addresses actions that may result in the expenditure by a State, local, or tribal government, in aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, the effects of this rule are discussed elsewhere in this preamble.

**Taking of Private Property**

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

**Civil Justice Reform**

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

**Protection of Children**

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

**Environment**

The Coast Guard considered the environmental impact of this rule and concluded that under Commandant Instruction M16475.1C, Figure 2–1, paragraph 32(e), this rule is categorically excluded from further environmental documentation, because it is a Bridge Administration Program action involving the promulgation of operating requirements or procedures for a drawbridge. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under **ADDRESSES.**

**List of Subjects in 33 CFR Part 117**

Bridges.

For the reasons set out in the preamble, the Coast Guard amends Part 117 of Title 33, Code of Federal Regulations, as follows:

## PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

**Authority:** 33 U.S.C. Sec. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.225 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.181 is amended to read as follows:

**§ 117.181 Oakland Inner Harbor Tidal Canal.**

The draws of the Alameda County highway drawbridges at Park Street, mile 5.2; Fruitvale Avenue, mile 5.6; and High Street, mile 6.0; and the U.S. Army Corps of Engineers railroad drawbridge, mile 5.6 at Fruitvale Avenue, shall open on signal; except that, from 8 a.m. to 9 a.m. and 4:30 p.m. to 6:30 p.m. Monday through Friday except Federal holidays, the draws need not be opened for the passage of vessels. However, the draws shall open during the above closed periods for vessels which must, for reasons of safety, move on a tide or slack water, if at least two hours notice is given. The draws shall open as soon as possible for vessels in distress and emergency vessels, including commercial vessels engaged in rescue or emergency salvage operations.

Dated: March 29, 2001.

**E.R. Riutta,**

*U.S. Coast Guard, Commander, Eleventh Coast Guard District.*

[FR Doc. 01–8895 Filed 4–10–01; 8:45 am]

**BILLING CODE 4910–15–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–301110; FRL–6774–8]**

**RIN 2070–AB78**

## Zoxamide 3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for the combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH–1455 and RH–141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH–1452 and RH–141452) in or on potato, tuber; potato, granule/flake; potato, wet peel and residues of zoxamide in or on grape; and grape, raisins. Rohm and Haas requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective April 11, 2001. Objections and requests for hearings, identified by docket control number OPP–301110 must be received by EPA on or before June 11, 2001.

**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–301110 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: CynthiaGiles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-7740; and e-mail address: Cynthia Giles-Parker@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

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

| Categories | NAICS | Examples of potentially affected entities |
|---|---|---|
| Industry | 111 | Crop production |
| | 112 | Animal production |
| | 311 | Food manufacturing |
| | 32532 | Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not thisaction 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'', ''Regulations and Proposed Rules,'' 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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr—00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301110. 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 September 1, 1999 (64 FR 47795) (FRL–6096–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Rohm and Haas. This notice included a summary of the petition prepared by Rohm and Haas, the registrant. There were no comments received in response to thenotice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the fungicide zoxamide 3,5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2- oxopropyl)-4-methylbenzamide, and its metabolites in or on grapes, raisins and potatoes at 5.0, 15.0 and 0.1 part per million (ppm), respectively.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for the combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH–1455 and RH–141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH–1452 and RH–141452) in or on potato, tuber at 0.060 ppm; potato, granule/flake at 0.30 ppm; potato, wet peel at 0.10 ppm and zoxamide in or on grape at 3.0 ppm; grape, raisins at 15 ppm. Several of the tolerances that are being established by this rule ae different from those proposed by Rohm and Haas. EPA's review of the data submitted by the company lead to an Agency decision to modify the proposed tolerances. 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 zoxamide are discussed in Table 2 below as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

Zoxamide has low acute toxicity (Toxicity Category IV for acute oral, inhalation toxicity and Category III for acute dermal toxicity and ocular irritation). Zoxamide is considered to be a dermal sensitizer, but it is not a skin irritant (Toxicity Category IV). In addition, a concern was identified for the potential of zoxamide to be an inhalation sensitizer for the following reasons: (1) up to 50% of the wettable powder formulation's dispersed particle size is less than 5 μm, and thus inhalable to the alveolar region in humans; and (2) zoxamide's mechanism of action is binding to tubulin, and therefore may bind to other proteins. See Table 1 for a discussion of EPA's our findings.

TABLE 1.—ACUTE TOXICITY OF ZOXAMIDE—TECHNICAL (RH–117,281)

| Guideline No. | Study Type | Results | Toxicity Category |
|---|---|---|---|
| 870.1100 | Acute Oral-Rat | $LD_{50}$ > 5,000 mg/kg (males and females, combined) | IV |
| 870.1100 | Acute-Oral-Mouse | $LD_{50}$ > 5,000 mg/kg (males and females, combined) | IV |
| 870.1200 | Acute Dermal-Rat | $LD_{50}$ > 2,000 mg/kg (males and females, combined) | III |

TABLE 1.—ACUTE TOXICITY OF ZOXAMIDE—TECHNICAL (RH–117,281)—Continued

| Guideline No. | Study Type | Results | Toxicity Category |
|---|---|---|---|
| 870.1300 | Acute Inhalation-Rat | $LC_{50}$ > 5.3 mg/L (males and females, combined) | IV |
| 870.2400 | Primary Eye Irritation-Rabbit | Moderate irritant; Corneal opacity on 6/6 rabbits with resolution by day 7. Iritis on 1/6 rabbits at 24 hours with resolution by 48 hours. Conjunctivitis on all rabbits at one hour with resolution by day 7. | III |
| 870.2500 | Primary Skin Irritation-Rabbit | Not an irritant | IV |
| 870.2600 | Dermal Sensitization: Maximization-Guinea pig | Strong sensitizer. Maximization Test: 100% treated showed erythema. | NA |
| 870.2600 | Dermal Sensitization: Buehler's Method-Guinea pig | Strong sensitizer. Buehler's Test: 80–90% treated showed erythema, grade 3 out of possible 4, appearing at 3rd induction phase and challenge phase. | NA |

The primary target organ for oral exposure is the liver. In chronic and subchronic dog studies, liver and thyroid weights were increased along with liver histopathological changes and increases in alkaline phosphatase in the chronic study. There was no evidence of developmental or reproductive toxicity. The data demonstrate no increase sensitivity of rats or rabbits to *in utero* or early postnatal exposure to zoxamide. Carcinogenicity studies in rats and mice did not show increased incidence of spontaneous tumor formation. Zoxamide is classified as ''not likely'' human carcinogen. There was no evidence of neurotoxicity in the acute or subchronic neurotoxicity studies or in any other study in the data base. The toxicity data base for zoxamide is complete. See the following Table 2 for a discussion EPA's findings.

TABLE 2.—TOXICITY PROFILE OF ZOXAMIDE TECHNICAL

| Guideline No. | Study Type (All Studies Acceptable) | Results |
|---|---|---|
| 870.3100 | 90–Day oral toxicity rodents-mouse | NOAEL = 1,666 mg/kg/day; LOAEL not established |
| 870.3150 | 90–Day oral toxicity in nonrodents-dog | NOAEL = 62 mg/kg/day in females, 281 mg/kg/day in males.LOAEL = 322 mg/kg/day in females and 1,139 mg/kg/day in males based on increased liver weights, hepatocellular hypertrophy (males), decrease inalbumin and albumin/golbulin ratios (males). |
| 870.3200 | 28-Day dermal toxicity-rat | Systemic: NOAEL ≥1,000 mg/kg, LOAEL not established; Dermal: NOAEL not established LOAEL < 150 mg/kg/day based on dermal scabbing increase with dosage in males and females, and epidermis of treated skin sites showed hyperplasia, hyperkeratosis, and inflammation. |
| 870.3700a | Prenatal developmental in rodents-rat | Maternal NOAEL = 1,000 mg/kg/day; LOAEL > 1,000 mg/kg/day. Developmental NOAEL = 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day. |
| 870.3700b | Prenatal developmental in nonrodents-rabbit | Maternal NOAEL = 1,000 mg/kg/day; LOAEL > 1,000 mg/kg/day. Developmental NOAEL = 1,000 mg/kg/day; LOAEL > 1,000 mg/kg/day. |
| 870.3800 | Reproduction and fertility effects-rat | Parental/Systemic NOAEL = 409 mg/kg/day in females, 1,474 mg/kg/day in males; LOAEL = 1,624 mg/kg/day based on female decreased body weight and body weight gains. Reproductive NOAEL ≥ 2,091 mg/kg/day in males, 2,239 mg/kg/day in females; LOAEL = not established.Offspring NOAEL ≥ 2,091 mg/kg/day in males, 2,239 mg/kg/day in females; LOAEL = not established. |
| 870.4100b | Chronic toxicity dogs | NOAEL = 50 mg/kg/day in males, 48 mg/kg/day in females; LOAEL = 255 mg/kg/day in males, 278 mg/kg/day in females based on decreased body weights, increased liver and thyroid weights, and increased alkaline phosphatase. |
| 870.4300 | Chronic/Carcinogenicity rats | NOAEL = 1,058 mg/kg/day; LOAEL = not established. No evidence of carcinogenicity |
| 870.4300 | Carcinogenicity mice | NOAEL = 1,021 mg/kg/day in males, 1,289 mg/kg/day infemales; LOAEL = not established. No evidence of carcinogenicity |

TABLE 2.—TOXICITY PROFILE OF ZOXAMIDE TECHNICAL—Continued

| Guideline No. | Study Type (All Studies Acceptable) | Results |
|---|---|---|
| 870.5265 | Gene Mutation | Non-mutagenic when tested up to 5,000 µg/plate, in presenceand absence of activation, in *S. typhimurium*. |
| 870.5300 | Cytogenetics | Non-mutagenic at the HGPRT locus in CHO cells tested upto 65 µg/mL, in presence and absence of activation. |
| 870.5375 | Chromosome aberration | Did not induce structural chromosome aberration up to limitof toxicity (100 µg/mL), but did induce increased levels of numericalaberrations, in presence and absence of activation. |
| 870.5395 | Micronucleus | Non-mutagenic in mouse bone marrow micronucleus assayup to 2,000 mg/kg. |
| 870.6200a | Acute neurotoxicity screening battery-rat | NOAEL = 2,000 mg/kg/day; LOAEL = not established. |
| 870.6200b | Subchronic neurotoxicity screening battery-rat | NOAEL = 1,509 mg/kg/day in males, 1,622 mg/kg/day in females; LOAEL = not established. |
| 870.7485 | Metabolism and pharmacokinetics - rat | 120 hours post-dosing, 96–102% recovered from the low and high single-dose groups. Fecal excretion was the primary route of elimination. Parent compound was the principal component excreted, a total of 36 metabolites were detected in the urine and feces. |
| 870.7600 | Dermal penetration-rat | Total dermal absorption rate after 10–hour is 8.8% (includes amount on skin after wash). |

*B. Toxicological Endpoints*

The dose at which no 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. The Agency evaluated the available hazard and exposure data for zoxamide and made the recommendation for the FQPA safety factor to be used in human health risk assessments (as required by the FQPA of August 3, 1996). The Agency concluded that the FQPA safety factor could be removed (i.e., reduced to 1x) in assessing the risk posed by this chemical because:

1. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

2. A developmental neurotoxicity study conducted with zoxamide is not required.

3. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children. Additionally, there are currently no residential uses.

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 $1 \times 10^{-6}$ 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. A summary of the toxicological endpoints for zoxamide used for human risk assessment is shown in the following Table 3:

TABLE 3.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ZOXAMIDE FOR USE IN HUMAN RISK ASSESSMENT

| Exposure Scenario | Dose Used in Risk Assessment, UF | FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute Dietary general population including infants and children | None | None | No appropriate endpoint was identified by the Hazardous Assessment Review Committee on 11/18/99 for acute dietary exposure. |
| Chronic Dietary all populations | NOAEL= 48 mg/kg/day; UF = 100; Chronic RfD = 0.48 mg/kg/day | FQPA SF = 1X; cPAD = chronic Rfd/FQPA SF = 0.48 mg/kg/day | Chronic Toxicity Study - Dog (MRID 44731817) LOAEL in males/females = 255/277 mg/kg/day based on body weight changes, increases in liver and thyroid weights, and increases in alkaline phosphatase. |
| Short-, Intermediate-, and Long-Term Dermal (Occupational/ Residential) | None | No systemic toxicity was seen at the limit dose (1000 mg/kg/day). | 28-Day Repeated Dose Dermal - Rat (MRID 44731818) |
| Any time period Inhalation (Occupational/ Residential) | Oral NOAEL= 48 mg/kg/day Use route-to-route extrapolation (inhalation absorption rate = 100% of oral) | LOC for MOE = 100 (Occupational/ Residential) | Chronic Toxicity Study - Dog (MRID 44731817) LOAEL in males/females = 255/277 mg/kg/day based on body weight changes, increases in liver and thyroid weights, and increases in alkaline phosphatase. |

*Reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* Tolerances are being established under 40 CFR part 180 for the combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH–1455 and RH–141455) and (3,5-dichloro-1,-4-hydroxymethylbenzoic acid (RH–1452 and RH–141452), in or on potato and zoxamide in or on grape raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from zoxamide 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. Based on available data, a suitable endpoint for acute dietary risk assessment was not identified since no effects were observed in oral toxicity studies (including developmental studies) which could be attributed to a single-dose exposure. Therefore, an acute dietary risk assessment was not performed.

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. The following assumptions were made for the chronic exposure assessments:

A Tier I chronic DEEM® analysis was performed. The assumptions of this Tier I analysis were tolerance level residues and 100 percent crop-treated. The following tolerance levels were used in the analysis: grapes at 3.0 ppm, raisins at 15.0 ppm, potatoes at 0.060 ppm, potato flakes and chips at 0.30 ppm, and potato wet peel at 0.10 ppm. Since the tolerance levels for processed commodities used in the analysis were based upon processing studies, default concentration factors for grape juice; raisins; wine and sherry; potatoes, white-dry; potatoes, white peeled; and potatoes, white peel only, were set to 1x.

The chronic dietary exposure (food only) to zoxamide for some population subgroups are presented in the following Table 3. The resulting dietary food exposures occupy <1% of the Chronic PAD for all population subgroups included in the analysis, except for Children (1 to 6 years old) which is the highest exposed subgroup. The exposure for Children (1 to 6 years old) utilizes 1% of the cPAD. The results of this dietary exposure analysis should be viewed as very conservative (health protective). Refinements such as use of percent crop-treated information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure.

TABLE 4.—CHRONIC DIETARY EXPOSURE ESTIMATES

| Population subgroup [1] | Exposure, mg/kg/day | % cPADpad [2] |
|---|---|---|
| U.S. population | 0.0015 | <1.0 |
| All infants(<1 year) | 0.0038 | <1.0 |
| Children 1–6 yrs [3] | 0.0050 | 1.0 |
| Children 7–12 yrs | 0.0015 | <1.0 |
| Females 13–50 yrs | 0.0011 | <1.0 |
| Males 13–19 yrs | 0.00064 | <1.0 |
| Males 20+ yrs | 0.00092 | <1.0 |
| Seniors 55+ | 0.0011 | <1.0 |

[1] The subgroups listed are: (1) the U.S. Population (total); (2) those for infants and children; and, (3) the most highly exposed of the adult females and males subgroups (in this case, Females, ≤13 years, nursing)

[2] Percent Chronic PAD = (Exposure ÷ Chronic PAD) x 100%.

[3] There are no other subgroups, with the exception of Children, 1 to 6 years old, for which the percentage of the Chronic PAD occupied is greater than that occupied by the subgroup U. S. Population (total).

iii. *Cancer.* Zoxamide is not mutagenic in Ames assays, in CHO cells assay at the Hypoxonthine guanine phosphoribosyle transferase (HGPRT) locus, and in the mouse bone marrow micronucleus assay. Zoxamide did not induce structural chromosome aberrations in cultured CHO cells treated up to the limit of toxicity, but

did induce increased levels of numerical aberrations. Carcinogenicity studies in rat and mice did not show increased incidence of spontaneous tumor formation. The Agency classified zoxamide as not likely to be a human carcinogen. Thus, a cancer risk assessment is not required for zoxamide.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for zoxamide 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 zoxamide.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) 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, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/ EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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 zoxamide they are further discussed in the aggregate risk sections below.

Based on the GENEEC and PRZM/ EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of zoxamide and its degradates for acute and chronic exposures are as follows:

Tier 1 (GENEEC) modeling estimates that zoxamide residues (zoxamide + degradation products) in surface water, from aerial and ground application, are not likely to exceed 61.1 and 57.0 µg/ L for the annual peak concentration (acute) for grape and potato uses, respectively, and 48.3 and 45.1 µg/L for the 56 day average concentration (chronic) for grape and potato uses, respectively.

Tier 2 (PRZM/EXAMS) surface water modeling for zoxamide residues (zoxamide + degradation products), using the index reservoir with the percent cropped area (PCA=0.87 for grapes and potatoes), predicts the 1 in 10 year peak (acute) concentration of zoxamide residues from grapes is not likely to exceed 77.7 µg/L and from potatoes is not likely to exceed 20.9 µg/ L. The 1 in 10 year annual average concentration (non-cancer chronic) of zoxamide residues from grapes is not likely to exceed 21.8 µg/L and from potatoes is not likely to exceed 6.2 µg/ L. The 36 year annual average concentration (cancer chronic) of zoxamide residues from grapes is not likely to exceed 12.4 µg/L and from potatoes is not likely to exceed 4.1 µg/ L.

The SCI-GROW predicted concentration of zoxamide in shallow ground water is not expected to exceed 0.064 µg/L. The SCI-GROW predicted concentration of zoxamide residues (zoxamide + degradation products) in shallow ground water is not expected to exceed 2.07 µg/L.start

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). Zoxamide 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 zoxamide 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, zoxamide 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 zoxamide (3,5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide 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 database 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.

2. *Conclusion*. There is a complete toxicity database for zoxamide and exposure data are complete or are estimated based on data that reasonably account for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed (i.e. reduced to 1x). The FQPA factor is removed because:

i. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure;

ii. A developmental neurotoxicity study conducted with zoxamide is not required; and

iii. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children. Additionally, there are currently no residential uses.

*E. Aggregate Risks and Determination of Safety*

1. *Acute risk*. Based on the data, EPA concluded that zoxamide does not pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to zoxamide from food will utilize <1% of the cPAD for the U.S. population, 1% of the cPAD for children (1–6 years old). There are no residential uses for zoxamide that result in chronic residential exposure to zoxamide.

Chronic risk estimates resulting from aggregate exposure to zoxamide in food and water are below the Agency's level of concern. Surface and ground water EECs were used to compare against back-calculated Drinking Water Levels of Comparison (DWLOCs) for the aggregate assessment. For the chronic scenario, the DWLOCs are 17,000 µg/L for the U.S. population and 4,800 µg/L for the most highly exposed subpopulation (children 1–6 years old). The chronic EECs (highest 48.3 µg/L) are less than the Agency's DWLOCs for zoxamide residues in drinking water as a contribution to chronic aggregate exposure. EPA thus concludes with reasonable certainty that residues of zoxamide in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from zoxamide residues in food and drinking water will not exceed the Agency's level of concern (100% of the Chronic PAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the Chronic PAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, very conservative, and very protective of human health.

3. *Short-term risk*. The Agency did not identify a short-term dermal endpoint for zoxamide. There are no residential uses proposed for this fungicide, short-term aggregate risk assessments based on exposure from oral, inhalation, and dermal routes. For these reasons, no short-term risk is expected.

4. *Intermediate-term risk*. The Agency did not identify an intermediate-term dermal endpoint for zoxamide. There are no residential uses proposed for this fungicide, intermediate-term aggregate risk assessments based on exposure from oral, inhalation and dermal routes. For these reasons, no intermediate-term risk is expected.

5. *Aggregate cancer risk for U.S. population*. The Agency classified zoxamide as not likely to be a human carcinogen. Therefore, no cancer risk is expected.

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 zoxamide residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

The petitioner has proposed a method (TR 34–98–150, MRID No. 44732115) utilizing gas chromatography with electron capture detection (GC/ECD) for enforcement of tolerances for zoxamide in/on grape and grape processed commodities and Method TR 34–98–142 (MRID No. 44732114) for enforcement of tolerances for zoxamide and its acid metabolites in/on potatoes and potato processed commodities. Method TR 34–98–142 utilizes GC with mass selection detection (GC/MSD).

For zoxamide and the two acid metabolites (RH–1452 and RH–1455), in/on potato tubers and potato processed fractions, the GC/MSD method is proposed as the primary method and the GC/ECD method as the confirmatory method of analysis. The estimated limit of detection (LOD) and validated limit of quantitation (LOQ) for the analysis of residues of zoxamide and its acid metabolites in/on potato commodities, were 0.006 and 0.02 ppm, respectively. For zoxamide in/on grape commodities, the GC/ECD method is proposed as the primary enforcement method and the GC/MSD method is proposed as the confirmatory method of analysis. The reported LOD and the validated LOQ for the analysis of zoxamide residues in/on grape commodities were 0.003 and 0.01 ppm, respectively. For both methods, each method of analysis may be used as the confirmatory method for the other.

The above methods are proposed for tolerance enforcement, and are used as the data-collection methods in the analyses of samples obtained from the field, processing, and storage stability studies. The concurrent method recovery data indicate that the methods are adequate for data collection. Both methods were successfully radiovalidated using samples from the grape and potato metabolism studies. These methods were also successfully validated by an independent laboratory.

This method is currently being validated by the Analytical Chemistry Branch Laboratories, BEAD (7503C), Office of Pesticide Programs. Upon successful completion of the EPA validation and the granting of this registration, the method will be forwarded to FDA for publication in a future revision of the Pesticide Analytical Manual, Vol-II (PAM-II). Prior to publication and upon request, the method will be available prior to the harvest season from the Analytical Chemistry Branch (ACB), BEAD (7503C) Environmental Science Center, 701 Mapes Road,Ft. George C. Meade, MD 20755–5350. Contact Francis D. Griffith, Jr., telephone (410) 305–2905, e-mail: griffith.francis@epa.gov. The analytical standars are also available from the EPA National Pesticide Standard Repossitory at the same location.

The petitioner submitted data concerning the recovery of residues of zoxamide and its metabolites RH–1452 and RH–1455 using FDA multi-residue method protocols (PAM Vol. I). Zoxamide was successfully recovered using Protocols D and E. RH–1452 and RH–1452 RH–1455 did not chromatograph acceptably on any of the GC columns tested. Therefore, these would not be expected to be analyzable by Protocols D and E. The methylation of the compounds produced derivatives that are analyzable by GC but have poor and variable recoveries through Protocol B, indicating that none of the protocols are suitable for the recovery of either of the acid metabolites RH–1452 and RH–1455. The MRMs are adequate for enforcement of the proposed tolerances for residues in/on grapes, but not for potatoes. The submission will be forwarded to FDA for complete evaluation.

Adequate enforcement methodology (example: gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

*B. International Residue Limits*

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of zoxamide in/on plant or livestock commodities. Section F of the petition indicated that MRLs are being sought in Canada and Mexico concurrently with this U.S. registration. As the registration of zoxamide is a joint review with Canada , the US tolerances and Canadian MRLs for Zoxamide in or on grape and potato commodities will be set at identical levels.Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances discussed in this petition review.

**V. Conclusion**

Therefore, the tolerances are established for the combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH–1455 and RH–141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH–1452 and RH–141452), in or on potato, tuber; potato, granule/flake; potato, wet peel at 0.060 ppm; 0.30 ppm; and 0.10 ppm, respectively and zoxamide in or on grape at 3.0 ppm and grape, raisins at 15 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–301110 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 June 11, 2001.

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 judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 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–301110, 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 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 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 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).

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. 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: March 30, 2001.

**Joseph J. Merenda,**

*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 180.567 is added to read as follows:

### § 180.567 Zoxamide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of zoxamide (3,5-dichloro-*N*-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide) in or on the following commodities:

| Commodity | Parts per million |
|---|---|
| Grape | 3.0 |
| Grape, raisins | 15.0 |

(2) Tolerances are established for the combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH–1455 and RH–141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH–1452 and RH–141452) in or on the following commodities:

| Commodity | Parts per million |
|---|---|
| Potato, tuber | 0.060 |
| Potato, granule/flakes | 0.30 |
| Potato, wet peel | 0.10 |

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

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

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

[FR Doc. 01–8931 Filed 4–10–01; 8:45 am]

BILLING CODE 6560–50–S

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 01–858, MM Docket No. 01–3, RM–10010]**

### Digital Television Broadcast Service; Jacksonville, NC

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of The University of North Carolina, licensee of noncommercial station WUNM–TV, NTSC channel *19, substitutes DTV channel *18 for DTV channel *44 at Jacksonville, North