XI. Regulatory Assessment Requirements

This final rule establishes a tolerance under section 408 of the FFDCA and is in response to a petition received by the Agency requesting the establishment of such a tolerance. 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). In addition, 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, because tolerances 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 rwule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Prior to the recent amendments to the FFDCA, however, EPA had treated such actions as subject to the RFA. The amendments to the FFDCA clarify that no proposed rule is required for such regulatory actions, which makes the RFA inapplicable to these actions. Nevertheless, the Agency has 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 (46 FR 24950, May 4, 1981). In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

XII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: May 16, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. By adding § 180.506 to read as follows:

§ 180.506 Cyclanilide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator, cyclanilide, [1-(2,4-dichlorophenylaminocarbonyl)-cyclopropane carboxylic acid] determined as 2,4-dichloroaniline (calculated as cyclanilide) in or on the following food commodities and processed feed:

Commodity	Parts Per Million
Cattle, fat	0.10
Cattle, meat	0.20
Cattle, mbyp (except kidney)	0.2
Cattle, kidney	2.0
Cottonseed	0.60
Cotton gin byproducts	25.0
Goats, fat	0.10
Goats, meat	0.20
Goats, mbyp (except kidney)	0.20
Goats, kidney	2.0
Horses, fat	0.10
Horses, meat	0.20
Horses, mbyp (except kidney)	0.20
Horses, kidney	2.0
Hogs, fat	0.10
Hogs, meat	0.20
Hogs, mbyp (except kidney)	0.20
Hogs, kidney	2.0
Milk	0.04
Sheep, fat	0.10
Sheep, meat	0.20
Sheep, mbyp (except kidney)	0.20
Sheep, kidney	2.0

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

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

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

[FR Doc. 97–13645 Filed 5–22–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300493; FRL–5718–5]

RIN 2070–AB78

Pendimethalin; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite (CL 202, 347) in or on fresh mint hay and mint oil in connection with EPA's granting an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on mint in Idaho, Oregon, South Dakota and Washington. These tolerances will expire and are revoked on May 31, 1998.

DATES: This regulation becomes effective May 23, 1997. Objections and requests for hearings must be received by EPA on or before July 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300493], 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–300493], must be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division, (7506C), 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. 1132, CM #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@epamail.epa.gov. Copies of 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 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300493]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308–8337, e-mail: schaible.stephen@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the combined residues of the herbicide pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite (CL 202, 347), hereafter referred to in this document as pendimethalin, in or on fresh mint hay at 0.1 parts per million (ppm) and in or on mint oil at 5.0 ppm. These tolerances will expire and be revoked by EPA on May 31, 1998. After May 31, 1998, EPA will publish a document in the **Federal Register** removing the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 CFR 58135, November 13, 1996) (FRL–5572–9).

New 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....''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166. Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Pendimethalin on Mint and FFDCA Tolerances

On March 3, 1997, the Idaho, Oregon, and Washington State Departments of Agriculture availed of themselves the authority to declare the existence of a crisis situation within their states, thereby authorizing use under FIFRA section 18 of pendimethalin on mint to control kochia (*Kochia scoparia*) and redroot pigweed (*Amaranthus retroflexus*). The South Dakota Department of Agriculture has since requested a specific exemption for the same use. Kochia and redroot pigweed have become serious pests for mint growers in these states. The loss of mechanical control as a weed control option (due to potential spread of Verticillium wilt by tillage equipment), lack of a satisfactory herbicide, and the presence of herbicide-resistant pigweed and kochia have all contributed to the development of this emergency condition. Additionally, the presence of these weeds in the harvested mint results in reduction in quality and price of the mint oil. Without effective control of these weeds, yield losses of up to 35% in these states are expected, resulting in significant economic losses to the mint growers.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of pendimethalin in or on mint. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. These tolerances will permit the marketing of mint treated in accordance with the provisions of the section 18 emergency exemption. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on May 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on mint hay and mint oil after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, section 18 of FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

EPA has not made any decisions about whether pendimethalin meets EPA's registration requirements for use on mint or whether permanent tolerances for this use would be appropriate. These tolerances do not serve as a basis for registration of

pendimethalin by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than Idaho, Oregon, South Dakota or Washington to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for pendimethalin, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold margin of exposure is based on the same rationale as the hundredfold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants <1 year old) was not regionally based.

