

CHEMICAL FILE

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 19 1995

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND
RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY
DOCUMENT FOR NALED

TO: Karen Whitby, Acting Branch Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

FROM: Peg Perreault *Peg Perreault*

THRU: Steven M. Knott, Section Head *Laura Morris for Steven Knott*
Special Review and Registration Section I
Occupational and Residential Exposure Branch
Health Effects Division (7509C)
Al Neilsen for
Larry C. Dorsey, Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find below the OREB review of naled.

DP Barcode: D199395

Pesticide Chemical Codes: 034401

EPA Reg. Nos.: 10163-46, 1769-203, 2517-43, 2517-44, 2517-45, 2517-46,
2517-52, 2935-284, 34704-351, 34704-546, 34704-616, 5011-
60, 5011-71, 51036-73, 59639-14, 59639-15, 59639-18, 59639-
19, 59639-21, 59639-25, 59639-43 59639-46, 59639-72, 59639-
74, 6218-40.

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LUIS Report Date: 8/31/94

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OCCUPATIONAL AND RESIDENTIAL EXPOSURE

This memorandum presents the OREB science chapter review for the Naled Registration Eligibility Document (RED). Postapplication/reentry exposure data requirements to support the reregistration of naled and risks from postapplication exposure are discussed in this chapter. However, occupational and residential exposure data requirements for handlers (mixer/loader/applicators) of naled will be determined pending the outcome of the handler risk-mitigation decision. It should be noted that labeling requirements for naled presented in this document will be revised based on the outcome of the risk-mitigation decision. Any further risk-mitigation options need to be identified by the registrant and submitted to OREB.

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

(EXPOSURE)

Occupational and Residential Exposure Assessment

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) during use or to persons entering treated sites after application is complete.

Use Information

Use patterns

Naled, 1,2-dibromo-2,2,-dichloroethyl dimethyl phosphate, is a short residual contact insecticide used to control insects on vegetables, cotton, grapes, some citrus, strawberries, sugar beets, tobacco, ornamental and shade trees, ornamental herbaceous plants, forests, dogs, cats, animals used as food, and in greenhouses. The insecticide is formulated as a soluble concentrate/liquid (20 percent a.i. to 85 percent a.i.), an emulsifiable concentrate (36 percent a.i. to 58 percent a.i.), liquid ready to use (1 percent a.i. to 35 percent a.i.), ultra low volume (1 percent a.i. to 35 percent a.i), dust (4 percent a.i.), and impregnated collar/tag (7 percent a.i. and 15 percent a.i.). Dichlorvos or DDVP (2,2,-dichlorovinyl dimethyl phosphate) is a potential metabolite and/or contaminant of Naled.

Naled is currently registered for a wide variety of food and non-food uses. Food uses include vegetables, fruits, nuts, some citrus, animals raised for meat (including pest control in feedlots) and dairy animals. Naled is also currently registered for the following non-food uses: cotton, pastures, rangeland, tobacco, ornamental plants and forest trees, residential lawns, cull/compost piles, dog and cat treatment collars, household crack and crevice, mosquito control in populated areas and in wetland areas, nuisance-insect control in public

areas and livestock premises, industrial premise insect control, and refuse sites.

Naled is applied by the following methods: aerial equipment/helicopter; tractor-drawn groundbooms; airblast (mist blower); backpack sprayer; low pressure hand wand; thermal fog generator; sewage system injection; dog/cat collar or tags; dust by hand; hand pump sprayer; hand held sprinkler can; ultra low volume cold fog; thermal fog generators; paint on heating/steam pipe; and by hot plate/pan.

Occupational-use products and home-use products

Currently registered products containing naled include some products intended primarily for homeowner use and some products intended primarily for occupational use¹.

Summary of Toxicity Concerns Impacting Occupational and Residential Exposures

Acute Toxicity Categories

Guideline studies indicate that naled is classified as a category II for acute oral toxicity, II for acute dermal toxicity, II for acute inhalation toxicity, I for eye irritation, and I for dermal irritation. In addition, naled has been found to be a mild skin sensitizer.

Other Endpoints of Concern

Based upon the Toxicology Branch I review of the toxicology database for naled, a toxicological endpoint and dose level of concern were identified in the *Toxicology Endpoint Selection Document* dated September 4, 1994. Naled has a NOEL of 1 mg/kg/day in both a 28-day dermal study in rats (toxicological endpoints: cholinesterase inhibition, dermal irritation, and systemic toxicity) and a 28-day oral study in rats (endpoint: cholinesterase inhibition).

Naled has not been classified for carcinogenicity. Studies with rats and mice demonstrated no carcinogenic potential.

