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)

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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

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–2004–0288. 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–2004–0288. 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–2004–0288.

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–2004–0288. 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 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.

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 section 408(d)(3) of the FFDCA. 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 4E6824

EPA has received a pesticide petition (PP 4E6824) from the Interregional Research Project Number 4 (IR-4), 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 180.446 by establishing a tolerance for residues of the miticide, clofentezine, (3,6-bis (2-chlorophenyl)-1,2,4,5-tetrazine) in or on the raw agricultural commodity persimmon at 0.05 parts per million (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. The registrant, Makhteshim-Agan of North America, Inc., New York, NY 10176 has prepared this summary in support of the pesticide petition. This summary does not necessarily reflect the findings of EPA. Additional data may be needed before EPA rules on the petition.

Clofentezine is marketed in the U.S. under tradenames including APOLLO SC. APOLLO®SC Ovicide/Miticide (42% active ingredient (a.i.)) is registered for use on apples, pears, almonds, walnuts, apricots, cherries, nectarines, and peaches to control European red mites and several spider mite species (tolerance for grapes is pending, petition 0F6119). APOLLO SC is an environmentally friendly, IPM-compatible product used at low dose rates, and only once per season. The product has been shown to be relatively non-toxic in studies conducted on mammals, fish, birds, aquatic invertebrates, predacious and other beneficial mites, bees, algae, and plants.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of clofentezine residues in plants is adequately understood. The metabolism of clofentezine has been studied in three crops representative of the use pattern for APOLLO SC: Apples (pome fruit), peaches (stone fruit), and grapes (vines/small fruit). In each case, unchanged clofentezine was the major extractable residue present. Non-extractable residues (fiber-bound) were negligible. Minor amounts of 2-chlorobenzonitrile, the major photo-degradation product, were detected, predominantly on the fruit surface. Dissipation of this component may be a significant route in the degradation of clofentezine on the surface of these crops. The nature of the residue in grapes, and in all the other registered crops, is therefore adequately understood. The residue of concern is the parent, clofentezine.

2. *Analytical method*. An adequate method for purposes of enforcement of the proposed clofentezine tolerance is available. An independent method validation was successfully completed, and the method was found acceptable. An extensive database of method validation data using this method on various crop commodities is available. The Limit of Quantitation (LOQ) and Minimum Detection Limit (MDL) were determined to be 0.01 ppm and 0.003 ppm, respectively. The method was forwarded to FDA for inclusion in PAM-II.

3. *Magnitude of residues*. Residue data covering the major growing area for persimmon has been submitted in support of the requested tolerance. The magnitude of residues for the proposed tolerance is adequately understood. The results demonstrate that the maximum residue of clofentezine in or on persimmon was 0.0305 ppm, measured 133 to 140 days after application (0.25 pounds active ingredient (lb a.i.)/acre).

B. Toxicological Profile

The toxicology of clofentezine has been thoroughly evaluated by EPA as part of previous regulatory actions. The studies are considered to be valid, reliable and adequate for the purposes of evaluating potential health risks and for establishing tolerances. The primary studies submitted in support of the registration of clofentezine are summarized below.

1. *Acute toxicity*. Clofentezine has a relatively low degree of acute toxicity and irritation potential. It is classified as toxicity category III for oral, dermal and inhalation toxicity, and toxicity category IV for eye and skin irritation. The acute oral lethal dose (LD_{50}) of clofentezine was determined to be >5,200 milligrams/kilograms (mg/kg) in rats and mice, >3,200 mg/kg in hamsters, and >2,000 mg/kg in beagle dogs. The acute rat dermal LD_{50} was >2,100 mg/kg. Clofentezine is considered to be practically non-irritating to eyes and skin but is considered to be a week skin sensitizer in the guinea pig maximization assay.

APOLLO SC is classified as toxicity category IV for oral toxicity and skin irritation, and as toxicity category III for dermal toxicity and eye irritation. The

acute oral LD_{50} of APOLLO SC was determined to be >5,000 mg/kg in rats; the acute dermal LD_{50} in rats was >2,400 mg/kg. APOLLO SC is considered slightly irritating to eyes and skin.

