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. 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 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).

XI. Submission to Congress and the General Accounting Office

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: May 25, 2000.

Susan B. Hazen,

Acting Director, 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), 346(a), and 371.

2. Section 180.1201 is revised to read as follows:

§ 180.1201 Trichoderma harzianum strain T-39; exemption from the requirement of a tolerance.

Trichoderma harzianum strain T-39 is exempt from the requirement of a tolerance on all food commodities.

[FR Doc. 00–15723 Filed 6–21–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301010; FRL–6592–4]

RIN 2070–AB78

Cloquintocet-mexyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of the inert ingredient (herbicide safener) cloquintocet-mexyl and its acid metabolite in or on wheat grain, forage, hay, and straw. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective June 22, 2000. Objections and requests for hearings, identified by docket control number OPP–301010, must be received by EPA on or before August 21, 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–301010 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–308–8373; and e-mail address: alston.treva@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	111 112 311 32532	Crop production Animal production Food manufacturing 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–301010. 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 April 15, 1998 (63 FR 18417) (FRL–5781–9), 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 7E4920) for tolerances by Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, North Carolina 27419. This notice included a summary of the petition prepared by Novartis Crop Protection, Inc., the petitioner. The petition was subsequently amended to increase the original proposed tolerances and an additional notice of filing was published in the **Federal Register** on April 19, 2000 (65 FR 20972). There were no comments received in response to the notice of filing.

The April 19, 2000 (FRL–6554–3) petition requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the inert ingredient (herbicide safener) cloquintocet-mexyl (acetic acid, [(5-chloro-8-quinolinyl)oxy]-, 1-methylhexyl ester) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid), in or on wheat, grain at 0.1 parts per million (ppm); wheat, forage at 0.1 ppm; and wheat, hay at 0.1 ppm and wheat, straw at 0.1 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 a tolerance for combined residues of cloquintocet-mexyl and its acid metabolite) on wheat, grain at 0.1 ppm; wheat, forage at 0.1 ppm; wheat, hay at 0.1 ppm; and wheat, straw at 0.1 ppm. EPA's assessment of 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 cloquintocet-mexyl are discussed in this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY

Guideline No./Study Type	Results
870.3100 28-Day Oral in Rodents	NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on microscopic kidney lesions.
870.3100 28-Day Oral in Rodents	NOAEL = 10 mg/kg/day (females only) LOAEL = 400 mg/kg/day based on transient decrease in body weight gain, microscopic alterations of the pituitary and thyroid and possible increased SGPT.
870.3100 90-Day Oral Toxicity Rodents	NOAEL = males: 150 ppm (9.7 mg/kg/day), females: 6,000 ppm (407) mg/kg/day LOAEL = males: 1000 ppm (63.9 mg/kg/day); females: ≥ 6,000 ppm (≥ 407 mg/kg/day based on urinary bladder hyerplasia, kidney hydronephrosis and increased serum bilirubin in males.
870.3150 90-Day Oral Toxicity in Non-rodents.	NOAEL = 100 ppm (2.9 mg/kg/day in males and 3.3 mg/kg/day in females) LOAEL = 1,000 ppm (30.2 mg/kg/day in males and females based on perivascular mixed inflammatory cell infiltrates and multicellular multifocal necrosis of the liver and thymic atrophy.
870.3200 28-Day Dermal Toxicity	NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based on mottled or reddish livers accompanied by histopathological changes including necrosis and fibrosis.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No./Study Type	Results
870.3700a Prenatal Developmental in Rodents.	Maternal NOAEL = 100 mg/kg/day LOAEL = 400 mg/kg/day based on clinical signs and decrease in body weight gain and food consumption. Developmental NOAEL = 100 mg/kg/day LOAEL = 400 mg/kg/day based on the higher incidence of skeletal variants and decrease in fetal body weights in the high dose group.
870.3700b Prenatal Developmental in Nonrodents.	Maternal NOAEL = 60 mg/kg/day LOAEL = 300 mg/kg/day based on maternal toxicity (death) in high dose group. Developmental NOAEL = 300 mg/kg/day LOAEL '' 300 mg/kg/day
870.3800 Reproduction and Fertility Effects.	Parental/Systemic NOAEL = 5,000 ppm (males: 370.7 mg/kg/day; females: 442.8 mg/kg/day LOAEL = 10,000 ppm (males: 721.7 mg/kg/day; females: 846.9 mg/kg/day based on decreased body weight, decreased food consumption, and pathological changes in the kidney (dilated renal pelvis, nephrolith, hydronephrosis, urethral constrictions) and urinary bladder (cytoliths, hyperemia, cystitis and urothelial hyperplasia). Reproductive NOAEL = 10,000 ppm (721.7 mg/kg/day) LOAEL = 10,000 ppm (721.7) mg/kg/day. Developmental NOAEL = 5,000 ppm (442.8) mg/kg/day LOAEL = 10,000 ppm (846.9 mg/kg/day based on decreased pup weight and dilated renal pelvis.
870.4100b Chronic Toxicity in Nonrodents.	NOAEL = 1,500 ppm (males: 43 mg/kg/day; females: 45 mg/kg/day LOAEL = 15,000/10,000 ppm M: 196 F: 216 mg/kg/day based on decreased body weight/weight gain and food consumption, anemia, increased serum iron, protein alterations, bone marrow hypoplasia and possible decreased testes/prostate weights and interstitial nephritis.
870.4200 Carcinogenicity Mice	NOAEL = 1,000 ppm (males: 111 mg/kg/day; females: 102 mg/kg/day LOAEL = 5,000 ppm (males: 583 mg/kg/day; females: 520 mg/kg/day based on decreased body weight/weight gain in both sexes, urinary bladder lesions (chronic inflammation, ulceration, calculus and submucosa edema) in males and possible slightly increased water consumption in both sexes. Negative for oncogenicity.
870.4300 Combined Chronic/oncogenicity in rat.	NOAEL = females: 100 ppm (4.3 mg/kg/day); males: 1,000 ppm 36.4 mg/kg/day). LOAEL = females: 1,000 ppm (41.2 mg/kg/day); males: 2,000 ppm (81.5 mg/kg/day) based on increased incidence of thyroid follicular epithelial hyperplasia in females and based on lymphoid hyperplasis of the thymus in males.
870.5100 Gene Mutation	Testing up to 5,000 μg/plate with or without S9 microsomes produces no evidence that cloquintocet-mexyl technical induced a mutagenic effect in any strain. Negative mutagen.
870.5200 Gene Mutation	There was no evidence of any mutagenic effect at any dose (up to 500 μg/plate) with or without S9 activation. Negative mutagen.
870.5375 Human Lymphocytes *in vitro* ..	Human lymphocytes were exposed *in vitro* up to 75 μg/mL with or without S9 activation showed no evidence of inducing a cytogenetic effect at any dose. Negative mutagen.
870.5395 Micronucleus Test	Chinese hamsters dosed from 625 to 2,000 mg/kg showed no evidence of inducing a clastogenic or aneugenic effect in either sex at any dose or sacrifice time. Negative mutagen.
870.5550 DNA Repair Human Fibroblasts.	Cultured human fibrocytes were exposed *in vitro* to up to 60 μg/mL for 5 hrs. and scored for silver grains in the nucleus. There was no evidence that cloquintocet-mexyl technical in the absence of S9 activation induced a genotoxic response.
870.5550 DNA Repair Rat Hepatocytes	Primary rat hepatocytes exposed to 200 μg/mL for 16–18 hours and scored for nuclear grain showed no evidence that cloquintocet-mexyl technical induced a genotoxic response. Negative mutagen.
870.7485 Metabolism and pharmcokinetics.	Absorption after a single low oral dose (50 mg/kg bw), was between 40.2% (males) and 35.6% (females). The major metabolite in the 0 to 24 hour fecal and urinary pools was determined to be quinolinoxy acetic acid, accounting for approximately 95% of the recovered radioactivity.
870.7485 Metabolism and pharmacokinetics.	The major metabolic pathway was determined to be hydrolysis of the ester group, resulting in the formation of 5-chloro-8-quinolinoxy acetic acid. The major metabolic pathway was not significantly affected by sex, dose level or dosing regime.

B. Toxicological Endpoints

The dose at which no observed adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the

extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD=NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^6 or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOQUINTOCET-MEXYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF [1] and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50 years of age.	NOAEL = 100 mg/kg/day. UF =100 ..... Acute RfD = 1.0 mg/kg/day	FQPA SF = 1x aPAD = acute RfD/FQPA ... SF = 1.0 mg/kg/day	Developmental toxicity study in rats. LOAEL = 400 mg/kg/day based on higher incidence of skeletal variants and decrease in fetal body weights.
Acute Dietary general population including infants and children.	None	Not applicable	Not applicable.
Chronic Dietary all populations ..	NOAEL = 4.3 mg/kg/day. UF = 100 ..... Chronic RfD = 0.04 mg/kg/day.	FQPA SF = 1x cPAD = chronic RfD/FQPA SF = 0.04 mg/kg/day	Chronic/Oncogenicity Toxicity-Rats LOAEL = 41.2 mg/kg/day based on observation of thyroid hyperplasia in females.
Short-Term Dermal (1 to 7 days)	Dermal NOAEL = 200 mg/kg/day.	LOC for MOE = 100.	28-Day Dermal Toxicity-Rats. LOAEL = 1,000 mg/kg/day based on mottled or reddish livers accompanied by histopathological changes including necrosis and fibrosis in two of five female rats.
Intermediate-Term Dermal (1 week to several months).	Dermal NOAEL = 200 mg/kg/day.	LOC for MOE = 100.	28-Day Dermal Toxicity-Rats LOAEL = 1,000 mg/kg/day based on mottled or reddish livers accompanied by histopathological changes including necrosis and fibrosis in two of five female rats.
Long-Term Dermal (several months to lifetime).	None	Not applicable	Based on the current use pattern, no long-term dermal exposure is expected to occur.
Short-Term Inhalation (1 to 7 days).	Oral NOAEL = 100 mg/kg/day. absorption rate = 100%	LOC for MOE = 100.	Developmental toxicity study in rats LOAEL = 400 mg/kg/day based on higher incidence of skeletal variants and decrease in fetal body weights in the high dose group.
Intermediate-Term Inhalation (1 week to several months).	Oral NOAEL = 4.3 mg/kg/day. absorption rate = 100%	LOC for MOE = 100	Chronic/Oncogenicity Toxicity Rat. LOAEL = 41.2 mg/kg/day based on observation of thyroid hyperplasia in females.
Long-Term Inhalation (several months to lifetime).	None	Not applicable	Based on the current use pattern, no long-term inhalation exposure is expected to occur.

[1] The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

In accordance with the Proposed EPA Weight-of-the-Evidence Categories, August 1999, the Agency classified cloquintocet-mexyl as ''not likely to be a human carcinogen''. Carcinogenicity studies in rats and mice did not show increased incidence of spontaneous tumor formation. With negative mutagenicity test battery, it is suggested that cloquintocet-mexyl is not likely to be a human carcinogen.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. No tolerances have previously been established for the combined residues of cloquintocet-mexyl and its acid metabolite 5-chloro-8-quinolinoxyacetic acid. A risk assessment was conducted by EPA to assess dietary exposures from cloquintocet-mexyl and its acid metabolite in food as follows:

i. *Acute exposure*. 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 one day or single exposure. The Agency has conducted Tier 1 acute food exposure assessments for cloquintocet-mexyl using the Dietary Exposure Evaluation Model (DEEM). This model incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989–1992. For this acute food risk assessment, the entire distribution of single day food consumption events is combined with a single residue level (deterministic analysis) to obtain a distribution of exposure in mg/kg/day. For a Tier 1 analysis, the Agency considers exposure at the 95th percentile of exposure. The following assumptions were made for the Tier 1 acute exposure assessment: (1) Residues of cloquintocet-mexyl and its acid metabolite would be present in/on wheat at the tolerance level (0.1 ppm); and (2) 100% of the wheat crop would be treated.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. For chronic food risk assessments, the three-day average of consumption for each sub-population is combined with residues in commodities to determine average exposure in mg/kg/day. The following assumptions were made for the chronic exposure assessments: (1) Residues of cloquintocet-mexyl and its acid metabolite would be present in/on wheat at the tolerance level (0.1 ppm); and (2) 100% of the wheat crop would be treated.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for cloquintocet-mexyl and its acid metabolite 5-chloro-8-quinolinoxyacetic acid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of cloquintocet-mexyl and its acid metabolite.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to cloquintocet-mexyl and its acid metabolite 5-chloro-quinolinoxyacetic acid they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of cloquintocet-mexyl in surface water and ground water for acute exposures are estimated to be 0.038 parts per billion (ppb) for surface water and 0.0060 ppb for ground water. The EECs for chronic exposures are estimated to be 0.0053 ppb for surface water and 0.0060 ppb for ground water. The EECs for ground water for the acid metabolite for acute and chronic exposures are estimated to be 0.00017 ppb. The EEC for surface water for acute exposure for the acid metabolite is estimated to be 0.031 ppb, while the chronic exposure is estimated to be 0.017 ppb for surface water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Cloquintocet-mexyl is not registered for use on any sites that would result in residential exposure.

4.*Cumulative exposure to substances with a 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 cloquintocet-mexyl 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, cloquintocet-mexyl 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 cloquintocet-mexyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. 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 on toxicity and exposure 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.

ii. *Prenatal and postnatal sensitivity*. There was no evidence of developmental or reproductive toxicity for cloquintocet-mexyl. The data demonstrate no increased sensitivity of rats or rabbits to in utero or early post-natal exposure to cloquintocet-mexyl. NOAELs for maternal/parental toxicity were either less than or equal to the NOAELs for fetal or reproductive toxicity.

iii. *Conclusion*. There is a complete toxicity data base for cloquintocet-mexyl. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA has determined that the 10X safety factor to protect infants and children should be removed (i.e., reduced to 1X) because the toxicology database (i.e., developmental toxicity studies in rats and rabbits; 2-generation reproduction study in rats) is complete, and there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits in the available toxicity data.

E. Aggregate Risks and Determination of Safety

The following text is based on the assumption that water models were used to estimate residues in drinking water. If exposure to residues in drinking water is not expected, delete the following three paragraphs. If exposure is based on monitoring data, the text must be revised.

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD -(average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to cloquintocet-mexyl and its acid metabolite will occupy < 1.0 % of the aPAD for females 13–50 years. In addition, there is potential for acute dietary exposure to cloquintocet-mexyl and its acid metabolite in drinking water. The acute DWLOC for the population subgroups females of child-bearing age is 30,000 ppb. After calculating the acute DWLOC and comparing the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD since the DWLOC greatly exceeds the EEC.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cloquintocet-mexyl and its acid metabolite from food will utilize < 1 % of the cPAD for the U.S. population, infants (< 1 year), and male and female adult populations. Exposure from food will utilize 1 % of the cPAD for children (1–6) and (7–12 years). There are no residential uses for cloquintocet-mexyl that result in chronic residential exposure.

