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–2003–0248. 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–2003–0248.

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–2003–0248. 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 is making available preliminary risk assessments that have been developed as part of EPA's process for making reregistration eligibility decisions for creosote. The Agency is providing the opportunity, through this notice, for interested parties to provide written comments and input to the Agency on the preliminary risk assessments for the chemical specified in this notice. Such comments and input could address, for example, the availability of additional data to further refine the risk assessments, or could address the Agency's risk assessment methodologies and assumptions as applied to this specific chemical. Comments should be limited to issues raised within the preliminary risk assessments and associated documents. EPA will provide other opportunities for public comment on other science issues associated with creosote. Failure to comment on any issues as part of this opportunity will in no way prejudice or limit a commenter's opportunity to participate fully in later notice and comment processes. All comments should be submitted by February 3, 2004.

List of Subjects

Environmental protection, Chemicals, Creosote, Pesticides and pests.

Dated: November 25, 2003.

Jack E. Housenger,

Acting Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 03–30270 Filed 12–4–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0276; FRL–7334–6]

Pyridalyl; 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–2003–0276, must be received on or before January 5, 2004.

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: Susan Stanton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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–2003–0276. 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 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.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 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–2003–0276. 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–2003–0276. 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–2003–0276.

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–2003–0276. 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: November 20, 2003.

Susan Lewis,

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 the Valent U.S.A. Corporation 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.

Valent U.S.A. Corporation

PP 2F6459, and PP 2E6592

EPA has received pesticide petitions (PP 2F6459, and PP 2E6592) from Valent U.S.A. Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596–8025, and IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ, 08902–3390, 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 tolerances for residues of the insecticide chemical pyridalyl, pyridine,2-[3-[2,6-dichloro-4-[(3,3-dichloro-2-propenyl)oxy]phenoxy]propoxy]-5-(trifluoromethyl), in or on the raw agricultural commodities: Cottonseed at 0.4 parts per million (ppm); vegetable, fruiting, group 8, at 1.1 ppm; vegetable, leafy, except Brassica, group 4, at 20.0 ppm; Brassica, head and stem, subgroup 5A, at 5.0 ppm; Brassica, leafy greens, subgroup 5B, at 30.0 ppm; turnip greens at 30 ppm; meat at 0.04 ppm; meat by-products at 0.05 ppm; animal fat at 1.0 ppm; and whole milk at 0.1 ppm and to establish tolerances for residues of the insecticide chemical pyridalyl, pyridine,2-[3-[2,6-dichloro-4-[(3,3-dichloro-2-propenyl)oxy]phenoxy]propoxy]-5-(trifluoromethyl) plus the metabolite S-1812-DP, 3,5-dichloro-4-[3-(5-trifluoromethyl-2-pyridyloxy)]propoxy phenol, in or on the raw agricultural commodity cotton gin by-products at 23.0 ppm. EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of pyridalyl in plants is well understood, having been investigated in cabbage, tomato, and cotton. The major residue in all crops is pyridalyl. A minor metabolic pathway in plants involves cleavage of the dichloropropenyl group to the phenol, S-1812-DP, which can be conjugated. Other minor metabolic pathways in cotton are oxidation of the dichloropropenyl group to the acid, S-1812-PhCH2COOH, and hydrolysis to give the pyridone, HTFP, which can be further hydroxylated to 3-hydroxy-5-trifluoromethylpyridone (HPDO).

2. *Analytical method*. Based on the metabolism of pyridalyl in plant and animals and the toxicology of the parent and metabolite, quantification of the parent pyridalyl and the metabolite S-1812-DP are sufficient to determine toxic residues. Practical analytical

methods for detecting and measuring levels of pyridalyl and its metabolite S-1812-DP have been developed and validated in all appropriate agricultural commodities and respective processing fractions. These analytical methods are suitable for monitoring of food with residues at the levels proposed for the tolerances. Methods have also, been developed and validated for determining pyridalyl and S-1812-DP in animal matrices. The limit of quantitation (LOQ) of pyridalyl in the crop methods are 0.02 ppm in cottonseed, 0.1 ppm in cotton gin trash, and 0.02 ppm in vegetables. The LOQs of pyridalyl in the animal methods are 0.01 ppm in milk, 0.02 ppm in tissues, liver and kidney, and 0.10 ppm in fat.

