ENVIRONMENTAL PROTECTION AGENCY

[PF–1078; FRL–6828–9]

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 control number PF–1078, must be received on or before April 29, 2002.

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–1078 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8263; e-mail address: hollis.linda@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'' 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–1078. 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 Hwy., 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–1078 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 Hwy., 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–1078. 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 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 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: March 19, 2002.

Kathleen D. Knox,

Acting 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 section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it 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.

Valent BioSciences Corporation

PP 2G6378

EPA has received a pesticide petition (2G6378) from Valent BioSciences Corporation, 870 Technology Way, Suite 100, Libertyville, IL 60048, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180, to expand an existing tolerance exemption for the biochemical pesticide 6–benzyladenine in or on agricultural commodities apples and pistachios.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, 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–benzyladenine 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–benzyladenine (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 active ingredient/acre/season (g/ai/acre/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 g/ai/acre/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 have 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 (MI, NY, OR, PA, VA, and WA) and on various apple cultivars, support the proposed temporary exemption from the requirement of a tolerance. Residue levels following the maximum number (four) 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, derivitization and quantitation by gas chromatography (GC). These were developed by Valent BioSciences Corporation, constituting a practical analytical method for detecting and measuring levels of 6–BA in or on commodities with a limit of quantitation (LOQ) of 0.005 ppm that allows for monitoring of food, with the residues at or above the LOQ which has been submitted to EPA.

Residue data on 6–BA use on pistachio have 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 (two) of applications at normal harvest, which averaged 60 days after the last application.

An analytical method based on extraction, clean up and derivitization 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. *Analytical method.* 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 experimental use of 6–BA on apples and pistachios.

C. Mammalian Toxicological Profile

1. *Acute toxicity*. The oral LD_{50} of 6–benzyladenine is estimated by probit analysis at 1.3 grams/kilogram (g/kg) in the rat. The dermal LD_{50} in the rabbit is >5.0 g/kg. The acute inhalation LC_{50} in the rat is 5.2 milligrams/Liter/hour (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–benzyladenine (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–benzyladenine (99% pure) was manifested as significantly decreased fetal body weight (bwt), increased incidence of hydrocephaly 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 were 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 temporary 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 (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 agriculture 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 (cPAD) 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 cPAD of 0.05 mg/kg bwt/day. Daily exposure for the overall U.S. population was estimated by Valent BioSciences Corporation to be 0.000014 mg/kg bwt/day, representing less than 0.1% of the estimated cPAD.

2. *Infants and children*. Estimated daily exposures from tolerance level residues on 100% of the apple and pistachio commodities 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 cPAD.

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–benzyladenine. Last, there is no evidence that 6–benzyladenine bioaccumulates in the environment.

H. Existing Tolerances

The plant growth regulator 6–benzyladenine 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.

I. International Tolerances

There are no Codex, Canadian, or Mexican maximum residue limits for use of 6–benzyladenine on apples or pistachio.

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