customer. Affix the label to the item. Affix a Priority Mail Global Guaranteed sticker (Item 107RGG3X) to the front and back of a mailer-supplied package.

215.83 Customs Forms Required

The mailing label contains space for the sender to declare the contents. A separate postal customs declaration is not used.

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A transmittal letter changing the relevant pages in the International Mail Manual will be published and automatically transmitted to all subscribers. Notice of issuance of the transmittal will be published in the **Federal Register** as provided by 39 CFR 20.3.

Stanley F. Mires,

Chief Counsel, Legislative.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300843; FRL–6075–6]

RIN 2070–AB78

Clofentezine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of clofentezine in or on apples and apple pomace. AgrEvo USA Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 19, 1999. Objections and requests for hearings must be received by EPA on or before June 18, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300843], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300843], must also be submitted 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 a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300843]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Peg Perreault, 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. 209, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5417, e-mail: perreault.peg@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 28, 1999 (64 FR 4414) (FRL–6056–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP) for tolerance by AgrEvo USA Company, Little Falls Centre One, 2711 Centerville Road, Wilmington, DE 19808. This notice included a summary of the petition prepared by AgrEvo USA Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.446(b) be amended by establishing a tolerance for residues of the insecticide clofentezine, in or on apples at 0.5 parts per million (ppm) and apple pomace at 3.0 ppm.

I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of clofentezine (3,6-bis(chlorophenyl)-1,2,4,5-tetrazine) and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of clofentezine on apples at 0.5 ppm and apple pomace at 3.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by clofentezine are discussed in this unit.

1. *Acute toxicity*. Technical clofentezine has a relatively low degree of acute toxicity by the oral, dermal, and inhalation routes of exposure (Toxicity Category III for oral, dermal and inhalation toxicity). The acute oral LD_{50}

of clofentezine was determined to be > 5,200 milligrams per 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_{50} was > 2,100 mg/kg. Clofentezine is considered to be a mild eye irritant (Toxicity Category IV) and practically non-irritating to the skin (Toxicity Category IV), but is considered to be a weak skin sensitizer based on a guinea pig maximization assay.

The end-use product APOLLO SC Ovicide/Miticide (42% a.i.) is classified as Toxicity Category IV for oral toxicity and skin irritation, and as Toxicity Category III for dermal toxicity and eye irritation. APOLLO SC is considered slightly irritating to eyes and skin.

2. *Subchronic toxicity.* In a 90–day feeding study, clofentezine was administered to rats at dietary concentrations of 0, 40, 400 and 4,000 ppm. Elevated cholesterol levels, increased liver weights, increased liver-to-body-weight ratios, and centrilobular hepatocyte enlargement were noted at 400 and/or 4,000 ppm. In addition, there was a depletion of thyroid colloid in all dose groups and follicular cell hypertrophy in mid- and high dose male rats. Although present in females, the thyroid effects were less marked. All thyroid effects were reversible after the recovery period. The NOAEL for this study was considered to be 40 ppm (2.8 milligrams per kilograms per day (mg/kg/day)).

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 or any other treatment-related effects were observed.

3. *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. Treatment related effects were noted in dogs in the mid- (1,000 ppm) and high dose (20,000 ppm) groups. These effects included liver changes with hepatocyte enlargement concurrent with eosinophilic cytoplasm, increased liver weight (both sexes), increased thyroid weight (high dose males only), and increased adrenal weight (high dose females only). Also in the mid- and high dose groups elevated serum cholesterol and triglycerides were noted. There was a statistically significant increase in alkaline phosphatase in both sexes at the high dose primarily during the early part of the study and again at term in high dose males and mid- and high dose females. The NOAEL for this study was considered to be 50 ppm (~1.25 mg/kg/day[1]).

4. *Chronic toxicity/Carcinogenicity.* In a 27–month feeding study, clofentezine was administered to rats at dietary concentrations of 0, 10, 40 and 400 ppm. Treatment related effects were noted in the liver and thyroid at 400 ppm (primarily in males). These effects are discussed below. The NOAEL for this study was considered to be 40 ppm (~2 mg/kg/day).

