governments, or to the private sector, result from this action.

G. 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 United States Senate, the United States House of Representatives, and the United States Comptroller General 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).

H. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 13, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 7, 1999.

William Rice,

Acting Regional Administrator, Region VII.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart AA—Missouri

2. In § 52.1320 the following entry for paragraph (c), EPA-approved regulations, is revised to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) EPA-approved regulations.

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanations
	Missouri Department of Natural Resources			
*	*	*	*	*
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri				
*	*	*	*	*
10–6.020	Definitions and common reference tables	5/30/99	January 12, 2000 and FR cite.	
*	*	*	*	*

PART 70—[AMENDED]

1. The authority citation for Part 70 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

2. Appendix A to part 70 is amended by adding paragraph (f) to the entry for Missouri to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Program

* * * * *

Missouri

* * * * *

(f) The Missouri Department of Natural Resources submitted Missouri rule 10 CSR 10–6.020, ''Definitions and Common Reference Tables,'' on September 30, 1999, approval effective May 30, 1999.

[FR Doc. 00–355 Filed 1–11–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300962; FRL–6485–4]

RIN 2070–AB78

Mepiquat Chloride; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for mepiquat chloride regulated as *N,N*-dimethylpiperidinium chloride in or on grapes and raisins. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective January 12, 2000. Objections and requests for hearings, identified by docket control number OPP–300962, must be received by EPA on or before March 13, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300962 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703 305–7740; and e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300962. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 24, 1999 (64 FR 66181) (FRL–6396–4), 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) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for a tolerance by BASF Corporation. This notice included a summary of the petition prepared by BASF Corporation the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.384 be amended by establishing tolerances for residues of the plant growth regulator mepiquat chloride, in or on grapes at 1.0 parts per million (ppm), and raisins at 5.0 ppm.

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).

III. 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of mepiquat chloride in or on grapes at 1.0 ppm, and raisins at 5.0 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 results of the toxicity studies for mepiquat chloride are listed below.

1. *Subchronic toxicity study— Rat.* The no-observed-adverse- effect level (NOAEL) for males and females is 4,632 ppm (about 346 mg/kg/day) and the lowest-observed-adverse-effect level (LOAEL) for males and females is 12,000 ppm (about 889 mg/kg/day) based on tremors in all rats; decreased body weight gain, food consumption and food efficiency; increase in thromboplastin time; decrease in serum calcium, creatinine glucose, total protein, albumin, globulin and the triglycerides; reduced grip strength of forelimbs and hindlimbs in both sexes; prolonged reaction time in the hot-plate test on day 93 in males; decreased absolute weight of liver, kidneys and adrenals in males, and liver and adrenals in females; decreased relative weight of liver in males; and increased relative weight of kidneys and testes in males and of kidneys in females.

2. *Subchronic toxicity study— dog.* The LOAEL is 3,000 ppm (95.3 mg/kg/day), based on clinical signs of toxicity (slight sedation), body weight loss (up to 14%) and hematological effects (up to 14% reduction in hemoglobin content and number of erythrocytes and reduced hematocrit). The NOAEL is 1,000 ppm (32.4 mg/kg/day).

3. *Chronic toxicity study—rat.* The NOAEL is 2,316 ppm (106 mg/kg/day). The LOAEL is 5,790 ppm (268 mg/kg/day), based upon decreased body weights and body weight gains for both males and females, increases in urinary crystals for males, and pathological

changes in the adrenal cortex in females.

4. *Chronic toxicity Study— dog*. Study 1 and 2. The NOAEL is 1,800 ppm (58.4 mg/kg/day) and the LOAEL is 6,000 ppm (170 mg/kg/day), based on impaired neurological functions (slight sedation, abdominal/lateral positioning, spasms, and salivation) and epithelial vacuolization of the renal distal tubules.

5. *Carcinogenicity study—rat*. The LOAEL for males (269 mg/kg/day) and females (370 mg/kg/day) is 5,790 ppm, based upon decreased body weights, body weight gains, food consumption, food efficiency, and macroscopic and non-neoplastic findings. The NOAEL for males (105 mg/kg/day) and females (141 mg/kg/day) is 2,316 ppm. There were no treatment-related neoplastic findings for males or females treated with mepiquat chloride. Thus, mepiquat chloride does not exhibit carcinogenic potential in a 2–year feeding study involving male and female, rats.

6. *Carcinogenicity study— mice*. The NOAEL for mepiquat chloride administered for 2 years in food is 7,500 ppm for male (1,140 mg/kg/day) and female (1,348 mg/kg/day) B6C3F1 mice. There were no treatment-related neoplastic findings for males or females treated with mepiquat chloride. Thus, mepiquat chloride does not exhibit carcinogenic potential in a 2–year feeding study involving male and female B6C3F1 mice over this dose range. Based upon the lack of treatment-related findings, mepiquat chloride was not administered at the Maximum Tolerated Dose (MTD). However, the high dose (7,500 ppm) for the study was sufficient to assess carcinogenicity since the limit dose of 1,000 mg/kg/day was exceeded.

7. *Developmental toxicity study— rat*. Based on the clinical signs of toxicity and decreases in the food consumption and body weight gains, the maternal toxicity LOAEL is 300 mg/kg/day and the maternal toxicity NOAEL is 150 mg/kg/day. Since developmental toxicity was not observed in this study, the developmental NOAEL is greater than or equal to 300 mg/kg/day, the highest dose tested.

8. *Developmental toxicity study—. rabbit*. The maternal LOAEL is 150 mg/kg body weight/day, based on reduced body weight gains and reduced food consumption. The maternal NOAEL is 100 mg/kg body weight/day. The developmental LOAEL is 150 mg/kg/day, based on increased skeletal variations. The developmental NOAEL is 100 mg/kg/day.

9. *Reproductive toxicity study—two-generation—rat*. The LOAEL for systemic toxicity is 5,000 ppm for male and female rats, based on neurological impairment, decreased body weight and body weight gain in the adults, and retarded growth of F_1 and F_2 pups. This dose corresponds to dietary concentrations of 499.3 and 574.5 mg/kg/day, respectively, for F_0 and F_1 males and 530.0 and 626.5 mg/kg/day, respectively, for F_0 and F_1 females. The corresponding NOAEL is 1500 ppm. There were no treatment-related effects on reproductive parameters. The LOAEL for reproductive toxicity is greater than 5,000 ppm. This study did not establish a reproductive NOAEL; however, the systemic NOAEL of 1,500 ppm would also be regarded as the reproductive NOAEL.

10. *Reverse Gene Mutation Assay. Negative*.

11. *Structural Chromosome Aberration Assay. Negative*.

12. *Unscheduled DNA Synthesis Assay. Negative*.

13. *Metabolism study*. Mepiquat chloride did not accumulate in tissues of rats. Urine, feces and bile samples from various treatments were used for studies of the metabolic fate of mepiquat chloride. In all cases, only the unchanged compound could be detected. There was no biotransformation of mepiquat chloride *in vivo*. The potential metabolites, such as 1-methylpiperidine or piperidine, were not detected.

B. Toxicological Endpoints

The following endpoints were used in the risk assessments for mepiquat chloride.

1. *Acute toxicity*. The endpoint for the acute dietary risk assessment was estimated, based on the 1–year dog feeding study with the 90–day dog feeding as a supporting study. The NOAEL was 58.4 mg/kg/day, the Uncertainty Factor (UF) was 100, and the FQPA safety factor was reduced to 1X and applies to all population subgroups. The endpoints were impaired neurological functions (salivation, sedation, spasms, abdominal/lateral positioning), epithelial vacuolation of renal distal tubules, decrease in body weight, and hematology changes (decrease in RBC, hemoglobin, and hematocrit). The acute reference dose (aRfD) was 0.6 mg/kg/day. Since the FQPA safety factor was reduced to 1x the Acute Population Adjusted Dose (aPAD) was 0.6 mg/kg/day.

2. *Short- and intermediate-term toxicity*. The oral NOAEL of 58.4 mg/kg/day from the combined chronic and subchronic toxicity studies in dogs was selected for the short- and intermediate-term dermal endpoint. The LOAEL was 95.3 mg/kg/day, based on clinical signs of toxicity (sedation, abdominal and lateral positions and tonic/clonic spasms), decreased body weight, and hematological changes. An oral dose was selected due to the lack of a dermal toxicity study. An UF of 100 was selected, based on 10x for interspecies extrapolation and 10x for intraspecies variability. The Dermal Absorption Factor (DAF) is 25%. The inhalation absorption factor is 100%..

3. *Chronic toxicity*. The chronic dietary endpoint is the NOAEL of 58.4 mg/kg/day from the 1–year and the 90–day dog feeding studies for the general U.S. population. The LOAEL was 95.3 mg/kg/day, based on clinical signs of toxicity (sedation, abdominal and lateral positions and tonic/clonic spasms), decreased body weight, and hematological changes. An UF of 100 was selected, based on 10x for interspecies extrapolation and 10x for intraspecies variability. The chronic RfD, 0.6 mg/kg/day is the chronic NOAEL divided by the UF which equals 58.4 mg/kg/day divided by 100. Since the FQPA safety factor was reduced to 1x the chronic population adjusted dose (cPAD) equals 0.6 mg/kg/day.

4. *Carcinogenicity*. Mepiquat chloride is classified as a ''not likely'' human carcinogen.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.384) for the residues of mepiquat chloride, in or on cotton seed, cotton forage, meat, milk, poultry and eggs. Tolerances are proposed on grapes and raisins. Risk assessments were conducted by EPA to assess dietary exposures from mepiquat chloride 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. The Dietary Exposure Evaluation Model (DEEM) detailed acute analysis estimates the distribution of single exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989–1992 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of mepiquat chloride in the commodity supply.

A Tier 1 (assumptions: tolerance level residues and 100 percent crop treated,) acute dietary risk assessment was

conducted via DEEM. The DEEM processing factor was set at 1.00 for grape juice, based on the lack of concentration of residues therein; the default ratio of 3.0 was applied to grape juice concentrate. The commodities included in the acute DEEM analysis were: cottonseed (meal, oil); grapes (grapes, juice, juice concentrate, leaves, raisins, wine and sherry); and, the meat, fat, and meat by-products of cattle, goats, hogs, horses (meat only), and swine. Milk, egg, and poultry tolerances were not included, as these have recently been revoked, based upon the Regegistration Eligibility Determinations that the data indicate no finite residues are likely to occur in these commodities (40 CFR 180.6a(3)).

The resulting dietary food exposures (95th percentile) occupy up to 1.5% of the aPAD for the most highly exposed population subgroup (Children 1–6 years). These results should be viewed as conservative, health protective risk estimates. Refinements such as taking into account that only two grape varieties are to be treated; the percent-treated of their market share; and, Monte Carlo analysis, would yield even lower estimates of acute dietary exposure.

ii. *Chronic exposure and risk.* A Tier 1, chronic dietary risk assessment was conducted via DEEM. The DEEM processing factor settings for grape juice (1.0) and grape juice concentrate (3.0), and the commodities included in the chronic DEEM analysis, were exactly the same as those included in the acute DEEM analysis.

The resulting dietary food exposures occupy up to 0.3% of the cPAD for the most highly exposed population subgroup (Children 1–6 years). These results should be viewed as conservative, health protective risk estimates. Refinements such as taking into account that only two grape varieties are to be treated; the percent-treated of their market share; and, anticipated residues would yield even lower estimates of chronic dietary exposure.

iii. *Cancer dietary risk from food sources.* Mepiquat chloride was classified as a ''not likely human carcinogen.'' Therefore, a cancer risk assessment was not conducted.

2. *From drinking water.* EPA does not have monitoring data available to perform a quantitative drinking water risk assessment for mepiquat chloride. In the absence of reliable, available monitoring data, EPA uses models which incorporate chemical-specific data on the characteristics in question to estimate concentrations of pesticides in ground and surface water. A drinking water estimate for mepiquat chloride in ground water was generated by the screening concentratin in ground water (SCI-GROW) model. Conservative assumptions were built into the ground water scenario used by the SCI-GROW model, such as assuming shallow ground water, coarse soils and high levels of irrigation. The estimate from SCI-GROW (0.004 parts per billion (ppb)) represents an upper bound on the concentration of mepiquat chloride in ground waters as a result of agricultural use.

Estimates of concentrations of mepiquat chloride in surface water were made using the generic expected environmental concentration (GENEEC) model. The peak estimate for mepiquat chloride using the GENEEC model is 1.86 ppb. The 56–day average for mepiquat chloride is 1.06 ppb.

A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit of a pesticide's concentration in drinking water in light of total aggregate exposure to that pesticide in food and through residential uses. A DWLOC will vary depending on the toxic endpoint, consumption and body weight. Different populations will have different DWLOCs. EPA uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, the DWLOC is used as a point of comparison against conservative model estimates of potential pesticide concentration in water. DWLOC values are not regulatory standards for drinking water. EPA has calculated DWLOCs for acute and chronic (non-cancer) exposure to mepiquat chloride for the U.S. population and selected subgroups.

The DWLOCs for acute and chronic risk range from 6,000 ppb for infants and children to 21,000 ppb for the U.S. population. The estimated concentration of mepiquat chloride in ground water is 0.004 ppb and 1.86 ppb in surface water, which are less than the DWLOCs as a contribution to acute and chronic exposure. The estimated concentrations of mepiquat chloride in ground and surface water are considered conservative estimates. Therefore, EPA concludes with reasonable certainty that residues of mepiquat chloride in food and drinking water would not result in an unacceptable estimate of acute or chronic (non-cancer) aggregate human health risk.

3. *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 mepiquat chloride 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, mepiquat chloride 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 mepiquat chloride has a common mechanism of toxicity with other substances. For information regarding EPA 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

1. *Acute risk.* The acute aggregate risk is the sum of exposures resulting from acute dietary food and acute dietary drinking water. This acute aggregate risk assessment was conducted for all population subgroups, and the aPAD (0.6 mg/kg/day) was applied in determining exposures to all population subgroups. The Estimated Environmental Concentrations (EEC) for assessing acute aggregate dietary risk are 0.004 ppb (in ground water, based on SCI-GROW) and 1.9 ppb (in surface water, based on the GENEEC peak value). The back-calculated DWLOCs for assessing acute aggregate dietary risk range from 6,000 ppb for the most highly exposed population subgroup (Non-nursing infants, < 1 year old, and Children, 1–6 years old) to 21,000 ppb for the U.S. population (all seasons).

The SCI-GROW and GENEEC acute EEC values are less than the Agency's level of concern (the acute DWLOC value for each population subgroup) for mepiquat chloride residues in drinking water as a contribution to acute aggregate exposure. The Agency thus concludes with reasonable certainty that residues of mepiquat chloride in drinking water will not contribute significantly to the aggregate acute human health risk and that the acute aggregate exposure from mepiquat chloride residues in food and drinking water will not exceed the Agency's level

of concern (100% of the aPAD) for acute dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the aPAD. This risk assessment is considered high confidence, conservative, and protective of human health.

2. *Chronic risk.* Chronic (non-cancer) aggregate risk is the sum of exposures resulting from chronic dietary food, chronic dietary drinking water and chronic residential uses. Mepiquat chloride has no registered residential uses. Therefore, this risk assessment is the aggregate of chronic dietary food and chronic dietary drinking water exposures only. This chronic aggregate risk assessment was conducted for all population subgroups, and the cPAD was applied in determining exposures to all population subgroups.

The EECs for assessing chronic aggregate dietary risk are 0.004 ppb (in ground water, based on SCI-GROW) and 1.1 ppb (in surface water, based on the GENEEC 56–day average value). The back-calculated DWLOCs for assessing chronic aggregate dietary risk range from 6,000 ppb for the most highly exposed population subgroup (Non-nursing infants and Children, 1–6 years old) to 21,000 ppb for the U.S. population (all seasons).

The SCI-GROW and GENEEC chronic EEC values are less than the Agency's level of concern (the chronic DWLOC value for each population subgroup) for mepiquat chloride residues in drinking water as a contribution to chronic aggregate exposure. The Agency thus concludes with reasonable certainty that residues of mepiquat chloride in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from mepiquat chloride residues in food and drinking water will not exceed the Agency's level of concern (100% of the cPAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the cPAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, conservative, and protective of human health.

3. *Short- and intermediate-term risk.* These aggregate risk assessments take into account chronic dietary exposure from food and water, considered to be a background exposure level, plus short- and/or intermediate-term indoor and outdoor residential exposures, as applicable.

The Agency selected a dose and toxicological endpoint for assessments of short- and intermediate-term dermal and inhalation risk. However, since there are no residential uses for mepiquat chloride, either established or pending, at this time there is no exposure. Therefore, short-term and intermediate risk were not performed.

4. *Aggregate cancer risk for U.S. population.* Cancer aggregate risk is the sum of exposures resulting from chronic dietary food, chronic drinking water and chronic residential uses. Mepiquat chloride is classified as a ''not likely'' human carcinogen and thus not expected to pose a concer risk to humans.

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 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 mepiquat chloride, 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 prenatal and postnatal toxicity and the completeness of the data base 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 interspecies and intraspecies 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.

The Agency determined that the FQPA safety factor for mepiquat should be reduced to 1x for both acute and chronic risk assessments for all population subgroups, because:

- The toxicology database is complete for the assessment of the effects following *in utero* and/or postnatal exposure to mepiquat chloride.
- The toxicity data provided no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.
- The requirement of a developmental neurotoxicity (DNT) study is not based on the criteria reflecting some special concern for the developing fetuses or young which are generally used for requiring a DNT study and an FQPA safety factor (e.g.: neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring) and therefore does not warrant an FQPA safety factor. This is an interim step towards accordance with the proposed safety factors for use in the tolerance-setting process which was presented to the FIFRA SAP meeting in May, 1999 and placed in the Docket for Public Comment (64 FR 37001, July 8, 1999; Docket No. 37001).
- The exposure assessments will not underestimate the potential dietary (food and water) exposures for infants and children from the use of mepiquat chloride (currently, no residential exposure is expected).

2. *Short-or intermediate-term risk.* For a discussion of aggregate acute, chronic, and short- or intermediate-term risk to infants and children refer to Unit III.D. on Aggregate Risks and Determination of Safety of U.S. population.

3. *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 residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

Acceptable studies in cotton plants, grapes ruminants, and poultry have previously been submitted and evaluated. Residues of mepiquat chloride are systemic, with the residue of concern in plant and animal commodities being mepiquat chloride per se.

B. Analytical Enforcement Methodology

The analytical method (GLC/NPD) used for analysis of mepiquat chloride

residues in grapes, grape juice, and raisins is the enforcement procedure submitted for the Pesticide Analytical Manual, Volume II. This procedure has previously undergone a successful Agency validation using plant and animal matrices. The reported limit of quantitation is 0.05 ppm in grapes, 0.10 ppm in grape juice, and 0.25 ppm in raisins. The method is adequate to enforce the tolerance expression. A copy of the method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

Crop field trials. The grape field trials are adequate in number, geographically representative, and reasonably reflect the proposed use pattern. Residues of mepiquat chloride ranged from < 0.05 to 0.76 ppm. The data support the proposed 1.0 ppm tolerance for grapes.

Processed commodities. No concentration of residues was reported in grape juice; no tolerance is required. Residues concentrated up to 5X in raisins. The data support the proposed 5.0 ppm tolerance for raisins.

D. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for mepiquat chloride. Harmonization is thus not an issue at this time.

E. Rotational Crop Restrictions

Not applicable. Grape vines are long-lived perennials.

V. Conclusion

Therefore, tolerances are established for residues of mepiquat chloride in or on grapes at 1.0 ppm, and raisins at 5.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300962 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 13, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

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 the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300962, 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 or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the

requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) 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) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

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 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 this final rule in the **Federal Register**. This final 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 21, 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. In § 180.384, by revising the section heading, paragraph (a) introductory text and by alphabetically adding entries for grapes and raisins to the table in paragraph (a) to read as follows:

§ 180.384 Mepiquat chloride; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator mepiquat chloride, *N,N*-dimethylpiperidinium chloride in or on the following commodities:

Commodity	Parts per million
* * * * *	
Grapes	1.0
* * * * *	
Raisins	5.0
* * * * *	

* * * * *

[FR Doc. 00–362 Filed 1–11–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300958; FRL–6398–5]

RIN 2070–AB78

Emamectin Benzoate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of emamectin benzoate and its metabolites and photodegradates emamectin benzoate, 4'-epi-methylamino- 4'-deoxyavermectin B_1 benzoate (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B_{1a} and a maximum of 10% 4'-epi-methlyamino-4'deoxyavermectin B_{1b} benzoate) and its metabolites 8,9 isomer of the B_{1a} and B_{1b} component of the parent insecticide (8,9 ZMA); 4'-deoxy-4'-epi-aminoavermectin B_1 (AB_{1a}); 4'deoxy-4'-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4'-deoxy-4'-epi-(*N*-formyl)amino-avermectin B_1(FAB_{1a}) (CAS No.137512–74–4), in or on cottonseed, cottonseed oil, cotton meal, hulls, and gin trash; and the milk, meat, fat, kidney, and liver of cattle, goats, sheep, and swine. 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 on cotton. This regulation establishes maximum permissible levels for residues of emamectin benzoate in these food and feed commodities. The tolerances will expire and are revoked on December 31, 2001.

DATES: This regulation is effective January 12, 2000. Objections and requests