2. *Genotoxicity*. No evidence of genotoxicity was noted in a battery of *in vitro* and *in vivo* studies. Studies submitted included Ames *Salmonella* and mouse lymphoma gene mutation assay, a mouse micronucleus assay, a rat dominant lethal assay, and a gene conversion and mitotic recombination assay in yeast. Therefore, the registrant concludes that clofentezine has no potential to induce genotoxicity.

3. *Reproductive and developmental toxicity*. A multigeneration rate reproduction study was conducted at dietary concentrations of 0, 4, 40, and 400 ppm. The parental no observed adverse effect level (NOAEL) was 40 ppm based on slightly reduced body weights, increased liver weights and hepatocellular hypertrophy at 400 ppm. No treatment-related reproductive effects were noted at any dose level.

In a rat developmental toxicity study, clofentezine was administered by gavage at dose levels of 0, 320, 1, 280 and 3,200 mg/kg/day during gestation days 6 to 20. Evidence of maternal toxicity was noted at 3,200 mg/kg/day and consisted of decreased weight gain, increased liver weights and centrilobular hepatocellular enlargement. No developmental effects were observed at any dose level.

In a rabbit developmental toxicity study, clofentezine was administered by gavage at dose levels of 0, 250, 1,000 and 3,000 mg/kg/day during gestation days 7 to 28. Slight maternal toxicity (decreased maternal food consumption and weight gain) and a slight decrease in fetal weight were noted at 3,000 mg/kg/day. Thus, the NOAEL was considered to be 1,000 mg/kg/day for both maternal and developmental effects.

4. *Subchronic toxicity*. In a preliminary 90-day feeding study designed to select a suitable high dose level for a subsequent chronic rate study, clofentezine was administered to rats at dietary concentrations of 0, 3,000, 9,000 and 27,000 ppm. A significant reduction in weight gain was noted at 9,000 and 27,000 ppm. In addition, a marked, dose-related hepatomegaly and centrilobular hepatocyte enlargement was noted in all treatment groups.

In a subsequent 90-day feeding study, clofentezine was administered to rats at dietary concentrations of 0, 40, 400, and 4,000 ppm. Slightly reduced weight gain, alterations in several clinical pathology parameters, increased liver, kidney and spleen weights, and centrilobular hepatocyte enlargement were noted at 400 and/or 4,000 ppm. Thus, 40 ppm (2.8 mg/kg/day) was considered to be the NOAEL for this study.

Clofentezine was administered to beagle dogs for 90 days at dietary concentrations of 0, 3,200, 8,000 and 20,000 ppm. Increased liver weights were noted at all dose levels but no histopathological changes nor any other treatment-related effects were observed.

5. *Chronic toxicity*. In a 12-month feeding study, clofentezine was administered to beagle dogs at dietary concentrations of 0, 50, 1,000, and 20,000 ppm. An increase in adrenal and thyroid weights, as well as moderate hepatotoxicity consisting of minimal periportal hepatocyte enlargement with cytoplasmic eosinophilia, hepatomegaly and increased plasma cholesterol, triglycerides and alkaline phosphatase levels, were noted at 20,000 ppm. Evidence of slight hepatotoxicity was also noted at 1,000 ppm. Thus, the NOAEL for this study was considered to be 50 ppm (1.25 mg/kg/day).

In a 27-month feeding study, clofentezine was administered to rats at dietary concentrations of 0, 10, 40, and 400 ppm. Effects noted at 400 ppm were limited to the liver and thyroid, primarily of males, and consisted of increased liver weights, a variety of microscopic liver lesions (centrilobular hepatocyte hypertrophy and vacuolation, focal cystic hepatocellular degeneration and diffuse distribution of fat deposits), increased serum thyroxine levels, and a slight but statistically significant increase in the incidence of thyroid follicular cell tumors. The NOAEL was considered to be 40 ppm (2 mg/kg/day).

Clofentezine was not oncogenic to mice when administered for 2 years at dietary concentrations of 0, 50, 500, and 5,000 ppm. Decreased weight gain, increased liver weights, and increased mortality were noted at 5,000 ppm. An increased incidence of eosinophilic or basophilic hepatocytes was noted at 5,000 ppm, and possibly 500 ppm.

