excess iodine intake for the general population are thyroiditis, goiter, hypothyroidism, hyperthyroidism, sensitivity reactions, thyroid papillary cancer, and acute responses in some individuals. There may be other unrecognized sources (i.e., in addition to food, water, and supplements) of iodine that increase the risk of adverse effects. Available evidence clearly corroborates that the adverse effects of iodine deficiency far outweigh the risks associated with the ingestion of excess iodine.

C. Aggregate Exposure

1. *Dietary exposure.* An exemption from the requirement of tolerance is proposed for iodine-potassium iodide on bananas, grapes, and melons. For purposes of assessing the potential dietary exposure to iodine, a review of the open literature has been conducted.

i. *Food.* Nearly every food (raw agricultural commodity or processed/prepared food item) contains measurable amounts of iodine. As discussed in the Residue Chemistry, Magnitude of the Residues section (A.3.), residue studies conducted to date for AJ1629 demonstrated that residues from AJ1629 in the soil-treated grapes and melons and foliar applied banana crops are virtually identical to the residues found in the control samples. Therefore, exposure to iodine through dietary intake is not expected to increase due to the use of AJ1629.

ii. *Drinking water.* An exposure assessment for drinking water is not necessary due to the proposed use pattern of iodine-potassium iodide.

2. *Non-dietary exposure.* Iodine is widely used in disinfectants, germicides, and related products. These products are readily available and have been widely used for many years. A non-dietary exposure assessment is not necessary due to the proposed use pattern of iodine-potassium iodide.

D. Cumulative Effects

To our knowledge there are currently no available data or other reliable information indicating that any toxic effects produced by iodine would be cumulative with those of other chemical compounds; thus only the potential risks of iodine have been considered in this assessment of its aggregate exposure.

E. Safety Determination

1. *U.S. population.* Iodine is a naturally occurring element, present in air, soil, water and food at levels that vary, depending on geographic location. It is ubiquitous and is found in all non-treated crops in varying amounts. Residue studies with crops from AJ1629 trials have shown that the average residues of iodine (as iodide) in treated crops are indistinguishable from residues in untreated crops. Since the dietary intake of iodine is not expected to increase because of the proposed uses of AJ1629, there is a reasonable certainty that no harm will result from its use.

2. *Infants and children.* As noted above, iodine is a naturally occurring element that infants and children will be exposed to through a variety of sources including water and food. In the U.S. iodine is a mandated nutrient in baby formula, required to be present at levels of 5 to 75 micrograms/100 kilocalories of formula. Residues from the use of AJ1629 are virtually indistinguishable from residues in untreated crops, therefore, exposure from pesticidal use will be very minimal.

F. International Tolerances

There are no known international tolerances for residues of iodine-potassium iodide in food or animal feed.

[FR Doc. 04–19620 Filed 8–26–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0270]; FRL–7675–2]

Fenhexamid; 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–2004–0270, must be received on or before September 27, 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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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. 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. Other types of entities not listed in this unit could also be affected. 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–2004–0270. 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 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–2004–0270. 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–2004–0270 . 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– 2004–0270.

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–2004–0270. 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), 21U.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: August 20, 2004.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner 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.

Interregional Research Project Number 4

PP 3E6799

EPA has received a pesticide petition (PP 3E6799) from the IR-4 Project, Center for Minor Crop Pest Management, Technology Centre of New Jersey. Rutgers, the State University of New Jersey, 681 U.S. Highway 1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.553 by establishing tolerances for residues of the fungicide, fenhexamid, (N-2,3-dichloro-4-hydroxypheny)-1-methyl cyclohexanecarboxamide), in or on the raw agricultural commodity fruit, pome, group 11 pre- and post-harvest at 10.0 parts per million (ppm) and apple, wet pomace at 25 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition. The petition summary was prepared by the registrant, Arvesta Corporation, 100 First Street, San Francisco, CA 94106.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of fenhexamid residues in plants is adequately understood.

2. *Analytical method*. An adequate method for purposes of enforcement of the proposed fenhexamid tolerances in plant commodities is available.

