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

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

[FR Doc. 98–33121 Filed 12–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300762; FRL–6048–1]

RIN 2070–AB78

Bifenthrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of bifenthrin in or on citrus, whole fruit; citrus oil; and citrus dried pulp. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide bifenthrin on citrus. This regulation establishes a maximum permissible level for residues of bifenthrin in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 2000.

DATES: This regulation is effective December 16, 1998. Objections and requests for hearings must be received by EPA on or before February 16, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300762], 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–300762], 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 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 5.1/6.1 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–300762]. 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: Barbara Madden, 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) 305–6463, e-mail: madden.barbara@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the insecticide bifenthrin in or on citrus, whole fruit at 0.03 parts per million (ppm); 0.3 ppm for citrus oil; and 0.3 ppm for citrus dried pulp. This tolerance will expire and is revoked on December 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New 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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Bifenthrin on Citrus and FFDCA Tolerances

Recently Diaprepes root weevil has spread into citrus areas in Florida. Much of the infested citrus acreage is exhibiting severe decline or is out of production. Registered controls only provide 75% control of Diaprepes root

weevil. That level of control is inadequate to prevent tree or grove losses, and contain the spread of the pest. EPA has authorized under FIFRA section 18 the use of bifenthrin on citrus for control of Diaprepes root weevils. After having reviewed the submission, EPA concurs that emergency conditions exist.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of bifenthrin in or on citrus. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on citrus after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether bifenthrin meets EPA's registration requirements for use on citrus or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of bifenthrin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Florida to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for bifenthrin, contact the Agency's Registration Division at the address provided above.

III. Aggregate Risk Assessment and Determination of Safety

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).

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 bifenthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of bifenthrin on citrus, whole fruit at 0.03 ppm; citrus oil at 0.3 ppm; and citrus dried pulp at 0.3 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 bifenthrin are discussed below.

1. *Acute toxicity*. The acute reference dose (RfD) of 0.01 milligram/kilogram/day (mg/kg/day) was established based on a maternal no observable adverse effect level (NOAEL) of 1 mg/kg/day from a developmental toxicity study in rats. At the lowest observable adverse effect level (LOAEL) of 2 mg/kg/day, tremors from day 7-17 of dosing were observed. An uncertainty factor of 100 (10X for inter-species extrapolation and 10X for intra-species variability) was applied to the NOAEL of 1 mg/kg/day to calculate the acute RfD of 0.01 mg/kg/day. EPA has determined that the 10X factor to account for enhanced susceptibility of infants and children (as required by FQPA) can be removed. This determination is based on the results of reproductive and developmental toxicity studies. No evidence of additional sensitivity to young rats or rabbits was observed following pre- or post-natal exposure to bifenthrin.

2. *Short - and intermediate - term toxicity*. The maternal NOAEL of 1 mg/kg/day from the oral developmental toxicity study in rats (discussed in Unit A. 1. of this preamble) was also identified as the toxicological endpoints for short- or intermediate-term dermal and inhalation toxicity. A dermal absorption rate of 25%, based on the weight-of-the-evidence available for structurally-related pyrethroids, is appropriate for dermal risk assessments. One-hundred percent absorption is assumed for inhalation risk assessments. Margin of exposures (MOEs) of 100 or greater to account for inter-species extrapolation (10X) and for intra-species variability (10X) are acceptable.

3. *Chronic toxicity*. EPA has established the chronic RfD for bifenthrin at 0.015 mg/kg/day. This RfD is based on the NOAEL of 1.5 mg/kg/day from a chronic toxicity study in dogs. Tremors in both sexes of dogs were observed at the LOAEL of 3.0 mg/kg/day. An uncertainty factor of 100 to account for inter-species extrapolation and intra-species variability was applied to the NOAEL. As discussed in Unit A. 1. of this preamble, EPA has determined that the 10X factor to account for enhanced susceptibility of infants and children can be removed.

4. *Carcinogenicity*. Bifenthrin has been classified as a Group C chemical (possible human carcinogen) based upon urinary bladder tumors in mice. No Q* was assigned because the RfD approach was recommended for cancer risk assessment. Based on this recommendation, a quantitative dietary cancer risk assessment was not performed since, dietary risk concerns due to long-term consumption of bifenthrin are adequately addressed by the chronic exposure analysis using the RfD.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin, in or on a variety of raw agricultural commodities. Tolerances, in support of registrations, currently exist for residues of bifenthrin on hops; strawberries; corn grain, forage, and fodder; cotton seed; and livestock commodities of cattle, goats, hogs, horses, sheep, and poultry. Additionally, time-limited tolerances associated with emergency exemptions have been established for broccoli, cauliflower, cucurbits, and canola. Risk assessments were conducted by Novigen Sciences, Inc., and reviewed by EPA, to assess dietary exposures and risks from bifenthrin as follows:

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. An acute dietary (food) risk assessment was submitted by the petitioner where the Novigen DEEM (Dietary Exposure Evaluation Model) system Tier 3 (Monte Carlo) approach was used. This methodology incorporates distributions of residues and refined percent of crop treated estimates for some crops, and thus results in refined risk estimates. For citrus, it was assumed 100% crop treated and half of the limit of detection (LOD) value, (0.01 ppm) was used in this Monte Carlo analysis. This acute dietary exposure analysis from food sources was conducted using the acute RfD of 0.01 mg/kg/day. The analysis evaluated individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulated exposure to bifenthrin for each commodity and expresses risk as a function of dietary exposure. For the most highly exposed population subgroup, Children 1-6 years old, the resulting high-end exposure (at the 99.9th percentile) results in a dietary (food only) percentage of the acute RfD at 80%. For the overall U.S. Population, the high-end exposure (99.9th percentile) percentage of the acute RfD is 50%.

ii. *Chronic exposure and risk.* This chronic dietary exposure analysis from food sources was conducted using the chronic RfD of 0.015 mg/kg bwt/day. In conducting this chronic dietary (food only) risk assessment, the petitioner used anticipated residue field trial values and percent crop treated information. A mean field trial residue value for citrus of 0.005 ppm was used. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to bifenthrin for each commodity and expresses risk as a function of dietary exposure. The existing bifenthrin tolerances published, pending, and including the necessary section 18 tolerances result in chronic dietary risk estimates (food only) for the U.S. population of 3% of the RfD and the most highly exposed population subgroup, children, (1-6 years) 9% of the RfD.

2. *From drinking water.* The Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water exposure analysis and risk assessment for bifenthrin. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency is currently relying on GENEEC and PRZM/EXAMS for surface water, which are used to produce estimates of pesticide concentrations in a farm pond and SCI-GROW, which predicts pesticide concentrations in groundwater. None of these models include consideration of the impact processing of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Drinking water levels of comparison (DWLOCs) are calculated and compared to the models' estimates for both surface and ground water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. Since DWLOCs address total aggregate exposure to bifenthrin they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure.* Bifenthrin is currently registered for use on the following residential non-food sites: turf, home gardens and pets. Exposure estimates were calculated for the turf use, which is considered the use pattern with the highest exposure potential for adults, children (1-6 years) and infants (<1 year). MOEs were then calculated for each exposure scenario using the following equation: MOE = NOAEL/Exposure. MOEs for short- and intermediate-term oral, dermal and inhalation non-dietary exposure for the U.S. Population, infants (< 1 year) and children (1-6 years) were all greater than 100. As discussed in Unit A. 2. of this preamble, MOEs of 100 or greater are considered acceptable.

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 bifenthrin 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, bifenthrin 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 bifenthrin has a common mechanism of toxicity with other substances. For more 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).

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

1. *Acute risk.* As discussed earlier, no monitoring data are available for drinking water. Therefore, for acute aggregate risk, a DWLOC was calculated for the U.S. population. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. The DWLOCs was calculated for bifenthrin taking into account acute exposure assumptions from food. Exposure from residential uses are not included in acute aggregate risk estimates. For purposes of risk assessment, the estimated maximum concentration of bifenthrin in surface water (0.26 parts per billion (ppb)) was used for comparison to the back-calculated human health DWLOC for the acute endpoint. For bifenthrin, it was determined that an acute dietary exposure (food plus water) of 100% or less of the Acute RfD is acceptable to protect the safety of all population subgroups. The back-calculated DWLOC for the U.S. population is 180 ppb for acute dietary risk. Based on a comparison of the calculated DWLOC and the estimated exposure to bifenthrin in drinking water (0.26 ppb), the Agency does not expect the aggregate exposure to exceed 100% of the acute RfD for adults.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 3% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1-6 years), 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 bifenthrin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate risk takes into account chronic dietary exposure from food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. The short- and intermediate-term aggregate risks are estimated by combining exposure from food, water and residential uses (in this case, turf use). For adults, the routes of exposure from turf use include dermal and inhalation. As with the acute dietary aggregate risk estimate, for the short- and intermediate-term aggregate risk, DWLOCs were calculated. For purposes of risk assessment, the estimated chronic concentration of Bifenthrin in surface water (0.018 ppb) were used for comparison to the back-calculated human health DWLOCs for both the short-and intermediate-term endpoints. The back-calculated DWLOC for the U.S. population is 310 ppb for short- and intermediate-term risk. Based on a comparison of the calculated DWLOC and the estimated exposure to bifenthrin in drinking water (0.018 ppb), the Agency concludes that there is a reasonable certainty that no harm will result to adults from short- or intermediate-term aggregate exposure to bifenthrin.

4. *Aggregate cancer risk for U.S. population*. As discussed earlier, cancer risk concerns due to exposure of bifenthrin are adequately addressed by the chronic aggregate risk analysis.

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 bifenthrin residues.

D. 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 bifenthrin, 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 during 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 MOE and 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.

ii. *Developmental toxicity studies*. In a rabbit developmental toxicity study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal NOAEL was 2.67 mg/kg/day based on head and forelimb twitching at the LOAEL of 4 mg/kg/day.

In the rat developmental study, the maternal NOAEL was 1 mg/kg/day, based on tremors at the LOAEL of 2 mg/kg/day. The developmental (pup) NOAEL was also 1 mg/kg/day, based upon increased incidence of hydroureter at the LOAEL of 2 mg/kg/day. There were 5/23 (22%) of the litters affected (5/141 fetuses since each litter only had one affected fetus) in the 2 mg/kg/day group, compared with zero in the control, 1, and 0.5 mg/kg/day groups. According to recent historical data (1992–1994) for this strain of rat, background incidence of distended ureter averaged 11% with a maximum incidence of 90%.

iii. *Reproductive toxicity study*. In the rat reproduction study, parental toxicity occurred as decreased body weight and tremors at 5.0 mg/kg/day with a NOEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day (highest dose tested).

iv. *Pre- and post-natal sensitivity*— a. *Pre-natal*. Since there was not a dose-related finding of hydroureter in the rat developmental study and in the presence of similar incidences in the recent historical control data, the marginal finding of hydroureter in rat fetuses at 2 mg/kg/day (in the presence of maternal toxicity) is not considered a significant developmental finding. Nor does it provide sufficient evidence of a special dietary risk (either acute or chronic) for infants and children which would require an additional safety factor.

b. *Post-natal*. Based on the absence of pup toxicity up to dose levels which produced toxicity in the parental animals, there is no evidence of special post-natal sensitivity to infants and children in the rat reproduction study.

v. *Conclusion*. There is a complete toxicity database for bifenthrin and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk*. The back-calculated DWLOCs for children (1-6 years) and infants (<1 year) are 20 parts per billion (ppb) and 32 ppb, respectively. Based on a comparison of the calculated DWLOC and the estimated exposure to bifenthrin in drinking water (0.26 ppb), the Agency does not expect the aggregate exposure to exceed 100% of the Acute RfD for children and infants.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 9% 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 bifenthrin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. The short- and intermediate-term aggregate risks are estimated by combining exposure from food, water and residential uses (in this case, turf use). For infants and children, the routes of exposure from turf use include oral (nondietary), dermal and inhalation. The back-calculated DWLOCs for infants and children are 77 ppb and 70 ppb, respectively. Based on a comparison of the calculated DWLOCs and the estimated exposure to bifenthrin in drinking water (0.018 ppb), the Agency concludes that there is a reasonable certainty that no harm will

result to infants and children from short- or intermediate-term aggregate exposure to bifenthrin.

5. *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 bifenthrin residues.

IV. Other Considerations

A. Metabolism In Plants and Animals

The residue of concern in citrus is the parent compound only. Therefore, the Agency has determined that only the parent compound, bifenthrin, should appear in the tolerance expression.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

Residues of bifenthrin per se are not expected to exceed 0.05 ppm for citrus whole fruit; 0.3 ppm for citrus oil; and 0.3 ppm for citrus dried pulp as a result of the section 18 use.

D. International Residue Limits

CODEX has established MRL's for bifenthrin on grapefruit, lemon and sweet orange at 0.05 ppm. No Canadian or Mexican MRL's have been established for bifenthrin on citrus. The recommended tolerance levels for bifenthrin in/on citrus are harmonized with CODEX.

E. Rotational Crop Restrictions

Rotational crop restrictions are not applicable for citrus.

V. Conclusion

Therefore, tolerances are established for residues of bifenthrin in citrus, whole fruit at 0.05 ppm; 0.3 ppm for citrus oil; and 0.3 ppm for citrus dried pulp.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) 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 February 16, 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 above (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 rulemaking. 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). 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300762] (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 Highway, Arlington, VA.

Electronic comments may 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.

The official record for this rulemaking, as well as the public version, as described above 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 rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408 (l)(6). 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 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 under

FFDCA section 408 (l)(6), 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 has 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 to 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.

IX. 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 to 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: December 7, 1998.

Arnold E. Layne,

Acting 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. 346a and 371.

2. In § 180.442, by amending paragraph (b), by alphabetically adding the following commodities in the table to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
*	* *	* *
Citrus, dried pulp	0.3	12/31/00
Citrus oil ..	0.3	12/31/00
Citrus, whole fruit	0.05	12/31/00
*	* *	* *

* * * * *

[FR Doc. 98–33120 Filed 12–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300765; FRL 6048–5]

RIN 2070–AB78

Copper Ammonium Complex; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of copper ammonium complex in or on raw agricultural commodities when used in accordance with good agricultural practices as an active ingredient in pesticide formulations applied to growing crops. Chemical Specialties, Inc., submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170), requesting this tolerance exemption.

DATES: This regulation is effective December 16, 1998. Objections and requests for hearings must be received by EPA on or before February 16, 1999.

ADDRESSES: Written objections and hearing requests, identified by the