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLOQUINTOCET-MEXYL

Population Subgroup [1]	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.04	<1.0	0.0053	0.0060	1,400
Children 1–6	0.04	1.0	0.0053	0.0060	400
Females 13+ Nursing	0.04	< 1.0	0.0053	0.0060	1,200
Males 13–19	0.04	< 1.0	0.0053	0.0060	1,400

[1] For all population subgroups, EPA does not expect the aggregate exposure to exceed 100% of a cPAD since the DWLOC greatly exceeds the EEC.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cloquintocet-mexyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). There are no established residential uses for cloquintocet-mexyl.

Cloquintocet-mexyl is not registered for use on any sites that would result in residential exposure. Therefore the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.Cloquintocet-mexyl is classified as ''not likely'' to be a human carcinogen*. Therefore, cloquintocet-

mexyl is not expected to pose a cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to residues of cloquintocet-mexyl and its acid metabolite.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed residue analytical methods for tolerance enforcement that use high performance liquid chromatography with UV detection (HPLC-UV). These methods are currently being validated by the Analytical Chemistry Branch laboratories, BEAD (7503C), Office of Pesticide Programs. Upon successful completion of the EPA validation, these methods will be forwarded to FDA for publication in a future revision of the Pesticide Analytical Manual. Vol-II (PAM-II). Prior to publication in PAM-II and upon request, the methods will be available prior to the harvest season from the Analytical Chemistry Branch (ACB), BEAD (7503C), Environmental Science Center, 701 Mapes Road, Fort George G. Meade, MD 20755–5350; contact Francis D. Griffith, Jr., telephone (410) 305–2905, e-mail griffith.francis @epa.gov. The analytical standards for these methods are also available from the EPA National Pesticide Standard Repository at the same location.

B. International Residue Limits

There are no Codex, Canadian, or Mexican tolerances for cloquintocet-mexyl on wheat. Therefore, no compatibility issues exist.

C. Conditions

The following residue chemistry data gaps have been identified for cloquintocet mexyl: (1) additional wheat metabolism data; (2) additional information on meat, milk, poultry, and egg analyses; (3) storage stability data; and (4) additional field trial residue studies. Because of these deficiencies, the Agency incorporated several conservative assumptions into the risk assessment for cloquintocet-mexyl. The Agency believes that the available data and risk assessment support the determination that there is a reasonable certainty of no harm and the establishment of permanent tolerances for cloquintocet-mexyl.

Cloquintocet-mexyl will be used with the active ingredient, clodinafop-propargyl. The registration of clodinafop-propargyl will be time-limited and conditional upon submission of additional information/data to satisfy certain toxicology, residue chemistry, ecological effects, and environmental fate data deficiencies. Several guideline requirements are either data gaps or are only partially fulfilled, and the additional information is required to confirm and/or refine the parameters of the Agency's risk assessment. The required data for both cloquintocet-mexyl and clodinafop-propargyl must be submitted to maintain this registration.

V. Conclusion

Therefore, the tolerances are established for combined residues of cloquintocet-mexyl (acetic acid, [(5-chloro-8-quinolinyl)oxy]-, 1-methylhexyl ester) and its acid metabolite (5-chloro-8-quinolinoxy acetic acid), in or on wheat, grain at 0.1 ppm (parts per million); wheat, forage at 0.1 ppm; wheat, hay at 0.1 ppm; and wheat, straw at 0.1 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–301010 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 August 21, 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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 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 judgment 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, 1200 Pennsylvania Ave., NW., 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, 1200 Pennsylvania Ave., NW., 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–301010, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., 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 6.1/8.0 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 a tolerance 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 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. 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: June 6, 2000.

Susan B. Hazen

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.560 is added to read as follows:

§ 180.560 Cloquintocet-mexyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of cloquintocet-mexyl (acetic acid, [(5-chloro-8-quniolinyl)oxy]-, 1-methylhexyl ester)(CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinlinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the herbicide, clodinafop-propargyl in a 1:4 ratio of safener to active ingredient in or on the following food commodities:

Commodity	Parts per million
Wheat, forage	0.1
Wheat, straw	0.1
Wheat, hay	0.1
Wheat, grain	0.1

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

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

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

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