US ERA ARCHIVE DOCUMENT





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

FEE 20 1990

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND

RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY

DECISION DOCUMENT FOR PENDIMETHALIN

TO:

Mike Metzger, Branch Chief

Risk Characterization and Analysis Branch

Health Effects Division (7509C)

FROM:

John Leahy, Environmental Protection Specialist

THRU:

Alan P. Nielsen, Section Head

Reregistration Section II

Occupational and Residential Exposure Branch

Health Effects Division (7509C).

Larry C. Dorsey, Chief

Occupational and Residential Exposure Branch

Health Effects Division (7509C)

Please find the OREB review of pendimethalin.

DP Barcode:

D221532

Pesticide Chemical Codes:

108501

EPA Reg. Nos.:

241-337, 241-305, 10404-52, 241-268, 538-195,

538-214-10404, 538-188, 10404-74, 241-297,

241-340, 538-251

EPA MRID Nos.:

None

LUIS Report Date:

9/5/95

PHED:

Yes, Version 1.1

OCCUPATIONAL AND RESIDENTIAL EXPOSURE CHAPTER

In this document, which is for use in EPA's development of the Pendimethalin Reregistration Eligibility Decision Document (RED), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to pendimethalin. Included is a discussion of the adequacy of the occupational and residential exposure data that have been submitted in support of the reregistration of pendimethalin.

(RED SECTION III - TOXICITY, EXPOSURE, AND RISK)

(EXPOSURE)

Occupational and Residential

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

Use Summary

Use Patterns

Pendimethalin, [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], is a herbicide used on a wide variety of food and non-food crops and residential turf.¹ Pendimethalin is formulated as a water-dispersible granular/dry flowable (60 percent active ingredient), granular (0.45 to 2 percent active ingredient), emulsifiable concentrate (2 to 42 percent active ingredient), wettable powder (50 to 60 percent active ingredient), and a soluble concentrate/liquid (3.7 to 22 percent active ingredient).¹

Pendimethalin can be applied using aerial equipment, groundboom sprayers, chemigation systems (solid set, center pivot, moving wheel, and hand-move irrigation), backpack sprayers, hand-held sprayers, and solid-broadcast spreaders. Application rates vary from 1.98 to 4.0 lb ai/acre. Pendimethalin, used most often as a preemergent herbicide, is applied to the following:

alfalfa (seed), carrots (seed), corn (field and sweet), cotton, edible beans, forage legumes, garlic, grain sorghum, jojoba, landscape and grounds plantings, nonbearing fruit and nut trees and vines, non-cropland, onions, ornamentals, peanuts, peas, potatoes, rice, rights-of-way, soybeans, sugarcane, sunflowers, tobacco, and turfgrass (residential, golf-course, landscape, and sod-farm).

Occupational-use products and homeowner-use products

At this time products containing pendimethalin are intended for both occupational and homeowner uses.

Acute Toxicity

The toxicological data base for pendimethalin is adequate and will support reregistration. Guideline studies for acute toxicity indicate that pendimethalin (test material not identified) is classified as category III for acute oral toxicity, category IV for acute dermal toxicity, category IV for acute inhalation toxicity, category III for eye irritation potential, and category IV for dermal irritation.³ Pendimethalin is not classified as a skin sensitizer.³

Other Endpoints of Concern

The Toxicological Selection Endpoint Document, dated January 17, 1996, indicates that there are toxicological endpoints of concern for pendimethalin. Two endpoints have been identified: a short-term NOEL of 1,000 mg/kg/day (21-day dermal study using New Zealand white rabbits, no adverse effects at the highest dose tested); and, an intermediate-term NOEL of 12.5 mg/kg/day (chronic dog study, according to the EPA's endpoint selection document, "although this is a chronic dog study, it is felt that the study is appropriate since some effects relating to thyroid endocrine disruption occur in other studies at 21 mg/kg/day and progress in severity at 51 mg/kg/day and are observed as early as 15 to 28 days"). Because the short-term study was a dermal toxicity study, it is not necessary to apply a dermal absorption value. However, for the intermediate-term toxicity study, a dermal absorption of 10 percent is used. Additionally, pendimethalin has been classified as a "Group C" possible human carcinogen and the Toxicological Selection Endpoint Document recommends using the RfD approach for quantification of human risk. However, no chronic exposures to pendimethalin have been identified. The RfD for pendimethalin is 0.13 mg/kg/day.³

Handler Exposures & Assumptions

EPA has determined that there is potential exposure to persons handling pendimethalin. Handler exposures may occur to:

- occupational handlers involved in food, feed, fiber, ornamental, turf, rights-ofway and other noncrop treatments, and
- homeowner handlers making applications to residential turf and gardens.

No handler exposure studies were conducted by the registrant for pendimethalin.

EPA has determined that there is potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with pendimethalin. Based on the use patterns and potential exposures described above, thirteen major exposure scenarios were

identified for pendimethalin: (1a) mixing/loading water-dispersible granulars (dry flowables) for rights-of-way sprayers; (1b) mixing/loading water-dispersible granulars (dry flowables) for groundboom applications; (2) mixing/loading wettable powders for groundboom application (Note: all currently registered wettable powder end-use products are packaged in water soluble packets); (3) loading granulars for solid-broadcast applications; (4a) mixing/loading liquid for aerial applications and irrigation systems (the mixer/loader scenario for aerial and irrigation applications were combined since they use the same mixing/loading techniques and similar acres treated and application rates); (4b) mixing/loading liquid formulations for rights-of-way spraying; (4c) mixing/loading liquid formulations for groundboom applications or to impregnate dry bulk fertilizer. (Note: impregnating dry bulk fertilizer is included in this scenario since the daily amount of liquid formulation handled would be approximately the same as the amount handled to support groundboom applications); (5) applying as a spray with aerial (fixed wing) equipment; (6) applying as a spray with rights-of-way equipment; (7) applying as a spray with groundboom equipment; (8) applying granulars with a tractor-drawn broadcast spreader; (9) flagging during aerial spray application; (10) mixing/loading/applying as a spray with backpack sprayer; (11) mixing/loading/applying with a low-pressure handwand sprayer; (12) mixing/loading/applying with a push-type granular broadcast spreader; and (13) mixing/loading/applying using a highvolume turf sprayer (similar to those used for turfgrass applications by commercial handlers).

