www.epa.gov/pesticides/reregistration/status.htm/.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: February 28, 2005.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 05–4469 Filed 3–8–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0035; FRL–7699–4]

Benthiavalicarb-Isopropyl; Notice of Filing Petition for the Establishment of Tolerances on Imported Grapes and Tomatoes

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–2005–0035, must be received on or before April 8, 2005.

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: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@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–2005–0035. 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, 1801 S. Bell St., 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 the EPA 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. 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 on 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–2005–0035. 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–2005–0035. 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–2005–0035.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2005–0035. 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: February 18, 2005.

Betty Shackleford, Acting

Director, Registration 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 K-I Chemical U.S.A., Inc., 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.

K-I Chemical U.S.A., Inc.

PP 3E6545

EPA has received a pesticide petition PP 3E6545 from K-I Chemical U.S.A., Inc., 11 Martine Avenue, Suite 970,

White Plains, New York 10606 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, by establishing a tolerance for residues of [[isopropyl[(S)-1-[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl-2-methylpropyl]carbamate] in or on the raw agricultural commodity imported grapes at 0.5 parts per million (ppm) and on grape processed commodities juice and wine at 0.5 ppm, as well as in or on the raw agricultural commodity imported tomato at 0.5 ppm, and tomato processed commodities at 0.5 ppm. For tomato paste the proposed tolerance is 1.5 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; 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.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of benthiavalicarb-isopropyl was investigated in grapes, tomatoes, and potatoes. The rate of degradation in grapes and tomatoes is low and the unchanged parent is the major component, accounting for 90% or more of the total radioactive residue (TRR). The metabolites were below quantifiable levels in both grapes and tomatoes. Residues in foliar treated potato tubers showed more extensive metabolism with the unchanged parent accounting for only 4.7%, unidentified metabolites 76.5%, and unextracted radioactivity, 17.5%. About 21.9% of the unidentified metabolites are present as sugar conjugates. Analysis of the potato foliage from foliage treated plants indicated that 90% of the residue is unchanged parent and that no conversion to other isomers had occurred. Metabolites in the foliage were different than in the tubers and were identified as sugar conjugates of phenyl ring hydroxylated parent. The metabolism in potatoes occurs primarily via ring hydroxylation of the parent molecule. Secondary metabolism then occurs via. conjugation of sugar to the hydroxyl group. The residue of concern can be quantified as the unchanged parent.

2. *Analytical method*. The proposed residue method involves analysis by gas chromatography with a nitrogen-phosphorous detector (GC/NPD). The limit of quantification (LOQ) for all matrices, raw agricultural and relevant processed fractions, was determined to be 0.01 ppm. The method is capable of measuring the unchanged parent as well a minor isomer present in the technical. However, the minor isomer is generally present at extremely low levels, often below the LOQ. Mean recoveries ranged from a low of 77% to a high of 112%, with standard deviations ranging from 2.0 to 18.7%.

3. *Magnitude of residues*. The maximum average field trial residue measured in grapes was 0.22 ppm, although, the majority of the data at the proposed label rates was significantly below this level. The maximum residues observed in raisins and wine were 0.16 ppm and 0.08 ppm, respectively.

The maximum average residue observed in tomatoes was 0.22 ppm from trials conducted in the greenhouse. The residues observed in the field trials were significantly lower, with the residues in two of the three trials below the LOQ. The maximum residues observed in the processed commodities (all from greenhouse treated tomatoes) were as follows: Juice at 0.06 ppm, ketchup at 0.183 ppm, canned tomatoes at 0.035 ppm, and puree at 0.21 ppm.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral LD_{50} in Wistar rats is >5,000 milligrams/kilogram (mg/kg).

2. *Genotoxicity*. Benthiavalicarb-isopropyl is negative in all tests conducted:

i. Reverse mutation (*S. typhimurium* and *e. coli*).

ii. *In vitro* chromosomal aberration (CHL cells),

iii. *In vitro* mouse lymphoma (L5178Y cells),

iv. *In vitro* unscheduled DNA synthesis (UDS) (rat hepatocytes),

v. *In vivo* mouse miconucleus (mouse bone marrow),

vi. *In vivo* gene mutation assay in transgenic mice (transgenic mouse liver), and

vii. *In vivo/in vitro* UDS (rat hepatocytes).