In both the chronic (27–month) and the subchronic (1 and 3 month) feeding studies in rats, conducted with doses of clofentezine ranging from 0.43 to 1,500 mg/kg/day, non-neoplastic compound related effects were noted. Liver was the primary target organ with secondary effects to the thyroid and perturbations of the general metabolism. The induction of the liver enzyme, uridine-diphosphate-glucuronyl-transferase (UDPGT) and the subsequent increase in the metabolism and the excretion of the thyroid hormone thyroxine (T_4) reduced the availability of T_4 required for the general metabolism and the maintenance of homeostasis. The decreased levels of plasma T_4 resulted in the stimulation of the thyroid by the pituitary gland to raise the plasma T_4 levels. Thyroid changes in the form of colloid depletion, thyroid follicular cell hypertrophy and hyperplasia were observed as a means to regain the homeostasis. Body weights and body weight gains were decreased whereas liver weights were increased and hepatocellular enlargement was reported along with other observations on the liver. Increases in plasma cholesterol and triglyceride levels were also recorded with these effects supported by the liver and thyroid pathology. Cessation of dosing accompanied by a recovery period allowed for the attainment of normal physiological levels of T_4 and a reversal of the above noted changes.

Tumors of the thyroid were only recorded in male rats during chronic treatment indicating a sensitivity for this species and sex. The mode of action appears to be one of endocrine disruption and follows the generally recognized adaptive physiology of decreased plasma thyroxine levels followed by a positive feedback to the pituitary which then signals the thyroid to produce more thyroxine to raise the plasma thyroxine levels and regain the homeostasis. Structural changes in the thyroid in the manner of hypertrophy and hyperplasia of the thyroid cells then results. However, a chronic over stimulation of the thyroid from an inability to regain the normal levels of plasma thyroxine results in the transformation of cells at some unknown time point from a controlled state of hypertrophy and hyperplasia to an uncontrolled state of hyperplasia with the result of thyroid follicular cell tumor formation.

EPA has classified clofentezine as a likely human carcinogen [classification of C]. The doses in the rat study were, however, considered to be below the maximum tolerated dose (MTD) based on the results in the subchronic studies as well as little evidence of toxicity even at the high dose tested. It was concluded that a new study was not required but may be required at some future date to support the appropriate characterization and quantification of potential risks associated with the use of clofentezine. Biologically or statistically significant tumors were not observed in female rats and clofentezine was not carcinogenic to mice when administered for 2 years at dietary concentrations of 0, 50, 500 and 5,000 ppm. The NOAEL for the mouse study was 500 ppm (50.7 mg/kg/day). Mice were also much less sensitive to the effects of clofentezine as seen in the comparative values of the NOAELS. However the liver was also the target organ in the mouse as seen by histological changes. Decreases in body weight and body weight gain were also reported in mice. Non-neoplastic changes in the mouse thyroid were not remarkable. Increased mortality was observed in female mice at the highest dose tested with amyloidosis considered to be a contributing factor.

5. *Reproductive toxicity.* A 2–generation reproduction study in rats was conducted at dietary concentrations of 0, 4, 40 and 400 ppm (0, 0.2, 2, and 20 mg/kg/day). Systemic effects observed at 400 ppm were limited to minimal centrilobular hepatocyte hypertrophy in adult male rats. The parental NOAEL was considered to be at or above 400 ppm (20 mg/kg/day). There were no reproductive effects and no effects on offspring observed at any dose level. The reproductive NOAEL was considered to be at or above 400 ppm (20 mg/kg/day).

6. *Developmental toxicity.* In a rat developmental toxicity study, clofentezine was administered by gavage to female rats at dose levels of 0, 320, 1,280 and 3,200 mg/kg/day for days 7 through 20 of gestation. In dams, there was differential staining and slight enlargement of the centrilobular hepatocytes at 3,200 mg/kg/day. The maternal NOAEL was considered to be 1,280 mg/kg/day (above the limit test of 1,000 mg/kg/day). There were no developmental effects on offspring at any dose level. The developmental

NOAEL was considered to be at or above 3,200 mg/kg/day.

In a rabbit developmental toxicity study, clofentezine was administered by gavage to female rabbits at dose levels of 0, 250, 1,000 and 3,000 mg/kg/day for days 7 through 29 of gestation Evidence of maternal toxicity included body weight reduction throughout treatment and decreased maternal food consumption at the 3,000 mg/kg/day dose level. The maternal NOAEL was considered to be 1,000 mg/kg/day. Evidence of developmental toxicity included a reduced mean fetal weight reduction of 13% which occurred at 3,000 mg/kg/day. The developmental NOAEL was considered to be 1,000 mg/kg/day.