Exposure assessments using PHED V1.1 data are presented in Table 1. Daily dermal and inhalation exposure is calculated using the following formula:

Daily Exposure (mg ai/day) =
Unit Exposure (mg ai/lb ai) x Use Rate (lb ai/A or lb ai/gallon) x Daily Area Treated (A/day)

The calculations incorporate the following assumptions for area treated:

- For aerial applications: 800 acres per day (upper-end estimate for field corn, soybeans, and grain sorghum);
- For groundboom applications: 80 acres per day;
- For rights-of-way applications: 10 acres per day;
- For spot treatments using backpack and low-pressure handwand sprayers: 1,000 square feet per day by homeowner applicators and one acre per day by commercial applicators; and
- For residential turf applications: one acre per day by homeowner applicators using a broadcast spreader and eight acres per day by commercial applicators using high-volume turf sprayers.

Table 1. Short-Term and Intermediate-Term Exposure of Pendimethalin

| Mixer/Loader Exposure 3.96 10 2.8 22.2 2.6 | Exposuré Scenario (Scen. 1) | Baseline Dermal Unit Exposure ^a (mg/lb ai) | Baseline Inhalation Unit Exposure ^b (µg/lb ai) | Application Rate (lb ai/acre) | Daily Acres Treated ^d | Daily Dermal Exposure ^e (mg/day) | Daily Inhalation Exposure ^f (mg/day) | Daily Total Exposure ^t (mg/day) |
|--|---|---|---|-------------------------------------|-------------------------------------|---|---|--|
| 0.07 0.8 3.96 10 2.8 | | | Mixer/Loader E | Stpoeure | | • | | |
| 0.02 | Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Rights-of-Way Spraying (1a) | 40.0 | 9.0 | 96'8 | 10 | 2.8 | 0.032 | 2.8 |
| (wr. ed. pk.) 3.0 80 4.8 0.005 1.7 3.0 80 4.8 0.005 1.7 3.0 80 1.2 2.9 1.2 4.0 10 116 2.9 1.2 4.0 10 116 Applicator Exposure 1.98 80 4.59 0.005 0.07 1.98 80 7.9 1.2 3.9 4.0 10 48 0.015 0.7 3.96 80 7.9 Abjector Applicator 1.98 80 4.8 7.4 0.01 0.23 1.98 80 4.8 7.4 Mixer/Loader/Applicator Abjector 4.8 7.9 7.4 7.4 2.6 30 3.96 (H) 1,000H² (H) 0.24 (O) 1.03 (O) 1.1 (O) 1.1 (O) 1.1 (O) 1.1 </th <th>Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Groundboom Applications (1b)</th> <th></th> <th></th> <th>3.96</th> <th>08</th> <th>22.2</th> <th>0.25</th> <th>22.5</th> | Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Groundboom Applications (1b) | | | 3.96 | 08 | 22.2 | 0.25 | 22.5 |
| 0.005 1.7 3.0 80 1.2 1.2 4.0 10 116 2.9 1.2 4.0 10 116 1.98 800 4,594 1.98 800 4,594 4.0 10 116 2.9 4.0 10 48 1.2 3.9 4.0 10 48 0.015 0.7 3.96 80 4.8 0.01 0.3 1.2 3.0 80 15.8 0.01 0.3 1.2 3.0 80 15.8 0.01 0.3 3.96 (H) 1,000f² (H) 0.24 (O) 1.0 (O) 10.3 2.6 30 6.3 3.0 1.0 8.7 (H) 9.4 (O) 1.0 2.9 6.3 3.0 1.0 8.7 (H) 9.4 | Mixing/Loading Wettable Powders (water soluble packets) for Groundboom Applications(2) | | 0.2 (wtr. sol. pk.) | 3.0 | 80 | 4.8 | 0.048 | 8.4 |
| iones 1.98 800 4,594 2.9 1.2 4.0 10 116 1.98 80 459 0.005 0.07 1.98 80 7.9 1.2 3.9 4.0 10 48 0.015 0.7 3.96 80 4.8 Flagger Mixer/Loader/Applicator Applicator 103.8 30 3.96 (H) 1,000042 (H) 0.24 103.8 3.96 (H) 1,000042 (H) 9.4 103.9 (H) 1,000042 (H) 9.4 103.9 (H) 1,00043 (H) 9.4 103.9 (H) 1,00043 (H) 9.4 103.9 3.0 1.0 (H) 1,00043 103.0 1.0 (H) 1,00043 (H) 1,00043 <th>Loading Granulars for Solid Broadcast Applications (3)</th> <th>0.00\$</th> <th>1.7</th> <th>3.0</th> <th>08</th> <th>1.2</th> <th>0.41</th> <th>1.6</th> | Loading Granulars for Solid Broadcast Applications (3) | 0.00\$ | 1.7 | 3.0 | 08 | 1.2 | 0.41 | 1.6 |
| 1.2 1.2 4.0 10 116 | Mixing/Loading Liquid (B.C.) for Aerial Applications and Irrigation Systems (4a) | | • | 861 | 008 | 4,594 | 6.1 | 4,596 |
| Applicator Exposure 1.2 3.9 4.0 1.0 48 1.2 3.9 4.0 10 48 0.015 0.07 3.96 80 7.9 0.018 0.07 3.96 80 4.8 0.01 1.2 3.0 80 2.4 1.2 3.0 1.98 800 15.8 | Mixing/Londing Liquid (B.C.) for Rights-of-Way Spenying (4b) | 2.9 | 1.2 | 0.4 | 01 | 116 | 0.048 | 911 |
| Applicator Exposure osed cockpit (liquid) (5) 0.005 0.07 1.98 800 7.9 (tractor drawn) (8) 0.015 0.07 3.96 80 4.8 4.8 (tractor drawn) (8) 0.01 1.2 3.96 80 4.8 4.8 (tractor drawn) (8) 0.01 1.2 3.96 80 4.8 2.4 (10) 2.6 0.01 0.3 1.98 800 15.8 6.9 15.8 (apot treatment) (11) 103.8 31.2 3.96 (H) 1,000ff² (H) 0.44 (O) 1.0 (O) 1.0 (O) 1.0 (O) 1.0 (O) 1.0 8.7 8.7 | Mixing/Loading Liquid (E.C.) for Groundboom Applications (4c) | | | 1.98 | 08 | 459 | 0.19 | 459 |
| oned cockpit (liquid) (5) 0.005 0.07 1.98 800 7.9 (tractor drawn) (8) 0.015 0.07 3.96 80 4.8 4.8 (tractor drawn) (8) 0.01 1.2 3.0 80 4.8 2.4 Flagger Alixer/Loader/Applicatior Mixer/Loader/Applicatior (apot treatment) (11) 103.8 31.2 3.96 (H) 1,000f² (H) 0.24 (O) 1.0 (apot treatment) (11) 103.8 31.2 3.96 (H) 1,000f² (H) 9.4 (O) 1.0 (apot treatment) (11) 2.9 6.3 3.0 (H) 1,000f² (H) 9.4 (O) 1.0 | | | Applicator Ex | poeure | | | | |
| (tractor drawn) (5) 0.015 3.9 4.0 10 48 4.0 10 4.8 | Aerial-Fixed Wing - enclosed cockpit (liquid) (5) | 0.005 | 0.02 | 1.98 | 800 | 7.9 | 0.11 | 8.0 |
| (tractor drawn) (8) 0.015 0.77 3.96 80 4.8 7.4 8.0 4.8 7.4 | Rights-of-Way (6) | 1.2 | 3.9 | 4.0 | 10 | 48 | 0.16 | 48.2 |
| Plager 3.0 | Groundboom Tractor (7) | 0.015 | 0.7 | 3.96 | 08 | 4.8 | 0.22 | 5.0 |
| Flagger 1.98 800 15.8 | Solid Broedcast Spreader (tractor drawn) (8) | 10.0 | 1.2 | 3.0 | 08 | 2.4 | 0.29 | 2.7 |
| 0.01 0.3 1.98 800 15.8 Mixer/Loader/Applicator 2.6 30 3.96 (H) 1,000ft ³ (H) 0.24 103.8 31.2 3.96 (H) 1,000ft ³ (H) 9.4 2.9 6.3 3.0 1.0 8.7 | | | Flagger | | | | | |
| Mixer/Loader/Applicator 2.6 30 3.96 (H) 1,000ft ² (H) 0.24 (O) 1.0 (O) 1.0 (O) 1.0.3 103.8 31.2 3.96 (H) 1,000ft ² (H) 9.4 (O) 1.0 (O) 1.1 (O) 1.1 (O) 1.1 (O) 1.1 (O) 1.1 (O) 4.1 | Flagging (liquid) (9) | 0.01 | 0.3 | 1.98 | 900 | 15.8 | 0.48 | 16.3 |
| 2.6 30 3.96 (H) 1,000ft ³ (H) 0.24 103.8 31.2 3.96 (H) 1,000ft ³ (H) 9.4 2.9 6.3 3.0 1.0 8.7 | | • | Mixer/Loader/A | pplicator | | 7 | | |
| 103.8 31.2 3.96 (H) 1,000ft ² (H) 9.4 (O) 1.0 (O) 411 (O) 2.9 6.3 3.0 1.0 8.7 | Backpack (spot treatment) (10) | 2.6 | 30 | 3.96 | (H) 1,000ft ² (O) 1.0 | (H) 0.24 (O) 10.3 | (H) 0.003 (O) 0.12 | (H) 0.24 (O) 10.4 |
| 2.9 6.3 3.0 1.0 8.7 | Low Pressure Handwand (apot treatment) (11) | 103.8 | 31.2 | 3.96 | (H) 1,000ft ² (O) 1.0 | (H) 9.4 (O) 411 | (H) 0.003 (O) 0.12 | (H) 9.4 (O) 411.1 |
| | Residential Broadcast Spreader (12) | 2.9 | 6.3 | 3.0 | 1.0 | 8.7 | 0.019 | 8.7 |
| 1.4 3.96 8 24.4 | High Volume Turf Sprayer (13) | 0.77 | 1.4 | 3.96 | 66 | 24.4 | 0.044 | 24.4 |