Numerous studies were conducted to investigate the mechanism for the increased incidence of male thyroid follicular tumors that was observed in the chronic rat study. These studies suggest that the tumors may have been caused by increased thyroid stimulating hormone (TSH) levels, which, in turn, resulted from clofentezine's liver toxicity, and were not attributable to a genotoxic mode of action.

6. *Animal metabolism*. The metabolism, tissue distribution and excretion of clofentezine have been evaluated in a number of species. In all species, almost all of the administered dose was recovered within 24 to 48 hours after treatment, primarily via the feces. The major route of metabolism was found to be ring hydroxylation, sometimes preceded by the replacement of a chlorine atom with a methyl-thio group. Blood and tissue levels in the fetuses of pregnant rats that had been treated with clofentezine were much lower than the levels found in the mother, indicating that clofentezine does not readily pass across the placenta. In addition, less than 1% of the administered dose was absorbed through the skin of rats following a 10-hour exposure to the end use formulation of clofentezine, APOLLO SC.

Following oral dosing of a cow and three goats with 14C-labeled clofentezine, the residue in milk was identified as a single metabolite, 4-hydroxyclofentezine. Similarly, 4-hydroxyclofentezine has been shown to be the only metabolite present in fat, liver, and kidney. No unchanged clofentezine or other metabolites were found. Therefore, the nature of the residue in animals is adequately understood. The residues of concern in ruminant commodities and milk are the combined residues of the parent, clofentezine, and the 4-hydroxyclofentezine metabolite.

7. *Metabolite toxicology*. There are no metabolites of toxicological concern and therefore, no metabolites need to be included in the tolerance expression and require regulation.

8. *Endocrine disruption*. Except for the thyroid mechanistic studies mentioned above, no special studies have been conducted to investigate the potential of clofentezine to induce estrogenic or other endocrine effects. However, the standard battery of required toxicity studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. Repeated dose studies are generally considered to be of substantial value as a means for detection of any endocrine effects. However, with the exception of a slightly increased incidence of thyroid tumors in male rats, no such effects were noted in any of the repeated dose toxicity studies with clofentezine. The male rat is known to be much more susceptible than humans to the carcinogenic effects resulting from thyroid hormone imbalance and/or increased levels of TSH. Therefore, the alterations in thyroid hormone and subsequent thyroid pathological

changes, which have been noted following administration of high doses of clofentezine, are considered to be of minimal relevance to human risk assessment, particularly considering the low levels of clofentezine to which humans are likely to be exposed.

C. Aggregate Exposure

1. *Dietary exposure*. Current tolerances (40 CFR 180.446) have been established for almonds (hulls, nutmeat), apples (fruit, pomace), apricots, cherries, nectarines, peaches, pears, walnuts, ruminant commodities, and milk. There is also a proposed tolerance for grapes pending (PP OF6119). A notice of filing for grapes was published in the **Federal Register** of July 12, 2000 (65 FR 43004; FRL–6591–8). In addition to the registered and pending uses, this notice of filing includes exposure assessments for potential residues of clofentezine in or on persimmon. Presently and in the future, clofentezine is not considered for residential uses. Thus, potential sources of non-occupational exposure to clofentezine would consist only of any potential residues in food and drinking water. No acute dietary assessments were conducted since no appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies. Therefore, only chronic exposure calculations were compared against the chronic RfD of 0.0125 mg/kg/day.

i. *Food*. A conservative dietary exposure assessment was performed for clofentezine using Exponent's Dietary Exposure Evaluation Model (DEEM) software, and consumption data derived from the 1994–1996 USDA Continuing Surveys of Food Intake by Individuals (CSFII). This assessment used all existing and proposed tolerances, residue levels at current and proposed tolerance levels, and percent crop treated (PCT) data based on the following assumptions: 24% apples, 0% apricots, 6% cherries, 30% nectarines, 12.2% peaches, 16% pears, 1.4% plums and prunes, 9.2% almonds, 7.4% walnuts, and 25% for grapes and 25% persimmon. The PCT data for current uses are in agreement with USEPA earlier assessment for clofentezine (April 19, 1999, 64 FR 19042; FRL–6075–6).

Based on these assumptions, the chronic dietary exposure estimates (DEEM) from the existing and proposed tolerances are well below the chronic RfD, ranging from 2.7% to 10.3% of the cRfD for the U.S. and its subpopulations.

ii. *Drinking water*. Sufficient ground or surface water monitoring data are not available to perform a quantitative risk assessment for clofentezine at this time. However, in the final rule published in the **Federal Register** on April 19, 1999 (see cite above), EPA previously determined estimated drinking water environmental concentrations (DWECs) for clofentezine in ground and surface water using available environmental fate data and the screening model for ground water (SCI-GROW) and the generic expected environmental concentration (GENEEC) model for surface water. The DWEC of clofentezine in groundwater was estimated to be 0.04 parts per billion (ppb) using SCI-GROW, and the chronic DWEC for surface water was estimated to be 0.3 ppb using GENEEC. EPA's policy allows the 90/56-day GENEEC value to be divided by 3 to obtain a value for chronic risk assessment calculations. Therefore, a surface water estimate of 0.1 ppb was used in the chronic risk assessment.

2. *Non-dietary exposure*. Not applicable.

3. *Chronic exposure (diet plus water)*. EPA uses the Drinking Water Level Of Comparison (DWLOC) as a theoretical upper limit on a pesticide's concentration in drinking water when considering total aggregate exposure to a pesticide in food, drinking water, and residential uses (not applicable for this assessment). DWLOCs are not regulatory standards for drinking water. However, EPA uses these values in the risk assessment process as a point of comparison against conservative model estimates of a pesticide's concentration in water. To calculate the DWLOC for chronic exposure relative to a chronic toxicity endpoint, the chronic dietary exposure analysis (DEEM) was subtracted from the RfD to obtain the acceptable chronic exposure to clofentezine in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption factors. If the DWLOC exceeds the DWEC value then there is reasonable certainty that no harm will result from the aggregate exposure.

The estimated average concentration of clofentezine in surface drinking water (0.1 ppb) is far below the range of calculated DWLOCs: 442 ppb (U.S. population), 233 ppb (children 1-6 years) and 117 ppb (All infants < 1 year, and Non-nursing infants). Therefore, Makhteshim-Agan believes there is reasonable certainty that no harm will result from aggregate exposure to residues arising from all current and proposed clofentezine uses.

D. Cumulative Effects

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

E. Safety Determination

1. *U.S. population*. The toxicity and residue databases for clofentezine are considered to be valid, reliable, and essentially complete. No acute dietary assessment was conducted because there is no toxicological endpoint attributable to a single exposure. Although clofentezine has been classified by EPA as category C for oncogenicity (April 3, 1990), quantitative oncogenic risk assessment was considered inappropriate given the weight of the evidence presently supported by the Agency's position that human health risk associated with long-term exposure to clofentezine is most appropriately evaluated by a chronic RfD value derived from the 1-year dog feeding study (NOAEL of 1.25 mg/kg/day), and using a 100-fold uncertainty factor. No effect on the thyroid, including the induction of thyroid follicular cell tumors would be expected at exposure levels that did not affect the liver. Furthermore, male rats are believed to be much more susceptible than humans to this type of effect. Therefore, the registrant concludes that quantification of carcinogenic risk based on thyroid follicular cell tumors in male rats is not appropriate.

Using worst-case assumptions of 100% percent crop treated, and that all crops and animal commodities contain residues of clofentezine at the current tolerance levels data maximum percent crop treated data, the aggregate exposure of the general population to clofentezine from the established and proposed tolerances utilizes about 8.7% of the chronic RfD or 2.7% if more realistic estimates of percent crop treated data have been used. The theoretical maximum residue contribution (TMRC) for the proposed use on persimmon is negligible. There is generally no concern for exposures, which utilize less than 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime would not pose significant risks to human health. Therefore, Makhteshim-Agan concludes that there is a reasonable certainty that no harm will result to the general population from aggregate exposure to clofentezine residues.

2. *Infants and children*. The toxicology database for clofentezine regarding potential prenatal and

postnatal effects in children is complete according to existing Agency data requirements and does not indicate any developmental or reproductive concerns.