3. *Magnitude of residues*. The magnitude of residues for fenhexamid on the proposed commodities is adequately understood.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral toxicity study resulted in a lethal dose (LD_{50}) of > 5,000 milligrams/kilogram(mg/kg) for both sexes. The acute dermal toxicity in rats resulted in an LD_{50} of > 5,000 mg/kg for both sexes. The acute inhalation was investigated in two studies in rats. Inhalation by aerosol at the maximum technically possible concentration of 0.322 mg/liter(L) resulted in no deaths or symptoms at lethal concentration $(LC)_{50}$ > 0.322 mg/L). A dust inhalation study resulted in a LC_{50} > 5.057 mg/L. Fenhexamid was not irritating to the skin or eyes after a 4-hour exposure period. The Buehler dermal sensitization study in guinea pigs indicated that fenhexamid is not a sensitizer. Based on these results fenhexamid technical is placed in toxicity Category IV and Arvesta concludes that fenhexamid does not pose any acute dietary risks.

2. *Genotoxicity*. The potential for genetic toxicity of fenhexamid was evaluated in six assays including two Ames tests, a HGPRT forward mutation assay, an unscheduled DNA synthesis (UDS) assay, an *in vitro* chromosomal aberration assay in Chinese hamster ovary (CHO) cells, and a micronucleus test in mice. The compound was found to be devoid of any mutagenic activity in each of these assays; including those tests that investigated the absence or presence of metabolic activating systems. Arvesta believes the weight of evidence indicates that fenhexamid technical does not pose a risk of mutagenicity or genotoxicity.

3. *Reproductive and developmental toxicity*.—i. In a 2–generation reproduction study (one mating per generation), 30 Sprague-Dawley rats per sex per dose were administered 0, 100, 500, 5,000, or 20,000 ppm of fenhexamid in the diet. The reproductive toxicity no observed adverse effect level (NOAEL) was 20,000 ppm. The neonatal NOAEL was 500 ppm, and the lowest observed adverse effect level (LOAEL) was 5,000 ppm based on decreased pup body weight. The parental toxicity NOAEL was 500 ppm based on lower adult pre-mating body weights at 5,000 and 20,000 ppm, lower gestation body weights at 20,000 ppm, lower lactation body weights at 5,000 and 20,000 ppm, and statistically significant changes in clinical chemistry parameters, terminal body weights, and organ weights at 5,000 and 20,000 ppm. Based on this study, Arvesta concludes that the only toxic effects in the neonates occurred at parentally toxic doses.

ii. In rats, fenhexamid was administered by gavage at doses of 0 or 1,000 mg/kg for gestation days 6-15. No maternal toxicity, embryotoxicity, fetotoxicity, or teratogenic effects were observed at the limit dose of 1,000 mg/kg/day. Therefore, the NOAEL for maternal and developmental toxicity was 1,000 mg/kg/day.

iii. In rabbits, fenhexamid was administered by gavage at doses of 0,

100, 300, and 1,000 mg/kg for gestation days 6-18. Body weight gain and feed consumption of the dams were reduced at the two top doses. One abortion occurred in each of the top two dose groups and two total resorptions occurred in the top dose group. The placental weights were slightly decreased at 300 mg/kg/day and above. In the 1,000 mg/kg/day group, slightly decreased fetal weights and a slightly retarded skeletal ossification were observed. All other parameters investigated in the study were unaffected. Therefore, the NOAELs for maternal and developmental toxicity were 100 mg/kg/day in this study.

Based on the 2–generation reproduction study in rats, Arvesta concludes that fenhexamid should not be considered a reproductive toxicant and shows no evidence of endocrine effects. The data from the developmental toxicity studies on fenhexamid show no evidence of a potential for developmental effects (malformations or variations) at doses that are not maternally toxic. The NOAEL for both maternal and developmental toxicity in rats was 1,000 mg/kg/day, and for rabbits the NOAEL for both maternal and developmental toxicity was 100 mg/kg/day.

4. *Subchronic toxicity*.—i. Fenhexamid was administered in the diet to rats for 13 weeks at doses of 0, 2,500, 5,000, 10,000, and 20,000 ppm. The NOAEL was 5,000 ppm (415 mg/kg/day in males and 549 mg/kg/day in females). Reversible liver effects were observed at 10,000 ppm.

ii. Fenhexamid was administered in the diet to mice for approximately 14 weeks at doses of 0, 100, 1,000, and 10,000 ppm. The NOAEL was 1,000 ppm (266.6 mg/kg/day in males and 453.9 mg/kg/day in females). Increased feed and water consumption and kidney and liver effects were observed at 10,000 ppm.

iii. Fenhexamid was administered in the diet to beagle dogs for 13 weeks at doses of 0, 1,000, 7,000, and 50,000 ppm. The NOAEL was 1,000 ppm (33.9 mg/kg/day in males and 37.0 mg/kg/day in females). Increased Heinz bodies were observed at 7,000 ppm. .