Baseline dermal unit exposures represent long pants, long sleeve shirts, no gloves, open mixing/loading, enclosed cockpit, open cab tractor.

Baseline inhalation unit exposure represents no respirator.

Application rates were derived from the following labels (EPA Reg. Nos.): E.C. 241-337 and 241-365, Granular 538-188, WDG 10404-52, 241-340, and 241-268 (CA only), WP 538-195 (water soluble packets only). Values represent the area [(H) = homoownex; (O) = occupational] which can be used in a single day to complete treatments for each exposure scenario of concern.

Daily dermal exposure (mg/day) = Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre or lb ai/gal) * Max. Treated (acres or gallons of spray solution).

Daily inhalation exposure (mg/day) = Exposure (ug/lb at) * (Img/1000ug) conversion * Max Appl Rate (lb at/A or lb at/gal) * Max Treated (acres or gallons of spray solution). Daily total exposure (mg/day) = Daily dermal exposure + Daily inhalation exposure.

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| Science # December | | | | | | | | Risk Mitigation Measure | Measure | | |
|--|---|--------------------------|--------------------------|-----------------------------|-----------------------------|--|--|--------------------------------------|---|----------------|---------------------------|
| Does | Exposure Scenario (Scen. #) | Baseline Daily Dermal | Baseline Total Dose | Baseline Dermal | Baseline Total | | | Additional P | PE | | |
| 0.040 | | Dose (mg/kg/day)* | (mg/kg/day) ^b | MOE | MOE | Dermal Unit Exposure (mg/lb ai) | Inhalation Unit Exposure (ug/lb ai) | Daily Dermal Dose (mg/kg/day)* | Daily Total Dose (mg/kg/day) ^b | Dermal MOE° | Total MOE ^d |
| 0.000 0.000 25,000 25,000 NA | | | | Mixer/ | Loader Risk | | | | | | |
| 0.00 | Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Rights-of-Way Spraying (1s) | 0.040 | 0,040 | 25,000 | 25,000 | NA | NA | ٧N | NA | VN | NA |
| 0.0069 0.0069 1,449 1,449 1,449 NA NA NA NA NA NA NA N | Mixing/Loading Water Dispensible Granulars (Dry Flowables) for Groundboom Applications (1b) | 0.32 | 0.32 | 3,125 | 3,125 | NA | NA | NA | ΨN | NA | NA |
| Colit | Mixing/Loading Wettable Powders (Water Soluble Packets) for Groundboom Applications (2) | 0.069 | 690'0 | 1,449 | 1,449 | NA | NA | NA | NA | NA | NA |
| 65.6 65.7 15.2 15.2 0.04 1.2 0.91 0.94 1,099 oc Way 1.7 1.58 588 NA < | Loading Granulars for Solid Broadcast Applications (3) | 0.017 | 0.023 | 58,824 | 43,478 | NA | NA | NA | VN | NA | NA |
| 1.7 1.7 588 588 NA NA NA NA NA NA NA | Mixing/Loading Liquids (B.C.) for Aerial Applications and Irrigation Systems (4s) | 65.6 | 65.7 | 15.2 | 15.2 | 0.04 | 1.2 | 0.91 | 0.94 | 1,099 | 1,064 |
| 6.6 6.6 152 152 NA NA NA NA NA NA NA N | Mixing/Loading Liquid (B.C.) for Rights-of-Way Spraying (4b) | 1.7 | <i>L</i> .1 | 588 | 885 | NA | NA | NA | NA. | Y. | NA NA |
| Applicator Riuk 1,449 1, | Mixing/Loading Liquid (B.C.) for Groundboom Applications (4c) | 9.9 | 6.6 | 152 | 152 | NA | NA | NA AN | V V | V. | V. |
| 1, 449 1 | | | | Appli | cator Riak | | | | | | |
| (oc. (7)) (0.69) 0.69 1,449 1,449 NA NA </th <th>Aerial-Fixed Wing - enclosed cockpit (liquid) (5)</th> <th>0.11</th> <th>0.11</th> <th>9,091</th> <th>160'6</th> <th>NA</th> <th>NA</th> <th>VV</th> <th>٧٧</th> <th>NA NA</th> <th>ΥN</th> | Aerial-Fixed Wing - enclosed cockpit (liquid) (5) | 0.11 | 0.11 | 9,091 | 160'6 | NA | NA | VV | ٧٧ | NA NA | ΥN |
| 14,065 1 | Rights-of-Way (6) | 0.69 | 69'0 | 1,449 | 1,449 | NA | NA | NA | VV | NA A | ٧× |
| Hager Risk | Groundboom Tractor (1) | 0.069 | 0.071 | 14,492 | 14,085 | NA | NA | NA | NA | ¥X | ΥN |
| Higger Risk (H) 0.003 (H) | Solid Broadcast Spreader (tractor drawn) (8) | 0.034 | 0.039 | 29,412 | 25,641 | NA | NA | NA | Ϋ́Υ | VV | ¥ |
| Harrian Harr | | | | Flag | ger Risk | | | | | | |
