

Department of Defense, Department of Energy, Environmental Protection Agency, Food and Drug Administration, National Institute of Standards and Technology, Nuclear Regulatory Commission, and U.S. Geological Survey are meeting to develop a joint interagency guidance manual for programs and laboratories to use when planning and implementing the analysis of environmental samples for radioactivity. The manual uses a performance based approach and will provide guidance to both project planners and laboratory personnel. The guidance is being developed as a draft document, entitled the Multi-Agency Radiation Laboratory Protocols (MARLAP) Manual, and it is anticipated that the final product will be a consensus document each agency can agree upon and adopt. Meetings of the group are open to the public on a first come, space available basis with advance registration. The agenda for this meeting will be available on the appropriate INTERNET sites listed below.

**DATES, ADDRESS, AND REGISTRATION:** A meeting will be held on February 8, 9, 10, from 9:00 AM until 5:30 PM and on February 11 from 8:30 AM until 12:30 PM. The meeting will be held at the National Institute of Standards and Technology (NIST), Gaithersburg, MD, Building 245, Room C-301. Persons wishing to attend this meeting should contact Kenneth Inn at 301-975-5541 to register. The schedule, location, and registration information for future meetings will be posted at the following INTERNET sites:

EPA <http://www.epa.gov/radiation/marlap>

DOD <http://chppm-www.apgea.army.mil/dls/marlap.htm>.

DOE <http://www.em.doe.gov/namp> (National Analytical Management Program, Office of Site Operations, EM-70)

DOE <http://tis.eh.doe.gov/oepa> (Office of Environmental Policy and Assistance, EH-41)

NRC <http://www.nrc.gov/NRC/PUBLIC/meet.html#OTHER>

**FOR FURTHER INFORMATION CONTACT:** Persons needing further information concerning this group and the work of developing the Multi-Agency Radiation Laboratory Protocols Manual should contact John Griggs, U.S. Environmental Protection Agency/ORIA, 540 South Morris Avenue, Montgomery, AL 36115-2601, (334) 270-3450.

Dated: January 21, 1999.

**Larry Weinstock,**

*Director, Radiation Protection Division, EPA Office of Radiation and Indoor Air.*

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6225-7]

### National Environmental Justice Advisory Council Workgroup on Waste Transfer Stations; Notice of Public Meeting

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of public meeting.

**SUMMARY:** The National Environmental Justice Advisory Council (NEJAC) working group on Waste Transfer Stations (WTS) and the United States Environmental Protection Agency (EPA) is sponsoring a meeting in Washington, DC on February 17, 1999. The purpose of the meeting is for the working group to gather information related to potential environmental issues related to Waste Transfer Stations nationwide. Information gathered from these hearings will be gathered in a report for recommendations to EPA from the NEJAC.

The WTS working group was formed after a NEJAC resolution calling for EPA to "examine the risks from the siting and operation of Waste Transfer Stations for the purpose of determining its regulatory responsibilities and prescribe requirements to reduce health risks associated with such facilities." The WTS working group consists of representatives of community based organizations, business interests, and elected officials from impacted communities for the purposes of advising on the design and implementation of the WTS study.

To examine waste transfer stations in New York, the working group hosted a fact-finding meeting in New York on November 10, 1998. The Washington, DC meeting will be held on February 17, 1999 at the Washington Convention Center from 8:30 to 5:30. The Washington Convention Center is located at 900 Ninth Street, NW, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Please call Kent Benjamin, Office of Solid Waste and Emergency Response at (202) 260-2822 or Nancy Wilson, Office of Solid Waste and Emergency Response at (202) 260-1910 for more information.

Dated: January 21, 1999.

**Linda Garczynski,**

*Director, Outreach and Special Projects, Office of Solid Waste and Emergency Response.*

[FR Doc. 99-1905 Filed 1-27-99; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[PF-854; FRL-6056-3]

### AgrEvo USA Company; Pesticide Tolerance Petition Filing

**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 the docket control number PF-854, must be received on or before March 1, 1999.