7. *Mutagenicity*. No evidence of mutagenicity 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, and a gene conversion and mitotic recombination assay in yeast.

8. *Metabolism*. Male and female rats given clofentezine technical at 1,000 mg/kg manifested peak plasma levels of between 14 and 16 ppm at 6–8 hours post dosing which then declined to 3 ppm at 24 hours post dosing. Plasma half life was approximately 3.5 hours. Whole body autoradiography of rats given a 10 mg/kg dose indicated poor gastrointestinal absorption with 60–70% of the given dose excreted in the feces during the first 24 hours and about 20% excreted in the urine. Major metabolites were 3-(2′-methyl-thio-3′ hydroxy phenyl)-6-(2′-chloro-phenyl)-1,2,4,5-tetrazine and 3-,4-, and 5-hydroxyclofentezine. Both liver and kidney had the highest tissue concentration after 72 hours.

B. Toxicological Endpoints

1. *Acute toxicity*. An acute RfD was not established. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies, including the rat and the rabbit developmental studies. The study data indicate that clofentezine does not directly affect the thyroid. It induces uridine diphosphate glucuronyl transferase (UDPGT) activity in the liver, the enzyme associated with conjugation of thyroxine (T_4 with glucuronic acid prior to the excretion of the hormone. This allows the hormone to be excreted and indicates an increased excretion rate of the hormone. There is also weak evidence that clofentezine increases biliary flow and biliary excretion of T_4. Increased excretion of T_4 reduces circulating T_4 in the blood. The reduction in circulating thyroid hormone is detected by the pituitary, which in turn stimulates the thyroid to generate more thyroid hormone through cell enlargement (hypertrophy) and an increase in the cell numbers (hyperplasia). This is a well recognized and normal adaptive mechanism reacting to decreased thyroid hormone levels resulting in the reestablishment of the homeostasis process and is not considered to be an adverse effect after a single exposure.

2. *Short- and intermediate-term toxicity.* Short- and intermediate- term dermal endpoints were selected from a 90–day rat feeding study. The NOAEL of 2 mg/kg/day and the LOAEL of 20 mg/kg/day were based on increased cholesterol, increased liver weights, thyroid colloid depletion and thyroid follicular cell hypertrophy. An inhalation endpoint was not identified. Short and intermediate term risk assessments would be required for the dermal route of exposure; however, since there are no proposed residential uses of clofentezine that will result in post-application residential exposure, a risk assessment for residential non-dietary (dermal) exposure is not required. An inhalation risk assessment is not required based on the label specified maximum of one application per year per crop, the low toxicity of the chemical, and the low maximum application rate of 8 ounces per acre.

3. *Chronic toxicity*. EPA has established the Chronic RfD for clofentezine (3,6-bis(chlorophenyl)-1,2,4,5-tetrazine) at 0.013 mg/kg/day. This Reference Dose (RfD) for dietary exposure is based on a chronic dog feeding study in which liver changes and elevated serum cholesterol, triglycerides, and alkaline phosphatase were seen at 25.0 mg/kg/day (LOAEL). The NOAEL in this study was 1.25 mg/kg/day. An uncertainty factor (UF) of 100 was applied to the NOAEL to account for both inter-species extrapolation (10) and intra-species variability (10). The chronic RfD applies to all populations.

4. *Carcinogenicity*. EPA has classified clofentezine as a likely human carcinogen (classification of C). Clofentezine causes thyroid tumors only in male rats as a result of chronic over stimulation of the thyroid. This leads to failure to elevate T_4 to physiologically normal levels and regain homeostasis as noted above in the toxicological profile section. The cancer risk was quantified using a linear low dose extrapolation method resulting in a Q* of 0.0376 $(mg/kg/day)^{-1}$ (based upon male rat thyroid follicular cell adenoma and/or carcinoma combined tumor rates).

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.446(b)) for the residues of clofentezine, in or on a variety of raw agricultural commodities and in meat at 0.05 ppm and milk at 0.01 ppm. Risk assessments were conducted by EPA to assess food exposures from clofentezine (3,6-bis(chlorophenyl)-1,2,4,5-tetrazine) as follows:

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent of crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information to conduct a routine chronic dietary exposure analysis for clofentezine based on likely maximum percent of crop treated as follows: 24% apples, 0% apricots, 6% cherries, 30% nectarines, 12.2% peaches, 16% pears, 1.4% plums and prunes, 9.2% almonds, 7.4% walnuts (walnuts were not included in the dietary exposure analysis).

The Agency believes that the three conditions, discussed in section 408

(b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which clofentezine may be applied in a particular area.

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. As previously stated, an Acute RfD was not established for clofentezine as no appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies, including the rat and the rabbit developmental studies. Therefore, an acute risk assessment was not conducted.

ii. *Chronic exposure and risk.* The chronic dietary risk assessment for clofentezine from food sources was conducted using the Chronic RfD of 0.013 mg/kg bwt/day. EPA determined that the Uncertainty Factor (UF) of 100 used to calculate the Chronic RfD is adequate for the protection of the general U.S. population including infants and children from exposure to clofentezine and that FQPA Safety Factor should be removed (refer to unit II.E. of this preamble for a detailed discussion concerning the FQPA Safety Factor with respect to clofentezine). As indicated below, the results of the chronic dietary exposure analysis indicate an acceptable chronic dietary exposure of 100% or less of the Chronic RfD for all population subgroups.

A Dietary Exposure Evaluation Model (DEEM™) analysis for clofentezine was performed in order to provide an estimate of the food exposure and associated risk for clofentezine resulting from existing tolerances and the proposed tolerance level for apples. The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–91 Nationwide Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The chronic and cancer DEEM analysis for clofentezine estimated the food exposure using ARs and PCT data for all commodities except walnuts. The chronic DEEM™ analysis used mean consumption (3 day average). EPA's level of concern for the analysis is 100% RfD. A summary of the food exposures for the U.S. general population and other subgroups is presented in the following Table 1. The other subgroups included in Table 1 represent the highest food exposures for their respective subgroups (i.e., children, females, and the other general population subgroup higher than U.S. population).

TABLE 1.—SUMMARY OF FOOD EXPOSURE AND RISK FOR CLOFENTEZINE

Subgroups	Exposure (mg/kg/day)	% RfD
U.S. Population (48 states)	0.000022	0.2
Non-Hispanic Other Than Black or White	0.000025	0.2
Non-Nursing Infants (< 1 year old)	0.00018	1.4
Females (13+ years, nursing)	0.000029	0.2

The chronic food risk does not exceed the Agency's level of concern.

iii. *Cancer risk.* The upper bound cancer risk for the U.S. population subgroup was calculated to be 8.4×10^{-7} (based on a Q_1* value of 0.0376 $(mg/kg/day)^{-1}$). EPA's level of concern for the cancer risk are risks in the range of 1×10^{-6}. The cancer risk is below the Agency's current level of concern.

2. *From drinking water.* EPA does not have sufficient ground or surface water monitoring data available to perform a quantitative risk assessment for clofentezine at this time. However, EPA determined estimated drinking water environmental concentrations (DWECs) 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 ground water was estimated to be 0.04 ppb using SCI-GROW, and the DWECs for surface water were estimated to be 6.5 ppb (acute DWEC) and 0.3 ppb (chronic DWEC) using GENEEC. EPA policy allows the 90/56–day GENECC 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.

i. *Acute exposure and risk.* Acute exposure and risk assessments are performed for a pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. As previously stated, an Acute RfD was not established for clofentezine as no appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies, including the rat and the rabbit developmental studies. Therefore, an acute risk assessment was not conducted.

ii. *Chronic exposure and chronic and cancer risk.* 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 through residential uses. DWLOCs are not regulatory standards for drinking water; however, EPA uses DWLOCs in the risk assessment process as a surrogate measure of potential exposure from drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water.

EPA has calculated DWLOCs for both chronic and cancer risks. The results are listed in the following Tables 2 and 3.

TABLE 2.— SUMMARY OF DWLOC CALCULATIONS - CHRONIC (NON-CANCER SCENARIO)

Population Subgroup[1]	Chronic (Non-Cancer) Scenario					
	RfD mg/kg/day	Food Exposure mg/kg/day	Maximum Water Exposure mg/kg/day[2]	SCI-GROW (ppb)[3]	GENEEC (ppb)	DWLOC (ppb)
U.S. Population	0.013	0.000022	0.01298	0.04	0.1	454
Non-Hispanic other than black or white	0.013	0.000025	0.01298	0.04	0.1	454
Non-Nursing Infants (< 1 yr old)	0.013	0.00018	0.01282	0.04	0.1	128
Females (13+/nursing)	0.013	0.000029	0.01297	0.04	0.1	389

[1] Population subgroups chosen were U.S. population (70 kg. body weight assumed), the Non-Hispanic subgroup (70 kg body weight assumed) which has higher dietary exposure than the U.S. population, the infant/child subgroup with the highest food exposure (10 kg. body weight assumed), and the female subgroup with the highest food exposure (60 kg. body weight assumed).
[2] Maximum Water Exposure (mg/kg/day) = RfD (mg/kg/day) - TMRC from DRES (mg/kg/day).
[3] The crop producing the highest level was used.

TABLE 3.— SUMMARY OF DWLOC CALCULATIONS - CHRONIC (CANCER SCENARIO)

Population Subgroup[1]	Chronic (Cancer) Scenario					
	Q_1*	Food Exposure mg/kg/day	Maximum Water Exposure mg/kg/day[2]	SCI-GROW (ppb)[3]	GENEEC (ppb)	DWLOC (ppb)
U.S. Population	0.0376	0.000022	0.000004	0.04	0.1	0.16

[1] Because there is a Q*, the U.S. population is the population of concern.
[2] Maximum Water Exposure (mg/kg/day) = RfD (mg/kg/day) - TMRC from DRES (mg/kg/day).
[3] The crop producing the highest level was used.

To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to clofentezine in drinking water. To calculate the DWLOC for chronic exposures relative to a carcinogenic toxicity endpoint, the chronic (cancer) dietary food exposure was subtracted from the ratio of the negligible cancer risk to the Q^* to obtain the acceptable chronic (cancer) exposure to clofentezine in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

The estimated average concentration of clofentezine in surface water is 0.1 ppb. This value is less than EPA's DWLOCs for clofentezine as a contribution to both chronic and cancer aggregate exposures (454 ppb and 0.16 ppb, respectively). Therefore, taking into account the present uses and the proposed new use, EPA concludes with reasonable certainty that residues of clofentezine in drinking water (when considered along with other sources of exposure for which EPA has reliable data) will not result in unacceptable levels of aggregate human health risk. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, DWLOCs may vary as those uses change. If additional new uses are proposed in the future, EPA will reassess the potential impacts of clofentezine on drinking water as a part of the aggregate risk assessment process.

3. *From non-dietary exposure.* Clofentezine is not registered for residential non-food use sites. Because there are no proposed residential uses of clofentezine that will result in post-application residential exposure, risk assessments for residential non-dietary exposure are not required.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether clofentezine has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, clofentezine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that clofentezine has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

Because there are no proposed residential uses of clofentezine that will result in post-application residential exposure, aggregate exposure risk assessment will be limited to food and water only. The aggregate chronic and acute risk estimate will be based on the exposure from food and water only for the most highly exposed population subgroups and the general population as appropriate. The aggregate cancer risk estimate will be based on the exposure from food and water exposure for the U.S. general population.

1. *Acute risk.* As explained previously, no toxicological endpoint attributable to a single exposure was identified, and therefore, EPA concludes

that clofentazine does not pose any significant acute risk.

2. *Chronic risk.* Using the Theoretical Maximum Residue Contribution (TMRC) exposure assumptions described in this unit, EPA has concluded that aggregate exposure to clofentezine from food will utilize 0.2 percent of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants, < 1 year old (1.4% of the RfD), discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to clofentezine in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to clofentezine residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Since there are currently no residential uses or exposure scenarios for clofentezine, no short- and intermediate-term aggregate risk is expected.

4. *Aggregate cancer risk for U.S. population.* Clofentezine has been classified as a category C carcinogen as a result of three Cancer Peer Reviews. The upper bound cancer risk for the U.S. population subgroup was calculated to be 8.4×10^{-7} (based on a Q_1* value of 0.0376 $(mg/kg/day)^{-1}$). The cancer risk is below the Agency's current level of concern. The estimated average concentrations of clofentezine in surface and ground water are less than EPA's DWLOC for clofentezine as a contribution to cancer aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of clofentezine in drinking water do not contribute significantly to the aggregate cancer human health risk at the present time considering the present uses and uses proposed in this action.
EPA bases this determination on a comparison of estimated concentrations of clofentezine in surface waters and ground waters to DWLOCs for clofentezine. The estimates of clofentezine in surface and ground waters are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, DWLOCs may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impact of clofentezine on drinking water as a part of the aggregate cancer risk assessment process.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to clofentezine residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of clofentezine, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

There are no data gaps in the consideration of FQPA safety factor. The available studies showed no evidence of an increased susceptibility of fetus/pups in the developmental toxicity or reproductive studies. There was no evidence of neurotoxicity in any of the available toxicology studies. There were no exposure or toxicity data gaps critical to the assessment of the potential hazard to infants and children. The 10x factor for infants and children was removed as there were no developmental effects on offspring in developmental rat and rabbit studies at or above the limit dose of 1.0 gram/kg/day and there were no reproductive or pre- or post-developmental effects in a two-generation study. Clofentezine is not related to any known neurotoxic agent and there is no evidence in the subchronic or chronic studies that this chemical causes neurotoxic effects. Based on the current data set no developmental neurotoxicity study was required.

In conclusion, the FQPA safety factor was removed since: (1) The toxicology database is complete; (2) there is no indication of increased susceptibility of rats or rabbit fetuses to in utero and/or postnatal exposure in the developmental and reproductive toxicity studies; (3) a developmental neurotoxicity study is not required; (4) EPA screening models are used for ground and surface source drinking water exposure assessments resulting in estimates that are upper-bound concentrations; and (5) there are currently no registered residential uses of clofentezine.

2. *Acute risk.* As explained previously, no toxicological endpoint attributable to a single exposure was identified, and therefore, EPA concludes that clofentazine does not pose any significant acute risk.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to clofentezine from food will utilize 1.4 percent of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to clofentezine in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to clofentezine residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in both plants and animals is adequately understood. In plants, the only residue

of concern is the parent, clofentezine. In animals, the residues of concern are the combined residues of the parent, clofentezine, and the 4-hydroxyclofentezine metabolite.

1. *Plants.* Apple metabolism studies with radiolabeled clofentezine were conducted. C^{14}-Clofentezine was applied to apples at doses equivalent to 1.5X and 12X the maximum proposed rate. The fruit were harvested at maturity (25 and 64 days after treatments). The apples were separated into peel and flesh, and each was analyzed for clofentezine residues. Sixty-five to 84% of the extractable activity was the parent compound, 4% was 2-chlorobenzonitrile, and 8.5% was a combination of several minor polar components (no single component was greater than 4% of the activity). Approximately 90 to 96% of the TRR remained in the peel. About 4 to 11% was fiber bound, and the remainder was solvent-extractable activity. In plants, the only residue of concern is the parent, clofentezine.

2. *Animals.* A bovine metabolism study was conducted. ^{14}C-clofentezine was orally administered to a lactating cow at a rate of 2.21 mg/kg/day over a 3–day period. In milk samples radioactivity showed up within 8 hours and by 26 hours reached approximately 0.20 ppm ^{14}C-clofentezine. The residues ranged from 0.144 to 0.175 ppm over the following 3 days. The dominant metabolite was 4-hydroxyclofentezine 75% of the TRR, the remaining 25% of the TRR was not identified. Analysis of the liver, kidneys, renal fat, subcutaneous fat, and muscle showed ^{14}C-clofentezine equivalents of 0.76, 0.36, 0.26, and 0.02 ppm, respectively. Free or unbound 4-hydroxyclofentezine comprised of 67, 83, and 90% of the liver, kidney, and fat residue. The residues of concern are the combined residues of the parent and the 4-hydroxyclofentezine metabolite.

B. Analytical Enforcement Methodology

A HPLC analytical method for the determination of clofentezine residues in/on apples was submitted with PP 3F3392. A PMV was successfully completed by ACL, and the method was found acceptable. The Limit of Quantitation (LOQ) and Minimum Detection Limit (MDL) were determined to be 0.01 ppm and 0.003 ppm, respectively. EPA concluded that the method was suitable for enforcement purposes. The method was forwarded to FDA for inclusion in PAM-II.

C. Magnitude of Residues

EPA previously determined that existing meat/milk tolerances would be adequate to support a proposed 10 ppm tolerance for apple pomace (PP 9F3705). No increases in the established meat/milk tolerances are required to support the recommended tolerance of 3.0 ppm for apple pomace.

Apple pomace does not constitute a significant portion of the poultry diet; therefore, poultry feeding studies and tolerances have not been required.

Data from a crop field trial study indicated that residues ranged from < 0.01 to 0.44 ppm. Therefore, the proposed tolerance level for apples, 0.5 ppm, is appropriate.

Processed residue data showed that clofentazine can concentrate by a factor of 5.8 in wet pomace. The appropriate tolerance level for pomace is thus 3.0 ppm (5.8 x 0.44 ppm = 2.5 ppm, rounded up to 3.0).

D. International Residue Limits

There is a Codex MRL of 0.5 ppm for the parent compound clofentezine on pome fruit at 0.5 ppm. A Canadian tolerance of 0.5 ppm has been established for clofentezine and the 2-chlorobenzoyl metabolite on apples. Tolerance compatibility problems do not exist with respect to the Codex MRL, but do exist with respect to the Canadian MRL. As EPA has concluded the submitted residue chemistry data support tolerances based on the parent only, it is not appropriate to harmonize the proposed tolerance for residues of clofentezine in/on apples with the Canadian MRL.

IV. Conclusion

Therefore, the tolerance is established for residues of clofentezine in or on apples at 0.5 ppm and apple pomace at 3.0 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by June 18, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, 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. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request 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 information 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300843] (including any comments and data submitted electronically). 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 public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specficed by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 8, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a), and 371.

2. Section 180.446 is amended as follows:

a. By adding a paragraph heading to paragraph (a).

b. By redesignating paragraphs (b) and (c) as paragraphs (a)(1) and (a)(2), respectively.

c. By amending newly designated paragraph (a)(1) by adding alphabetically to the table the commodity ''apple pomace'' and revising the tolerance for ''apples''.

d. By adding and reserving with paragraph headings new paragraphs (b), (c) and (d).

The added and revised portions read as follows:

§ 180.446 Clofentezine; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * *	* *
Apple pomace	3.0
Apples	0.5
* * *	* *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 99–9710 Filed 4–16–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300844; FRL–6075–4]

RIN 2070–AB78

Diflubenzuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) in/on rice grain at 0.02 ppm and rice straw at 0.8 ppm. Uniroyal Chemical Company, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 requesting these tolerances.

DATES: This regulation is effective April 19, 1999. Objections and requests for hearings must be received by EPA on or before June 18, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300844], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300844], must also be submitted 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 a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300844]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Rita Kumar, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–8291, e-mail: kumar.rita@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 25, 1998 (63 FR 9528) (FRL–5775–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 6G4771) from Uniroyal Chemical Company, Inc., Bethany, CT proposing to amend 40 CFR part 180 by establishing a tolerance for residues of the insect growth regulator, diflubenzuron and metabolites convertible to p-chloroaniline, expressed as diflubenzuron in or on rice at 0.02 parts per million (ppm) and rice straw at 0.8 ppm. The notice included a summary of the petition prepared by Uniroyal Chemical Company, Inc., the registrant. In the **Federal Register** of March 9, 1998 (63 FR 11445) (FRL–5777–8), a clarification of the notice of filing was published explaining that Uniroyal had submitted two petitions, 6G4771, for the establishment of a temporary tolerance in or on rice at 0.01 ppm in association with a 3,000 acre Experimental Use Permit, and 8F4925, to amend 40 CFR 180.377 to include a permanent tolerance for residues of the insect growth regulator, diflubenzuron and metabolites convertible to p-chloroaniline, expressed as diflubenzuron in or on rice at 0.02 parts per million (ppm) and rice straw at 0.8 ppm. There were no comments received in response to the notice of filing or the clarification.

I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate