

Inert Ingredients	Limits	Uses
Sorbic acid (CAS Reg. No. 110-44-1)		Preservative for formulations

■ 3. In § 180.920, the table is amended by removing the entries for: Potassium carbonate and vanillin and adding the

following two entries to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

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Inert Ingredients	Limits	Uses
Carbonic acid, dipotassium salt (CAS Reg. No. 584-08-7)		Buffering agent
Carbonic acid, dipotassium salt, trihydrate (CAS Reg. No. 18662-52-7)		Buffering agent

§ 180.930 [Amended]

■ 4. In § 180.930, the table is amended by removing the entries for: Carnauba wax (CAS Reg. No. 8015-86-9); glycerol (glycerin); isopropyl alcohol; and sodium benzoate.

a. By removing from the table in paragraph (a) the entries for 2-propanol (isopropanol) and sodium bicarbonate.

b. By removing from the table in paragraph (b) the entry for 2-propanol (isopropanol).

c. By removing from the table in paragraph (c) the entries for 2-propanol (isopropanol) and sodium bicarbonate.

■ 6. In § 180.950, the table in paragraph (e) is amended by adding alphabetically the following 12 entries to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e) * * *

§ 180.940 [Amended]

■ 5. Section 180.940 is amended as follows:

Chemical Name	CAS Reg. No.
Ascorbic acid (vitamin C)	50-81-7
Beeswax	8012-89-3
Benzoic acid, sodium salt	532-32-1
Carbonic acid, monopotassium salt	298-14-6
Carbonic acid, monosodium salt (sodium bicarbonate)	144-55-8
Carnauba wax	8015-86-9
D-Glucitol (sorbitol)	50-70-4
Glycerol (glycerin) (1,2,3-propanetriol)	56-81-5
2-Propanol (isopropyl alcohol)	67-63-0
Soap (The water soluble sodium or potassium salts of fatty acids produced by either the saponification of fats and oils, or the neutralization of fatty acid).	None
Sorbic acid, potassium salt	24634-61-5
Vanillin	121-33-5

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0215; FRL-8057-9]

Terbacil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of terbacil in or on watermelon. The Interregional Research Project Number 4 (IR-4), on behalf of the registrant, DuPont Crop Protection, requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting an existing time-limited terbacil tolerance that is no longer needed as a result of this action.

DATES: This regulation is effective May 31, 2006. Objections and requests for

hearings must be received on or before July 31, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2005-0215. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Docket Facility is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: jackson.sidney@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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site 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.gov/opptsfrs/home/guidelin.htm>.

C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-0215 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 July 31, 2006.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2005-0215, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket’s

normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The telephone number for the Docket Facility is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of September 7, 2005 (70 FR 53180) (FRL-7731-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6640) by IR-4, on behalf of DuPont Crop Protection, P.O. Box 30, Newark, Delaware 19714-0030. The petition requested that 40 CFR 180.209 be amended by establishing a tolerance for combined residues of the herbicide terbacil, (3-tert-butyl-5-chloro-6-methyluracil) and its metabolites [3-tert-butyl-5-chloro-6-hydroxymethyluracil], [6-chloro-2,3-dihydro-7-hydroxymethyl 3,3-dimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one], and [6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one], in or on watermelon at 1.0 parts per million (ppm). That notice included a summary of the petition prepared by DuPont Crop Protection, the registrant. There were no comments received in response to the notice of filing.

EPA is also deleting an established tolerance in section 40 CFR 180.209(b) that is no longer needed, as a result of this action. The tolerance deletion under section 40 CFR 180.209(b) is a time-limited tolerance established under section 18 emergency exemptions that is superseded by the establishment of a general tolerance for terbacil section 40 CFR 180.209(a). The revision to 40 CFR 180.209 is as follows:

Delete the time-limiting tolerance for watermelon at 0.4 ppm under 40 CFR 180.209(b). Tolerance for watermelon at 1.0 ppm is established by this action under 40 CFR 180.209(a).

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

chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of terbacil on watermelon at 1.0 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 their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by terbacil as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from available toxicity studies as summarized in Table 1 below:

TABLE 1: TOXICITY PROFILE FOR TERBACIL — SUBCHRONIC, CHRONIC AND OTHER TOXICITY

Guideline No.	Study Type	Assessment Results
870.3100	90-Day oral toxicity rat Dosage at 0, 8, 20, and 200 milligrams/kilogram/day (mg/kg/day)	NOAEL = 500 ppm (20 mg/kg/day) LOAEL = 5,000 ppm (200 mg/kg/day), based on focal necrosis and triaditis in females (F), vacuolization in males (M) and increased relative liver weight and hypertrophy of hepatocytes in both sexes.
870.3200	21-Day dermal rabbit Dosage at 0 and 5,000 mg/kg/day	NOAEL = 5,000 mg/kg/day LOAEL was not established. There were no clinical signs of toxicity, gross or histopathologic changes.
870.4100	Chronic oral 2-year dog Dosage at 0, 1.0, 5.0, 50, and 200 mg/kg/day	NOAEL = 250 ppm (equivalent to 5.0 mg/kg/day) LOAEL = 2500 ppm (equivalent to 50 mg/kg/day), based on increased relative thyroid weights and thymic involution in both sexes.
870.4200	Carcinogenicity mouse Dosage for M/F: 0/0, 6.5/8.0, 162/199, and 746/895 mg/kg/day	NOAEL = 162 mg/kg/day LOAEL = 746 mg/kg/day, based on increased liver weights, hyperplastic nodules, necrosis, and vacuolation in the liver in males. There was no oncogenic potential at the doses tested.
870.3700	Developmental toxicity rat Dosage at 0, 24, 104 and 392 mg/kg/day	Maternal NOAEL was not established Maternal LOAEL = 24 mg/kg/day based on decreased body weight gain. Developmental NOAEL = 24 mg/kg/day Developmental LOAEL = 104 mg/kg/day, based on decreased number of live fetuses/litter.
870.3700	Developmental Toxicity rabbit Dosage at 0, 30, 200, and 600 mg/kg/day	Maternal NOAEL = 200 mg/kg/day Maternal LOAEL = 600 mg/kg/day, based on mortality, clinical findings (anorexia, discharge), decreased body weight and body weight gain. Developmental NOAEL = 200 mg/kg/day Developmental LOAEL = 600 mg/kg/day, based on decreased body weight, increased incidence of skeletal malformations (fused ribs) and increase frequency of skeletal variations.

TABLE 1: TOXICITY PROFILE FOR TERBACIL — SUBCHRONIC, CHRONIC AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Assessment Results
870.3800	3-generation reproduction - rat Dosage at 0, 2.0, and 10 mg/kg/day	Parental NOAEL = 50 ppm (equivalent to 2.0 mg/kg/day) Parental LOAEL = 250 ppm (equivalent to 10 mg/kg/day) based on decreased body weight, Reproductive NOAEL = 250 ppm (equivalent to 10 mg/kg/day) Reproductive LOAEL was not established Offspring NOAEL = 250 ppm (equivalent to 10 mg/kg/day) Offspring LOAEL was not established
870.4300	Combined Chronic Toxicity/Carcinogenicity rat Dosage M/F: 0/0, 0.9/1.4, 58/83, 308/484 mg/kg/day	NOAEL (M/F)= 58/1.4 mg/kg/day LOAEL (M/F)= 308/83 mg/kg/day, based on decreased body weight and body weight gain and increased absolute and relative liver weights in males and females. There was no oncogenic potential at the doses tested.
870.4300	Combined Chronic Toxicity/ Carcinogenicity rat Dosage at 0, 2.0, 10 and 100/400 mg/kg/day)	Systemic NOAEL = 250 ppm (equivalent to 10 mg/kg/day) Systemic LOAEL = 2,500/10,000 ppm (equivalent to 100/400 mg/kg/day) based on increased mean relative liver weights, hepatocyte centrilobular hypertrophy in males and females and vacuolation in females. There was no oncogenic potential at the doses tested.
870.5300	Mutagenic- (HGPRT) Dosage at 0, 2, 3, 5 and 6 mM (-S9); 0, 1, 2, 2.5, 2.75, 3.25 and 3.50 mM (+S9)	Did not induce mutation in chinese hamster ovary cells with or without metabolic activation.
870.5375	<i>In vitro</i> chromosome aberration assay CHO cells Dosage at 0, 20, 100 and 500 mg/kg	Negative for clastogenic activity in the rat bone marrow cytogenetic assay.
870.5500	Unscheduled DNA synthesis assay rat primary hepatocyte Dosage at 0, 0.010, 0.033, 0.10, 0.33, 1.0, 2.5, 5.0, 7.5, and 10 mM	Did not induce unscheduled DNA synthesis in primary rat hepatocytes.
870.5100	Mutagenicity study (bacteriophage assay)	Did not show the suspected (5-bromo-uracil metabolite) mutagenic action.
870.7485	Metabolism study rat Doseage at single doses of 6.5 or 500 mg/kg	Approximately 57–82% of the administered dose was absorbed in 24 hours. Ninety one to 103% of radioactivity was recovered within 5 days; with 70 to 86% in urine and 14–28% in feces. The major metabolites were glucuronide, sulfate and sulfate/N-acetylcysteine conjugates. The primary metabolic pathway is hydroxylation of the 6-methyl group to form the alcohol which is conjugated to form the glucuronide (35% of the dose) and the sulfate derivatives (11%). Terbacil is also metabolized to the 5-hydroxy intermediate, which is further conjugated to form a sulfate derivative (17%). There was no evidence suggestive of bioaccumulation.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which 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 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.

The linear default risk methodology (Q*) is the primary method currently

used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk

characterization at <http://www.epa.gov/pesticide/health/human.htm>.

A summary of the toxicological endpoints for terbacil used for human

risk assessment is presented in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TERBACIL 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 (General Population and Females 13–50 years of age)	NA	NA	An endpoint of concern attributable to a single dose for the general population or female 13+ was not identified
Chronic dietary (All populations)	NOAEL= 1.4 mg/kg/day UF = 100X Chronic RfD = cRfD= 0.014 mg/kg/day	Special FQPA SF = 1X cPAD = cRfD divided by Special FQPA SF = 0.014 mg/kg/day	Combined Chronic Toxicity/carcinogenicity - rat LOAEL = 83 mg/kg/day based on decreased body weight and body weight gain in females
Short (1–30 days) and Intermediate (1–6 months) Term Incidental oral	Oral NOAEL = 2.0 mg/kg/day (inhalation absorption rate = 100% oral equivalent)	LOC for margin of exposure (MOEs) <100 (occupational and residential)	3–Generation reproduction - rat LOAEL = 10 mg/kg/day based on decreased body weight
Dermal (any time period)	NA	NA	Quantification of dermal risk is not required; the lack of dermal or systemic toxicity at 5,000 mg/kg (5X the limit dose) in a 21 day dermal toxicity study in rats which indicates poor dermal absorption.
Short- (1 to 30 days) and Intermediate- (1 to 6 months) term inhalation	NOAEL= 2.0 mg/kg/day (inhalation absorption rate = 100% oral equivalent)	LOC for MOEs <100 (residential)	3–Generation reproduction - rat LOAEL = 10 mg/kg/day, based on decreased body weight
Long-term inhalation (> 6 months)	Oral NOAEL= 1.4 mg/kg/day (inhalation absorption rate = 100% oral equivalent)	LOC for MOE <100 (residential and occupational)	Combined Chronic Toxicity/Carcinogenicity - rat LOAEL = 83 mg/kg/day based on decreased body weight and body weight gain in females
Cancer (oral, dermal, inhalation)	NA	NA	Classification: Not likely to be carcinogenic to humans

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.209) for the combined residues of terbacil, in or on a variety of raw agricultural commodities. Tolerances are currently established for the combined residues of terbacil, (3-tert-butyl-5-chloro-6-methyluracil) and its metabolites [3-tert-butyl-5-chloro-6-hydroxymethyluracil], [6-chloro-2,3-dihydro-7-hydroxymethyl 3,3-dimethyl-5H-oxazolo(3,2-a)pyrimidin-5-one], and [6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo(3,2-a)pyrimidin-5-one], calculated as terbacil, in/on alfalfa, apple, asparagus, blueberry, caneberry, peach, peppermint, spearmint, strawberry, and sugarcane ranging from 0.1–2.0 ppm. A time-limited tolerance at 0.4 ppm in/on watermelon is currently established under section 18 exemption of the FIFRA and scheduled to expire June 30, 2007. Tolerances in/on livestock are not currently established. There are no feed

commodities associated with watermelon.

Risk assessments were conducted by EPA to assess dietary exposures from terbacil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

An appropriate endpoint attributable to a single dose for the general population or females 13 years and older was not identified in the toxicological studies for terbacil; therefore, a quantitative acute dietary exposure assessment is not needed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™ ver. 2.3), which incorporates food consumption data as reported by respondents in the U.S. 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 chronic exposure assessments: The chronic dietary analysis incorporated tolerance level residues, 100% crop treated, and DEEM™ (ver 7.81) default processing factors for all registered/proposed crops. The chronic analysis also assumed the Screening Concentration in Ground Water (SCI-GROW) modeled water estimates for all water sources (direct and indirect). The ground water estimate was generated using the highest registered/proposed application rate. Although rotational crop tolerances are not currently established, the Agency concluded that the dietary analysis should incorporate residue estimates for rotated crops. Of the registered/proposed crops, alfalfa, mint, strawberry, sugar cane, and watermelon are crops which are rotated. Based on the field rotational crop data (residues <

= 0.19 ppm, 0.3–2.1 × the maximum application rate, 30–day plant-back intervals (PBIs)), the registered proposed PBIs, and the application rates, residues in/on crops rotated into alfalfa, mint, and sugar cane fields which were treated with terbacil are possible. Based on the field rotational crop data, the dietary analysis assumed a residue of 1.0 ppm for cereal grains and soybean (these crops are commonly rotated into alfalfa, mint, and sugarcane fields) Based on the tolerances for the primary crops (0.1–2.0 ppm) and the field rotational crop data, EPA anticipates that the 1.0 ppm residue for rotated crops is conservative.

The Agency notes that the assessment assumes, based on cultural practices, that only cereal grains and soybean are rotated into alfalfa, sugar cane, and mint fields while the registered application scenario for these crops permits the rotation of any crop. When the residue estimates used to generate the dietary exposure estimates are taken in total ((SCI-GROW) drinking water estimates, tolerance level residue, 100% crop treated for all registered/proposed crops, conservative residue estimates for cereal grain and soybean rotation crops), EPA concludes that chronic dietary exposure to terbacil is likely to be less than the estimates provided in this document.

iii. *Cancer.* Terbacil is classified as not likely to be carcinogenic to humans based on the lack of evidence of carcinogenicity in a carcinogenicity study in mice and two combined chronic toxicity/carcinogenicity studies in rats. Therefore, a cancer exposure assessment was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for terbacil 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 terbacil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and SCI-GROW models, the estimated environmental concentrations (EECs) of terbacil for acute exposures are estimated to be 123 parts per billion (ppb) for surface water and 111 ppb for ground water. The EECs for chronic exposures are estimated to

be 25.4 ppb for surface water and 111 ppb for ground water.

The drinking water estimates are based upon the crop with the highest application rate (sugarcane). The use of terbacil on sugarcane has the highest single application rate at 3.0 pounds active ingredient/acre (lb ai/A), this application rate was used in the PRZM/EXAMS and SCI-GROW models to estimate the concentrations of this chemical in surface water and ground water, respectively.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM™ - FCID). For chronic dietary risk assessment, the annual average concentration of 111 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Terbacil 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 the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to terbacil and any other substances and terbacil 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 terbacil has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website 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 database 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.* There is no indication of increased susceptibility of rat and rabbit fetuses to *in utero* and/or postnatal exposure to terbacil.

3. *Conclusion.* There is a complete toxicity database for terbacil and exposure data are complete or are estimated based on data that reasonably account for potential exposures. Based on analyses of available exposure data, as outlined in Unit III.C.1.ii., the Agency believes that exposure to terbacil from existing and potential sources has been adequately assessed and is likely to be less than the estimates provided. EPA concludes that the FQPA SF can be reduced to 1x for the following reasons: (i) There is no evidence of increased susceptibility in rat and rabbit fetuses to *in utero* exposure to terbacil; (ii) there is no evidence of increased susceptibility to terbacil following prenatal exposure in a 3-generation reproduction study in rats; (iii) there are no residual toxicological uncertainties or concerns for increased susceptibility; (iv) there are well established NOAELs and LOAELs in the developmental and reproduction studies; (v) the environmental fate database is adequate to access the nature and magnitude of the residue in drinking water; (vi) the dietary exposure analysis assumed tolerance-level residues and 100% crop treated.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a

pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but 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. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at <http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf>.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

1. *Acute risk.* An endpoint of concern attributable to a single exposure was not identified in the hazard database and therefore no acute risk is expected from exposure to terbacil.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to terbacil from food and water will utilize 40% of the cPAD for the U.S. population, 99% of the cPAD for all infants <1 year old (subpopulations at greatest exposure), and 94% of the cPAD for children 1–2 years old. There are no residential uses for terbacil that result in chronic residential exposure to terbacil. Based on the use pattern, chronic residential exposure to residues of terbacil is not expected since there are no registered residential use. The Agency believes that exposure to terbacil from existing and potential sources has been adequately assessed and that chronic exposure to terbacil is likely to be less than the estimates provided in this document as discussed in Unit III.C.1.ii.

3. *Short-term and Intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered

to be a background exposure level). Terbacil 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. *Aggregate cancer risk for U.S. population.* Terbacil has been classified as "not likely to be carcinogenic to humans" based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. Therefore, terbacil is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to terbacil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

There is a practical analytical method gas chromatography/electron capture detection (GC/ELCD) for detecting and measuring levels of terbacil in or on food with residues at or above the level set by the terbacil tolerance (Method II of PAM Vol. II). EPA has provided information on this method to the Food and Drug Administration (FDA). The method is available to anyone who is interested and 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, Canadian, or Mexican maximum residue limits in or on watermelon.

C. Conditions of Registration

Data gaps exist as follow and are required to be satisfactorily filled as conditions of registration for this use.

1. Petition Method Validation (PMV) of the plant method(s).

2. FDA multiresidue testing of terbacil and its metabolites through protocol D.

3. Additional watermelon field trial, conducted with application after crop emergence, in Region 3 (n=1), 5 (n=1), and 6 (n=1).

V. Conclusion

Therefore, tolerance is established for combined residues of the herbicide, terbacil (3-tert-butyl-5-chloro-6-methyluracil) and its metabolites [3-tert-butyl-5-chloro-6-hydroxymethyluracil], [6-chloro-2,3-dihydro-7-hydroxymethyl 3,3-dimethyl-5H-oxazolo(3,2-a)

pyrimidin-5-one], and [6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one], calculated as terbacil, in or on watermelon at 1.0 ppm.

VI. 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.

VII. 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.

May 16, 2006.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.209 is revised to read as follows:

§ 180.209 Terbacil; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide terbacil, (3-tert-butyl-5-chloro-6-methyluracil) and its metabolites [3-tert-butyl-5-chloro-6-hydroxymethyluracil], [6-chloro-2,3-dihydro-7-hydroxymethyl 3,3-dimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one], and [6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one], calculated as terbacil, in or on the following raw agricultural commodities:

Commodity	Parts per million
Alfalfa, forage	1.0
Alfalfa, hay	2.0
Apple	0.3
Asparagus	0.4
Blueberry	0.2
Caneberry	0.2
Peach	0.2
Peppermint, tops	2.0
Spearmint, tops	2.0
Strawberry	0.1
Sugarcane, cane	0.4
Watermelon	1.0

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

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

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

[FR Doc. E6-8275 Filed 5-30-06; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket No. 03-123; FCC 06-57]

Telecommunications Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities

AGENCY: Federal Communications Commission.

ACTION: Clarification.

SUMMARY: In this document, the Commission addresses a petition (Petition) requesting clarification that a Video Relay Service (VRS) provider may not receive compensation from the Interstate telecommunications relay service (TRS) Fund (Fund) if it blocks calls to competing VRS providers from equipment it gives to consumers.

DATES: Effective July 31, 2006.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT:

Thomas Chandler, Consumer & Governmental Affairs Bureau, Disability Rights Office at (202) 418-1475 (voice), (202) 418-0597 (TTY), or e-mail at Thomas.Chandler@fcc.gov.

SUPPLEMENTARY INFORMATION: This document does not contain new or modified information collection requirements subject to the PRA of 1995, Public Law 104-13. In addition, it does not contain any new or modified “information collection burden for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506 (c)(4). This is a summary of the Commission’s document FCC 06-57, *Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities*, Declaratory Ruling, CG Docket No. 03-123, adopted May 3, 2006, released May 9, 2006 addressing issues raised in the California Coalition of Agencies Serving the Deaf and Hard of Hearing (CCASDHH or Petitioner) Petition for Declaratory Ruling: Petition for Declaratory Ruling on Interoperability, CC Docket No. 98-67, CG Docket No. 03-123, filed February 15, 2005.

The full text of document FCC 06-57 and copies of any subsequently filed documents in this matter will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW.,