toxicity.* The oral LD₅₀ of 6-BA is estimated by probit analysis at 1.3 gram/kilogram (g/kg) in the rat. The dermal LD₅₀ in the rabbit is >5.0 g/kg. The acute inhalation LC₅₀ in the rat is

5.2 milligrams/Liter (mg/L)/hour. A primary eye irritation study in the rabbit showed moderate conjunctival effects which cleared within 7 days. A dermal irritation study in the rabbit showed slight dermal irritation, which lasted for 5 days. Sensitization potential has been examined, and 6-BA (99% pure) was demonstrated not to be a dermal sensitizer in guinea pigs under conditions of the study.

2. *Genotoxicity.* Mutagenicity studies including Ames test, mouse micronucleus assay, and unscheduled DNA synthesis (UDS) assay in rat were negative for mutagenic effects.

3. *Developmental toxicity.* Developmental toxicity in rats fed 6-BA (99% pure) was manifested as significantly decreased fetal body weight, increased incidence of hydrocephalus and unossified sternbrae, incompletely ossified phalanges, and malaligned sternbrae at 175 milligrams/kilogram body weight/day (mg/kg bwt/day).

Maternal toxicity was also observed at 175 mg/kg bwt/day, which was manifested as significantly decreased body weight, weight gain, and food consumption. Thus the no observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) for maternal and developmental toxicity was 50 and 175 mg/kg bwt/day, respectively.

4. *Subchronic toxicity.* 6-Benzyladenine (99% pure) fed to rats for 13 weeks produced decreased weight gain at 1,500 and 5,000 ppm (121 and 322 mg/kg bwt/day) in females, and 5,000 ppm (295 mg/kg bwt/day) in males. This decreased weight gain appeared to be related to decreased food consumption. Serum alkaline phosphatase activity and blood urea nitrogen levels were increased in both sexes receiving 5,000 ppm; thus the NOAEL was 1,500 ppm (approximately 111 mg/kg bwt/day in both sexes combined) and the LOAEL was 5,000 ppm (approximately 304 mg/kg bwt/day in both sexes), based on the decreased body weight gain, food consumption, increased blood urea nitrogen, and minimal histological changes in the kidneys.

D. Aggregate Exposure

1. *Dietary exposure—i. Food.* In conducting this exposure assessment, Valent BioSciences Corporation used very conservative assumptions, 100% of all commodities were assumed to be treated, and those residues would be at twice the LOQ -- which result in a large overestimate of human exposure. The analysis assumes that all residues have the same magnitude, and the treated

commodity is 100% of a daily diet. Thus, in making a safety determination for these tolerance exemptions, Valent BioSciences Corporation took into account this very conservative exposure assessment.

The last application precedes harvest by approximately 2.5 months in apples, therefore the potential for dietary exposure is considered negligible by Valent BioSciences Corporation. Application precedes harvest by approximately 2 months in pistachios. Also pistachios have their hulls, which cover the shell, removed at harvest, therefore the potential for dietary exposure is considered negligible by Valent BioSciences Corporation. Residues are below the LOQ (LOQ = 0.05 ppm) in pistachio.

ii. *Drinking water.* The proposed uses on apples and pistachios are not expected to add potential exposure to drinking water. Soil leaching studies have suggested that 6-BA is relatively immobile, absorbing to sediment. Residues reaching surface waters from field runoff should quickly absorb to sediment particles and be partitioned from the water column. 6-Benzyladenine also has low solubility in water, 0.061 mg/mL, and detections in ground water are not expected. Valent BioSciences Corporation concludes that together these data indicate that residues are not expected in drinking water.

2. *Non-dietary exposure.* The proposed uses involve application of 6-BA to crops grown in an agricultural environment. The only non-dietary exposure expected is that to applicators. However, the protective measures prescribed by the product's label are expected to be adequate to minimize exposure and protect applicators of the chemical.

E. Cumulative Exposure

No cumulative adverse effects are expected from long-term exposure to this chemical. There is no reliable information to indicate that toxic effects produced by 6-BA would be cumulative with those of any other pesticide chemical.

F. Safety Determination

1. *U.S. population.* Chronic dietary exposure estimates were conducted for the overall U.S. population and 25 population subgroups, including infants and children. These estimated daily intakes were compared against a chronic population adjusted dose (PAD) based on a NOAEL of 50 mg/kg bwt/day from a developmental study in rats. To account for intraspecies and interspecies variation and the use of an

acute toxicological endpoint for a chronic assessment, an uncertainty factor (UF) of 1,000 was applied to the acute NOAEL. This resulted in a chronic PAD of 0.05 mg/kg bwt/day. Daily exposure for the overall U.S. population was estimated to be 0.000014 mg/kg bwt/day, representing less than 0.1% of the estimated chronic PAD.

2. *Infants and children.* Estimated daily exposures, assuming that 100% of the apple and pistachio commodities in the United States are treated with 6-BA, for the most highly exposed population subgroup, non-nursing infants, was estimated to be 0.000085 mg/kg bwt/day, or 0.2% of the estimated chronic PAD.

G. Effects on the Immune and Endocrine Systems

6-Benzyladenine is a naturally occurring cytokinin which has plant growth regulator properties. There is no indication that this plant growth regulator belongs to a class of chemicals known or suspected of having adverse effects on the immune and endocrine systems. It can be concluded that based upon the existing toxicology there would be no adverse effects on the immune or endocrine systems from the use of 6-BA. Last, there is no evidence that 6-BA bioaccumulates in the environment.

H. Existing Tolerances

The plant growth regulator 6-BA is exempt from the requirement of a tolerance when used as a fruit-thinning agent at an application rate not to exceed 30 grams of active ingredient per acre in or on apples.

6-Benzyladenine is temporarily exempt from the requirement of a tolerance in or on apples at ≤ 182 grams of active ingredient per acre per season, and in or on pistachio at ≤ 60 grams of active ingredient per acre per season when used in accordance with the Experimental Use Permit 73049-EUP-2. The exemption from a tolerance will expire on January 31, 2005.

I. International Tolerances

There are no codex, Canadian, or Mexican maximum residue limits for use of 6-BA on apple or pistachio. [FR Doc. 03-19280 Filed 7-29-03; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0256; FRL-7319-7]

Indian Meal Moth Granulosis Virus; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket ID number OPP-2003-0256, must be received on or before August 29, 2003.

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

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5412; e-mail address: cole.leonard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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