| (H) 0.003 (H) 0.003 <t< th=""><th>Flagging (liquid) (9)</th><th>0.23</th><th>0.23</th><th>4,348</th><th>4,348</th><th>NA</th><th>NA</th><th>NA</th><th>NA</th><th>ΥN</th><th>٧×</th></t<> | Flagging (liquid) (9) | 0.23 | 0.23 | 4,348 | 4,348 | NA | NA | NA | NA | ΥN | ٧× |
| (H) 0.003 (H) 0.003 (H) 0.003 (H) 0.003 (H) 0.003 (H) 0.003 (H) 0.15 (H) 0.15 (H) 0.15 (H) 0.15 (H) 0.165 (H) 7,692 (H) 0.169 (O) 169 | | | | Mixer/Loade | r/Applicator Risk | | | | | | |
| (H) 0.13 (H) 0.13 (H) 7,692 (H) 7,692 (H) RA | Backpack Sprayer (10) | (H) 0.003 (O) 0.15 | (H) 0.003 (O) 0.15 | (H) 333,333 (O) 6,667 | (H) 333,333 (O) 6,667 | NA | NA | V V | ∀ X | Y _N | Y _N |
| 0.12 0.12 8,333 8,333 NA | Low Pressure Handwand (11) | (H) 0.13 (O) 5.9 | (H) 0.13 (O) 5.9 | (H) 7,692 (O) 169 | (H) 7,692 (O) 169 | NA. | NA NA | ¥ Z | ٧N | YN. | Ϋ́Α V |
| 0.35 0.35 2,857 2,857" NA NA NA NA NA NA | Residential Broadcast Spreader (12) | 0.12 | 0.12 | 8,333 | 8,333 | NA | NA | ΝΑ | NA AN | V. | ٧× |
| | High Volume Turf Sprayer (13) | 0.35 | 0.35 | 2,857 | 2,857 | Ŋ | NA | NA | NA | ٧× | ÝŽ |

NA = Not applicable since previous MOE was over 100.

Daily dermal dose = daily dermal exposure / 70 kg.

Baseline Total Dose = (daily dermal exposure + daily inhalation exposure)/70 kg.

Dermal MOE = NOEL (abort-term NOEL = 1,000 mg/kg/day)/ daily dermal dose.

Total MOE = NOEL (ahort-term NOEL = 1,000 mg/kg/day) / daily total dose.

Additional PPE for Scenario 4s = single layer clothing and chemical resistant gloves.

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| | | Baseline | Baseline Total | • | | | | Risk Mitigation Measure | Measure | | |
|---|--------------------------|---|----------------------|--------------------|----------|--|--|---|--|----------------------------|--------------|
| . Exposure Scenario (Scen. #) | Baseline Daily Dermal | Daily Absorbed | Daily Absorbed | Baseline Dermal | Baseline | | | Additional PPE | PE | | |
| | Dose (mg/kg/day)* | Dermal Dose (mg/kg/day) ^b | Dose (mg/kg/day)° | MOE | MOE | Dermal Unit Exposure (mg/lb si) | Inhalation Unit Exposure (ug/lb ai) | Daily Dermal Absorbed Dose (mg/kg/day) ^b | Daily Total Absorbed Dose (mg/kg/day)° | Dermal MOE ^d | Total MOF |
| | | | | Mixer/Loader Risk | r Risk | | • | | | | |
| Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Rights-of- Way Spraying (1s) | 0.040 | 0.004 | 0.004 | 3,125 | 3,125 | | | NA | VN | NA | NA |
| Mixing/Loading Water Dispersible Gramlars (Dry Flowables) for Groundboom Application (1b) | 0.32 | 0.032 | 9:00:0 | 391 | 347 | Ž | Ž | NA | VN | NA | NA |
| Mixing/Loading Wettable Powders (Water Soluble Packets) for Groundboom Applications (2) | 690.0 | 0.007 | 0.00 | 1,786 | 1,563 | | | NA | VN | V N | NA |
| Loading Granulars for Solid Broadcast Applications (3) | 0.017 | 0.002 | 900:0 | 6,250 | 1,563 | | | NA | VN | NA. | NA |
| Mixing/Loading Liquid (B.C.) for Aerial Applications and Irrigation Systems (4e) | 65.6 | 6.36 | 6.59. | 1.9 | 1.9 | | | 0.00 | 0.12 | 139 | 104 |
| Mixing/Loading Liquid (B.C.) for Rights-of-Way Spraying (4b) | 1.7 | 0.17 | 0.17 | 73.5 | 73.5 | 0.04 | 1.2 | 0.002 | 0.003 | 6,250 | 4,167 |
| Mixing/Loading Liquid (B.C.) for Groundboom Applications (4c) | 6.6 | 0.66 | 99'0 | 18.9 | 18.9 | | | 0.009 | 0.01 | 1,389 | 1,250 |
| | | | | Applicator Risk | Risk | | | | | | |
| Aerial-Fixed Wing - enclosed cockpit (liquid) (5) | 0.11 | 0.011 | 0.013 | 1,136 | 962 | ΝΑ | NA | NA AN | NA NA | Y. | NA |
| Rights-of-Way (6) | 69.0 | 0.069 | 0.071 | 181 | 176 | NA | NA | VV | V. | V. | ٧× |
| Groundboom Tractor (7) | 0.069 | 0.007 | 0.010 | 1,786 | 1,250 | NA | NA | NA | NA | NA | ٧٧ |
| Solid Broadcast Spreader (tractor drawn) | 0.034 | 0.003 | 0.007 | 4,167 | 1,786 | NA | YN . | NA | Y. | Y. | ٧× |
| | | | | Flagger Risk | Ä | | | | | | |
| Flagging (liquid) (9) | 0.23 | 0.023 | 0:030 | 543 | 417 | NA NA | NA | Y. | V. | YZ | Y. |
| | | | | | | | | | | | |