3. *Magnitude of residues*. Magnitude of residues were conducted in fruiting vegetables tomato and peppers (bell and non-bell), leafy vegetables (head and leaf lettuce, celery, and spinach), head and stem brassica vegetables (broccoli and cabbage), mustard greens, and cotton. Trials were conducted in all of the major use area for each of the crops as specified in the OPPTS Harmonized Guidelines OPPTS 860.1500 with applications at the maximum use rate for each crop. As a result of the field trials, the following tolerances for the residues of pyridalyl are proposed for each of the crop groups, crops or matrices: Cottonseed at 0.4 ppm; turnip greens at 30 ppm; vegetables, leafy, except Brassica, group 4 at 20.0 ppm; brassica, head and stem, subgroup 5A at 5.0 ppm; Brassica, leafy greens, subgroup 5B at 30 ppm; and vegetables, fruiting, group 8 at 1.1 ppm. Tolerances for the residues of pyridalyl plus the metabolite S-1812-DP are proposed for cotton gin by-products at 23.0 ppm. Processing studies were conducted with tomato and cottonseed. No tolerances are proposed for cottonseed and tomato processing commodities since no concentration factor was observed. Tolerances for residues of pyridalyl are also proposed for milk at 0.1 ppm; meat at 0.04 ppm; animal fat at 1.0 ppm; and meat by-products at 0.05 ppm.

B. Toxicological Profile

A full battery of toxicology testing including studies of acute, subchronic, chronic, oncogenicity, developmental, reproductive and genotoxicity effects is available for pyridalyl. The acute toxicity of pyridalyl is low by all routes. Subchronic and chronic studies exhibit no observed adverse effect level (NOAEL) values from a low of 3.4 milligrams/kilogram/day (mg/kg/day) (male rat combined toxicity/oncogenicity study) to 1,000 mg/kg/day (28–day dermal toxicity study). Pyridalyl is not oncogenic and the weight-of-evidence indicates it is not genotoxic. There are no developmental concerns or reproductive effects.

The lowest acute NOAEL of 50 mg/kg/day is derived from both the maternal and reproductive toxicity endpoint of the rabbit developmental toxicity study.

The lowest chronic NOAEL of 40 ppm (2.8 mg/kg/day in males) is taken from the premating growth period in the 2–generation reproduction study.

1. *Acute toxicity*. The acute toxicity of pyridalyl technical is low by all routes. Pyridalyl was not toxic when administered in limit tests orally, dermally and via inhalation to rats. It is not a skin irritant and is only a mild eye irritant. Pyridalyl was positive in skin sensitization tests. Pyridalyl and its formulated products will be placed into Toxicity Category III.

2. *Genotoxicty*. The genotoxic potential of pyridalyl was studied *in vitro* in bacteria (ames test), in mammalian cells hypoxanthine-guanine phosphoribosyl transferase (HGPRT) and mouse lymphoma L5178Y TK+/−), in the chromosome aberration assay, and *in vivo* in the unscheduled DNA synthesis (UDS) test and the mouse micronucleus test. The test systems assayed did not show any evidence of pyridalyl genotoxicity except the *in vitro* mammalian cytogenetics (chromosome aberration) assay. The weight of the evidence indicates that pyridalyl does not raise significant genotoxicity concerns.

3. *Reproductive and developmental toxicity*. Developmental effects of pyridalyl were studied in rats and rabbits and multigenerational effects on reproduction were studied in rats.

i. *Rat developmental.* In a developmental toxicity study conducted with rats, the maternal NOAEL was 10 mg/kg/day based on the non-acute effects of reduced body weight gain and food consumption. There were no developmental effects, and the developmental NOAEL is 250 mg/kg/day, the highest dose tested (HDT).

ii. *Rabbit developmental.* In a rabbit developmental toxicity study, the acute effects of maternal toxicity and decreased fetal weight was observed at 150 mg/kg/day. The maternal and developmental NOAEL is 50 mg/kg/day.

iii. *Reproduction.* In a rat reproduction study, there were no adverse effects of pyridalyl on reproductive parameters in the absence of parental toxicity. The reproductive, parental and offspring toxicity NOAEL is 40 ppm.

4. *Subchronic toxicity.* Subchronic toxicity studies have been conducted with pyridalyl in the rat, mouse, and dog.

i. *Rats.* Pyridalyl technical was tested in rats in a 3–month feeding study. Effects included decreased body weight gain, altered blood biochemistry, increased relative liver weight and histopathological changes in the liver, ovary, adrenal and lung. The NOAEL is 100 ppm (5.56 mg/kg/day in males and 6.45 mg/kg/day in females).

ii. *Mice.* A 13–week feeding study in mice was conducted. Effects included decreased body weight gain, hematological and blood biochemical effects,increased liver weight, decreased kidney and ovary weights and histopathological changes in liver, kidney, ovary and adrenal. The NOAEL is 70 ppm in males (8.169 mg/kg/day) and 700 ppm in females (86.78 mg/kg/day).

iii. *Dogs.* A 13–week oral (capsule) toxicity study was conducted in dogs. Effects included decreased body weight gain, clinical signs indicative of respiratory distress, hematological and blood biochemistry effects, increased liver, lung and kidney weights and histopathological alterations of the lung, kidney, adrenal and liver. The NOAEL was 10 mg/kg/day.

iv. *Dermal rat.* A 28–day dermal toxicity study in rats with pyridalyl did not produce any signs of dermal or systemic toxicity at 1,000 mg/kg/day, the highest dose tested (HDT).

