

Commodity	Parts per million	Expiration/revocation date
Potato	0.10	12/31/04
Potato, granules/flakes	0.20	12/31/04
Potato, wet peel	0.15	12/31/04

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-2002-0178; FRL-7192-2]

Clomazone; Pesticide Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes for tolerances for residues of clomazone in or on peppermint tops and spearmint tops. Interregional Research Project Number 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).

DATES: This regulation is effective August 21, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0178, must be received on or before October 21, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0178 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this Action Apply to Me?**

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide

manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0178. The official record consists of the documents specifically referenced in this action, and other information

related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of July 17, 2002 (67 FR 46981) (FRL-7185-8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 2E6407) by IR-4, 681 U.S. Highway # 1 South, North Brunswick, New Jersey 08902-3390. This notice included a summary of the petition prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.425 be amended by establishing tolerances for residues of the herbicide clomazone, 2-(2-chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone, in or on peppermint tops and spearmint tops at 0.05 part per million (ppm).

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

occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of clomazone on peppermint tops and spearmint tops at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

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 clomazone is discussed in Unit III.A. of the Final Rule on Clomazone Pesticide Tolerance published in the **Federal Register** of February 14, 2001 (66 FR 10196) (FRL-6764-2).

B. Toxicological Endpoints

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

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

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

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

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure} / exposures$) is calculated. A summary of the toxicological endpoints for clomazone used for human risk assessment is discussed in Unit III.B. of the Final Rule on Clomazone Pesticide Tolerance published in the **Federal Register** of February 14, 2001 (66 FR 10196).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.425) for the residues of clomazone, in or on a variety

of raw agricultural commodities ranging from 0.1 to 0.05 ppm as follows: Snaps beans; cabbage; cottonseed; cucumber; succulent peas; peppers; pumpkins; rice grain; rice straw; soybeans; summer squash; winter squash; sugar cane; sweet potato; cucurbit vegetables; and tuberous and corm vegetables (except potato). Risk assessments were conducted by EPA to assess dietary exposures from clomazone 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 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A Tier 1 acute analysis was performed for females 13-50 years old using existing and recommended tolerance level residues, 100 percent of crop treated (% CT) information, and DEEM® default processing factors.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 1 chronic analysis was performed for the general U.S. population and all population subgroups using existing and recommended tolerance level residues, 100% CT information, and DEEM® default processing factors.

iii. *Cancer.* The Agency has classified clomazone as a "not likely human carcinogen" based on the lack of a carcinogenic response in rats and mice and the lack of mutagenic concern. Therefore, a cancer risk assessment was not performed for this action.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

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

The EECs were based on the proposed uses of clomazone as specified on the CommandR 3 ME label (maximum application rate = 1.25 pound active ingredient per acre (lb ai/A)).

i. *Surface water.* The maximum acute and chronic surface water EECs for both parent clomazone and FMC 65317 were estimated by the Tier 1 screening models GENEEC and GENEECX. For

surface water, the maximum acute EEC was 95 parts per billion (ppb) and the maximum chronic (56-day) EEC was 68 ppb. EPA's interim policy allows the 56-day GENEEC value to be divided by an adjustment factor of 3 to obtain a value for chronic risk assessment calculations. Therefore, a surface water value of 23 ppb was used for chronic risk assessment.

ii. *Ground water.* The predicted maximum ground water EEC for both parent clomazone and FMC 65317, using the Tier 1 screening model SCI-GROW2, was 2.4 ppb which was considered as both an acute and chronic value for risk assessment purposes.

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).

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

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether clomazone has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, clomazone 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 clomazone has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the

completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of susceptibility of rat or rabbit fetuses to *in utero* exposure in the available developmental studies. In the 2-generation reproduction study, no qualitative or quantitative evidence of increased susceptibility was observed.

3. *Conclusion.* There is a complete toxicity database for clomazone and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA factor was reduced to 1X because of the following reasons: There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required; and the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children (there are currently no registered residential uses).