IV. 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. Pendimethalin is already registered by EPA for numerous food and feed uses, as well as residential use on ornamental lawns, grasses, ground covers, turf, and ornamental plantings. For the purpose of this emergency exemption, EPA has sufficient data to assess the hazards of pendimethalin and to make a determination on aggregate exposure, consistent with 408(b)(2), for time-limited tolerances for residues of pendimethalin on fresh mint (peppermint, spearmint) hay at 0.1 ppm and mint (peppermint, spearmint) oil at 5.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pendimethalin are discussed below.

1. *Acute toxicity.* For acute dietary risk assessment, the Agency has determined that there are no toxicological endpoints of concern and that this risk assessment is not required.

2. *Short- and intermediate-term toxicity.* OPP has determined that short- and intermediate-term risk assessments are appropriate for non-occupational, non-dietary routes of exposure. OPP recommends that the NOEL of 10 milligrams per kilogram per day (mg/kg/day), taken from the 56–day thyroid function study in rats, be used for the

short and intermediate term MOE calculations. The lowest effect level (LEL) of 31 mg/kg/day from a 14–day intrathyroid metabolism study in rats was based on thyroid hormonal effects occurring as early as Day 3. Though these endpoints have been identified, no acceptable reliable exposure data to assess these potential risks are available at this time.

3. *Chronic toxicity.* The RfD of 0.1 mg/kg/day was established based on a combination of three studies in male rats: (i) A 56–day oral thyroid function study; (ii) a 92–day thyroid function study; and (iii) a 14–day intrathyroidal metabolism study. The NOEL was established at 10 mg/kg/day. The LOEL of 31 mg/kg/day was based on thyroid hormonal changes and histologic thyroid changes. An Uncertainty Factor (UF) of 100 was applied to account for both interspecies and intraspecies variability.

4. *Carcinogenicity.* Pendimethalin has been classified as a Group C, ''possible human carcinogen'', chemical by OPP, based on a statistically significant increased trend and pairwise comparison between the high dose group and controls for thyroid follicular cell adenomas in male and female rats. OPP recommends using the RfD approach for quantification of human risk. Therefore, the RfD is deemed protective of all chronic human health effects, including cancer.

B. Aggregate Exposure

Tolerances have been established (40 CFR 180.361) for the combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite (CL 202, 347), in or on a variety of raw agricultural commodities at levels ranging from 0.05 ppm in rice grain to 0.1 ppm in corn, peanuts, soybeans and other commodities. The proposed time-limited tolerances are based on residue data provided with the section 18 submissions. There are no livestock feed items associated with this section 18 use, so no additional livestock dietary burden is expected.

For the purpose of assessing potential chronic dietary exposure from pendimethalin, EPA assumed tolerance level residues and 100% crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for major identifiable subgroups of consumers, including infants and children, from the proposed and existing food uses of pendimethalin. The use of these assumptions results in a conservative dietary exposure assessment, which EPA takes into consideration when making a safety determination for the subject section 18 tolerances.

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Based on information in the Herbicide Handbook of the Weed Science Society of America (7th ed, 1994), pendimethalin has low solubility in water and strong absorption to soil. Pendimethalin is essentially immobile in all soil types, being strongly bound to organic matter and clay, thus minimizing its potential to runoff to surface water or leach to ground water.

No Maximum Concentration Level and no Health Advisory Level has been established for residues of pendimethalin in drinking water. Information in the Pesticides in Groundwater Database (EPA 734–12–92–001, 9/92) indicates that 1,405 wells were sampled for residues of pendimethalin. Detectable residues were reported (0.02 to 0.9 μ/L) in only 1% (14) of those sampled wells.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable, yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause exposure from pendimethalin to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with pendimethalin in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

Pendimethalin is currently registered for use on the following residential non-food sites: ornamental lawns, grasses, ground covers, turf, and ornamental plantings. While EPA does not consider that these types of outdoor residential uses constitute a chronic residential exposure scenario, EPA acknowledges that there may be short- and intermediate-term non-occupational exposure scenarios. OPP has identified toxicity endpoints for short- and intermediate-term residential risk assessment. However, no acceptable reliable exposure data to assess these potential risks are available at this time. Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to aggregate non-occupational exposure with dietary exposure, the Agency will make its safety determination for these tolerances based on those factors which it can reasonably integrate into a risk assessment.

C. 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of

such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether pendimethalin 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, pendimethalin 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 pendimethalin has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to pendimethalin from food will utilize less than 1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1 year old (discussed below). 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 pendimethalin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pendimethalin residues.

2. *Cancer risk.* Pendimethalin has been classified as a Group C, ''possible human carcinogen'', chemical by OPP; it is recommended that the RfD approach for quantification of human risk be used. Given that the RfD is considered protective of all chronic human health effects, including cancer, and that EPA does not expect aggregate exposure to the U.S. population to exceed 100% of the RfD, carcinogenicity resulting from aggregate exposure to pendimethalin residues is not of concern.

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

In assessing the potential for additional sensitivity of infants and children to residues of pendimethalin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

The pre- and post-natal toxicology data base for pendimethalin is complete with respect to current toxicological data requirements. The data base does not indicate a potential for increased sensitivity from pre- and post-natal exposure.

No developmental toxicity was observed in either the rat or rabbit developmental toxicity studies, nor was there any evidence in the 2-generation toxicity study that there was developmental or reproductive toxicity at dose levels below those in which parental toxicity was observed. For rabbits, the developmental toxicity NOEL was > 60 mg/kg/day, at the highest dose tested (HDT). The maternal NOEL was > 60 mg/kg/day, based upon mortality observed at 125 mg/kg/day in a pilot study. For rats, there were no maternal or developmental effects at any dose level and the NOELs were ≥ 500 mg/kg/day, the highest dose tested.

In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL could not be determined at the doses tested. The reproductive NOEL was 172 mg/kg/day. The reproductive LOEL of 346 mg/kg/day was based on decreased pup weight, which occurred in the presence of parental (systemic) toxicity at 346 mg/kg/day.

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 pre- and post-natal toxicity and the completeness of the database 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 analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard margin of exposure and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold margin of exposure/uncertainty factor when EPA has a complete database under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin of exposure/safety factor.

The reproductive NOEL of 172 mg/kg/day is seventeenfold higher than the NOEL of 10 mg/kg/day used for the RfD. Additionally, the reproductive LOEL occurred in the presence of parental (systemic) toxicity and there was no evidence of developmental toxicity in either the rat or the rabbit studies. Therefore, OPP concludes that these section 18 requests do not represent any unacceptable pre- or post-natal risk to infants and children.

Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to pendimethalin from food will utilize less than 2% 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 pendimethalin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pendimethalin residues.

V. Other Considerations

The nature of the residue in plants is adequately understood. The regulable residue in mint is pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite (CL 202,347), as per 40 CFR 180.361(a). Adequate enforcement methodology, GC/ECD, is available in the Pesticide

Analytical Manual, Vol. II, to enforce the tolerance expression. The combined residues of pendimethalin plus its regulated metabolite (CL 202,347) are not expected to exceed 0.1 ppm in/on fresh mint (peppermint, spearmint) hay or 5.0 ppm in mint (peppermint, spearmint) oil as a result of these section 18 uses. There are no Codex, Canadian, or Mexican international residue limits established for residues of pendimethalin in/on mint.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of pendimethalin in fresh mint hay at 0.1 ppm and in mint oil at 5.0 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) 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 22, 1997, file written objections to any aspect of this regulation (including the revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (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). 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.

VIII. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300493] (including comments and data submitted electronically as described below). 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 official rulemaking record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP–300493]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

IX. Regulatory Assessment Requirements

This action finalizes a tolerance under section 408 of the FFDCA. 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). In addition, 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 special 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, pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), 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 (46 FR 24950, May 4, 1981). In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This 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: May 15, 1997.

Peter Caulkins,

Acting Director, Registration Divison, 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. 346a and 371.

2. Section 180.361 is amended as follows:

i. In paragraph (a) by adding a paragraph heading.

ii. In paragraph (b) by transferring the entry in the table for ''Peanuts, hulls'' to the table in paragraph (a), and by revising the remainder of paragraph (b).

iii. In paragraph (c) by adding a paragraph heading.

iv. By adding and reserving paragraph (d).

§ 180.361 Pendimethalin, tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide pendimethalin in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/ Revocation Date
Mint hay, fresh	0.1 ppm	5/31/98
Mint oil	5.0 ppm	5/31/98

(c) *Tolerances with regional registrations.* * * *

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

[FR Doc. 97–13643 Filed 5–22–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300488/PP–6F04625; FRL–5716–9]

RIN 2070–AB78

Pelargonic Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of pelargonic acid when used as an herbicide in or on all food commodities. Mycogen Corporation submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of l996 (FQPA) requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this herbicide in or on all food commodities..

EFFECTIVE DATE: May 23, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300488/PP 6F04625], may 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 should be identified by the docket control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of 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 in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300488/PP 6F04625]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit VIII. of this preamble.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, U. S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor CS, 2800 Crystal Drive, Arlington, VA 22202, (703)–308–8715); email: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 24, 1997 (62 FR 3688)(FRL–5579–3), EPA issued a notice pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d) announcing the filing of a pesticide petition for an exemption from the requirement of a tolerance by Mycogen Corporation, 4980 Carroll Canyon Rd., San Diego, CA 92121. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the FQPA (Pub. L. 104–170). The petition requested that 40 CFR 180.1159 be amended to exempt pelargonic acid from the requirement for a tolerance for all food commodities (formerly raw agricultural commodities).

There were no comments received in response to the notice of filing. The data submitted in the petition and other relevant material have been evaluated. The toxicology data listed below were considered in support of this exemption from the requirement of a tolerance.

I. Toxicological Profile

Pelargonic acid, at high dose levels, showed no significant effects in a 14 day feeding study, a chronic dermal study, and a developmental toxicity study. In addition, there was no mutagenicity in an *in vivo* mouse micronucleus assay nor in a *Salmonella* reverse gene mutation assay. Further, the purported mutation observed at cytotoxic levels with S9 activation in the mouse lymphoma assay was determined not relevant to dietary risk. The results of these studies were determined applicable to evaluate human risk and the validity, completeness, and reliability of the available data from the studies were considered.

A. Acute Toxicity

A battery of acute toxicity studies place technical pelargonic acid in the following Toxicity Categories: primary eye irritation (Toxicity Category II), primary dermal irritation (Toxicity Category II), oral toxicity (Toxicity Category IV), dermal and inhalation toxicity (Toxicity Category III). Based on the results from the sensitization test, pelargonic acid was not considered a dermal sensitizer. (MRID Nos. 438435–01, –02, –03, –04, –05, and –06)

B. Mutagenicity

Pelargonic acid was shown not to be mutagenic via the Ames test (*Salmonella*/reverse mutation assay) or the *in vivo* cytogenetics study using the micronucleus assay (MRID Nos. 436037–02, and –03). In a mouse lymphoma forward mutation assay, pelargonic acid induced a purported weak mutagenic response at levels greater than or equal to 50 g/ml in