3. *Reproductive and developmental toxicity*—i. In a 2-generation reproduction study in Sprague Dawley rats receiving 0, 100, 1,000 or 10,000 ppm benthiavalicarb-isopropyl in the diet, the parental no observed adverse effect level (NOAEL) was 100 ppm based on hepatocyte hypertrophy at the next higher dose level. The reproductive NOAEL was 10,000 ppm.

ii. In a developmental toxicity study in New Zealand White rabbits receiving 0, 10, 20 or 40 mg/kg/day benthiavalicarb-isopropyl from day 6 to 28 of gestation, the maternal NOAEL was 20 mg/kg/day based on abortion and increased liver weights at the 40 mg/kg/day dose. The developmental NOAEL was 20 mg/kg/day based on increased incidence of small fetus and delayed ossification of the hindlimb talus at 40 mg/kg/day.

iii. In a developmental toxicity study in Sprague Dawley rats receiving 0, 10, 100 or 1,000 mg/kg/day from day 7 to day 19 of gestation, the maternal NOAEL was 10 mg/kg/day based on elevated liver and adrenal weights at 100 mg/kg/day. The NOAEL for developmental toxicity was 1,000 mg/kg/day.

4. *Subchronic toxicity*. i. In the 13–week feeding study with rats the dose levels were 0, 50, 200, 5,000, or 20,000 ppm in the diet. The NOAEL was 200 ppm, equivalent to 14.1 mg/kg/day and 15.3 mg/kg/day in males and females, respectively), based on blood chemistry and organ weight changes at 5,000 ppm.

ii. In the 13–week feeding study with mice, the dose levels were 0, 50, 200, 7,000, or 20,000 ppm. The NOAEL was 200 ppm (equivalent to 33.0 mg/kg/day and 45.2 mg/kg/day in males and females, respectively, based on systemic toxicity of decreased body weights, anemias, and generalized liver toxicity at 7,000 ppm.

iii. In the 3 month dog feeding study the dose levels were 0, 40, 200, or 1,000 mg/kg/day. The NOAEL was 40 mg/kg/day based on hematological and clinical chemistry changes, organ weight changes and the findings of hepatocyte hypertrophy and pigmentation in the spleen at 200 mg/kg/day.

5. *Chronic toxicity*. i. In a chronic/oncogenicity study Fisher rats received 0, 50, 200, 5,000, or 10,000 ppm of benthiavalicarb-isopropyl for up to 104 weeks. The NOAEL was 200 ppm (9.9 mg/kg/day and 12.5 mg/kg/day in males and females respectively), based on a variety of toxic effects, primarily in the liver and kidney, and adenocarcinomas of the *uterus* at 5,000 ppm.

ii. In an oncogenicity study in mice, the dietary doses were 0, 20, 100, 2,500 or 5,000 ppm. The NOAEL was 100 ppm (13.7 mg/kg/day and 18.6 mg/kg/day in males and females, respectively) based on a variety of toxic effects, primarily in the liver and kidney, and hepatocellular blastoma and carcinoma at 2,500 ppm.

iii. In a 52–week study with Beagle dogs, the dietary dose levels were 0, 4, 40, or 400 mg/kg/day. The NOAEL was 40 mg/kg/day based on increased liver weights in males and females at 400 mg/kg/day.

iv. Numerous supplemental mechanistic studies in the rodent were carried out to further elucidate the mechanisms involved in tumor formation in the lifetime rodent studies. These studies indicated that

benthiavalicarb-isopropyl behaves like a promotor following initiation with diethylnitrosamine (DEN), and does not have initiating activity. The compound did not cause oxidative damage in studies on rat or mouse liver, was a slight enzyme inducer, and did not cause hepatocyte proliferation.

6. *Animal metabolism*. Benthiavalicarb-isopropyl is rapidly absorbed at the dose levels tested in both sexes. The distribution of radioactivity was generally throughout the body, with the liver having the highest levels at all time points. Excretion was predominantly via the bile. The metabolism was complex. The predominant routes of metabolism were gluthione conjugation or hydroxylation on the benzene or valyl moieties. This resulted in a large number of metabolites, many present only in small quantities.

7. *Metabolite toxicology*. It was concluded that no specific metabolite toxicity studies were needed.