**ADDRESSES:** By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Peg Perreault, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW,

Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 207, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-5417; e-mail: perreault.peg@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-854] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:  
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF-854) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

#### List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 19, 1999.

**James Jones,**

*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 views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

#### AgrEvo USA Company

PP 9F3705 and 9H5572

EPA has received pesticide petitions (PP 9F3705 and 9H5572) from AgrEvo USA Company, Little Falls Center One, 2711 Centerville Road, Wilmington, DE 19808, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of clofentezine in or on the raw agricultural commodity apples at 0.5 parts per million (ppm), in the processed feed commodity wet apple pomace at 10 ppm, and in milk at 0.05 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.

APOLLO® SC Ovicide/Miticide (active ingredient clofentezine) is registered for use on apples (early season through tight cluster), pears, almonds, walnuts, apricots, cherries, nectarines, and peaches to control European red mites and several spider mite species. It is an environmentally-friendly, IPM-compatible product used at low dose rates, and only once per season. Clofentezine has been shown to be relatively non-toxic in studies conducted on mammals, fish, birds, aquatic invertebrates, predaceous and other beneficial mites, bees, algae, and plants.

On February 23, 1995, EPA conditionally approved the use of APOLLO® SC on apples (early season through tight cluster) and established a permanent tolerance for clofentezine on fresh apples of 0.01 ppm. The

registration was made permanent February 19, 1998, following the completion of a successful analytical method try-out (MTO) by EPA (at the 0.01 ppm limit of quantitation (LOQ)).

The information summarized below was previously submitted in support of the requested label amendment for use on apples with a 45 day pre-harvest interval. The studies on which this summary is based were thoroughly reviewed and approved by the Agency as part of previous regulatory actions. However, the accuracy of this summary has not been evaluated by the Agency.

Upon re-examination of this tolerance petition, AgrEvo trusts that EPA will agree that the label amendment to allow the use of APOLLO® SC (clofentezine) on apples through a 45 day pre-harvest interval would not pose a significant risk to human health, including that of infants, and children, and is in compliance with the requirements of the Food Quality Protection Act (FQPA) of 1996.

#### A. Residue Chemistry

1. *Plant metabolism.* 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 apples, and in all the other registered crops, is therefore adequately understood. The residue of concern is the parent, clofentezine.

2. *Analytical method.* EPA recently approved an analytical method for clofentezine on apples (MRID 43800801) at a LOQ of 0.01 ppm. In support of that effort, AgrEvo submitted an independent laboratory validation of the method (MRID 44038001) which involves organic extraction and then cleanup, followed by high-pressure liquid chromatography. This method is suitable for enforcement for the current registration of APOLLO® SC ovicide/miticide on apples through the tight cluster timing.

For the requested use on apples with a 45 day PHI, an analytical method similar to the above was previously approved during the review of the petition, PP 9F3705/9H5572. This method was deemed suitable for enforcement of the tolerances proposed

in the tolerance petition. Similar analytical methods suitable for enforcement purposes are available for all the other registered crops and relevant animal tissues/milk/fat.

3. *Magnitude of residues.* Extensive field residue trials have been conducted with APOLLO® SC on apples throughout the major apple-growing regions of the United States. Application through 45 days PHI at the maximum use rate resulted in residues of clofentezine on fresh apples of < 0.01 ppm to 0.44 ppm. In processing studies on apples which had been treated with APOLLO® SC at the maximum use rate through 45 days PHI, residues in the processed commodity apple juice were lower than those in the raw agricultural commodity; residues in wet apple pomace ranged from < 0.01 ppm to 0.03 ppm. In tolerance petition PP 9F3705/9H5572 tolerances were proposed and approved (although not enacted) for apples (0.5ppm), and apple pomace, wet and dry (10 ppm).

Residue trials were conducted for APOLLO® SC on pears, apricots, cherries, nectarines, peaches, almonds, and walnuts at the maximum use rates and minimum pre-harvest intervals (PHIs) throughout the major growing regions of the United States. Residues in pears ranged from < 0.01 to 0.2 ppm. Residues in stone fruit ranged from < 0.01 to 0.66 ppm. Residues on almond hulls ranged from 0.93 to 2.4 ppm, on almond nut meats from < 0.05 to 0.3 ppm, and on walnuts < 0.02 ppm. Tolerances were therefore established on pears (0.5 ppm); apricots, cherries, nectarines, and peaches (1.0 ppm); almond nutmeats (0.5 ppm); almond hulls (5.0 ppm); and walnuts (0.02 ppm).

Ruminant feeding studies were conducted to determine the magnitude of the clofentezine-derived residues in the tissues and milk of cows. Four groups of three dairy cattle were fed technical clofentezine in the diet at dose levels of 0, 10, 30, and 100 ppm over a period of 28 days. Daily milk samples were taken and at the termination of the study, the following organs were analyzed: liver, kidney, heart, muscle, peritoneal fat and subcutaneous fat. At the feeding level of 10 ppm, residues were 0.3 ppm in liver and < 0.05 ppm in kidney, milk, and other tissues. EPA established tolerances for cattle, goats, hogs, horses, and sheep as follows: 0.05 ppm in meat, fat, and meat by-products except liver; 0.4 ppm in liver; and 0.01 ppm in milk. The tolerances on meat, fat, meat by-products, and liver were also previously approved in tolerance petitions PP 9F3705/9H5572, the label amendment for use on apples through

45 days PHI. The tolerance for milk was approved (although not enacted) at 0.05 ppm in this tolerance petition.

#### 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. The conclusions presented are those determined by the Agency (as reported by the registrant).

1. *Acute toxicity.* Technical grade 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 LD<sub>50</sub> of clofentezine was determined to be >5,200 milligram/kilogram (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<sub>50</sub> was >2,100 mg/kg. Clofentezine is considered to be practically non-irritating to eyes and skin but is considered to be a weak 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<sub>50</sub> of APOLLO® SC was determined to be > 5,000 mg/kg in rats; the acute dermal LD<sub>50</sub> 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 assays, a mouse micronucleus assay, a rat dominant lethal assay, a gene conversion, and mitotic recombination assay in yeast.

3. *Reproductive and developmental toxicity.* A multigeneration rat 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 rat 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<sup>1</sup>).

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.

6. *Special studies.* 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.

7. *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 a 50 SC (50% suspension concentrate) formulation of clofentezine.

Following oral dosing of a cow and three goats with <sup>14</sup>C- 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 are the combined residues of the parent,

clofentezine, and the 4-hydroxyclofentezine metabolite.

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. These studies are generally considered to be sufficient to detect 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 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

Clofentezine is a miticide used on apples, pears, almonds, walnuts, apricots, cherries, peaches, and nectarines. Clofentezine has also been registered recently for use on ornamental plants, however, the product registered for use on ornamental plants (OVATION® miticide/insecticide) is not being marketed at this time. There are no other non-crop uses. Thus, potential sources of non-occupational exposure to clofentezine would consist only of any potential residues in food and drinking water. There are no acute toxicity concerns with clofentezine. Therefore, only chronic exposures are addressed here.

1. *Dietary exposure—Food.* A worst case dietary exposure assessment was performed for clofentezine using the Exposure® 1 software system (TAS, Inc.) and the 1977-78 USDA consumption data. This assessment assumed that 100% of all apples, pears, almonds, walnuts, apricots, cherries, nectarines, peaches, milk, and the fat, meat, and meat by-products of cattle, goats, horses, sheep, and hogs contained residues at the established and proposed tolerance levels. specify here or previously. A

more realistic assessment was also conducted using estimates of market share.

2. *Drinking water.* All EPA environmental fate data requirements have been satisfied. The potential for clofentezine to leach into groundwater was assessed in terrestrial field dissipation studies conducted in several locations and in varying soil types. Half-lives ranged from 32.4 to 83 days. No evidence of leaching of parent or degradation products was observed. Based upon these and other studies, EPA concluded that "clofentezine is a relatively short-lived, non-mobile compound which does not pose a risk to groundwater, and will not be expected to accumulate in rotational crops." Thus, the potential for finding significant clofentezine residues in drinking water is minimal and the contribution of any such residues to the total dietary intake of clofentezine will be negligible. No Maximum Contaminant Level for clofentezine has been established.

#### D. Cumulative Effects

The primary effects observed in the toxicity studies conducted with clofentezine appear to be a result of its potency as an enzyme inducer. Although many other chemicals are also known to induce microsomal enzymes, insufficient information is available at this time to determine whether or not the potential toxic effects from these chemicals are cumulative. Furthermore, realistic estimates of potential non-occupational exposure to clofentezine indicate that such exposures are minimal and far below the levels that might be expected to produce any effects. Thus, any contribution of clofentezine to cumulative risk will not be significant. Therefore, only exposure from clofentezine is being addressed at this time.

#### E. Safety Determination

1. *U.S. population.* The toxicity and residue data bases for clofentezine are considered to be valid, reliable and essentially complete. Although clofentezine has been classified by EPA as Category C for oncogenicity, quantitative oncogenic risk assessment was considered inappropriate for the following reasons:

- i. Evidence of tumors was limited to a single site in one sex of one species and occurred only at the high-dose level.
- ii. The increased incidence of thyroid follicular tumors was only marginally increased above both concurrent and historical control levels.

iii. No evidence of genotoxicity has been observed.

iv. Mechanistic data indicate that the thyroid tumors were likely a secondary, threshold-mediated effect associated with clofentezine's liver toxicity. Furthermore, humans are believed to be much less susceptible to this effect than rats. Therefore, no effect on the thyroid-pituitary axis or oncogenic response would be expected at exposure levels which did not affect the liver.

Thus, a standard margin of safety approach is considered appropriate to assess the potential for clofentezine to produce both oncogenic and non-oncogenic effects. Based on the previously described data, EPA has adopted an reference dose (RfD) value for clofentezine of 0.0125 mg/kg/day, which was calculated using the NOAEL of 1.25 mg/kg/day from the 1 year dog feeding study and a 100-fold safety factor.

Using the worst-case assumptions of 100% of crop treated and that all crops and animal commodities contain residues of clofentezine at the current tolerance levels, the aggregate exposure of the general population to clofentezine from the established tolerances utilizes about 5% of the RfD. Using more realistic estimates of percent crop treated and adjusting for contribution from livestock diet, this decreases to less than 0.5% of the RfD. Repeating these assessments with the proposed tolerances, the percent RfD for the worst case is less than 10%, and for the more realistic case the percent RfD decreases to less than 1.2%. 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, there is a reasonable certainty that no harm will result to the general population from aggregate exposure to clofentezine residues.

2. *Infants and children.* Data from rat and rabbit developmental toxicity studies and rat multi generation reproduction studies are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from prenatal and postnatal exposure to the pesticide.

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 maternal toxicity.

FFDCA Section 408 provides that EPA may apply an additional safety factor for infants and children to account for pre- and post-natal toxicity and the completeness of the data base. The toxicology database for clofentezine regarding potential pre- and post-natal 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 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 tolerances, 100% crop treated, and no adjustments for percent contribution from livestock diet), aggregate exposure to residues of clofentezine are expected to utilize about 65% of the RfD in non-nursing infants, 33% of the RfD in nursing infants, and 25% of the RfD in children aged 1 to 6 years old.

Using more realistic estimates of percent crop treated and adjusting for the percent contribution from livestock diet, the percent of RfD utilized is less than 8% for these population subgroups. These numbers would be lowered further if anticipated residues were utilized rather than tolerance values. Therefore, there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to clofentezine residues.

#### F. International Tolerances

Codex tolerances have been established for clofentezine on a wide variety of crops, including apples. The following MRLs were adopted by the Codex Committee on Pesticide Residues (CCPR) in April, 1988, except as noted in parentheses:

Commodity	MRL (mg/kg)
Cattle meat .....	0.05
Cattle, edible offal, ...	0.1
Cattle, milk .....	0.01
1Citrus fruits .....	0.5 (1995)
Cucumber .....	1.0 (1991)
Currants .....	0.01 (1993)
Eggs (poultry) .....	0.05
Grapes .....	1.0 (1995)
Pome fruits .....	0.5
Poultry, edible offal ...	0.05
Poultry meat .....	0.05
Stone fruits .....	0.2
Strawberry .....	2.0

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BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-30466; FRL-6054-1]

### Certain Companies; Applications to Register Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

**DATES:** Written comments must be submitted by March 1, 1999.

**ADDRESSES:** By mail, submit written comments identified by the document control number [OPP-30466] and the file symbols to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Environmental Protection Agency, Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the