| | | Baseline | Baseline Total | á | - | | | Risk Mitigation Measure | Measure | | |
|-------------------------------------|--------------|--------------------------|----------------------|-------------------------|-------------------|------------------------|------------------------|----------------------------------|-------------------------|----------------------------|--------------|
| Exposure Scenario (Scen. #) | Daily Dermal | Absorbed | Absorbed | Dermal | Total | | - | Additional PPE | PE | | . ** |
| | (mg/kg/day)* | (mg/kg/day) ^b | Lose (mg/kg/day)° | MOR | A OE | Dermal Unit | Inhalation Unit | Daily Dermal Absorbed | Daily Total Absorbed | Dermal MOE ^d | Total MOE |
| | • • | | | | | Exposure (mg/lb si) | Exposure (ug/lb ai) | Dose (mg/kg/day) ^b | Dose (mg/kg/day)° | 1. | |
| | | | M | Mixer/Loader/Applicator | Applicator | 1 | | | | | |
| Backpack Sprayer (10) | (O) 0.15 | (0) 0.015 | (0) 0.017 | (0) 🕄 | (0) 735 | NA | NA | ΥN | V. | NA NA | NA NA |
| Low Pressure Handwand (11) | 6) 5.9 | (O) 0.59 | (O) 0.59 | (0) 21 | (0) 21 | 4.1 | 31.2 | 0.023 | 0.025 | 543 | 900 |
| Residential Broadcast Spreader (12) | 0.12 | 0.012 | 0.012 | 1,042 | 1,042 | NA | NA | NA | Y.V | ٧× | ۸× |
| High Volume Turf Sprayer (13) | 0.35 | 0.035 | 0.036 | 357 | 347 | NA | NA | NA | NA | NA | ٧× |

NA Not applicable since previous MOE was over 100.

Deliy dermal dose = daily dermal exposure/70 kg.

Baseline absorbed dermal dose = daily dermal dose * dermal absorption rate 10.0%.

Baseline total absorbed dose = (daily absorbed dermal exposure + daily inhalation exposure)/70 kg.

Dermal MOE = NOEL (intermediate-term NOEL = 12.5 mg/kg/day) / daily absorbed dermal dose.

Total MOE = NOEL (intermediate-term NOEL = 12.5 mg/kg/day) / daily total absorbed dose.

Additional PPE = for Scenario 4s, b, c = Single layer of clothing and chemical resistant gloves.

for Scenario 11 = Single layer of clothing and chemical resistant gloves.

Table 4. Exposure Scenario Descriptions for Uses of Pendimethalin

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|--|--------------|---------------------------------|---|
| Exposure Scenario (Number) | Source | Assumptions* (8-hr work day) | Comments |
| | | | Flagger |
| Liquids (9) | PHED V1.1 | 800 acres | Baccinec "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 16 replicates; Dermal = 16 to 18 replicates; Inhalation = 18 replicates. High confidence in dermal and inhalation data. |
| | | | PHED data used for baseline, no PFs were necessary. |
| | | | Mixee/Loader Applicator |
| Backpack Sprayer (spot treatment) (10) | PHED V1.1 | Homeowner: 1,000ft; | Bassine: "Best Available" grades: Hands and dermal grades A.B.C. inhalation acceptable grades. Hands = 11 replicates; Dermal = 9 to 11 replicates; Inhalation = 11 replicates. Low confidence in dermal and inhalation data. |
| | | | PHED data used for baseline was derived from single layer clothing and chemical resistant gloves; a 90% PF was used to remove the chemical resistant gloves to simulate a no glove scenario. |
| Low Pressure Handwand (11) | PHED V1.1 | Homeowner: 1,000ft²; | Baseline: "Best Available" grades: Hands, dermal, and inhalation all grades. Hands = 70 replicates; Dermal = 25 to 96 replicates; inhalation = 96 replicates. Low confidence in both dermal and inhalation data. |
| | | Occupanonal: 1 acre | PPE: "Best Available" grades: Hands acceptable grades, dermal all grades. Hands = 15 replicates; Dermal = 25 to 96 replicates. Low confidence in dermal data. |
| | | • | PHED data used for baseline and PPE values, no PFs were necessary. |
| Residential Broadcast Spreader (12) | PHED V1.1 | l acro | Baseline: "Best Available" grades: Hands and dermal grades A,B,C, inhalation acceptable grades. Hands = 15 replicates; Dermal = 15 (no head data) replicates; Inhalation = 15 replicates. Low (no head data) confidence in dermal and high confidence in inhalation data. |
| | | | PHED data used for baseline, no PF were necessary. |
| High Volume Turf Sprayer (13) | PHED V1.1 | S acres | Baseline: "Best Available" grados: Hands and dermal all grades, inhalation acceptable grades. Hands = 14 replicates; Dermal = 14 (no besd data) replicates; Inhalation = 14 replicates. Low confidence in dermal and low to medium confidence in inhalation data. |
| | | | PHED data used for baseline was derived from single layer clothing and chemical resistant gloves; a 90% PF was used to remove the chemical resistant gloves to simulate a no glove scenario. |

Standard Assumptions besed on an 8-hour work day as estimated by OREB. BEAD data were not available.
"Best Available" grades are defined by OREB SOP for meeting Subdivision U Guidelines. Best available grades are satigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High Medium Low

grades A and B and 15 or more replicates per body part
grades A, B, and C and 15 or more replicates per body part
grades A, B, C, D, and E of any combination of grades with less than 15 replicates

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These calculations of daily exposure to pendimethalin by handlers are used to calculate the daily dose to those handlers.

Postapplication Exposures and Assumptions

EPA has determined that there is potential exposure to persons entering treated sites after application is complete. Post-application exposures may occur to:

- agricultural workers following applications to commercial or research food, feed, fiber, ornamental, and turf crops during routine crop-production tasks, such as planting, transplanting, incorporation, cultivation, hoeing, scouting, thinning, and harvesting;
- mowers and other golf-course maintenance workers following applications to turfgrass on golf courses;
- landscape and grounds maintenance workers following applications to commercial landscape plantings;
- workers following applications in rights-of-way and other noncrop areas; and
- persons, including children, following applications to residential turf or ornamental plantings.

No postapplication studies were conducted by the registrant for pendimethalin.

(RISK)

Occupational and Residential

Risk From Handler Exposures

Table 2 presents the risk assessment for the short-term toxicity endpoint of concern, while Table 3 presents the risk assessment for the intermediate-term toxicity endpoint of concern. Table 4 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment.

Daily Dose is calculated using the following formula:

Daily Dose (mg ai/kg bw/day) =
Unit Exposure (mg ai/lb ai) x Use (lb ai/A) x Daily Acres Treated (A/day) / Body Wt (kg)

The following assumptions are made:

- Some commercial mixers, loaders, flaggers, and applicators are exposed more than 7 days in a three-month (ninety-day) period (reasonable worse-case estimate). Therefore, the exposure/risk assessment for commercial handlers must use both short-term (less than 7 days per year) and intermediate-term (7 or more days per year) toxicological endpoints.
- Aerial applicators are in enclosed cockpits.
- Wettable powder formulations are contained in water-soluble packaging (all currently registered wettable powder products are in water soluble packaging).
- Homeowner handlers would be exposed fewer than 7 days in a three-month (ninety-day) period. Therefore, the exposure/risk assessment for homeowner handlers uses only the short-term toxicological endpoint.

These calculations of daily dose to pendimethalin by handlers are used to assess the risk to those handlers.

The following equation is for determining the risk (MOE) from short-term and intermediate-term exposures.

MOE = NOEL / Total Absorbed Dose

Short-term Exposures

Table 2 outlines the total doses and corresponding MOEs for the short-term toxicological endpoints for each scenario. The calculations using PHED data indicate that the MOEs for short-term exposures at baseline protection (long-sleeve shirt, long pants, shoes, and socks) are over 100 for all scenarios except mixing/loading liquid formulations for aerial applications and applications using irrigation systems. The risks to these mixer/loaders are mitigated (i.e., MOE > 100) by adding chemical-resistant gloves to the baseline protection.

Intermediate-term Exposures

Table 3 outlines the total doses and corresponding MOEs for the intermediate-term toxicological endpoints for each scenario. The calculations using PHED data indicate that the MOEs for intermediate-term exposures at baseline protection (long-sleeve shirt, long pants, shoes, and socks) are over 100 for all but the following scenarios: (4a, b, c) mixing/loading liquid formulations for aerial, chemigation, groundboom, and rights-of-way applications, and (11) mixing, loading, and applying using low-pressure handwand equipment. The risks are mitigated (MOEs > 100) for these scenarios by adding chemical-resistant gloves to the baseline protection. (Though not presented in the tables, aerial application in open cockpits would also result in MOEs greater than 100 at baseline protection.)

Risk From Postapplication Exposures

Exposures following applications to commercial or research food, feed, fiber, turf, and ornamental crops may be mitigated by restricted-entry intervals (REIs). REIs allow sufficient time to pass for field residues to dissipate to levels that result in MOEs greater than 100 for entering workers who contact treated surfaces. However, restricted-entry intervals are generally infeasible as a mitigation measure for post-application homeowner exposures and occupational exposures in noncrop areas (such as rights-of-ways), or in turf- and ornamental-plant settings such as parks and landscape plantings.

There are no pendimethalin-specific post-application exposure data available at this time. These chemical-specific data are necessary for EPA to establish permanent restricted-entry intervals since short-term and intermediate-term endpoints of concern have been identified. In the interim, EPA has qualitatively analyzed potential post-application exposure and risk based on the following:

- pendimethalin use-directions indicate that most applications to food, feed, and fiber crops occur early in the season--preplant, at plant, or preemergent to the weeds. Applications to areas with established plants are layby or otherwise directed to avoid contacting crop foliage, thus minimizing worker risk from foliar contact in these crops;
- most workers entering food, feed, and fiber crops would likely be performing non-hand-labor tasks such as scouting, mechanical incorporation, and

mechanical cultivation, given the timing of applications (early season) and the crops involved. Exceptions include hand-transplanting tobacco and hand-planting or hand-aligning mechanically-planted sugarcane seed pieces in recently treated areas;

- most applications to ornamentals and turf are to established plants and are often broadcast over the entire ornamental and turf foliage, thus increasing potential exposure risk from foliar contact with such treated foliage;
- workers entering turf and ornamental production areas following pendimethalin applications may perform hand-labor tasks such as transplanting, harvesting, weeding, or pruning. For these crops, the timing of applications make hand labor activities likely following pendimethalin applications.
- workers entering rights-of-way and other noncrop areas would likely perform non-hand-labor tasks;
- landscape and grounds maintenance workers performing tasks in commercial landscape plantings may perform hand-labor tasks, such as hoeing, thinning, or weeding, but exposures to treated surfaces are likely to be infrequent and short in duration;
- golf course workers may be exposed while mowing, tending greens, or performing other maintenance tasks, but their exposures are likely to be limited and relatively short in duration;
- persons, including children, may be exposed to treated turfgrass (lawns) at residential sites frequently and for relatively long periods of time.
- persons, including children, may be exposed to treated ornamentals at residential sites, but their exposures are likely to be limited and of short duration.

Given the above, HED estimates that postapplication risks are likely to be acceptable in the following use-scenarios, provided workers and others do not enter treated areas immediately following applications:

- food, feed, and fiber crops, except for sugarcane and tobacco;
- golf-course and turf other than that on sod farms and residential sites;
- ornamental landscape plantings in commercial and residential sites; and
- rights-of-way and other noncrop areas.

However, HED is concerned that postapplication risks are questionable at the following use-sites:

- tobacco and sugarcane (hand-transplanting tobacco and hand-planting or handaligning mechanically-planted sugarcane only);
- ornamentals grown for commercial (or research) purposes; and
- turf on sod farms and at residential sites.

ORER REQUESTS A MEETING WITH THE REGISTRANT TO DISCUSS POSTAPPLICATION EXPOSURES AND RISKS RESULTING FROM THESE USE SCENARIOS:

DUE TO THE POTENTIAL FOR FREQUENT AND PROLONGED EXPOSURES TO HOMEOWNERS, CHILDREN, AND OTHERS REENTERING TREATED LAWNS, AND BECAUSE OF THE TOXICOLOGICAL ENDPOINT, ORER DOES NOT RECOMMEND REREGISTRATION OF RESIDENTIAL TURF USES OF PENDIMETHALIN UNTIL EPAHAS EVALUATED CHEMICAL SPECIFIC DATA TO CONFIRM THAT REENTRY TO TREATED RESIDENTIAL LAWNS WOULD NOT POSE AN UNACCEPTABLE RISK TO HOMEOWNERS, CHILDREN, AND OTHERS

Additional Occupational/Residential Exposure Studies

Handler Studies

Because no chemical-specific data for pendimethalin exists and because of the low confidence level in PHED data for several scenarios, additional handler exposure studies are required as confirmatory data. Requirements for such studies are addressed in Subdivision U of the Pesticide Assessment Guidelines. The required studies are necessary to provide data on mixers, loaders, and applicators for:

- high-volume turf sprayer applications with WP/WDG/liquid formulations;
- low-pressure handward applications with WDG/liquid formulations;
- backpack sprayer applications with WDG/liquid formulations;
- rights-of-way applications with WDG/liquid formulations;
- tractor drawn solid broadcast spreader applications of granulars.

The studies are:

- a dermal exposure study (Guideline 231), and
- an inhalation exposure study (Guideline 232).

These studies should be conducted concurrently; i.e., dermal and inhalation samples should be collected from the same worker and at the same site during each trial.

PostApplication Studies

The registrant must submit postapplication exposure studies as confirmatory data. Requirements for such postapplication exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. Data are required to support the use of pendimethalin on the following crop groups/use sites:

- Food, feed, and fiber crops: (hand-transplanting tobacco and hand-planting or hand-aligning mechanically-planted sugarcane):
- Ornamental crops (transplanting ornamentals);
- Residential turfgrass; and
- Sod-farm turfgrass (harvesting).

Requirements for postapplication/reentry exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. The required data include:

| Guidelines: | 132-1(a) | Foliar Residue Dissipation, if applicable |
|-------------|----------|---|
| | 132-1(b) | Soil Residue Dissipation |
| | *133-3 | Postapplication Dermal |
| | | Passive Dosimetry |
| • | | Exposure |
| * | *133-4 | Postapplication Inhalation |
| | | Passive Dosimetry |
| • | | Exposure |

*Guidelines 133-3 and 133-4 may be reserved at this time pending completion of the databases on agricultural and residential postapplication/reentry exposure currently being developed by the Agricultural Reentry Task Force and Outdoor Residential Exposure Task Force, provided the registrant is a member of both Task Forces.

(SECTION IV - REGULATORY POSITION AND LABELING RATIONALE)

Occupational and Residential Labeling Rationale/Risk Mitigation

The Worker Protection Standard (WPS)

Scope of the WPS

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium in which the plants are (or will be) grown.

At this time some of the registered uses of pendimethalin are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Uses that are outside the scope of the WPS include use:

- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms ARE covered by the WPS).
- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other noncrop areas.

Compliance With the WPS

Any product whose labeling can be reasonably interpreted to permit use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by any person.

Personal Protective Equipment/Engineering Controls for Handlers

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

- 1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.
- 2. If EPA determines that REGULATORY ACTION ON AN ACTIVE INGREDIENT MUST BE TAKEN as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.

These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.

The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for pendimethalin for certain handler use-situations. The MOE's were less than 100 for certain occupational handler (mixers, loaders, and applicators) use-scenarios, unless chemical-resistant gloves were used in addition to the baseline protection of long-sleeve shirt, long pants, shoes, and socks. EPA is requiring active-ingredient-based protections for handlers of pendimethalin in these exposure situations: (1) mixing and loading emulsifiable concentrate formulations and (2) mixing, loading, and applying using low-pressure handwand equipment.

In addition, since wettable powder formulations are currently contained in water-soluble packaging and EPA's exposure and risk assessments were based on that assumption, EPA will require wettable powder formulations of pendimethalin to be contained in water-soluble packaging. If the registrant intends to register any wettable powder product not contained in water-soluble packaging, EPA must first conduct an exposure risk assessment to determine if mitigation measures such as PPE would be necessary.

WPS and NonWPS Uses: Since potential handler exposure is similar for WPS and nonWPS uses, there is only one set of active-ingredient-based minimum (baseline) PPE requirements for occupational uses of pendimethalin (specified in Section V). These requirements must be followed in the labeling of all pendimethalin end-use products intended primarily for occupational use.

Homeowner-Use Products

EPA is not establishing minimum (baseline) handler PPE for pendimethalin end-use products that are intended primarily for homeowner use, because the Agency has determined that the frequency, duration, and degree of exposure by such handlers do not warrant such risk mitigation measures.

Postapplication/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval:

Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REI's) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to shorten or lengthen the previously established REI.

The WPS REI in effect until now was 12 hours. This was an interim REI placed on pendimethalin products by PR Notice 93-7. EPA notes that the 12-hour interim WPS REI was established because data indicated that pendimethalin was in toxicity category III/IV for acute dermal toxicity, skin irritation potential, and eye irritation potential.

During the reregistration process, EPA has determined that the REI established under the WPS should be changed for some uses due to non-acute toxicity endpoints of concern, potential for significant postapplication worker exposure in certain crops, and an absence of exposure data for all use sites and scenarios. Therefore, EPA is now increasing the REI on sugarcane and tobacco from 12 to 24 hours, until postapplication data to set specific REIs for these crops are available. Thus, EPA is establishing a 24-hour restricted-entry interval for uses on sugarcane and tobacco of all occupational-use products that contain pendimethalin and have use-directions for food, feed, and fiber crops. This interim REI is being established due to the intermediate-term toxicity endpoint of concern that has been identified, the lack of pendimethalin-specific postapplication exposure data, and EPA's qualitative analysis of potential post-application exposure risk.

NOTE: AN INTERIM REI WILL BE ESTABLISHED FOR ORNAMENTAL AND TURFGRASS CROPS WITHIN THE SCOPE OF THE WPS PENDING THE OUTCOME OF THE PROPOSED MEETING WITH THE REGISTRANT.

Early-Entry PPE:

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry PPE are set in one of two ways:

- 1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.
- 2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since pendimethalin is classified as category IV for skin irritation potential and IV for acute dermal toxicity, and EPA has determined that no regulatory action must be taken due to the acute effects or other adverse effects of pendimethalin, the PPE for dermal protection required for early entry is the minimum early-entry PPE permitted under the WPS. Since pendimethalin is classified as toxicity category III for eye irritation potential, no protective eyewear is required.

WPS Notification Statement:

Under the WPS, the labels of some pesticide products must require employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The reregistration process also may decide that a product requires this type of "double notification."

EPA has determined that double notification is not required for pendimethalin end-use products.

Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about post-application exposures to persons after nonWPS occupational uses of pendimethalin, it is establishing entry restrictions for all nonWPS occupational uses of pendimethalin end-use products. For specific requirements, refer to Section V of this document.

Homeowner-Use Products

Since EPA has concerns about post-application exposures to persons after homeowner applications of pendimethalin, it is establishing entry restrictions for all homeowner uses of pendimethalin end-use products. For specific requirements, refer to Section V of this document.

NOTE: THIS SECTION MAY BE AMENDED PENDING THE GUTCOME OF THE MEETING WITH THE REGISTRANS

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing pendimethalin. For the specific labeling statements, refer to Section V of this document.

(RED SECTION V - LABELING REQUIREMENTS)

LABELING REQUIREMENTS FOR END-USE PRODUCTS

PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain pendimethalin, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain pendimethalin, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use (WPS and nonWPS)

Minimum (Baseline) PPE/Engineering Control Requirements

EPA is establishing minimum (baseline) engineering controls for occupational uses of pendimethalin end-use products formulated as wettable powders. All wettable powder formulations must be contained in water-soluble packaging.

EPA is establishing minimum (baseline) personal protective equipment (PPE) requirements for some occupational uses of pendimethalin end-use products. The minimum (baseline) PPE for occupational uses of pendimethalin end-use products are:

For emulsifiable concentrate formulations:

"Mixers and loaders must wear:

- long-sleeved shirt and long pants,
- -- chemical-resistant gloves*, and
- -- shoes plus socks."
- * For the glove statement, use the statement established for pendimethalin through the instructions in Supplement Three of PR Notice 93-7.

For water-dispersible granule, wettable powder, and emulsifiable concentrate formulations whose use directions reasonably permit application using hand-held sprayers:

- "Handlers (mixers, loaders, and applicators) who apply this product using hand-held equipment or hoses must wear:
 - long-sleeved shirt and long pants,
 - -- chemical-resistant gloves*, and
 - shoes plus socks."

* For the glove statement, use the statement established for pendimethalin through the instructions in Supplement Three of PR Notice 93-7.

Determining PPE Requirements for End-use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Products Intended Primarily for Homeowner Use

Minimum (baseline) PPE Requirements

EPA is not establishing active-ingredient-based minimum (baseline) handler PPE for pendimethalin end-use products that are intended primarily for homeowner use.

Determining PPE Requirements for End-Use Product Labels

Any necessary PPE for each pendimethalin end-use product intended primarily for homeowner use will be established on the basis of the end-use product's acute toxicity category.

Placement in Labeling

The personal protective equipment requirements, if any, must be placed on the enduse product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

Entry Restrictions

For sole-active-ingredient end-use products that contain pendimethalin the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

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For multiple-active-ingredient end-use products that contain pendimethalin the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use

WPS Uses

Restricted-entry interval:

A 12-hour restricted-entry interval (REI) is required for uses on food, feed, and fiber crops within the scope of the WPS on all pendimethalin end-use products, with the exception of uses on sugarcane and tobacco.

A 24-hour restricted-entry interval (REI) is required for uses on sugarcane and tobacco crops within the scope of the WPS on all pendimethalin end-use products.

"Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

NOTE: AN REL WILL BE ESTABLISHED FOR TURP AND GENAMENTAL USES WITHIN THE SCOPE OF THE WPS PENDING THE OUTCOME OF THE PROPOSED MEETING WITH THE REGISTRANT.

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:

- -- coveralls.
- chemical-resistant gloves, and
- shoes plus socks,

Placement in labeling:

The REI and PPE required for early entry must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions:

2. The Agency is establishing the following entry restrictions for nonWPS occupational uses of pendimethalin end-use products:

For liquid applications:

"Do not enter or allow others to enter the treated area until sprays have dried."

For dry applications:

"Do not enter or allow others to enter the treated area until dusts have settled."

Placement in labeling:

If WPS uses are also on label — Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

If no WPS uses are on the label — Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Products Intended Primarily for Homeowner Use

Entry restrictions: The Agency is establishing the following entry restrictions for all homeowner uses of pendimethalin end-use products:

For liquid applications:

"Do not allow people or pets to touch treated plants until the sprays have dried."

For dry applications:

"Do not allow people or pets to enter the treated area until dusts have settled."

Placement in labeling: Place the appropriate entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing pendimethalin that are intended primarily for occupational use.

Application Restrictions

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"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

<u>User Safety Requirements</u>

1. {Registrant: add the following statements if coveralls are required for pesticide handlers on the end-use product label:}

Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

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2. {Registrant: add the following statement always:}

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Products Intended Primarily for Home Use

Application Restrictions

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

cc: John Leahy, 7509C Mary Clock, 7509C Walter Waldrop, 7508C Chemical File 108501 Correspondence File

References:

- 1) Pendimethalin Labels.
- 2) U.S. EPA 1995. LUIS Report for Pendimethalin. Dated July 13, 1995.
- 3) U.S. EPA 1996. Toxicology Endpoint Selection Document. Dated January 17, 1996.