5. *Chronic toxicity.* Pyridalyl has been tested in chronic studies with dogs, rats and mice.

i. *Rats.* In a 104–week combined chronic/oncogenicity study in rats, effects included decreased body weight gain, increased frequency of rearing (high dose females only), hematological alterations and histopathological alterations of the spleen. No oncogenicity was found. The NOAEL for this study is 100 ppm (3.4 mg/kg/day in males and 4.1 mg/kg/day in females).

ii. *Mice.* Pyridalyl was administered in the diet to mice for 78–weeks. Effects included decreased body weight gain and food consumption/efficiency, and increased liver and kidney weights. The NOAEL of the study was 50 ppm (5.04 mg/kg/day in males and 4.78 mg/kg/day in females)

iii. *Dogs.* Pyridalyl was administered for 12–months by capsule to dogs. There were alterations in blood biochemistry (alkaline phosphatase and alanine aminotransaminase) and increased liver weights. The NOAEL of the study was 20 mg/kg/day.

iv. *Carcinogenicity.* Pyridalyl did not produce carcinogenicity in chronic studies with rats or mice. Valent anticipates that the oncogenicity

classification of pyridalyl will be ''E'' (no evidence of carcinogenicity for humans).

6. *Animal metabolism.* Rats metabolize and rapidly eliminate ^{14}C S-1812. Most of the administered dose was eliminated within 48 hours mainly in the feces. There were no apparent sex-related differences in either the rate of elimination of ^{14}C S-1812 or in the metabolite distribution. There was no apparent enzymatic induction as the metabolic pattern was unchanged by multiple (14–day) administrations of ^{14}C S-1812 at 5 mg/kg/day.

7. *Metabolite toxicology.* Two metabolites of pyridalyl, 2-hydroxy-5-trifluoromethylpyridine (HTFP) and HPDO that occur in extremely low levels in plants and animals, were also tested for genetic toxicity. Each metabolite was tested in an *in vitro* bacterial (Ames test) and mammalian HGPRT assay mutagenesis assay as well as in an *in vitro* chromosome aberration test. Both metabolites were positive in the bacterial assay, but were negative in the mammalian mutagenesis assay. One metabolite, HPDO, was positive in the chromosome aberration test. The biological significance of this finding is uncertain given that only low levels of these compounds are detectible in plants or animals and that pyridalyl does not appear to be carcinogenic at high and chronic doses.

8. *Endocrine disruption.* Data from the rat reproduction and subchronic studies indicated that pyridalyl may effect lipid metabolism and, consequently, hormone levels. These *in vivo* results suggested that S-1812 may have a modulating activity on steroid biosynthesis at doses generally exceeding MTD.

To further understand these finding, two additional, non-guideline, mechanistic studies were conducted. A detailed analysis of the effect of S-1812 on serum steroid hormone levels was performed in rats exposed for 4 weeks to dose levels equivalent to those used in the rat reproduction study. And an *in vitro* study was conducted in rat primary Leydig cell and ovary cell cultures to investigate the effects of S-1812 on the production of hormones and on the activity of enzymes that catalyze sex steroid hormone biosynthesis. These studies support the conclusion that S-1812 is not an endocrine disruptor in *in vivo* mammalian systems. Although, very weak inhibition of a single steroid biosynthesis pathway was observed in the *in vitro* study, effects possibly related to this conversion in mammalian systems were observed only at dose levels that greatly exceeded the maximum tolerated dose.

C. Aggregate Exposure

1. *Dietary exposure.* Acute and chronic dietary analyses were conducted to estimate exposure to potential pyridalyl residues in or on the following crops and crop groups: Cottonseed, turnip greens, vegetables, leafy, except Brassica, group 4, Brassica, group 5 and vegetables, fruiting, group 8. using the Cumulative and Aggregate Risk Evaluation System (CARES) Version 1.3. Exposure estimates to water were made based upon modeling First Index Screening Tool Reservoir (FIRST model).

i. *Food*—a. *Acute.* The acute dietary exposure estimate of pyridalyl residues in food at the 99.9th percentile was calculated to be 43% of the acute Reference Dose (aRfD) with a margin of exposure of 235. The population subgroup with the highest exposure was non-nursing infants. The aRfD was defined as the NOAEL from a developmental toxicity study in rabbits and includes an uncertainty factor of 100 (NOAEL = 50 mg/kg body weight (bwt)/day, aRfD = 0.5 mg/kg/day).

b. *Chronic.* The chronic dietary exposure estimate of pyridalyl residues in food at the 100th percentile was calculated to be 1.4% of the chronic Reference Dose (cRfD) with a margin of exposure of 732. The population subgroup with the highest exposure was children 1–2 years old. The cRfD was defined as the NOAEL from the 2–generation reproduction study in rats including an uncertainty factor of 100 (NOAEL = 2.8 mg/kg bwt/day, cRfD = 0.028 mg/kg/day).

These values are based on proposed tolerance level residues adjusted for percentages of the crop treated. No adjustments were made for common washing, cooking or preparation practices and as such are very conservative values.

ii. *Drinking water.* Since pyridalyl is applied outdoors to growing agricultural crops, the potential exists for the parent or its metabolites to reach groundwater or surface water that may be used for drinking water. Screening Concentration in Groundwater (SCIGROW) simulation predicted zero S-1812 concentration in ground water indicating that S-1812 will not leach. This result is expected due the very high Koc value of pyridalyl. For the surface water FIRST (version 1.0) simulation produced peak day concentration (acute) of 0.15 parts per billion (ppb). The peak FIRST concentration was used for both the acute and chronic exposure assessment. Based on these modeled drinking water concentrations, the worst-case acute/chronic dietary exposure from drinking water is estimated to be negligible (0.02% of the aRfD, and 0.003% of the cRfD for children).

2. *Non-dietary exposure.* Pyridalyl is proposed only for agricultural uses and no homeowner or turf uses. Thus, no non-dietary risk assessment is necessary.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that the Agency must consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Available information in this context include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanism of toxicity and conducting cumulative risk assessments. For most pesticides, although, the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way for most registered pesticides.

E. Safety Determination

1. *U.S. population.* Using the conservative assumption described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to the proposed uses of pyridalyl will utilize at most 43% of the acute RfD and 2% of the chronic RfD for the U.S. population and is likely to be much less, as more realistic data and models are developed. The Agency has no cause for concern if total acute residue contribution is less than 100% of the aRfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure to residues of pyridalyl under the proposed use patterns.

2. *Infants and children.* The toxicological data base for evaluating prenatal and postnatal toxicity for pyridalyl is complete with respect to current data requirements. There are no special prenatal and postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 2–generation reproductive toxicity study in rats. Using the conservative

assumption described above, based on the completeness and reliability of the toxicity data, it is concluded that, aggregate exposure to the proposed uses of pyridalyl will utilize at most 43% of the aRfD for non-nursing infants (the most highly exposed subgroup) and 2% of the cRfD for children 1–2 (the most highly exposed subgroup). The drinking water contribution to dietary exposure is insignificant. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of pyridalyl.

F. International Tolerances

There are currently no international tolerances for pyridalyl.

[FR Doc. 03–30164 Filed 12–4–03; 8:45 am]

BILLING CODE 6560–50–S

EXPORT-IMPORT BANK

[Public Notice 58]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Export Import Bank of the United States.

ACTION: Notice and request for comments.

SUMMARY: The Export-Import Bank, as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before February 3, 2004 to be assured of consideration.

ADDRESSES: Direct all comments and requests for additional information to Mr. Wayne Gardella, Director Operations, Export-Import Bank of the U.S., 811 Vermont Avenue, NW., Washington, DC 20571, (202) 565–3787.

SUPPLEMENTARY INFORMATION:

Titles and Form Numbers

Application for Quotation-Export Credit Insurance, Commercial Bank Insureds, EIB 92–34;

Beneficiary Certificate and Agreement, EIB 92–37;

Application for a Financial Institution Buyer Credit Policy, EIB 92–41;

Application for Export Credit Insurance Financing or Operating Lease Coverage, EIB 92–45;

Short-Term Multi-Buyer Export Credit Insurance Policy Application, EIB 92–50;

Exporter's Application for Short-Term Single-Buyer Policy, EIB 92–64;

Broker Registration Form, EIB 92–79.

OMB Number: 3048–0009.

Type of Review: Revision and extension of expiration date.

Need and Use: The information requested enables the applicant to provide Ex-Im Bank with the information necessary to obtain legislatively required assurance of repayment and fulfills other statutory requirements. The forms encompass a variety of export credit insurance policies.

Affected Public: They affect all entities involved in the export of U.S. goods and services including exporters, banks, insurance brokers and non-profit or state and local governments acting as facilitators.

Estimated Annual Respondents: 1,762.

Estimated Time per Respondent: 1 hour.

Estimated Annual Burden: 1,762.

Frequency of Reporting or Use: Applications submitted one time, renewals annually.

Dated: November 22, 2003.

Solomon Bush,

Agency Clearance Officer.

BILLING CODE 6690–01–M