No indication of increased sensitivity to infants and children was noted in any of the studies with clofentezine. No developmental effects were noted in rats, even at a dose level (3,200 mg/kg/day) that exceeded the 1,000 mg/kg/day limit dose and produced maternal toxicity. In addition, no evidence of reproductive toxicity was noted in the rat multigeneration reproduction study. Slight developmental toxicity (decreased fetal weights) was noted in rabbits, but only at a dose level (3,000 mg/kg/day) that exceeded the EPA limit dose and also produced maternaltoxicity.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity and the completeness of the database. The toxicology database for clofentezine regarding potential prenatal and postnatal effects in children is complete according to existing Agency data requirements and does not indicate any developmental or reproductive concerns. Furthermore, the existing RfD is based on a NOAEL of 1.25 mg/kg/day (from the 1-year dog study), which is already more than 800-fold lower than the NOAEL in the rabbit developmental toxicity study. Thus, the registrant believes that the existing RfD of 0.0125 mg/kg/day is considered to be appropriate for assessing potential risks to infants and children and an additional uncertainty factor is not warranted.

Using the conservative exposure assumptions described above (proposed and current tolerances, 100% crop treated, and no adjustments for percent contribution from livestock diet), aggregate exposure to residues of clofentezine are expected to utilize about 48% of the RfD in non-nursing infants, 20% of the RfD in nursing infants, and 36% of the RfD in children aged 1 to 6 years old. Using more realistic estimates of percent crop treated, the percent of RfD utilized is less than or equal to 10% for these population subgroups. These numbers would be lowered further if anticipated residues and/or an adjustment for percent contribution from livestock diet were utilized rather than tolerance values. The residue contribution for the proposed use on persimmon is negligible. Therefore, Makhteshim-Agan concludes that there is reasonable certainty that no harm will result to infants or children from aggregate exposure to clofentezine residues.

F. International Tolerances

There are no international maximum residue levels (MRL) established for clofentezine in or on the raw agricultural commodity, persimmon.

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FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to OMB for Review and Approval

August 13, 2004.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before September 27, 2004. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Leslie.Smith@fcc.gov* or Kristy L. LaLonde, Office of Management and Budget (OMB), Room 10236 NEOB, Washington, DC 20503, (202) 395–3087 or via the Internet at *Kristy_L._LaLonde@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copy of the information collection(s) contact Les Smith at (202) 418–0217 or via the Internet at *Leslie.Smith@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1050.

Title: New Allocation for Amateur Radio Service, ET Docket No. 02–98.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions; and Individuals or household.

Number of Respondents: 5,000 respondents.

Estimated Time per Response: 20 minutes (0.3 hours).

Frequency of Response: Recordkeeping; On occasion and one-time reporting requirements; third party disclosure.

Total Annual Burden: 1,500 hours.

Total Annual Cost: None.

Privacy Impact Assessment: Yes.

Needs and Uses: On April 29, 2003, the Office of Engineering and Technology adopted a Report and Order, *Amendment of Parts 2 and 97 of the Commission's Rules to Create a Low Frequency Allocation for Amateur Radio Service,* ET Docket No. 02–98, FCC 03–105. An amateur operator holding a General, Advanced or Amateur Extra Class license may only operate on the channels 5332 kHz, 5348 kHz, 5368 kHz, 5373 kHz, and 5404 kHz. Under the following limitations: (1) A maximum effective radiated power (e.r.p.) of 50 W; and (2) single sideband suppressed carrier modulation (emission designator 2K8J3E), upper sideband voice transmissions only. For the purpose of computing e.r.p. the transmitter PEP will be multiplied with the antenna gain relative to a dipole or the equivalent calculation in decibels. Licensees using other antennas must maintain in their station records either manufacturer data on the antenna gain or calculations of the antenna gain.

The FCC has determined that the information collection requirements affect ''individuals or household'' and has included the appropriate responses to address the Privacy Impact Assessment requirements as required by OMB Memorandum M–03–22 (September 22, 2003).

OMB Control Number: 3060–0173.

Title: Section 73.1207, Rebroadcasts.

Form Number: N/A.

Type of Review: Extension of currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions.