ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300719; FRL–6032–6]

RIN 2070–AB78

Mepiquat Chloride; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of mepiquat chloride, *N*,*N*-dimethylpiperidinium chloride) in or on grapes and raisins. 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 grapes. This regulation establishes a maximum permissible level for residues of mepiquat chloride 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 March 1, 2000.

DATES: This regulation is effective September 29, 1998. Objections and requests for hearings must be received by EPA on or before November 30, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300719] 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–300719], 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–300719]. 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: Andrew Ertman, 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) 308-9367, e-mail: ertman.andrew@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 plant regulator mepiquat chloride (*N*,*N*-dimethylpiperidinium chloride), in or on grapes at 1.0 part per million (ppm) and raisins at 6.0 ppm. These tolerances will expire and is be revoked on March 1, 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 Mepiquat Chloride on Grapes and FFDCA Tolerances

The applicants state that grape growers in Ohio, New York and Pennsylvania are facing an emergency situation brought on by freezing weather conditions that occurred on four days in April 1998. Regional experts called the frosts the most damaging freeze experienced in the past 30 years. The effects of the frost on the grapes include poor fruit set which will thus reduce fruit yield, with estimates of yield reductions in the 25% range. According to the applicants, there are no other registered alternative products available

to address this need other than mepiquat chloride. The use of mepiquat chloride could result in increased fruit set, and offset some of the damage caused by the late frost. EPA has authorized under FIFRA section 18 the use of mepiquat chloride on grapes for control of frost damage in Ohio, New York, and Pennsylvania. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of mepiquat chloride in or on grapes. 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 March 1, 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 grapes 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 mepiquat chloride meets EPA's registration requirements for use on grapes 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 mepiquat chloride 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 Ohio, New York, and Pennsylvania 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 mepiquat chloride, 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 mepiquat chloride and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of *N,N*-dimethylpiperidinium chloride on grapes at 1.0 ppm and raisins at 6.0 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 mepiquat chloride are discussed below.

1. *Acute toxicity*. For acute dietary risk assessment, the results from two 1-year feeding studies in the dog were combined with the results from a 90–day feeding study in the dog. The NOAEL for the acute dietary endpoint is 58.4 milligrams/kilogram/day (mg/kg/day) and the LOAEL is 95.3 mg/kg/day based on salivation and sedation. In the second 1-year study, salivation (an indicator of impaired neurological function) was observed in all dogs at 2 hours after each feeding. Salivation was slight at first, moderate to severe during the next 4 hours and then gradually disappeared. In the subchronic feeding study, sedation (also a neurotoxic sign) was observed for 1-6 hours after each dosing with 95.3 mg/kg/day, the LOAEL for the 3 studies combined. Using the hundredfold uncertainty factor (to account for both inter-species extrapolation and intra-species variability), the acute Reference dose (RfD) is calculated to be 0.6 mg/kg/day. This risk assessment will evaluate acute dietary risk to all population subgroups.

2. *Short - and intermediate - term toxicity.* The NOAEL is 58.4 mg/kg/day and the LOAEL is 95.3 mg/kg/day based on the combined results from two 1-year feeding studies and one 90-day feeding study in dogs. This endpoint is the same as that used for acute dietary and chronic RfD.

3. *Chronic toxicity*. EPA has established the RfD for mepiquat chloride at 0.6 (mg/kg/day). This RfD is based on the combined 1-year and subchronic feeding studies in the dog. The NOAEL is 58.4 mg/kg/day and the LOAEL is 95.3 mg/kg/day based on clinical signs of toxicity (salivation, sedation, abdominal and lateral positions, and xonoclonic spasms), decreased body weight, and hematological changes at 95.3 mg/kg/day. An uncertainty factor (UF) of 100 was applied to account for both inter-species extrapolation and intra-species variability. This risk assessment will evaluate chronic dietary risk to all population subgroups.

4. *Carcinogenicity*. EPA has classified mepiquat chloride as a Group E chemical - ''no evidence of carcinogenicity to humans.''

5. *FQPA safety factor*. The Agency removed the required 10x safety factor for all population subgroups except females and children.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.384) for the residues of *N,N*-dimethylpiperidinium chloride, in or on a variety of raw agricultural commodities at levels ranging from 3.0 ppm in cotton seed to 0.05 ppm in eggs and milk. Risk assessments were conducted by EPA to assess dietary exposures and risks 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 acute RfD = 0.6 mg/kg/day. The acute dietary (food only) risk assessment used the Dietary Exposure Evaluation Model (DEEM). In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions -- 100% of grapes and all other commodities having mepiquat chloride tolerances will contain mepiquat chloride residues and those residues would be at the level of the tolerance -- which result in an overestimation of human dietary exposure. The results of the DEEM are summarized below. These estimates

should be viewed as a conservative risk estimate; further refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate. For acute dietary exposure, the Agency determined that the 10X safety factor is applicable to the subpopulations females (13+ years), as well as infants and children because of a lack of developmental toxicity data.

Application of the 10X safety factor to the Acute RfD of 0.6 mg/kg/day results in an acceptable acute dietary exposure of 10% of the Acute RfD for the subpopulations females (13+ years old), infants, and children (1-6 years old). For the general U.S. Population and other subpopulations to whom the 10X factor does not apply, 100% or less of the Acute RfD would be acceptable. As shown in the following table 1, the amount of acute RfD utilized does not exceed HED's level of concern.

TABLE 1.—ACUTE DIETARY EXPOSURE AND PERCENT RFD

(Total from new and published tolerances at the 99th percentile)

Population of Concern[1]	TMRC[2] (mg/kg/day)	Percent of Acute RfD (%)[3]
U.S. Population	0.0092	2
Children (1–6 years old)	0.024	4
Females (13 + years old)	0.012	2

[1] Population for which the Acute RfD applies.
[2] TMRC - Theoretical Maximum Residue Concentration from DEEM.
[3] Percentage of reference dose (% RfD) = (TMRC/RfD) x 100%.

ii. *Chronic exposure and risk.* The chronic RfD = 0.6 mg/kg/day. A DEEM chronic exposure analysis was performed using tolerance level residues, and 100% crop treated to estimate the Theoretical Maximum Residue Concentration (TMRC) for the general population and subgroups of interest. In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions -- 100% of grapes and all other commodities having mepiquat chloride tolerances will contain mepiquat chloride residues and those residues would be at the level of the tolerance -- which result in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

The existing mepiquat chloride tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in a TMRC that is equivalent to the percentages of the Chronic RfD listed the following table 2 below. Application of the 10X safety factor to the Chronic RfD of 0.6 mg/kg/day results in an acceptable chronic dietary exposure of 10% or less of the chronic RfD for the subpopulations females (13+ years old), infants, and children (1–6 years old). For the general U.S. Population and other subpopulations to whom the 10X factor does not apply, 100% or less of the chronic RfD would be acceptable. As shown in the following table 2, the amount of chronic RfD utilized does not exceed HED's level of concern.

TABLE 2.—CHRONIC DIETARY EXPOSURE AND PERCENT OF RFD

Population of Concern[1]	TMRC (mg/kg/day)[2]	Percentage of Chronic RfD (%)[3]
U.S. Population (48 States)	0.0010	<1
Nursing Infants (<1 year old)	0.0011	<1
Non-Nursing Infants (<1 year old)	0.0024	<1
Children (1-6 years old)	0.0034	<1
Females (13 years +, nursing)	0.0014	<1

[1] The subgroups listed above are: (1) The U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states). The Chronic RfD applies to all popuplation subgroups.
[2] TMRC - Theoretical Maximum Residue Concentration from DEEM.
[3] Percentage of reference dose (% RfD) = (TMRC/RfD) x 100%.

2. *From drinking water.* Mepiquat chloride is stable to hydrolysis and photolysis. Soil and aqueous photolysis are not routes of dissipation. Under aerobic conditions, mepiquat chloride appears to degrade rapidly to CO_2. Under anaerobic conditions, it appears stable. Based on study results, mepiquat chloride is considered to be relatively non-mobile, and is not expected to accumulate in fish. Since the other mepiquat chloride metabolites also degrade rapidly to CO_2, parent mepiquat chloride is the only residue of concern. There are no established Maximum Contaminant Levels or health advisory levels for residues of mepiquat chloride in drinking water. Furthermore, mepiquat chloride is considered to have limited potential for groundwater contamination. Because of mepiquat chloride's low usage rate and its rapid degradation, significant migration to surface water is not expected.

i. *Acute exposure and risk.* Drinking water levels of concern (DWLOC) for acute and chronic dietary exposure are included as the following Tables 3 and 4.

TABLE 3.— DRINKING WATER LEVELS OF CONCERN (DWLOC) FOR ACUTE DIETARY EXPOSURE

Population[7]	Acute RfD (mg/kg/day)	Acute RfD with FQPA factor[1] (mg/kg/day)	Acute Dietary Exposure[2] (mg/kg/day)	Max Water Exposure[3] (mg/kg/day)	Acute DWLOC[4,5,6] (µg/L)
U.S. Population	0.6	0.6 (FQPA factor does not apply)	0.0092	0.59	21,000
Females 13 years +	0.6	0.06	0.012	0.048	1,400
Children/Infants	0.6	0.06	0.024	0.036	360

[1] Acute RfD with FQPA factor = Acute RfD/FQPA Safety Factor (10x).
[2] Acute Dietary Exposure from DEEM analysis.

[3] Max Water Exposure = Acute RfD with FQPA factor - Acute Dietary Exposure (mg/kg/day).
[4] Acute DWLOC(µg/L) = Max. water exposure (mg/kg/day) * body wt (kg)/(10^{-3} mg/µg) * water consumed daily (L/day).
[5] HED Default body weights are 70 kg for General US Population; 60 kg for females 13+ and 10 kg for infants and children.
[6] HED Default Daily Drinking Rates are 2 L/day for Adults and 1 L/day for infants and children.
[7] Within each of these categories, the subgroup with the highest food exposure was given.

TABLE 4.—DRINKING WATER LEVELS OF CONCERN (DWLOC) FOR CHRONIC DIETARY EXPOSURE

Population	Chronic RfD (mg/kg/day)	Chronic RfD with FQPA factor[1] (mg/kg/day)	Chronic Dietary Exposure[2] (mg/kg/day)	Max Water Exposure[3] (mg/kg/day)	Chronic DWLOC[4,5,6,7] (µg/L)
U.S. Population	0.6	0.6 (FQPA factor does not apply)	0.0010	0.599	21,000
Females 13 years +	0.6	0.06	0.0014	0.0586	1,800
Children/Infants	0.6	0.06	0.0034	0.0566	570

[1] Acute RfD with FQPA factor = Acute RfD/FQPA Safety Factor (10x).
[2] Acute Dietary Exposure from DEEM analysis.
[3] Max Water Exposure = Acute RfD with FQPA factor - Acute Dietary Exposure (mg/kg/day).
[4] Chronic DWLOC(µg/L) = Max. water exposure (mg/kg/day) * body wt (kg)/(10^{-3} mg/µg) * water consumed daily (L/day).
[5] HED Default body weights are 70 kg for General US Population; 60 kg for females 13+ and 10 kg for infants and children.
[6] HED Default Daily Drinking Rates are 2 L/day for Adults and 1 L/day for infants and children.
[7] Within each of these categories, the subgroup with the highest food exposure was given.

ii. *Chronic exposure and risk.* ''The Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments'' issued on November 24, 1997 was followed for this assessment. Thus, the generic expected environmental concentration (GENEEC) model and the SCI-GROW model were run to produce estimates of mepiquat chloride concentrations in surface and ground water, respectively. The primary use of these models is to provide a coarse screen for sorting out pesticides for which EPA has a high degree of confidence that the true levels of the pesticide in drinking water will be less than the human health drinking water levels of concern (DWLOCs). A DWLOC is the concentration of a pesticide in drinking water which would be acceptable as an upper limit in light of total aggregate exposure to that chemical from food, water, and non-occupational (residential) sources.

The DWLOC is the concentration in drinking water as a part of the aggregate chronic exposure that occupies no more than 100% of the RfD. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child).

For chronic (non-cancer) exposure to mepiquat chloride in surface and ground water, the drinking water levels of concern are 21,000 µg/L for the U.S. population, 1,800 µg/L for females (13+ years old), and 570 µg/L for children (1–6 years old). 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 mepiquat chloride in drinking water. DWLOCs were then calculated using default body weights and drinking consumption figures.

Estimated average concentrations of mepiquat chloride in surface and groundwater are 1.99 parts per billion (ppb) and 0.008 ppb, respectively. The DWLOCs are as stated above. The estimated average concentrations of mepiquat chloride in surface and groundwater are less than OPP EPA's level of concern for mepiquat chloride in drinking water as a contribution to chronic aggregate exposure.

3. *From non-dietary exposure.* Mepiquat Chloride is currently not registered for use on any sites that present a risk of non-occupational, non-dietary exposure.

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 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 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.* The acute risk for ''food only'' does not exceed EPA's level of concern. Since estimates of mepiquat chloride in drinking water do not exceed acute drinking water levels of concern (DWLOC) listed in Table 3 of this preamble, the Agency does not expect the acute aggregate risk to exceed the level of concern.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to mepiquat chloride from food will utilize < 1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is 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 mepiquat chloride 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 exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses. There are no registered residential uses of mepiquat chloride. Therefore, a

Short- and Intermediate-Term Aggregate Risk assessment is not applicable.

4. *Aggregate cancer risk for U.S. population*. The Agency has classified mepiquat chloride as a Group E chemical, ''no evidence of carcinogenicity to humans.'' Therefore, a risk assessment is not required.

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 mepiquat chloride 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 mepiquat chloride, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-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 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 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*.—a. *Rats*. In a developmental toxicity study, Wistar rats were dosed by oral gavage at levels of 0, 50, 150, or 300 mg/kg/day during gestation days 6 through 15. 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 Toxicity NOEL is ≧ 300 mg/kg/day (Hight Dose Tested).

b. *Rabbits*. In a developmental toxicity study, mepiquat chloride was administered to Himalayan rabbits at dose levels of 0 (untreated control), 0 (vehicle control), 50, 100 and 150 mg/kg/day during gestation days 6–18. The maternal NOAEL is 50 mg/kg/day (borderline value) and the LOAEL is 100 mg/kg/day based on body weight loss and decreased body weight gain; decreased food consumption; amber-colored liquid in the abdomens of six rabbits; diarrhea, trembling and apathy in one rabbit; and six abortions. Developmental effects were not observed in the 50 mg/kg group. Because of the high abortion rate in the 100 mg/kg group (37.5%) and high death and abortion rate in the 150 mg/kg group (58.8%), inadequate numbers of fetuses in the mid-dose and high-dose groups preclude the meaningful evaluation of developmental toxicity in this study. In order to evaluate developmental toxicity in the rabbit, the current study was to be considered with another study in which two doses of mepiquat chloride (75 and 100 mg/kg) were tested. However, because the results were reported only in the form of a brief summary, the second study cannot be presently evaluated. The developmental toxicity study in the rabbit is classified as supplementary/unacceptable and does not satisfy the guideline requirement 83-3b (OPPTS 870.3700). The study is upgradable following the review and acceptance of the second study.

iii. *Reproductive toxicity study*.—*Rats*. In the 2-generation reproductive toxicity study, groups of 25 male and 25 female Wistar rats were fed mepiquat chloride in their diets at concentrations of 0, 500, 1,500, or 5,000 ppm for 10 weeks (F_0) or 14 weeks (F_1) before mating, and during mating, gestation, and lactation. The doses corresponding to the dietary concentrations are 51.2 and 48.6, 153.1 and 146.6, and 499.3 and 574.5 mg/kg/day, respectively for F_0 and F_1 males and 54.0 and 53.3, 163.6 and 162.0, and 530.0 and 626.5 mg/kg/day, respectively for F_0 and F_1 females.

The LOAEL for parental (systemic) toxicity is 5,000 ppm (499 mg/kg/day) 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. The parental (systemic) NOAEL is 1,500 ppm (147 mg/kg/day). There were no treatment-related effects on reproductive parameters. The NOAEL for reproductive toxicity is > 5,000 ppm (499 mg/kg/day).

iv. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for mepiquat chloride is incomplete with respect to current data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat developmental toxicity study and the 2-generation rat reproductive toxicity study. However the developmental toxicity study in rabbits was unacceptable and requires a new study.

v. *Conclusion*. Based on the above, the Agency determined that the 10X safety factor for protection of infants and children should be retained and applied to all population subgroups involving women and children.

2. *Acute risk*. The acute risk for food and drinking water do not exceed EPA's level of concern and therefore the acute aggregate risk does not exceed the Agency's level of concern.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to mepiquat chloride from food will utilize < 1% 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.

4. *Short- or 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 uses. There are no registered residential uses of mepiquat chloride. Therefore, a Short- and Intermediate-Term Aggregate Risk assessment is not applicable.

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 mepiquat chloride residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

A previously submitted study of the metabolism of mepiquat chloride in grapes was found to be adequate. The residue-of-concern in grapes is considered to be the parent compound only. Secondary residues are not expected in animal commodities as no feed items are associated with this section 18 use.

B. Analytical Enforcement Methodology

The analytical method gas chromatography/nitrogen phosphorus

detector (GC/NPD) for mepiquat chloride in/on grapes was previously reviewed and found to be adequate for tolerance enforcement. The limit of quantification (LOQ) for this method was reported as 0.05 ppm in grapes, 0.1 ppm in grape juice, and 0.25 ppm in raisins.

C. Magnitude of Residues

The grape residue data provided with this action appear to be a summary of the data that were supplied with a previously submitted petition (PP 1F3955/1H5610). In support of that petition, 28 field trials in 8 different states (California, New York, Pennsylvania, Oregon, Michigan, New Jersey, Ohio, and Georgia) were conducted in 1984 and 1985. Residues of mepiquat chloride in/on grapes ranged from < 0.05 to 0.76 ppm with PHIs ranging from 77 to 135 days. The highest value, 0.76 ppm, is from a 0.4 lb/A treatment (1.6 times the recommended rate) and was found 106 days after application. In Ohio, residues of mepiquat chloride were 0.1 and 0.15 ppm for PHIs of 112 and 106 days, respectively.

A time-limited tolerance of 1 ppm for residues of mepiquat chloride in/on grapes will be established for purposes of this section 18 use only. Grapes processed from the field trials indicate that production of raisins resulted in a sixfold increase in mepiquat chloride residues. Mepiquat chloride did not concentrate in grape juice. A time-limited tolerance of 6 ppm for residues of mepiquat chloride in/on raisins will be established to support this section 18 use. Secondary residues are not expected in animal commodities as no feed items are associated with this section 18 use.

D. International Residue Limits

There are no Codex, Canadian, or Mexican tolerances established for mepiquat chloride on grapes. Thus, international harmonization is not an issue for these time-limited tolerances.

E. Rotational Crop Restrictions

Since grapes are not rotated to other crops, a discussion of rotational crop restrictions is not germane to this action.

V. Conclusion

Therefore, the tolerance is established for residues of *N*,*N*-dimethylpiperidinium chloride in grapes at 1.0 ppm and raisins at 6.0 ppm.

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 November 30, 1998, 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–300719] (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.

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 prior consultation as specified 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 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 Intergovernmental Partnerships (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 the Office of Management and Budget (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 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: September 18, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

1. In part 180:

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

Authority: 21 U.S.C. 346a and 371.

b. In § 180.384 as follows:

i. By designating the existing text as paragraph (a) and adding a paragraph heading.

ii. By adding paragraph (b) and by adding and reserving with headings paragraphs (c) and (d).

The added text reads as follows:

§ 180.384 N,N-Dimethylpiperidinium chloride; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for residues of the plant growth regulator mepiquat chloride, *N,N*-Dimethylpiperidinium chloride under section 18 emergency exemptions granted by EPA when used on the commodities in the table below. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Grapes	1.0	3/1/00
Raisins	6.0	3/1/00

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

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

PART 186— [AMENDED]

2. In part 186:

a. The authority citation for part 186 continues to read as follows;

Authority: 21 U.S.C. 348.

§ 186.2275 [Partially Redesignated and Removed]

b. In § 186.2275 by transfering the entry for ''cottonseed'' from the table and adding it alphabetically to the table in newly designated paragraph (a) of § 180.384, and by removing the remainder of § 186.2275.

[FR Doc. 98–25984 Filed 9–28–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6169–3]

National Priorities List for Uncontrolled Hazardous Waste Sites

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''EPA'' or ''the Agency'') in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds 1 new site to the General Superfund section of the NPL.

EFFECTIVE DATE: The effective date for this amendment to the NCP shall be October 29, 1998.

ADDRESSES: For addresses for the Headquarters and Regional dockets, as well as further details on what these dockets contain, see section II, ''Availability of Information to the Public'' in the ''Supplementary Information'' portion of this preamble.

FOR FURTHER INFORMATION CONTACT: Terry Keidan, phone (703) 603–8852, State and Site Identification Center, Office of Emergency and Remedial Response (mail code 5204G), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC, 20460, or the Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
A. What are CERCLA and SARA?
B. What is the NCP?
C. What is the National Priorities List (NPL)?
D. How are Sites Listed on the NPL?
E. What Happens to Sites on the NPL?
F. How are Site Boundaries Defined?
G. How are Sites Removed from the NPL?
H. Can Portions of Sites be Deleted from the NPL as They Are Cleaned Up?
I. What is the Construction Completion List (CCL)?
II. Availability of Information to the Public
A. Can I Review the Documents Relevant to this Final Rule?
B. What Documents are Available for Review at the Headquarters Docket?
C. What Documents are Available for Review at the Region 6 Docket?
D. How Do I Access the Documents?
E. How Can I Obtain a Current List of NPL Sites?
III. Contents of This Final Rule
A. Additions to the NPL
B. Status of NPL
C. What did EPA Do with the Public Comments It Received?
IV. Executive Order 12866
A. What is Executive Order 12866?
B. Is this Final Rule Subject to Executive Order 12866 Review?
V. Unfunded Mandates
A. What is the Unfunded Mandates Reform Act (UMRA)?
B. Does UMRA Apply to This Final Rule?
VI. Effects on Small Businesses
A. What is the Regulatory Flexibility Act?
B. Does the Regulatory Flexibility Act Apply to this Final Rule?
VII. Possible Changes to the Effective Date of the Rule
A. Has This Rule Been Submitted to Congress and the General Accounting Office?
B. Could the Effective Date of This Final Rule Change?
C. What Could Cause the Effective Date of This Rule to Change?
VIII. National Technology Transfer and Advancement Act
A. What is the National Technology Transfer and Advancement Act?
B. Does the National Technology Transfer and Advancement Act Apply to this Final Rule?
IX. Executive Order 13045
A. What is Executive Order 13045?
B. Does Executive Order 13045 Apply to This Final Rule?
X. Paperwork Reduction Act
A. What is the Paperwork Reduction Act?
B. Does the Paperwork Reduction Act Apply to This Final Rule?
XI. Executive Order 12875
What is Executive Order 12875 and is it Applicable to This Final Rule?
XII. Executive Order 13084
What is Executive Order 13084 and is it Applicable to this Final Rule?

I. Background

A. What Are CERCLA and SARA?

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601–9675 (''CERCLA'' or ''the Act''), in response to the dangers of uncontrolled releases of hazardous substances. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act (''SARA''), Public Law 99–499, 100 Stat. 1613 *et seq.*

B. What Is the NCP?

To implement CERCLA, EPA promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan (''NCP''), 40 CFR part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP sets guidelines and procedures for responding to releases and threatened releases of hazardous substances, pollutants, or contaminants under CERCLA. EPA has revised the NCP on several occasions. The most recent comprehensive revision was on March 8, 1990 (55 FR 8666).

As required under section 105(a)(8)(A) of CERCLA, the NCP also includes ''criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable, taking into account the potential urgency of such action for the purpose of taking removal action.'' (''Removal'' actions are defined broadly and include a wide range of actions taken to study, clean up, prevent or otherwise address releases and threatened releases 42 U.S.C. 9601(23).)

C. What Is the National Priorities List (NPL)?

The NPL is a list of national priorities among the known or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The list, which is appendix B of the NCP (40 CFR part 300), was required under section 105(a)(8)(B) of CERCLA,