

and pests, Reporting and recordkeeping requirements.

Dated: April 30, 1999.

James Jones,

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.

§ 180.507 [Amended]

2. In § 180.507, the table to paragraph (b) by revising the date for the commodity watercress, "6/30/99" to read "10/30/00".

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300857; FRL-6079-5]

RIN 2070-AB78

Dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a permanent tolerance for the residues of dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine in or on potatoes, wet peel and time-limited tolerances for the indirect or inadvertent residues of dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine in or on the cereal grains group for fo12er, forage, grain, hay and straw. American Cyanamid Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective May 12, 1999. Objections and requests for hearings must be received by EPA on or before July 12, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300857], must be submitted to: Hearing Clerk (1900), Environmental Protection

Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300857], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300857]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 249, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-308-9354, waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Registers** of March 26, 1997 (62 FR 14418) (FRL-5594-7) and of March 10, 1999 (64 FR 11874) (FRL-6063-3), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) announcing the filing of a pesticide petition (PP) for tolerance by American Cyanamid Company, P.O. Box 400, Princeton, NJ 08543-0400. These notices included a summary of the petition prepared by American

Cyanamid Company, the registrant. There were no comments received in response to the notices of filing.

The petition requested that 40 CFR 180.493 be amended by establishing a tolerance for residues of the fungicide dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine, in or on potatoes, wet peel at 0.15 parts per million (ppm) and time-limited tolerances for the indirect or inadvertent residues of the fungicide dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine, in or on cereal grains group: fodder at 0.15 ppm, forage at 0.05 ppm, grain at 0.05 ppm, hay at 0.10 ppm, and straw at 0.15 ppm. These time-limited tolerances will expire on May 12, 2004.

I. Background and Statutory Findings

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).

II. 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 dimethomorph and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a

tolerance for residues of the fungicide dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine, in or on potatoes, wet peel at 0.15 ppm and time-limited tolerance for the indirect or inadvertent residues of dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine in or on the cereal grains group: fodder at 0.15 ppm, forage at 0.05 ppm, grain at 0.05 ppm, hay at 0.10 ppm, and straw at 0.15 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has previously 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 tolerance for potatoes, wet peel, toxicological profile for dimethomorph were addressed in the risk assessment published in the Federal Register final rule of October 13, 1998 (63 FR 54587) (FRL-6036-7). The risk assessment for rotational crops addressed the changes which occurred as a result of the granting of time-limited tolerances for rotational crops.

B. Toxicological Endpoints

The toxicological endpoints for dimethomorph were addressed in the risk assessment published in the Federal Register final rule of October 13, 1998 (63 FR 54587) (FRL-6036-7).

C. Exposures and Risks

1. From food and feed uses.

Tolerances have been established (40 CFR 180.493) for the residues of dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine in or on potatoes at 0.05 ppm and time-limited tolerances for tomatoes at 1 ppm (expires May 15, 1999) and cantaloupe, cucumber, squash and watermelon at 1 ppm (expires March 31, 2000). Anticipated residues were not generated as part of this risk assessment. In the dietary analysis, the most highly exposed subgroup, children 1-6 years, utilized only 4.3% of the reference dose (RfD)/population adjusted dose (PAD) As a result, no refinement to the analysis was needed. Risk assessments were conducted by EPA to assess dietary exposures from dimethomorph as follows:

i. *Acute exposure and risk.* 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. EPA did not select a dose and endpoint for an acute dietary risk assessment because of the lack of toxicological effects attributable to a single exposure (dose) in either the rat or the rabbit developmental toxicity studies.

ii. *Chronic exposure and risk.* EPA's Dietary Exposure Evaluation Model (DEEM89) was used for conducting a chronic dietary (food only) exposure analysis (risk assessment). The analysis evaluates individual food consumption as reported by respondents in the USDA 1989-1991 Nationwide Continuing Surveys for Food Intake by Individuals, and accumulates exposure to the chemical for each commodity. The exposure for each subgroup is reported as a percentage of the PAD. As the 10x safety factor was removed for dimethomorph, the PAD is equivalent to the RfD.

In conducting this chronic tier 1 dietary risk assessment, EPA has made very conservative assumptions: that all commodities having dimethomorph tolerances contain residues of dimethomorph and those residues are at the level of the tolerance. These assumptions result in an overestimate of human dietary exposure. All Section 18 tolerances (i.e., cantaloupes, watermelons, cucumbers, squash, and tomatoes) are included in this dietary risk assessment. Using the assumptions and data parameters described above, the DEEM89 exposure analysis results in a theoretical maximum residue contribution (TMRC) that is equivalent to the following percentages of the PAD/RfD. The following table summarizes the estimated food exposures for the U.S. population, the population subgroups that include infants and children, the most highly exposed female subgroup, and all other population subgroups (excluding regions and seasons) with risk estimates above that of the U.S. population:

TABLE 1.— SUMMARY OF FOOD EXPOSURE TO DIMETHOMORPH

Population Subgroup	Exposure (mg/kg body wt/day)	%PAD/RfD
U.S. Population (total)	0.0020	2
Hispanics	0.0022	2
Non-Hispanic/non-white/non-black	0.0022	2

TABLE 1.— SUMMARY OF FOOD EXPOSURE TO DIMETHOMORPH—Continued

Population Subgroup	Exposure (mg/kg body wt/day)	%PAD/RfD
Nursing Infants	0.0006	0.6
Non-nursing Infants ..	0.0024	2
Children 1-6 years ...	0.0043	4
Children 7-12 years	0.0030	3
Females 13-19 (not pregnant or nursing)	0.0021	2
Males 13-19 years ...	0.0021	2

2. *From drinking water.* EPA used SCI-GROW (Screening Concentration In Ground Water) and GENEEC (Generic Estimated Environmental Concentration) models to determine the estimated environmental concentrations (EECs) of dimethomorph residues in ground and surface water. The EEC reported for dimethomorph residues in ground water is 0.26 parts per billion (ppb). The EEC for surface water is 28 ppb for acute and 24 ppb for chronic (56-day).

i. *Acute exposure and risk.* Because no acute dietary endpoint was determined, an acute water and dietary exposure risk assessment is not required.

ii. *Chronic exposure and risk.* EPA conducts the drinking water risk assessment by using the worst case scenario of estimated environmental concentration (EEC) found from either ground or surface water. The EEC reported for dimethomorph residues in ground water using SCI-GROW is 0.26 ppb. This is much less than the surface water EEC (24 ppb for 56 days) generated using GENEEC. Therefore, only the surface water EEC will be used in conducting the aggregate dietary (food + water) risk assessment. Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, chronic drinking water levels of comparison (DWLOCs) for drinking water were calculated. To calculate the chronic DWLOC, the chronic dietary food exposure (from DEEM analysis) is subtracted from the chronic PAD/RfD. DWLOCs are then calculated using the default body weights and drinking water consumption figures. EPA's surface drinking water levels of comparison from chronic exposure to dimethomorph using modeling data are 3,400 ppb for the U.S. Population and the population subgroup non-Hispanic/non-white/non-black, 2,900 ppb for females 13-19 (not pregnant or nursing),

and 960 ppb for children 1–6 years. These levels are all greater than the GENECC concentration level (24 ppb for 56 days). Therefore, EPA does not expect exposure to dimethomorph in drinking water to be above the level of concern.

3. *From non-dietary exposure.* There are no registered or proposed residential uses for dimethomorph. Therefore, residential or inhalation exposures were not evaluated in the risk assessment.

4. *Cumulative exposure to substances with 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 dimethomorph 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, dimethomorph 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 dimethomorph 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. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* No acute dietary endpoint was identified; therefore, EPA concludes that dimethomorph poses no appreciable acute risk.

2. *Chronic risk.* EPA has concluded that aggregate exposure to dimethomorph from food will utilize 2% of the RfD for the U.S. population, 2% for females 13–19 (not pregnant or nursing), 4% for children 1 through 6 years of age, and 2% for non-Hispanic/non-white/non-black. The surface drinking water levels of comparison from chronic exposure to dimethomorph using modeling data are 3,400 ppb for the U.S. population and population subgroup non-Hispanic/non-white/non-black, 2,900 ppb for females 13–19 (not pregnant or nursing), and 960 ppb for children 1–6 years. These

levels are all greater than the GENECC chronic concentration level (24 ppb for 56 days) and the SCI-GROW ground level water of 0.26 ppb. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. There are no registered residential uses of dimethomorph.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Although short- and intermediate-term endpoints were identified, there are no residential uses for dimethomorph.

4. *Aggregate cancer risk for U.S. population.* Dimethomorph was classified as “not likely” to be a human carcinogen. Therefore, a carcinogenic aggregate risk assessment was not required.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of dimethomorph.

E. Aggregate Risks and Determination of Safety for Infants and Children

EPA assessed the potential for additional sensitivity of infants and children to residues of dimethomorph. The aggregate risks for dimethomorph were published in the **Federal Register** final rule of October 13, 1998 (63 FR 54587)(FRL–6036–7). There is a complete toxicity database for dimethomorph and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. EPA has concluded that aggregate exposure to dimethomorph from food will utilize 4.3% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to dimethomorph in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to dimethomorph residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in potatoes is adequately understood. For purposes of time-limited tolerances, the residue of concern in rotational crops is the same as that in directly treated crops, i.e., dimethomorph per se. The nature of the residue in animals is adequately defined for section 3 registration on potatoes. Tolerances are not required for residues in livestock commodities at this time.

B. Analytical Enforcement Methodology

Method FAMS 002–04 high performance liquid chromatography using ultra-violet detection (HPLC, UV detection) is adequate for determining residues of dimethomorph per se in/on potatoes. A confirmatory method is also available (FAM 022–03).

The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229). Based on recovery data from the independent laboratory validation as well as concurrent recovery data from limited rotational field trials, EPA concludes that Method M 3112 gas chromatography, nitrogen phosphorus detection (GC, N-P detection) has been adequately validated and is suitable for collecting residue data on levels of dimethomorph per se in/on wheat raw agricultural commodities (RACs). The reported limit of quantitation of the method is 0.05 ppm. Prior to the establishment of permanent rotational crop tolerances, Method M 3112 must be submitted for Agency method validation. Acceptance of Method M 3112 as an enforcement method is predicated upon completion of a successful Agency method tryout. For the purpose of establishing time-limited tolerances on wheat RACs, EPA recommended using the Food and Drug Administration’s (FDA’s) multiresidue method Protocol D as the enforcement method for determining residues of dimethomorph per se in/on cereal grain RACs. EPA noted that Method FAMS 002–04 (HPLC, UV detection), a method submitted in conjunction with PP#2E4054, has been determined adequate as an enforcement method for determining residues of dimethomorph per se in/on potatoes. Although the extraction procedures of Method M 3112 are essentially similar to those of Method FAMS 002–04, the instrumentation and quantitation of

residues are different. Dimethomorph is recovered by Protocol D of FDA's multi-residue method protocols (PAM Vol. I).

C. Magnitude of Residues

EPA has concluded that residue data submitted in support of the tolerance for potatoes indicate that a tolerance level of 0.15 ppm is an adequate level for potatoes, wet peel. In addition, domestic field trial data supported the tolerance level of 0.15 ppm on potatoes, wet peel and indicated that dimethomorph residues do not pose an adverse health risk to humans under the use conditions. Therefore, EPA has no objection to the establishment of a tolerance of 0.15 ppm for residues of the fungicide dimethomorph in/on potatoes, wet peel under 40 CFR 180.493.

For the purpose of establishing permanent rotational crop tolerances for residues of dimethomorph in/on cereal grains, the limited wheat rotational field trial data are inadequate because of poor geographic representation of data, and because residue data are required for other crops representative of cereal grains. However, as the available data indicate that most treated wheat raw agricultural commodity (RAC) samples bore nonquantifiable (< 0.05 ppm) residues, EPA recommends in favor of the establishment of time-limited tolerances for the forage and grain of cereal grains at 0.05 ppm, for hay of cereal grains at 0.10 ppm, and for the fodder and straw of cereal grains at 0.15 ppm under 40 CFR 180.493.

D. International Residue Limits

There are no Canadian, Mexican, or Codex MRLs established for dimethomorph for the commodities associated with this request; consequently, a discussion of international harmonization is not relevant.

E. Rotational Crop Restrictions

The plant back intervals for rotational crops are: 0 days for potatoes; 1 month for barley, broccoli, cabbage, carrot, cauliflower, celery, lettuce, oats, onion, radish, spinach, sugarbeets, tobacco and wheat; 7 months for alfalfa, beans, clover, corn (field, sweet, seed, and pop), peas, rice, sorghum, and soybeans; 12 months for all other crops.

IV. Conclusion

Therefore, the tolerance for residues of the fungicide dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine, in or on potatoes, wet peel at 0.15 ppm and time-limited tolerances are established for the indirect or inadvertent residues of

dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine in the cereal grains group: fodder at 0.15 ppm, forage at 0.05 ppm, grain at 0.05 ppm, hay at 0.10 ppm, and straw at 0.15 ppm. These time-limited tolerances expire May 12, 2004.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 12, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under "ADDRESSES" section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is

requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300857] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies

in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the 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). 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) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR

58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action

does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do 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 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 the rule in the **Federal Register**. This 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: April 30, 1999

James Jones,

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. In § 180.493, by revising paragraphs (a) and (d) to read as follows:

§ 180.493 Dimethomorph, tolerances for residues.