5. *Chronic toxicity*—i. Fenhexamid was administered in the feed at doses of 0, 500, 3,500, or 25,000 ppm to 4 male and 4 female beagle dogs per group for 52 weeks. A systemic NOAEL of 500 ppm (an average dose of 17.4 mg/kg/day over the course of the study) was observed based on decreased food consumption and decreased body weight gain at 25,000 ppm, decreased erythrocyte, hemoglobin and hematocrit values at 25,000 ppm, increased Heinz bodies at 3,500 ppm and above, and a dose-dependent increase of alkaline phosphatase at 3,500 ppm and above. There were no treatment related effects on either macroscopic or histologic pathology.

ii. A combined chronic/oncogenicity study was performed in Wistar rats. Fifty animals/sex/dose were administered doses of 0, 500, 5,000, or 20,000 ppm for 24 months in the feed. A further 10 animals/sex/group received the same doses and were sacrificed after 52 weeks. The doses administered relative to body weight were 0, 28, 292, or 1,280 mg/kg/day for males and 0, 40, 415, or 2,067 mg/kg/day for females. The NOAEL in the study was 500 ppm (28 mg/kg/day for males and 40 mg/kg/day for females) based on body weight decreases in females at 5,000 ppm and above, changes in biochemical liver parameters in the absence of morphological changes in both sexes at 5,000 ppm and above, and caecal mucosal hyperplasia evident at 5,000 ppm and above.

The NOAEL in the chronic dog study was 17.4 mg/kg/day based on body weight, hematology and clinical chemistry effects. The lowest NOAEL in the 2-year rat study was determined to be 28 mg/kg/day based on body weight, clinical chemistry parameters in the liver, and caecal mucosal hyperplasia.

6. *Animal metabolism*.—i. A lactating goat was dosed at 10 milligrams (mg) ^{14}C- fenhexamid per kilograms/bodyweight on 3 consecutive days at 24-hour intervals. Fenhexamid was rapidly and almost completely absorbed, distributed and eliminated (24.9% in urine, 38.6% in feces, and 0.03% in milk). The half-life of biliary-fecal elimination (primary pathway) was 0.5 hours. The primary residues in tissues were unreacted fenhexamid, its glucuronide derivative and the 4-hydroxy derivative.

ii. Rats were administered radiolabeled fenhexamid (a single oral low dose of 1 mg/kg, a single oral high dose of 100 mg/kg, or 15 repeated low doses of 1 mg/kg/day). Radiolabeled fenhexamid was rapidly eliminated and tissue residues declined rapidly. After 48 hours the total radioactivity residue in the body excluding the GI tract, was < 0.3% of the administered dose in all dose groups. Excretion was rapid and almost complete with feces as the major route of excretion. Approximately 62-84% of the recovered radioactivity was found in feces, and 15-36% in urine within 48 hours post-dosing. Metabolite characterization studies showed that the main components detected in excreta were the unchanged parent compound (62-75%) and the glucuronic acid conjugate of the parent compound (4-23%). The proposed major pathway for biotransformation is via conjugation of the aromatic hydroxyl group with glucuronic acid. Identification of radioactive residues ranged from 88% to 99% and was independent of dose and sex.

7. *Metabolite toxicology*. As the primary residues found in rats and goat were the parent compound fenhexamid and its glucuronic acid conjugate, no additional metabolite toxicology studies are warranted.

8. *Endocrine disruption*. Fenhexamid has no endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, reproductive, subchronic, and chronic studies.

