''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: September 17, 2004.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.605 is added to read as follows:

§ 180.605 Penoxsulam; tolerances for residues.

(a) *General.* Tolerances are established for the herbicide, penoxsulam (2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4] triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide) in/on the following raw agricultural commodities:

Commodity	Parts per million
Rice, grain	0.02
Rice, straw	0.50

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

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

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

[FR Doc. 04–21502 Filed 9–23–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0315; FRL–7680–1]

Dimethenamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of dimethenamid in or on onions (dry bulb), garlic, shallots (dry bulb), tuberous and corm vegetables, sugar beets, garden beets, and horseradish. Interregional Research Project No. 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, this regulatory action is part of the tolerance reassessment requirements of section 408(q) of the FFDCA 21 U.S.C. 346a(q), as amended by the FQPA of 1996. By law, EPA is required to reassess all tolerances in existence on August 2, 1996 by August 2006. This regulatory action will count for thirteen reassessments towards this August 2006 deadline.

DATES: This regulation is effective September 24, 2004. Objections and requests for hearings must be received on or before November 23, 2004.

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 OPP–2004–0315. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. 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 South 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 March 12, 2003 (68 FR11850) (FRL–7295–9), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E6196) by Interregional Research Project No. 4 (IR–4), Technology Centre of New Jersey, Rutgers, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The petition requested that 40 CFR 180.464 be amended by establishing a tolerance for residues of the herbicide dimethenamid, (R,S)-2-chloro-*N*-[(1-methyl-2-methoxy) ethyl]-*N*-(2,4-dimethyl-thien-3-yl)-acetamide, in or on onions (dry bulb), garlic, shallots (dry bulb), tuberous and corm vegetables, sugar beets, garden beets, and horseradish at 0.01 parts per million (ppm). That notice included a summary of the petition prepared by IR–4, the registrant. There were no comments received in response to the notice of filing.

Dimethenamid was originally registered as a mixture of R and S-isomers (50:50, S:R), and tolerances for the 50:50 mixture were established for dry beans, field corn, sweet corn, peanuts, sorghum, and soybean. Manufacture of the 50:50 mixture has ceased and has been replaced by a mixture (dimethenamid-P) that is enriched in the biologically active S-isomer (90:10, S:R). Registration of the original 50:50 mixture will be cancelled when existing stock is depleted. Currently, both dimethenamid (50:50, S:R) and dimethenamid-P (90:10, S:R) are used. The petition sought to have tolerances established on a non-isomer specific bases. The existing toxicological and residue chemistry databases are established primarily on studies conducted with the 50:50 mixture. To address the uncertainty concerning qualitative or quantitative toxicological difference(s) between the original 50:50 mixture and the enriched 90:10 mixture, EPA reviewed several toxicological studies conducted using both products. EPA concluded that the dimethenamid toxicology database is adequate for the risk assessment of both dimethenamid and dimethenamid-P. Therefore, 40 CFR 180.464 is being revised to include tolerances for residues resulting from application of both dimethenamid (50:50, S:R) and dimethenamid-P (90:10, S:R).

In addition, existing tolerances for dimethenamid were reassessed as part of the tolerance reassessment requirements of section 408(q) of the FFDCA 21 U.S.C. 346a(q), as amended by the FQPA of 1996. By law, EPA is required to reassess all tolerances in existence on August 2, 1996 by August 2006.

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 FFDCA 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) 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 residues of dimethenamid on onions (dry bulb), garlic, shallots (dry bulb), tuberous and corm vegetables, sugar beets, garden beets, and horseradish at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by dimethenamid are discussed in Table 1. of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.1100	Acute oral/rats [Sprague Dawley] dimethenamid-P (90:10 S:R isomers)	LD_{50} = 429 mg/kg for males LD_{50} = 531 mg/kg for females LD_{50} = 480 mg/kg for both sexes Toxicity category II
870.1100	Acute oral/rats [Sprague Dawley] dimethenamid (50:50 S:R isomers)	LD_{50} = 500 mg/kg. The mean for both sexes Toxicity category II

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

Guideline No.	Study Type	Results
870.1200	Acute dermal/rabbits dimethenamid-P (90:10 S:R isomers)	LD_{50} = > 2,000 mg/kg Toxicity category III
870.1200	Acute dermal/rabbits dimethenamid (50:50 S:R isomers)	LD_{50} = > 2,000 mg/kg Toxicity category III
870.1300	Acute inhalation [Sprague Dawley] dimethenamid-P (90:10 S:R isomers)	LC_{50} = 2.2 mg/L Toxicity category III
870.1300	Acute inhalation/rats [Wistar] dimethenamid (50:50 S:R isomers)	LC_{50} = 4.99 mg/L Toxicity category III
870.2400	Acute eye irritation rabbits dimethenamid-P (90:10 S:R isomers)	Minimally irritating Toxicity category III
870.2400	Acute eye irritation/rabbits dimethenamid (50:50 S:R isomers)	Minimally irritating Toxicity category III
870.2500	Acute dermal irritation rabbits dimethenamid-P (90:10 S:R isomers)	Minimally irritating Toxicity category IV
870.2500	Acute dermal irritation/rabbits dimethenamid (50:50 S:R isomers)	Minimally irritating Toxicity category IV
870.2600	Skin sensitization [Guinea Pigs] dimethenamid-P (90:10 S:R isomers)	Mild skin senstizer
870.2600	Skin sensitization [Guinea Pigs] dimethenamid (50:50 S:R isomers)	Mild skin senstizer
870.3100	Subchronic Feeding/ Sprague Dawley Rat dimethenamid-P (90:10 S:R isomers)	NOAEL= 37/40(M/F) mg/kg/day [500 ppm] LOAEL= 110/125 (M/F) mg/kg/day [1,500 ppm] based on decreased body weight (bwt) and bwt gain in males and females, increased gamma-glutamyl transferase in both sexes, increased cholesterol in males, increased absolute and relative liver weight and periportal hepatocytic hypertrophy and periportal eosinophilic inclusions in males, centrilobular hypertrophy in females and liver necrosis in females
870.3100	Subchronic Feeding/ Sprague Dawley rat dimethenamid (50:50 S:R isomers)	NOAEL= 33.5/40.1 (M/F) mg/kg/day [500 ppm] LOAEL= 98/119 (m/f) mg/kg/day [1,500 ppm] based on decreased bwt and bwt gain, increased total protein in males; in females, increased cholesterol, increased liver weight and centrilobular hepatocytic enlargement
870.3150	Subchronic oral toxicity (dog) dimethenamid (50:50 S:R isomers)	NOAEL = 4.72/4.98 (M/F) mg/kg/day [100 ppm] LOAEL = 33.6/39.7 (M/F) mg/kg/day [750 ppm] based on decreased bwt and bwt gain in females, increased relative liver weight in both sexes, increased periportal vacuolation in both sexes and dilation of liver sinusoids in females
870.3200	21/28-Day dermal toxicity (rabbit) dimethenamid (50:50 S:R isomers)	NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on decreased blood phosphate in both sexes [15% at 150mg/kg/day and 15% at 500 mg/kg/day] [$p < 0.05$]
870.3250	Subchronic dermal toxicity dimethenamid (50:50 S:R isomers)	Not required
870.3465	Subchronic inhalation toxicity es) dimethenamid (50:50 S:R isomers)	Not required

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

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in (Sprague Dawley rats) dimethenamid-P (90:10 S:R isomers)	Maternal NOAEL = None LOAEL = 25 mg/kg/day based on bwt decrement on Gestation Day 13–19(Gday) (no single dose effect) and body weight gain decrease and food consumption decrease GDay 6–16 and 6–9, respectively Developmental NOAEL = 25 mg/kg/day LOAEL=150 mg/kg/day based on ossification delays in the pubis and at 300 mg/kg/day ossification delays in the pubis, sternal centra, incidences of microphthalmia, umbilical hernia and at 400 mg/kg/day increased post implantation loss in a range-finding study
870.3700	Prenatal developmental in (Sprague Dawley rats) dimethenamid (50:50 S:R isomers)	Maternal NOAEL = 50 mg/kg/day LOAEL = 215 mg/kg/day based on bwt decrement on GDay 12 (but not a single dose effect) and bwt decrement and food consumption decrease, both GDay 6–9 and 6–16 Developmental NOAEL = 215 mg/kg/day LOAEL= 425 mg/kg/day based on increased post implantation loss
870.3700	Prenatal Developmental (NZW/Rabbit) dimethenamid (50:50 S:R isomers)	Maternal NOAEL = 75 mg/kg/day LOAEL = 150 mg/kg/day based on slight bwt decrement (80g, GDay 12–15), bwt loss (75g GDay 15–19) and 2 abortions and in a 20 litter/group range-finding study, death (13/20) and abortions (7/20) at 250 mg/kg/day Developmental NOAEL = 75 mg/kg/day LOAEL = 150 mg/kg/day based on SS fetal incidence of irregular parietals and hyoid angulated. Litter incidence was nominally elevated by 50% and 100%, respectively, and nominally increase post implantation loss (double control)
870.3800	Reproduction and fertility effects (Wistar rats)dimethenamid (50:50 S:R isomers)	Parental/Systemic NOAEL = M/F 36/40 mg/kg/day [500 ppm] LOAEL =M/F 150/160 mg/kg/day [2,000 ppm] based on decrease bwt, bwt gain, food consumption and absolute and relative liver weight increase Reproductive NOAEL = M/F 150/160 mg/kg/day [2,000 ppm] LOAEL = None Offspring NOAEL = 40 mg/kg/day [500 ppm] LOAEL = 160 mg/kg/day [2,000 ppm] based on f1 pup weight decrement at LDay 21 and f2 pup weight decrease at LDay day 7 and 2
870.4100	Chronic toxicity (Rat) dimethenamid (50:50 S:R isomers)	Satisfied by data for 870.4300
870.4100	Chronic toxicity (dog) dimethenamid (50:50 S:R isomers)	NOAEL = M/F 10.1/9.1 mg/kg/day [250 ppm] LOAEL = M/F 48.7/49.3 mg/kg/day [1,250 ppm] based on decreased bwt and bwt gains [43% to 60%, 0–26 wk] both sexes 100% in males wk 26–52] alkaline phosphatase increased in females 109–2185 through out study and 80% in males. Portal vacuolation in males; vacuoles not lipid or glycogen
870.4200	Carcinogenicity (rat dimethenamid (50:50 S:R isomers)	Satisfied by data for 870.4300
870.4200	Carcinogenicity (mouse) dimethenamid (50:50 S:R isomers)	NOAEL = 300 ppm (M/F: 40.8/40.1 mg/kg/day) LOAEL = 1,500 ppm (M/F: 205/200 mg/kg/day) based on decreased bwt gain in both sexes No treatment related tumors were seen at adequate doses
870.4300	Chronic/carc-inogenicity (Sprague Dawley rat) dimethenamid (50:50 S:R isomers)	NOAEL = 100 ppm [M/F: 5.1/6.8 mg/kg/day] LOAEL = 7,000 ppm [M/F: 36/49 mg/kg/day] based on decreased bwt and bwt gain in both sexes and microscopic hepatic lesions in both sexes. A dose related increased incidence of liver tumors in males (benign and malignant combined) were seen at the 1,500 ppm dose both exceeding slightly historical controls. Dimethenamid (50:50 S:R isomers) characterized as a Group C - possible human carcinogen. For the purpose of risk assessment, the MOE approach will be used for human risk assessment)
870.5100	Bacterial Reverse mutation dimethenamid-P (90:10 S:R isomers)	*S. typhimurium* exposed to 500–4,000 µg/plate +/− S9 *E. coli* exposed to 20–5,000 µg/plate +/− S9 using the standard plate incorporation method or 4–2,500 µg/plate +/− S9 using the pre-incubation modification to the standard test. Highest doses were cytotoxic All assays were negative

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

Guideline No.	Study Type	Results
870.5100	Bacterial Reverse mutation dimethenamid-P (90:10 S:R isomers)	Exposed to 20–5,000 μg/plate in a plate incorporation assay. Marginal cytotoxicity at limit dose of 5,000 μg/plate +/− S9 Assays were negative with both bacteria +/− S9
870.5100	Bacterial Reverse mutation dimethenamid-P (90:10 S:R isomers)	Repeat of MRID # 44123502. *S. typhimurium* TA100 was exposed to 100–5,000 μg/plate +/− S9 Assay was negative
870.5100	Bacterial Reverse mutation dimethenamid-P (90:10 S:R isomers)	Exposed to 100–5,000 μg/plate, +/− S9, in a plate incorporation assay. Insolubility seen at 333 and 5,000 μg/plate, but no toxicity at any dose +/− S9 Assays were negative with both bacteria + S9, however, − S9 induced 1.5 fold increases at 333 μg/plate and 4.1 fold increases in reverents in TA100 strain at 5000 μg/plate. This mutagenic response was reproducible at 100 to 5,000 μg/plate
870.5100	Bacterial Reverse mutation dimethenamid-P (90:10 S:R isomers)	Strains tested at 1000–10,000 μg/plate, − S9 and 1,000–6,500 μg/plate, + S9. Cytotoxicity and precipitation were noted at higher doses Test was negative, +/− S9
870.5300	Mammalian cell mutation dimethenamid-P (90:10 S:R isomers)	Chinese hamster ovary (CHO) cells were exposed to 100–400 μg/mL, − S9, and 100–450 μg/mL, + S9. Slight cytotoxicity was seen at the highest dose and severe toxicity was seen at ≥ 500 μg/mL Test was negative for mutagenic effects, +/− S9
870.5395	Mouse erythrocyte micronucleus test dimethenamid (50:50 S:R isomers)	CD–1 mice dosed at 710 mg/kg in two daily doses. LD_{50} = 1,417 mg/kg. Bone marrow erythrocytes harvested 24 and 48 hours later Test negative
870.5395	Mouse erythrocyte micronucleus test dimethenamid (50:50 S:R isomers)	Mice dosed 0–1,000 mg/kg in single doses. Mice showed no toxicity; only one mouse died Test negative
870.5375	Chromosomal aberration test dimethenamid (50:50 S:R isomers)	Cells in 125–150 μg/mL, − S9 and 400 to 500 μg/mL, + S9; all doses were cytotoxic. Study needs repeating at none cytotoxic doses. Test considered equivocally positive
870.5550	Unscheduled DNA (deoxyribonucleic acid) Synthesis (UDS) in rat hepatocytes dimethenamid (50:50 S:R isomers)	Cell in 1.0–100 nl/mL. No cytotoxicity was seen Test was negative
870.5550	UDS in rat hepatocytes dimethenamid (50:50 S:R isomers)	Fisher 344 rat administered SAN 582H doses of 158 or 500 mg/kg. Sampled 2–4 and 12–14 hours after dosing. Only 0.2–3.6% cells in repair, but negative control was less than zero Test was negative for UDS at 158 and 500 mg/kg
870.5550	UDS in rat hepatocytes dimethenamid (50:50 S:R isomers)	SAN 582H administered at 0.01 to 50 μg/mL. Unscheduled DNA synthesis was seen well below cytotoxic doses. Unequivocally positive for UDS Test positive
870.5550	UDS in rat hepatocytes dimethenamid (50:50 S:R isomers)	SAN 582H administered at 0.0128 to 1,000 μg/mL to rat primary cultures of hepatocytes. Doses at 1,000 μg/mL were cytotoxic. No UDS was noted Test negative for UDS
870.5450	Dominant Lethal dimethenamid (50:50 S:R isomers)	Male Charles River (CR) rats (40–55) administered SAN 582H in single oral doses of 275, 550, or 1,100 mg/kg were mated starting at 10 weeks to 40–55 female undosed CR rats. Increased dead implants at week 1 and week 2 may suggest a dominant lethal effect. These were mostly late implant deaths, which some consultants claim are not characteristic of a dominant lethal effect
870.5450	Dominant Lethal dimethenamid (50:50 S:R isomers)	Male Sprague Dawley rats (40–60) administered SAN 582H in single oral doses of 275, 550, or 1,100 mg/kg were mated starting the day after dosing in Trial 1 and 2 days after dosing in Trial 2 to 80–120 female undosed Sprague Dawley rats . Each male was mated to 2 females over a five day sequence. Results equivocal Note: Both the high dose rabbit and rat developmental studies showed increased late and early resorptions

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

Guideline No.	Study Type	Results
870.5375	Cytogenetics in CHO cells dimethenamid-P(90:10 S:R isomers)	CHO cells were exposed to 2–120 μg/mL − S9; cytotoxic at ≥ 120 μg/mL. CHO cells were exposed to 15–120 μg/mL + S9; cytotoxic at ≥ 500 μg/mL Assay was negative +/− S9
870.5395	Cytogenetics; mouse erythrocyte micronclеus test dimethenamid-P (90:10 S:R isomers)	Mice (5/sex) were exposed to i.p. injections of 103, 205, 410 mg/kg Assay was negative, indicating no clastogenic or aneugenic response
870.5550	UDS in mammalian cell culture dimethenamid-P (90:10 S:R isomers)	Cells tested at 7.8–125 μg/mL. Cytotoxicity and insolubility were seen at ≥ 250 μg/mL Test was negative for UDS
870.6200	Acute neurotoxicity screening battery dimethenamid-P (90:10 S:R isomers)	Not required
870.6200	Acute neurotoxicity screening battery dimethenamid (50:50 S:R isomers)	Not required
870.6200	Subchronic neurotoxicity screening battery dimethenamid-P (90:10 S:R isomers)	Not required
870.6300	Developmental neurotoxicity dimethenamid-P (90:10 S:R isomers)	Not required
870.7485	Metabolism and pharmacokinetics (species) dimethenamid-P (90:10 S:R isomers)	Not required
870.7600	Dermal penetration (species) dimethenamid-P (90:10 S:R isomers)	Not required
870.7600	Dermal penetration (species) dimethenamid (50:50 S:R isomers)	Not required

B. Toxicological Endpoint

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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 dimethenamid used for human risk assessment is shown in Table 2. of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–49 years of age) Based on [RS] data	NOAEL = 75 mg/kg/day UF = 100 Acute RfD = 0.75 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.75 mg/kg/day	Developmental Toxicity in rabbits Maternal; LOAEL = 150 mg/kg/day based on abortions and decreased body weight gain and food consumption Developmental; LOAEL = 150 mg/kg/day based on post-implantation loss
Chronic Dietary (All populations) Based on [RS] data	NOAEL= 5 mg/kg/day UF = 100 Chronic RfD = 0.05 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.05 mg/kg/day	Chronic/rats LOAEL = M/F; 36/49 mg/kg/day based on decreased body weight and body weight gain in both sexes, increased food conversion ratios in females, and increased microscopic hepatic lesions in both sexes
Carcinogenicity Based on [RS] data	Classified as a Group C (possible human carcinogen)	N/A	Chronic risk assessment protective of any potential carcinogenic risk

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.464) for the residues of dimethenamid, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from dimethenamid 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. In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 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 acute exposure assessments: The residue estimate for each food commodity was the tolerance for that crop (0.01 ppm) and each crop was assessed as if 100% of the crop has been treated with dimethenamid.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The residue estimate for each food commodity was the tolerance for that crop (0.01 ppm) and each crop was assessed as if 100% of the crop has been treated with dimethenamid.

iii. *Cancer.* Dimethenamid (50:50 S:R isomers) was classified as a group ''C'' (possible human carcinogen). The Agency concluded that the chronic risk assessment, making use of the cPAD, to be protective of any potential carcinogenic risk. Dimethenamid is at best a weak carcinogen. An intermediate dose showed marginally significant results ($p = 0.056$) with liver adenomas one species (rat) and one sex (males). The incidence of liver tumors was just slightly increased from the level in the historical control data. Higher doses did not demonstrate the occurrence of liver adenomas significantly different from the controls. No dose-related tumors were seen in the mouse carcinogenicity study, and a battery of mutagenicity studies with dimethenamid-P (90:10 S:R isomers) were negative or equivocal for genetic mutations including unscheduled DNA synthesis.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/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.

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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 dimethenamid they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of dimethenamid for acute exposures are estimated to be 49 parts per billion (ppb) for surface water and 0.42 ppb for groundwater. The EECs for chronic exposures are estimated to be 7.9 ppb (non-cancer exposure) and 5.1 ppb (cancer exposure) for surface water and 0.42 ppb for groundwater.

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).

Dimethenamid is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of 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 dimethenamid and any other substances. Dimethenamid 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 dimethenamid 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 (OPP) 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. *Prenatal and postnatal sensitivity*. No offspring pre- or postnatal susceptibility to either dimethenamid (50:50 S:R isomers) or dimethenamid-P (90:10 S:R isomers) was seen in a rabbit or two rat developmental studies and reproduction study. There is low concern for pre- or postnatal toxicity since the developmental effects from the [S] and [RS] mixture are similar and occur at similar doses.

3. *Conclusion*. There is a complete toxicity data base for dimethenamid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the safety factor for dimethenamid should be 100 (10X safety factor for interspecies extrapolation and 10X for intraspecies variation). The additional FQPA SF was removed taking into account the low concerns and lack residual uncertainties with regard to prenatal and postnatal toxicity and the completeness of the toxicity and exposure data base.

E. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative

drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

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

1. *Acute risk.* The dimethenamid aPAD is 0.75 mg/kg/day (applicable to child bearing females only (females 13–49 years old) (Table 3.). The estimated acute (one day) aggregate exposure of females 13–49 years of age (0.006857 mg/kg/day) utilizes less than 1% of the dimethenamid aPAD. For the other population subgroups, an appropriate acute endpoint attributed to a single dose was not available in the toxicity data base including the developmental toxicity studies.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO DIMETHENAMID

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–49 yrs	0.75	< 1%	49	0.42	22,294

2. *Chronic risk.* The dimethenamid cPAD is 0.05 mg/kg/day. The estimated chronic aggregate exposure is the same as the chronic dietary exposure because dimethenamid has no residential uses. The chronic dietary exposure utilizes less than 1% of the cPAD for all population subgroups except infants less than 1 year old, which utilizes less than 2% of the dimethenamid cPAD. The chronic DWLOC was acceptable for chronic exposure to surface and groundwater (Table 4.).

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DIMETHENAMID

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.05	< 1	7.9	0.42	1,494
All infants (< 1 yr.)	0.05	< 2	7.9	0.42	494
Children 1–2 yrs.	0.05	< 1	7.9	0.42	497
Children 3–5 yrs.	0.05	< 1	7.9	0.42	248
Children 6–12 yrs.	0.05	< 1	7.9	0.42	249
Youth 13–19 yrs.	0.05	< 1	7.9	0.42	249
Adults 20–49 yrs.	0.05	< 1	7.9	0.42	1,494
Adults 50+ yrs.	0.024	< 1	7.9	0.42	719
Females 13–49 yrs.	0.024	< 1	7.9	0.42	719

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

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

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

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

5. *Aggregate cancer risk for U.S. population.* The Agency considers the chronic aggregate risk assessment, making use of the cPAD, to be protective of any aggregate cancer risk. See Table 4., Unit III.E.2.

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 dimethenamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (AM–0884–0193–1) is available to enforce the tolerance expression. AM–0884–0193–1 is a GC method using an HP–1 or HP–5 column and mass selective detection (MSD). The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex maximum residue levels (MRL's) for dimethenamid.

C. Conditions

There are no conditions of registration for establishment of tolerances on: onions (dry bulb), garlic, shallots (dry bulb), tuberous and corm vegetables, sugar beets, garden beets, and horseradish.

V. Conclusion

Therefore, the tolerance is established for residues of dimethenamid, (R,S)-2-chloro-*N*-[(1-methyl-2-methoxy) ethyl]-*N*-(2,4-dimethyl-thien-3-yl)-acetamide, in or on onions (dry bulb), garlic, shallots (dry bulb), tuberous and corm vegetables, sugar beets, garden beets, and horseradish at 0.01 ppm. This action results in the reassessment of thirteen tolerances as follows: bean, dry, seed at 0.01 ppm; corn, forage at 0.01 ppm; corn, grain at 0.01 ppm; corn, stover at 0.01 ppm; corn, sweet, fodder (stover) at 0.01 ppm; corn, sweet, forage at 0.01 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; peanut at 0.01 ppm; peanut, hay at 0.01 ppm; sorghum, grain, fodder at 0.01 ppm; sorghum, grain, forage at 0.01 ppm; sorghum, grain at 0.01 ppm; and soybeans at 0.01 ppm.

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 OPP–2004–0315 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 November 23, 2004.

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 (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 OPP–2004–0315, 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 20460–0001. 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 issues(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. 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: September 14, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 180.464 is amended as follows:

a. By revising paragraph (a).

b. By removing and reserving paragraph (b).

§ 180.464 Dimethenamid, 2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethylthien-3-yl)-acetamide.

(a) *General.* Tolerances are established for residues of the herbicide dimethenamid, 1(R,S)-2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethylthien-3-yl)-acetamide, applied as either the 90:10 or 50:50 S:R isomers, in or on the following food commodities:

Commodity	Parts per million
Bean, dry, seed	0.01
Beet, garden, roots	0.01
Beet, garden, tops	0.01
Beet, sugar, dried pulp	0.01
Beet, sugar, molasses	0.01
Beet, sugar, roots	0.01
Beet, sugar, tops	0.01
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, forage	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernal plus cob with husks removed	0.01
Corn, sweet, stover	0.01
Garlic	0.01
Onion, dry bulb	0.01
Peanut, hay	0.01
Peanut, nutmeat	0.01
Shallot, bulb	0.01
Sorghum, grain	0.01
Sorghum, grain, forage	0.01
Sorghum, grain, stover	0.01
Soybean, seed	0.01
Tuberous and corm vegetables	0.01

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

[FR Doc. 04–21501 Filed 9–23–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0293; FRL–7680–2]

Lactofen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of lactofen in or on cotton undelinted seed, cotton gin byproducts, and peanut. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 24, 2004. Objections and requests for hearings must be received on or before November 23, 2004.

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 OPP–2004–0293. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. 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,