DDVP, another common organophosphate insecticide, is a potential metabolite and/or manufacturing contaminant of naled. Three toxicological endpoints for DDVP have been identified; the NOEL values are 0.5 mg/kg/day for acute toxicity, 0.1 mg/kg/day for subchronic toxicity, and 0.05 mg/kg/day for chronic toxicity. Postapplication and handler (M/L/A) exposures to DDVP resulting from currently registered uses of naled are expected to be minimal based on the small percentage (< 1%) of the contaminant DDVP detected in naled products and in tank mix solutions.

Summary of Potential Occupational and Residential Exposures

Handler Exposures

EPA has determined that there is a potential for exposure to mixers, loaders, applicators, or other handlers resulting from the use-patterns associated with naled. Specifically, the Agency is concerned about potential exposures arising from mixing and loading liquids, aerial application, groundboom application, airblast application, backpack sprayer application, low pressure hand wand application, application by thermal fog generator, sewage system injection, application to livestock, application of dust by hand, hand pump sprayer application, hand held sprinkler can application, application of ready-to-use liquid, ultra low volume cold fog application, application by painting on heating/steam pipe, and application by hot plate/pan.

Post-Application Exposures

EPA has determined that there is a potential for exposure to persons entering treated sites after application is complete. The potential for exposure exists in a variety of post-application scenarios, including agricultural and residential settings. In agricultural settings, postapplication exposure to workers is of concern for (1) vine crops (grapes), (2) low- and medium- height crops (e.g. strawberries, cotton), (3) orchard-type tree crops (e.g., citrus, peaches), (4) outdoor ornamentals and turfgrass, (5) greenhouse-grown ornamentals and vegetable crops, (6) forestry uses, and (7) livestock sites. A significant potential for both dermal and inhalation postapplication exposure exists for greenhouse use scenarios because workers routinely enter greenhouses to perform a variety of cultural tasks. The Agency is particularly concerned about dermal and inhalation exposures in greenhouses following applications of naled by painting heat/steam pipes and by boiling naled in hot plates/pans, as well as postapplication exposures resulting from foliar applications in greenhouses. In residential settings, postapplication exposure to residents (children and adults) is of concern following applications (1) outdoors on turfgrass, fruits, vegetables, and ornamentals and (2) indoors when naled is applied as a crack-and-crevice treatment and on pets and ornamentals (houseplants). In addition, naled can be used in industrial-premise treatments and refuse sites, and as a mosquito control agent.

Handler Exposures & Assumptions

Mixer/loader/applicator (M/L/A) exposure data for naled were not required in the Guidance for the Reregistration of Pesticide Products Containing Naled issued in June 1983. PHED, Version 1.1, was used in this document to determine potential exposures to M/L/A resulting from registered uses of naled.

Based on the registered use-patterns for naled, 20 major exposure scenarios for handlers (M/L/A) were identified for naled: (1) mixing/loading liquids, (2) mixing/loading dusts, (3) applying with aerial equipment (liquid), (4) applying with aerial equipment (dust), (5) applying with groundboom equipment (liquid), (6) applying with groundboom equipment (dust), (7) applying with airblast equipment, (8) applying with thermal fog generator, (9) applying with ultra low volume cold fog generator, (10) applying dog/cat collars or tags, (11) applying ready-to-use liquid, (12) applying liquid by hand (as bait), (13) applying by painting

on heating/steam pipe in greenhouses, (14) applying by evaporating liquid using a hot plate and pan, (15) applying with backpack sprayer, (16) flagger (liquids), (17) flagger (dusts), (18) mixing/loading/applying with low pressure hand wand, (19) mixing/loading/applying to sewage systems by injection, and (20) mixing/loading/applying by hand-held sprinkler can.¹

The exposure scenarios and corresponding exposure/risk assessments are presented in Table 1 (agricultural uses) and Table 3 (non-agricultural uses). Daily exposure to handlers was calculated using the following formula:

Daily exposure (mg ai/kg bw/day) =

$$\frac{\text{Unit exposure (mg ai/lb ai)} \times \text{use (lb ai/A)} \times \text{daily acres treated (A/day)}}{\text{body wt (kg)}}$$

The parameters specific to each exposure scenario are summarized in Table 2 (agricultural uses) and Table 4 (non-agricultural uses). The actual clothing and equipment worn by all persons being monitored in the exposure studies are also described in Tables 2 and 4. There are no engineering control requirements, such as closed mixing systems or closed tractor cabs, currently required on labeling for naled products. Each exposure assessment under columns headed "PPE" in Table 1 is based on workers wearing long pants, long-sleeve shirts, and chemical resistant gloves, except for the flagger. The flagger exposure / risk assessment is based on workers wearing long pants, long-sleeve shirts, and no gloves. Exposure assessments are also presented for handlers using "engineering controls" in a separate column.