(a) *General.* A tolerance is established for the residues of the fungicide dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine in or on the following commodity:

Commodity	Parts per million
Potatoes, wet peel	0.15

* * * * *

(d) *Indirect or inadvertent residues.* Time-limited tolerances are established for inadvertent or indirect residues of the fungicide dimethomorph in or on

the following raw agricultural commodities when present therein as a result of the application of dimethomorph to growing crops. The

tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Cereal grains group, fodder	0.15	May 12, 2004
Cereal grains group, forage	0.05	May 12, 2004
Cereal grains group, grain	0.05	May 12, 2004
Cereal grains group, hay	0.10	May 12, 2004
Cereal grains group, straw	0.15	May 12, 2004

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 410, 413, 414, 415, 424, and 485

[HCFA-1006-CN]

RIN 0938-A152

Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1999; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Correction of final rule with comment period.

SUMMARY: This document corrects technical errors that appeared in the final rule with comment period published in the **Federal Register** on November 2, 1998, entitled "Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1999."

EFFECTIVE DATE: January 1, 1999.

FOR FURTHER INFORMATION CONTACT: Diane Milstead, (410) 786-3355

SUPPLEMENTARY INFORMATION:

Background

In FR Doc. 98-29181 of November 2, 1998, (63 FR 58814), there were a number of technical errors. The errors relate to the omission of background information, an incorrect reference, the qualification requirements for nonphysician practitioners, a typographical error, a correction to a CPT code modifier in Table 6, an inconsistency in the preamble and addendum, the omission of status indicator references, the omission of a

facility type in the regulations text, and revisions to Addendum B.

The provisions in this correction notice are effective as if they had been included in the document published in the **Federal Register** on November 2, 1998, that is, January 1, 1999.

Discussion of Addendum B

1. We inadvertently omitted the professional and technical portions for the following CPT code. Entries on the page listed below are corrected as follows: Page 59073 for CPT codes 78020-26 and 78020-TC. These corrections are reflected in correction number 19 to follow.

2. We assigned incorrect status codes to the following CPT codes. Entries on pages listed below are corrected as follows: Page 59087 for CPT code 82251; page 59114 for CPT codes 90471 and 90472; page 59181 for CPT code R0070; and page 59182 for CPT code R0075. These corrections are reflected in correction number 20 to follow.

3. We assigned incorrect RVUs or modifiers for the following CPT codes. Entries on pages listed below are corrected as follows: Page 59109 for CPT code 88141; page 59132 for CPT codes 94014, 94014-26, and 94014-TC; 94015, 94015-26, 94015-TC; and 94016; page 59168 for CPT code G0124; and page 59169 for CPT code G0141. These corrections are reflected in correction number 21 to follow.

4. We stated that we would not provide a transition for codes representing services that are new beginning in 1999. The codes identified below are new CPT codes, but do not represent new services. These codes were previously reported with a different CPT code. We failed to apply the transition to these services. The corrected RVUs for the codes are as follows: Page 58965 for CPT codes 31623, 31624, and 31643; page 58977 for CPT codes 35682, and 35683; page 59133 for CPT codes 94621, 94621-26, and 94621-TC. These corrections are

reflected in correction number 22 to follow.

5. We erroneously assigned relative value units to the following CPT codes in the facility setting. By definition the following CPT codes cannot be performed in the facility setting. Columns associated with facility relative value units should be set to NA in Addendum B. Entries on pages listed below are corrected as follows: Page 59144 for CPT codes 99321, 99322, 99323, 99331, 99332, 99333, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, and 99350; page 59145 for CPT codes 99374 and 99375. These corrections are reflected in correction number 23 to follow.

Correction of Errors

In FR Doc. 98-29181 of November 2, 1998, make the following corrections:

1. On page 58814, column three, "Table of Contents", after subsection "I.B", add a new subsection "C" to read as follows:

"C. Components of the Fee Schedule Payment Amounts"

2. On page 58816, column one, add a new subsection "C", to read as follows:

"C. Components of the Fee Schedule Payment Amounts"

Under the formula set forth in section 1848(b)(1) of the Act, the payment amount for each service paid for under the physician fee schedule is the product of three factors: (1) A nationally uniform relative value for the service; (2) a geographic adjustment factor (GAF) for each physician fee schedule area; and (3) a nationally uniform conversion factor (CF) for the service. The CF converts the relative values into payment amounts.

For each physician fee schedule service, there are three relative values: (1) An RVU for physician work; (2) an RVU for practice expense (NOTE: This RVU will vary on a code by code basis depending upon if the service is performed in a facility or non-facility setting); and (3) an RVU for malpractice