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be

taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable

data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary

exposure from food to clomazone will occupy <1% of the aPAD for females 13 years and older at the 95th percentile. Thus, the acute dietary risk associated with the existing and proposed uses of clomazone does not exceed EPA's level of concern (>100% aPAD). However, there is potential for acute dietary exposure to clomazone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLOMAZONE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50 years old	1.0	<1.0	95	2.4	30,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clomazone from food will utilize <1% of the cPAD for the U.S. population, and all population

subgroups. There are no residential uses for clomazone that result in chronic residential exposure to clomazone. However, there is potential for chronic dietary exposure to clomazone in drinking water. After calculating

DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO CLOMAZONE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.84	<1	23	2.4	29,000
All infants (<1 year old)	0.84	<1	23	2.4	8,400
Children (1–6 years old)	0.84	<1	23	2.4	8,400
Females(13–50 years old)	0.84	<1	23	2.4	25,000

3. *Short and intermediate-term risk.* Short and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Clomazone 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.* The Agency has classified clomazone as a "not likely human carcinogen" based on the lack of a carcinogenic response in rats and mice and the lack of mutagenic concern. Therefore, no cancer risk is expected.

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 clomazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for the determination of the residues of clomazone in plants. Briefly, samples are acid hydrolyzed, hexane extracted, Na₂CO₃ washed, and cleaned-up with a Florisil® column. The resulting samples are analyzed by gas chromatography (GC) using a nitrogen phosphorus detector (NPD) or mass spectrometer (MS). The limit of quantitation (LOQ) for this method is 0.05 ppm. A confirmatory procedure (GC/MS-SIM) is available (Method I, PAM II).

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone

number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican maximum residue limits (MRLs) for residues of clomazone in/on mint.

V. Conclusion

Therefore, tolerances are established for residues of clomazone, 2-(2-chlorophenyl)methyl- 4,4-dimethyl-3-isoxazolidinone, in or on peppermint tops and spearmint tops at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those

regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0178 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 October 21, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that

fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP-2002-0178, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the

requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General

of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 16, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.425 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.425 Clomazone; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Peppermint, tops	* * 0.05
* * *	* *
Spearmint, tops	* * 0.05
* * *	* *

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRL–7264–1]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) today is granting a petition submitted by the United States Department of Energy Savannah River Operations Office

(DOE–SR) to exclude (or “delist”) certain hazardous wastes from the lists of hazardous wastes under the Resource Conservation and Recovery Act (RCRA). DOE–SR generated the petitioned waste by treating wastes from various activities at the Savannah River Site (SRS). The petitioned waste meets the definitions of listed RCRA hazardous wastes F006 and F028. DOE–SR petitioned EPA to grant a one-time, generator-specific delisting for its F006 and F028 waste, because DOE–SR believes that its waste does not meet the criteria for which these types of wastes were listed. The waste is a radioactive mixed waste (RMW) because it is both a RCRA hazardous waste and a radioactive waste. EPA reviewed all of the waste-specific information provided by DOE–SR, performed calculations, and determined that the waste, which has a low level of radioactivity, could be disposed in a landfill for low-level radioactive waste without harming human health and the environment. The petition is for a one-time delisting, because the petitioned waste has been generated, will be completely disposed of at one time, and will not be generated again. Today’s final rule grants DOE–SR’s petition to delist its F006 and F028 waste. No public comments on the proposed rule were received. Today’s final action means that DOE–SR’s petitioned waste will no longer be classified as F006 and F028, and will not be subject to regulation as a hazardous waste under Subtitle C of RCRA, provided that it is disposed in a low-level radioactive waste landfill, in accordance with the Atomic Energy Act. The waste will still be subject to the Atomic Energy Act and local, State, and Federal regulations for low-level radioactive solid wastes that are not RCRA hazardous wastes.

EFFECTIVE DATE: This rule is effective on August 21, 2002.

ADDRESSES: The RCRA regulatory docket for this final rule is located at the EPA Library, U.S. Environmental Protection Agency, Region 4, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303, and is available for viewing from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays.

The reference number for this docket is R4–01–02–DOESRSF. The public may copy material from any regulatory docket at no cost for the first 100 pages, and at a cost of \$0.15 per page for additional copies. For copying at the South Carolina Department of Health and Environmental Control (SCDHEC), please see below.