C. Aggregate Exposure

1. *Dietary exposure*.—i. *Food*. Dietary exposure to fenhexamid is limited to the established tolerances for residues of fenhexamid on grapes (at 4.0 ppm), raisins (at 6.0 ppm), strawberries (at 3.0 ppm), almond nutmeat (at 0.02 ppm), almond hulls (at 2.0 ppm), stonefruit except plum, prune, fresh, post-harvest (at 10.0 ppm), plum, prune, dried (at 2.5 ppm); plum, prune, fresh (at 1.5 ppm); pear (at 15 ppm), bushberries (at 5.0 ppm), caneberries (at 20 ppm), pistachios (at 0.02 ppm); cucumber (at 2.0 ppm); fruiting vegetables, except non-bell peppers (at 2.0 ppm); kiwi, post-harvest (at 15.0 ppm); leafy greens, except spinach (at 30.0 ppm); and the proposed tolerances in the current submission which are as follows: Pome fruit (at 10 ppm); and apple pomace (at 25 ppm).

ii. *Drinking water*. Review of the environmental fate data indicates that fenhexamid is relatively immobile and rapidly degrades in the soil and water. Fenhexamid dissipates in the environment via several processes. Therefore, a significant contribution to aggregate risk from drinking water is unlikely.

2. *Non-dietary exposure*. There is no significant potential for non-occupational exposure to the general public. The proposed uses are limited to agricultural and horticultural use.

D. Cumulative Effects

Consideration of a common mechanism of fenhexamid toxicity is not appropriate at this time since it has a unique mode of action. Moreover, there is no significant toxicity observed for fenhexamid. Even at toxicology limit doses, only minimal toxicity is observed for fenhexamid. Therefore, only the potential risks of fenhexamid are considered in the exposure assessment.

E. Safety Determination

1. *U.S. population*. The percent of the cPAD utilized by all current uses (almonds, bushberries, caneberries, cucumbers, fruiting vegetables (except non-bell peppers), grapes, kiwifruits, leafy greens (except spinach), pears, pistachios, raisins, stonefruits and strawberries) was estimated by EPA to be 9.9% (September 26, 2003, 68 FR 55513; (FRL–7326–7)). Arvesta Corporation estimated the chronic dietary exposure to fenhexamid resulting from the use on pome fruit, using the DEEM-FCIDTM software version as had the US EPA and assuming 100 % of the crop treated and residues equal to the MRL. The percent cPAD utilized by all current and proposed uses was estimated to be 17.6%. Therefore, the estimates of dietary exposure indicate adequate safety margins for the overall U.S. population.

2. *Infants and children*. The percent of the cPAD utilized by all current uses was estimated by EPA to be 19.6% (infants < 1 year) and 21.8% (children 1 to 2 years) (September 26, 2003, 68 FR 55513; (FRL–7326–7)). Arvesta Corporation estimated the chronic dietary exposure to fenhexamid resulting from the use on pome fruit, as above. The percent cPAD utilized by all current and proposed uses was estimated to be 61.5% (infants < 1 year) and 60.0% (children 1 - 6 years). Therefore, the estimates of dietary exposure indicate adequate safety margins for children. In assessing the potential for additional sensitivity of infants and children to residues of fenhexamid, the available developmental toxicity and reproductive toxicity studies and the potential for endocrine modulation by fenhexamid were considered. Developmental toxicity studies in two species indicate that fenhexamid does not impose additional risks to developing fetuses and is not a teratogen. The 2–generation reproduction study in rats demonstrated that there were no adverse effects on reproductive performance, fertility, fecundity, pup survival, or pup development at non-maternally toxic levels. Maternal and developmental NOAELs and LOAELs were comparable, indicating no increase in susceptibility of developing organisms. No evidence of endocrine effects was noted in any study. Arvesta Corporation therefore concludes that fenhexamid poses no additional risk for infants and children and no additional uncertainty factor is warranted.

F. International Tolerances

International tomato tolerances are in effect in France, Germany, Greece, Italy, Slovenia, Spain, Turkey (1 ppm) and other EU countries (2 ppm). Kiwi tolerances are as follows: Greece, Italy and Slovenia (10 ppm). Stonefruit tolerances already exist in the USA for pre-harvest applications as well as in Canada (6 ppm), Austria (cherry, 5 ppm; plum, 2 ppm); Belgium (cherry, 5 ppm); Germany and Slovenia (cherry, 5 ppm; peach and plum, 2 ppm), Italy (cherry, 5 ppm; apricot, peach and plum, 2 ppm); Japan (peach, 1 ppm), Switzerland (cherry, 2 ppm) and the UK (plum, 1 ppm) and other EU countries (peach and plum, 1 ppm; cherry, 5 ppm)

[FR Doc. 04–19614 Filed 8–26–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0288; FRL–7676–3]

Clofentezine; 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–2004–0288, must be received on or before September 27, 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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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. 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. Other types of entities not listed in this unit could also be affected. 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–2004–0288. 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