8. *Endocrine disruption*. Benthiavalicarb-isopropyl was tested for its potential to induce hormomimetic effects in ovariectimized rats, potential effects on estradiol, progesterone, LH and aromatase activity in the rat, and potential effects on thyroid hormones in the rat and mouse. Under the conditions of these studies, no endocrine disrupting activity was displayed.

C. Aggregate Exposure

1. *Dietary exposure*. There are no registered uses of benthiavalicarb-isopropyl in the United States, (U.S.) and no other tolerance petitions have been submitted to EPA for this active ingredient. Dietary exposure is limited in the U.S. to residues in/on imported grapes and tomatoes and their processed components. A Tier I exposure analysis was conducted which assumed that 100% of the imported grape and tomato products consumed in the U.S. contained residues at the proposed tolerance levels. This is a ''worst case'' scenario in two ways–the product is not and will not be registered for use in many of the countries exporting these commodities to the U.S., and it is unlikely that all residues will be at the tolerance levels. Based on the expected reference dose (RfD) of 0.1 mg/kg/day, the exposure to the general population in this worst case scenario is 0.17% of the RfD. Based on an aRfD of 0.1 mg/kg/day, the exposure to the general population in this worst case scenario is 1.18 % of the aRfD. Cancer dietary exposure estimates were also conducted, which indicate that with a very conservative Q* and linear extrapolation, the cancer risk is acceptable.

i. *Food.* This is a new chemical and there are no other food uses except for the proposed uses on grapes and tomatoes.

ii. *Drinking water*. No exposure is expected from drinking water as this is an import tolerance and no U.S. registrations are expected.

2. *Non-dietary exposure*. There are no non-occupational sources of exposure to benthiavalicarb-isopropyl for the general population due to the fact that the requested action is to establish tolerances for import purposes only.

D. Cumulative Effects

There is no evidence available to suggest that benthiavalicarb-isopropyl has a mode of action that is common with other registered pesticides. Therefore K-I Chemical U.S.A. Inc. has considered only the potential risks of benthiavalicarb-isopropyl in the exposure assessments.

E. Safety Determination

1. *U.S. population*. Using the exposure assumptions described above, based on the completeness and the reliability of the toxicity data, K-I Chemical U.S.A. has estimated that aggregate exposure to benthiavalicarb-isopropyl will utilize less than 1% of the RfD for the U.S. population. EPA generally has no concern for exposure below 100% of the RfD. Therefore, based on the completeness and the reliability of the toxicity data, and the exposure assessment discussed above, K-I Chemical U.S.A. concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of benthiavalicarb-isopropyl, including all anticipated dietary and all other non-occupational exposures.

2. *Infants and children*. Benthiavalicarb-isopropyl did not display reproductive toxicity in rats and the data show that pups are not more sensitive to the effects of the compound than adults are. The compound was not a developmental toxicant in the tests conducted, with only delayed growth due to maternal toxicity observed. The rat and rabbit developmental studies indicate that the fetuses were not more sensitive than the adults to the effects of the test compound. Therefore, no additional safety factor is needed for children.

Using the same worst case assumptions as for the general population, K-I Chemical concludes that the most sensitive population group for chronic assessment is children 1–6. The exposure to this group is 0.56% of the chronic RfD. For acute exposure assessment, the most sensitive population is non-nursing infants, with an exposure estimate utilizing about 5% of the acute reference dose. Therefore, based on the toxicity data and the worst case estimates of exposure, K-I Chemical U.S.A. concludes that there is a reasonable certainty that no harm will result to infants and to children from aggregate exposure to residues of benthiavalicarb-isopropyl, including all anticipated dietary exposure and all other non-occupational exposures.

F. International Tolerances

Currently there are no international tolerances.

[FR Doc. 05–4273 Filed 3–8–05; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0034; FRL–7698–5]

Spiromesifen; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the California Department of Pesticide Regulation to use the pesticide Spiromesifen (CAS No.283594–90–1) to treat up to 7,000 acres of pepper to control potato psyllid. The Applicant proposes the use of a new chemical which has not been registered by the EPA. EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0034, must be received on or before March 24, 2005.

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: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; fax number: (703) 308–5433; e-mail address: *pemberton.libby@epa.gov*.

SUPPLEMENTARY INFORMATION: