technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

The Coast Guard analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g) from further environmental documentation. This rule fits the category selected from paragraph (34)(g), as it establishes a safety zone. An Environmental Analysis Checklist and Categorical Exclusion Determination are available for review at the location listed under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226 and 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. From 6 a.m. on November 29, 2005 until 11:59 p.m. on May 31, 2006, add temporary § 165.T01–106 to read as follows:

§ 165.T01–106 Regulated Navigation Area, East Rockaway Inlet to Atlantic Beach Bridge, Nassau County, Long Island, New York.

(a) *Location.* The following area is established as a Regulated Navigation Area: All waters of East Rockaway Inlet in an area bounded by lines drawn from the approximate position of the Silver Point breakwater buoy (LLN 31500) at 40°34′56″ N, 073°45′19″ W, running north to a point of land on the northwest side of the inlet at position 40°35′28″ N, 073°46′12″ W, thence easterly along the shore to the east side of the Atlantic Beach Bridge, State Route 878, over East Rockaway Inlet, thence across the bridge to the south side of East Rockaway Inlet, thence westerly along the shore and across the water to the beginning.

(b) *Regulations.* (1) Vessels carrying petroleum products as cargo, with a loaded draft greater than five feet, are prohibited from transiting within the regulated navigation area.

(2) Operators of vessels carrying petroleum products as cargo with a loaded draft greater than five feet must submit a request to transit the regulated navigation area to the Captain of the Port, Long Island Sound, at least 48 hours prior to transiting the area. Requests to transit the area shall consist of a general voyage plan identifying parameters for transit, to include the following: Weather conditions for transit, restrictions due to state of tide, the loaded draft of the vessel, and minimum acceptable under keel clearance. Once approved, vessels may transit the area in accordance with the approved voyage plan. Any modification or deviation from approved voyage plans must be submitted to the Captain of the Port, Long Island Sound at least 24 hours prior to the transit to which the modification applies.

(c) *Effective period.* This rule is effective from 6 a.m. on November 29, 2005 until 11:59 p.m. on May 31, 2006.

Dated: November 28, 2005.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 05–24135 Filed 12–15–05; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

Standards of Performance for New Stationary Sources

CFR Correction

In title 40 of the Code of Federal Regulations, Part 60 (§ 60.1 to End), revised as of July 1, 2005, on page 167, in § 60.41c, correct the definition of ''Annual capacity factor'' to read as follows:

§ 60.41c Definitions.

* * * * *

Annual capacity factor means the ratio between the actual heat input to a steam generating unit from an individual fuel or combination of fuels during a period of 12 consecutive calendar months and the potential heat input to the steam generating unit from all fuels had the steam generating unit been operated for 8,760 hours during that 12-month period at the maximum design heat input capacity. In the case of steam generating units that are rented or leased, the actual heat input shall be determined based on the combined heat input from all operations of the affected facility during a period of 12 consecutive calendar months.

* * * * *

[FR Doc. 05–55521 Filed 12–15–05; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0234; FRL–7753–4]

Acetic acid, [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester (Cloquintocet-mexyl); Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is granting in part, and denying in part, pesticide petition PP 4E6831 submitted by Syngenta Crop Protection, Inc. that requested certain amendments to 40 CFR 180.560 for acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; cloquintocet-mexyl; CAS Reg. No. 99607–70–2] and its acid metabolite (5-chloro-8-quinolinoxyacetic acid). EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3) in the **Federal Register** of June 2, 2004 (69 FR 31116) (FRL–7357–8) announcing the filing of this petition requesting that the tolerance expressions under § 180.560 for wheat forage and hay be increased, the addition of tolerances for barley commodities (grain, hay, and straw), and the inclusion of a reference to the active ingredient pinoxaden. Although EPA finds it is safe to add a reference to pinoxaden and tolerances for barley (grain, hay, and straw) to this tolerance regulation, EPA does not agree that grounds exist to increase the tolerance expressions for wheat forage and hay. Thus, EPA is granting Syngenta's petition in as far as it seeks to add the reference pinoxaden and tolerances for barley (grain, hay, and straw) but is denying the request to increase the tolerance expressions for wheat forage and hay.

DATES: This final rule is effective December 16, 2005. Objections and requests for hearings must be received on or before February 14, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0234. All documents in the docket are listed on the *http://www.regulations.gov* Web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: R. Tracy Ward, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703 308–9361; e-mail address: *ward.tracyh@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111).
- Animal production (NAICS 112).
- Food manufacturing (NAICS 311).
- Pesticide manufacturing (NAICS 32532).

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of June 22, 2004 (69 FR 31116) (FRL–7357–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E6831) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, North Carolina, 27419–8300. This notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the petitioner. The petition requested that 40 CFR 180.560 for combined residues of the inert ingredient herbicide safener acetic acid, [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester and its acid metabolite (5-chloro-8-quinolinoxyacetic acid) be amended by:

1. Increasing the tolerance expressions in or on wheat, forage to 0.20 ppm and wheat, hay to 0.50 ppm,
2. Adding tolerance expressions for barley, grain, hay and straw at 0.10 ppm, and
3. By adding a reference to the active ingredient pinoxaden.

For ease of reading this document, acetic acid, [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester will be referred to as cloquintocet-mexyl. The Chemical Abstracts Service (CAS) Registry Number of cloquintocet-mexyl is 99607–70–2 and the CAS name is acetic acid, [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester (9 CI).

One comment was received on the notice of filing from a private citizen questioning whether the Agency was going to use the most current and up-to-date information and data available when writing the final rule. In developing the final rule, EPA did evaluate the information and data submitted by the petitioner as well as more recent information that was available to the Agency.

In the final rule that EPA used to establish the existing tolerances under 40 CFR 180.560 (**Federal Register** of June 22, 2000 (65 FR 38757; FRL–6592-4; PP7E4920), EPA determined that additional data (for plant and livestock metabolism, plant analytical methods, multiresidue methods, storage stability, crop field trials, processing studies, and rotational crops) were required before a permanent registration for cloquintocet-mexyl in or on wheat commodities could be established. Syngenta submitted data in response to the previous risk assessment. Assessments of human exposures and risks were conducted for acute and chronic dietary risk, exposure and risk to cloquintocet-mexyl residues in water, residential exposure and risk, aggregate risk, and exposure and risk to workers.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, 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) of FFDCA, for a tolerance for combined residues of cloquintocet-mexyl and its acid metabolite on wheat, grain and straw at 0.10 ppm; wheat, forage at 0.20 ppm; wheat, hay at 0.50 ppm; barley, grain at 0.01 ppm; and barley, hay and straw at 0.10 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. Specific information on the studies received and the nature of the toxic effects caused by cloquintocet-mexyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are described in this section.

1. *Acute toxicity*. The acute toxicity data (see Table 1) indicated that cloquintocet-mexyl (CGA 185072) has low acute oral, dermal, and inhalation toxicity (Acute Toxicity Category III) and is slightly irritating to eyes. It is not a skin irritant. However, it is a skin sensitizer.

TABLE 1.—ACUTE TOXICITY DATA ON CLOQUINTOCET-MEXYL

GDLN	Study Type	Results
81–1	Acute Oral-Rat	LD_{50}>2,000 mg/kg (M&F)
81–1	Acute Oral-Mouse	LD_{50}>2,000 mg/kg (M&F)
81–2	Acute Dermal-Rat	LD_{50}> 2,000 mg/kg
81–3	Acute Inhalation-Rat	LC_{50}>0.935 µg/L
81–4	Primary Eye Irritation-Rabbit	Slight eye irritant
81–5	Primary Skin Irritation-Rabbit	Non-irritant
81–6	Dermal Sensitization-Guinea pig	Skin sensitizer

2. *Subchronic and chronic toxicity*. Available toxicity studies are described in Table 2.

i. *Systemic toxicity*. The primary target organs for subchronic exposure of cloquintocet-mexyl (CGA 185072) are the liver and the renal system. In a 90-day feeding study in rats, increased incidence of urinary bladder hyperplasia and increased serum bilirubin were observed in males at doses ≥ 1,000 ppm (equivalent to 64 mg/kg/day). This observation was supported by a 28-day oral gavage study in rats where renal papillary necrosis and inflammation with fibrosis were observed at doses ≥ 100 mg/kg/day. In a 28-day dermal toxicity study in rats, mottled or reddish livers accompanied by histopathological changes including necrosis and fibrosis were observed in two of five females exposed to 1,000 mg/kg/day of cloquintocet-mexyl (CGA 185072). In a 90-day feeding study in dogs, liver toxicity was evidenced by observations of liver necrosis and perivascular inflammatory cell infiltration. In the one-year dog study, increased relative liver weight and increased chronic interstitial nephritis were observed. It is notable that in the two-year chronic toxicity study in rats, no renal or liver toxicity was reported; however, there was an increase in lymphoid hyperplasia of the thymus in male rats and an increase in thyroid follicular epithelial hyperplasia in female rats at 73 mg/kg/day.

ii. *Developmental/reproductive toxicity*. 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 (CGA 185072). NOAELs for maternal/parental toxicity were either less than or equal to the NOAELs for fetal or reproductive toxicity.

iii. *Carcinogenicity*. In accordance with the EPA *Proposed EPA Weight-of-the-Evidence Categories*, August 1999 cloquintocet-mexyl was classified 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 mutagenic test battery, it is suggested that cloquintocet-mexyl (CGA 185072) is not likely to be a human carcinogen.

iv. *Mutagenicity*. Studies indicate that cloquintocet-mexyl is not mutagenic in bacteria (*Salmonella typhimurium* or *Escherichia coli*) or cultured mammalian cells (Chinese hamster V79 lung fibroblasts). There is also no evidence of clastogenicity either *in vitro* or *in vivo*. Similarly, cloquintocet-mexyl did not induce unscheduled DNA synthesis (UDS) in primary rat hepatocytes.

v. *Neurotoxicity*. There is no evidence of neurotoxicity based on observations in toxicity studies. Acute and subchronic neurotoxicity studies are not available for cloquintocet-mexyl; additional neurotoxicity testing is not being required at this time.

vi. *Metabolism*. Metabolism studies in rats indicated that approximately 40% of the administered dose of cloquintocet-mexyl was absorbed through the gastrointestinal tract and subsequently excreted via the urine. Fecal excretion accounted for approximately 60% of the administered dose. The chemical was rapidly eliminated (more than 80% of the administered dose) via feces and urine within 48 hours post-dosing. Sex, dosing regime, and dose levels had little effect on the excretion pattern. Excretion patterns were similar between the biliary cannulated and non-cannulated animals indicating that there was no enterohepatic circulation of the chemical. Three days after administration, tissue radioactivity accounted for less than 0.3% of the administered dose (or was non-detectable) and was not detectable in the expired air. At day three post-dosing, most tissue residues of radioactivity were below the limit of detection. The major metabolic pathway of cloquintocet-mexyl was ester hydrolysis to yield 5-chloro-8-quinolinoxy acetic acid, the major metabolite in the fecal and urinary pools.

TABLE 2.—TOXICITY PROFILE SUMMARY TABLE FOR CLOQUINTOCET-MEXYL

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 possibly increased SGPT.
870.3100	13 week oral in rodents	NOAEL = M: 150 ppm (9.7 mg/kg), F= 6,000 ppm (=407 mg/kg/day). LOAEL = M - 1,000 ppm (6.9 mg/kg); F ≥ 6,000 ppm (≥ 407 mg/kg/day), based on urinary bladder hyperplasia, kidney hydronephrosis and increased serum bilirubin in males.
870.3150	90-Day oral in non-rodent	NOAEL = 100 ppm (M: 2.9 mg/kg/day; F: 3.3 mg/kg/day). LOAEL = 1,000 ppm (M and F: 30.2 mg /kg/day) 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
870.3700	Prenatal developmental in rodent	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.
870.3700	Prenatal developmental in non-rodent	Maternal NOAEL = 60 mg/kg/day Maternal LOAEL = 300 mg/kg/day based on maternal toxicity (death) in the high dose group only. Developmental NOAEL = 300 mg/kg/day Developmental LOAEL ≥ 300 mg/kg/day
870.3800	2 Generation Reproduction	Parental/Systemic NOAEL = 5,000 ppm (M: 370.7; F: 442.8 mg/kg/day) Parental/Systemic LOAEL =10,000 ppm (M: 721.7 ; F: 846.9 mg/kg/day), based on decreased body weight, deceased 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). Reproductive LOAEL ≥ 10,000 ppm (721.7 mg/kg/day) Developmental NOAEL = 5,000 ppm (442.8 mg/kg/day) Developmental LOAEL = 10,000 (846.9 mg/kg/day) based on decreased pup weight and dilated renal pelvis.
870.4100	Chronic toxicity in nonrodent	NOAEL = 1500 ppm (M: 43, F: 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 possibly decreased testes/prostate weights and interstitial nephritis.
870.4200	Carcinogenicity in mice	NOAEL = 1,000 ppm (M: 111; F: 102 mg/kg/day) LOAEL = 5,000 ppm (M: 583; F: 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 possibly slightly increased water consumption in both sexes. Negative for oncogenicity.
870.4300	Combined chronic/oncogenicity in rat	NOAEL = F: 100 ppm (4.3 mg/kg/day) M: 1,000 ppm (36.4 mg/kg/day) LOAEL = F: 1,000 ppm (41.2 mg/kg/day); M: 2,000 ppm (81.5 mg/kg/day) based on increased incidence of thyroid follicular epithelial hyperplasia in females and based on lymphoid hyperplasia of the thymus in males.

TABLE 2.—TOXICITY PROFILE SUMMARY TABLE FOR CLOQUINTOCET-MEXYL—Continued

Guideline No.	Study Type	Results
870.5100	Gene Mutation	Testing up to 5,000 μg/plate with or without S9 microsomes produced no evidence that CGA 185072 technical induced a mutagenic effect in any strain. Negative mutagen
870.5200	Gene Mutation	There was no evidence mutagenic effect at any dose (up to 500 μg/plate) with or without S9 activation. Negative mutagen.
870.5315	Human Lymphocytes *in vitro*	Human lymphocytes were exposed in vitro up to 75 μg/mL with or without S9 activation showed no evidence that CGA 185072 induced a cytogenetic effects. at any dose. Negative mutagen.
870.5395	Micronucleus Test	Chinese hamsters dosed from 625 to 2,500 mg/kg showed no evidence that CGA 185072 induced 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 CGA 185072 technical in the absence of S9 activation induced a genotoxic response.
870.5550	DNA Repair Rat Hepatocytes	Primary rat hepatocytes expose to 200 μg/mL for 16-18 hour and scored for nuclear grains showed no evidence that CGA 185072 technical induced a genotoxic response. Negative mutagen.
870.7485	Metabolism and pharmacokinetics	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, reference material CGA 153433, accounting for approximately 95% of the recovered radioactivity.
870.7485	Metabolism and pharmacokinetics	The major metabolic pathway of CGA 185072 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

A summary of the toxicological endpoints for cloquintocet-mexyl used for human risk assessment is shown below in Table 3.

1. *Acute dietary exposure.* An acute reference dose (RfD) was selected for the subpopulation of females 13-50 years old. This acute RfD of 1 mg/kg/day is based on the no-observable-adverse-effect-level (NOAEL) of 100 mg/kg/day selected from a developmental toxicity in rats (MRID 44387429) where an increased incidence of skeletal variants and decreased fetal body weight was observed at 400 mg/kg/day. [The NOAEL of 100 mg/kg/day is divided by uncertainty factors (UF) for inter-species extrapolation (10x) and intra-species variability (10x).] Based on the conservative assumption that developmental toxicity could occur following a single exposure to a pregnant female, this endpoint is appropriate for acute risk assessment for females 13-50 years old.

An acute RfD for the general population was not identified. Based on the available toxicology data, toxic effects observed in oral toxicity studies could not be attributed to a single dose (exposure) for population subgroups other than females 13-50 years old. No acute or subchronic neurotoxicity studies are available for cloquintocet-mexyl at this time. No other neurotoxic effects were observed in available toxicity studies. It is also noteworthy that the acute oral LD_{50} for male and female rats for technical grade cloquintocet-mexyl (98% a.i.) is <2,000 mg/kg (Toxicity Category III).

2. *Chronic dietary exposure.* The Agency selected a chronic RfD of 0.04 mg/kg/day (NOAEL = 4.3 mg/kg/day; Uncertainty Factor = 100). This chronic RfD is based on a two year combined chronic/oncogenicity study in rats (MRID 44387431). In this study, the NOAEL of 4.3 mg/kg/day was based on increased incidence of thyroid follicular epithelial hyperplasia in females at 41.2 mg/kg/day (lowest-observable-adverse-effect-level; LOAEL). The Uncertainty Factor accounts for both interspecies extrapolation (10X) and intraspecies variability (10X). This study is considered an appropriate study for assessment of chronic dietary risk because the endpoint is based on chronic effects observed in thyroid pathology.

TABLE 3.—SUMMARY OF TOXICOLOGY ENDPOINT SELECTIONS FOR CLOQUINTOCET-MEXYL

EXPOSURE SCENARIO/STUDY	DOSE (mg/kg/day)	ENDPOINT
Acute Dietary(For females 13+)/Developmental toxicity study in rats	NOAEL=100 (UF=100)	Higher incidence of skeletal variants and decrease in fetal body weights in the high dose group at 400 mg/kg/day (LOAEL). Acute RfD (females 13+) = 1.0 mg/kg/day
Acute Dietary(For general population)	Based on available data, a suitable endpoint was not identified for general population because there were no effects observed in oral toxicity studies appropriate to this population that could be attributed to a single dose exposure.	Acute RfD (general population) = Not applicable
Chronic Dietary/Chronic/Oncogenicity Toxicity -Rat	NOAEL=4.3 (UF=100)	Observation of thyroid hyperplasia in females at 41.2 mg/kg/day (LOAEL). Chronic RfD = Chronic PAD = 0.04 mg/kg/day

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.02), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The 1994–96, and 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods as consumed (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994–96, and 98 CSFII consumption data, which took into account dietary patterns and survey respondents, the Agency concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

Established and recommended tolerances were used in acute and chronic dietary assessments. Percent crop treated data were not applied. DEEM™ default concentration factors were used.

i. *Acute exposure.* The acute food exposure analysis for cloquintocet-mexyl is a Tier 1 assessment because no additional data were used to refine the analysis. One hundred percent of proposed and registered crops are assumed treated with cloquintocet-mexyl (100% CT) and tolerance-level residues were used in the analysis. The acute dietary endpoint (incidence of skeletal variants and decrease in fetal body weights) is only applicable to the population subgroup females 13-49 years old. An acute dietary endpoint for the general population including infants and children was not identified. The highest estimate for acute drinking water exposure, 0.186 ppb, was used in the analysis. The estimated dietary exposure for females 13-49 years old is 0.000347 mg/kg/day, which occupies less than 1% of the aPAD and does not exceed EPA's level of concern.

ii. *Chronic exposure.* The chronic dietary exposure analysis for cloquintocet-mexyl is a Tier 1 assessment because no additional data were used to refine the analysis. One hundred percent of proposed and registered crops are assumed treated with cloquintocet-mexyl (100% CT) and tolerance-level residues were used in the analysis. The chronic dietary endpoint applies to all population subgroups including infants and children. The highest estimate for chronic drinking water exposure, 0.005 ppb, was used in the analysis. A listing of the subgroups are reported below in Table 4.

The results of the chronic dietary analysis estimates exposure for the general U.S. population, all infants < 1 year, children 6-12 years, youths 13-19 years, and adults 20+ years to be < 1% of the cPAD. The estimated dietary exposure for children 1-2 and 3-5 years occupies 1% of the cPAD. Risk estimates for all population subgroups are below EPA's level of concern (100% of the cPAD).

TABLE 4.—RESULTS OF CHRONIC DIETARY EXPOSURE ANALYSIS

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.04	0.000180	<1
All Infants (< 1 year old)	0.04	0.000077	<1
Children 1-2 years old	0.04	0.000403	1
Children 3-5 years old	0.04	0.000411	1
Children 6-12 years old	0.04	0.000289	<1
Youth 13-19 years old	0.04	0.000176	<1

TABLE 4.—RESULTS OF CHRONIC DIETARY EXPOSURE ANALYSIS—Continued

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
Adults 20-49 years old	0.04	0.000153	<1
Adults 50+ years old	0.04	0.000120	<1
Females 13-49 years old	0.04	0.000137	<1

iii. *Cancer*. In August 1999, EPA classified cloquintocet-mexyl as not likely to be a human carcinogen. Due to the classification, no quantitative cancer exposure assessment was performed.

2. *Dietary exposure from drinking water*. The mobility of cloquintocet-mexyl (as measured by its binding to soils) varies from low in a moderate organic soil to essentially immobile in a high organic soil. The persistence of cloquintocet-mexyl in soil is very low. Therefore, based upon the its low persistence and low mobility, the leaching potential of cloquintocet-mexyl should be negligible. The results of the aerobic aquatic metabolism studies indicate that cloquintocet-mexyl will rapidly degrade in aerobic ground and surface waters that have adequate microbial activity. The results of the direct photolysis (DT50 of several hours) indicate that cloquintocet-mexyl is also susceptible to rapid rates of direct photolysis in clear shallow water. However, based on the results of the abiotic hydrolysis study (half-lives of 4.4 yr. at pH 5, 134 days at pH 7 and 6.6 days at pH 9), it may be substantially more persistent in aerobic waters with low microbial activity. Data are not currently available to assess its persistence in anaerobic waters.

The Agency currently lacks sufficient water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for cloquintocet-mexyl. Therefore, the Agency is presently relying on computer-generated estimated environmental concentrations (EECs). GENEEC is a model used to generate EECs for surface water based on estimates of safener concentration in a farm pond. SCI-GROW is an empirical model based upon actual monitoring data collected for a number of pesticides which serve as benchmarks and has been used to predict EECs in ground water. The highest EECs from the current and proposed uses were the GENEEC estimates acute (peak) and chronic (56-year mean) concentrations of cloquintocet-mexyl and CGA–153433 in water at 0.186 ppb and 0.005 ppb, respectively.

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).

Residential uses are not proposed in this petition and there are no residential uses registered for products in which cloquintocet-mexyl serves as a safener, and therefore, a residential exposure assessment is not required.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA 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.

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cloquintocet-mexyl and any other substances, and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA 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 based on reliable data 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Conclusions*. EPA concluded that the FQPA safety factor could be removed for cloquintocet-mexyl for the following reasons. The toxicology database is complete for cloquintocet-mexyl. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to cloquintocet-mexyl in the available toxicity data, and EPA determined that a developmental neurotoxicity study is not required for cloquintocet-mexyl. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children from the use of cloquintocet-mexyl (currently there are no proposed residential uses and therefore non-occupational exposure is not expected).

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. The aggregate acute risk estimates include exposure to residues of cloquintocet-mexyl in food and water, and does not include dermal, inhalation or incidental oral exposure. Since the dietary exposure assessment already includes the highest acute exposure from the drinking water modeling data, no further calculations are necessary. The food and water exposure estimates for females 13-49 yrs old is <1% aPAD. The acute risk estimate for females 13-49 years, resulting from aggregate exposure to cloquintocet-mexyl in food and drinking water is below EPA's level of concern.

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

EPA selected doses and toxicological endpoints for assessments of short- and intermediate-term dermal and inhalation risk. However, since there are no residential uses for cloquintocet-mexyl (either established or pending) at this time, these risk assessments are not needed.

3. *Chronic aggregate risk*. The aggregate chronic risk assessment takes into account average exposure estimates from dietary consumption of cloquintocet-mexyl (food and drinking water) and residential uses. Since there are no residential uses for cloquintocet-mexyl (either established or pending) at this time, the aggregate chronic assessment included exposures from food and drinking water only. Since the dietary exposure assessment already includes the highest chronic exposure from the drinking water modeling data, no further calculations are necessary. The general U.S. population and all population subgroups have exposure and risk estimates which are below the Agency's level of concern (i.e., the percentages of the chronic population adjusted doses (cPADs) are all below 100%). The exposure to the U.S. population is <1% cPAD and the most highly exposed subgroup, children 3-5 yrs old is 1% cPAD. Therefore, chronic risk estimates resulting from aggregate exposure to cloquintocet-mexyl in food and drinking water are below the Agency's level of concern from all population subgroups.

4. *Cancer aggregate risk*. EPA has concluded cloquintocet-mexyl is unlikely to pose a cancer risk.

5. *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 cloquintocet-mexyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Residue Analytical Methods*. Adequate enforcement methods are available for enforcement of the proposed/existing tolerances on wheat and barley. The two enforcement methods are the HPLC/UV method REM 138.01 for determination of cloquintocet-mexyl (parent) and the HPLC/UV Method REM 138.10 for determination of the metabolite CGA–153433. Adequate EPA petition method validations have been conducted on wheat grain, straw, and forage for the two enforcement methods. Both methods have been forwarded to FDA for publication in *Pesticide Analytical Manual*, Vol. II. The validated LOQs for Method REM 138.01 are 0.05 ppm for wheat forage, hay, and straw, and 0.02 ppm for wheat grain, processed commodities, and aspirated grain fractions. The validated LOQ for Method REM 138.10 is 0.05 ppm for all wheat commodities.

Syngenta submitted analytical Methods REM 199.02, REM 199.03, and 117-01 for analysis of residues of CGA–153433, the metabolite of cloquintocet-mexyl, in cereal grain matrices. Method REM 199.02 was used to determine residues of CGA–153433 in barley grain, hay, and straw in one barley field trial study (MRID 46203205) and in wheat field trials conducted in Canada (MRID 46302206). Method 117–01 was used to determine residues of CGA–153433 in barley grain, hay, and straw in one barley field trial study (MRID 46203204) and in the barley grain and processed commodities in the processing study (MRID 46203204). All three methods possessed the same extraction procedure consisting of acid hydrolysis (1N HCl) by boiling under reflux for two hours. The acid hydrolysis is intended to convert the parent cloquintocet-mexyl (CGA–185072) to the acid metabolite, CGA–153433; however, validation/recovery data for CGA–185072 was not provided. The three methods are adequate for data gathering methods for cloquintocet-mexyl in cereal grain commodities.

Method REM 117–01 (MRID 46203138) is also proposed as an enforcement method. To be an enforcement method for cloquintocet-mexyl, EPA's analytical chemistry laboratory (ACB/BEAD) would have to validate the Method 117–01 for cloquintocet-mexyl (CGA–185072) and its metabolite CGA–153433 in cereal matrices and radiovalidation data for the method would have to be submitted. This is not a deficiency for these actions.

2. *Multiresidue Methods*. Cloquintocet-mexyl and CGA–153433 were tested through the FDA multiresidue methods according to the decision tree and protocols in the *Pesticide Analytical Manual*, Volume I, Appendix II. Cloquintocet-mexyl was tested per Protocols C, D, and E; recovery was variable using protocol D, and the test substance was not recovered using Protocol E. CGA-153433 was tested per Protocols B and C; the compound was not recovered using Protocol B, and based on the results of Protocol C testing, no further testing was required for this compound. The submitted multiresidue methods data have been forwarded to FDA.

B. International Residue Limits

There are no Codex tolerances established for cloquintocet mexyl. Australia has established maximum residue limits (MRLs) for cloquintocet-mexyl on wheat and barley at 0.1 ppm.

V. Conclusion

EPA has reviewed the data and information submitted by the petitioner in support of the establishment of tolerances for the combined residues of cloquintocet-mexyl and its acid metabolite (5-chloro-8-quinolinoxyacetic acid) in or on wheat (grain, straw, forage, and hay) and barley (grain, hay, and straw) as required in the **Federal Register** of June 22, 2000 (65 FR 38757; FRL–6592–4).

The residue data show that residues are not expected to exceed 0.01 ppm in barley grain (LOQ) and 0.05 ppm in barley hay and straw. The Agency will establish permanent tolerances 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), in/on barley (straw, hay and grain) at 0.1 ppm.

The available data indicate that no revisions to the current tolerance levels of 0.1 ppm on wheat, forage and wheat, hay are needed. EPA does not agree that grounds exist to increase the tolerance expressions for wheat forage and hay because residues of cloquintocet-mexyl will not exceed 0.1 ppm.

EPA established tolerances for the combined residues of pinoxaden in or on barley and wheat in the **Federal Register** on July 27, 2005 (70 FR 43313) (FRL–7725–5). Therefore, EPA is granting Syngenta's petition to allow the use of the safener cloquintocet-mexyl with pinoxaden in a 1:4 ratio of safener to active ingredient in or on wheat (grain, straw, forage, and hay) and barley (grain, hay, and straw).

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number EPA–HQ–OPP–2005–0234 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 February 14, 2006.

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 issue(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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2005–0234, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or 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 section 408(d) of FFDCA, 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. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. 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 section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule

does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: December 6, 2005.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

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

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

■ 2. Section 180.560 is amended by revising paragraph (a) 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 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 active ingredients pinoxaden (wheat or barley) or clodinafop-propargyl (wheat only) in a 1:4 ratio of safener to active ingredient in or on the following food commodities:

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

* * * * *

[FR Doc. 05–24097 Filed 12–15–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0276; FRL–7746–5]

Bifenazate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of bifenazate in or on tart cherries and soybeans. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on tart cherries and soybeans. This regulation establishes maximum permissible levels for residues of bifenazate in these food commodities. The tolerance will expire and is revoked on December 31, 2009.

DATES: This regulation is effective December 16, 2005. Objections and requests for hearings must be received on or before February 14, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0276. All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Marcel Howard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6784; e-mail address:*howard.marcel@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to