Table 1. Summary Exposure/Risk Values for Agricultural Uses of Naled

Exposure Scenario (Number)	Dermal Exposure* (mg/lb ai)		Inhalation Exposure* (ug/lb ai)		Maximum Label Application Rate* (lb ai/acre)	Daily Max. Treated* (acres)	Daily Dermal Dose* (mg/kg/day)		MOE/(dermal)	
	PPE	Engineering Controls	PPE	Engineering Controls			PPE	Engineering Controls	PPE	Engineering Controls
Mixer/Loader Exposure										
Mixing All Liquids for Aerial Application (1a)	0.02	0.009	0.12	0.08	1.875	800	5.0 x 10 ⁻¹	1.9 x 10 ⁻¹	2	5.2
Mixing All Liquids for Groundboom Application (1b)	0.02	0.009	0.12	0.08	1.875	80	5.0 x 10 ⁻²	1.9 x 10 ⁻²	20	52
Mixing of Liquids for Backpack Sprayer (1c)	0.02	0.009	0.12	0.08	4.69x10 ⁻² lb ai/ gal	200 gal	3.2 x 10 ⁻³	1.2 x 10 ⁻³	320	830
Loading Dusts for Aerial Application (2a)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Loading Dusts for Groundboom Application (2b)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Applicator Exposure										
Aerial equipment (liquids) (3a)	0.02	0.005	0.09	0.07	1.875	800	4.3 x 10 ⁻¹	1.1 x 10 ⁻¹	2.3	9.3
Aerial equipment (dusts) (3b)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Groundboom (liquids) (4a)	0.013	0.007	0.07	0.04	1.875	80	2.8 x 10 ⁻²	1.5 x 10 ⁻²	36	67
Groundboom (dusts) (4b)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Airblast equipment (5)	0.15	0.1	0.5	0.4	3.75	40	3.2 x 10 ⁻¹	2.1 x 10 ⁻¹	3.1	4.7
Thermal fog generator (6)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Ultra low volume cold fog generator (7)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Painting heat/steam pipe (8)	75	N/A	57	N/A	7.5	1	8.0	N/A	0.1	N/A
Hot plate/pan (9)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Backpack Sprayer (10)	148	N/A	38	N/A	4.69x10 ⁻² lb ai/gal	40 gal	4.0	N/A	0.3	N/A
Flagger										
Liquids (11)	0.01	0.0002	0.03	0.0006	1.8	800	3.1 x 10 ⁻¹	4.1 x 10 ⁻¹	3.2	240
Dusts (12)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data

- * The PPE represents coveralls over long pants, long sleeve shirt, chemical resistant gloves using open systems. The engineering controls represents long pants, long-sleeve shirt, chemical resistant gloves, and closed systems (i.e., closed mixing/loading or enclosed cockpit/cabs).
- * PPE Inhalation Exposure Values are for workers wearing a respirator with organic vapor removing cartridge (10 fold PF used). The engineering controls values are for workers wearing no respirators, but mixing/loading and applying the pesticide within enclosed systems (e.g., enclosed cab).
- * Dibrom 8 Emulsive Label, Reg. No. 59639-15; LUIS Reports for Naled dated 08/30/94 and 08/31/94.
- * Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.
- * $\text{Daily Dermal Dose (mg/kg/day)} = \frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated Area (70 kg)}}{70 \text{ kg}}$
- * $\text{MOE} = \text{NOEL} / \text{Daily Dermal Dose (mg/kg/day)}$. NOEL = 1 mg/kg/day, 28-day dermal study.

Table 2. Exposure Scenario Descriptions for Agricultural Uses of Naled

Exposure Scenario (Number)	Data Source	PPE		Engineering Controls		Standard Assumptions* (8-hr work day)	Comments
		Clothing Scenario	Equipment	Clothing Scenario	Equipment		
Mixer/Loader Exposure							
Mixing All Liquids for Aerial Application (1a)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Open mixing liquids for aerial or chemigation applications	Closed mixing liquids for aerial or chemigation applications	Long sleeved shirt and long pants; chemical resistant gloves	800 acres	PPE: Dermal and inhalation acceptable grades. Dermal = 59 to 122 replicates Inhalation = 85 replicates High confidence in dermal and inhalation data. Engineering Controls: Dermal and inhalation acceptable grades. Dermal = 16 to 31 replicates Inhalation = 27 replicates High confidence in dermal and inhalation data.
Mixing All Liquids for Groundboom Application (1b)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Open mixing liquids for aerial or chemigation applications	Closed mixing liquids for aerial or chemigation applications	Long sleeved shirt and long pants; chemical resistant gloves	800 acres	PPE: Dermal and inhalation acceptable grades. Dermal = 59 to 122 replicates Inhalation = 85 replicates High confidence in dermal and inhalation data. Engineering Controls: Dermal and inhalation acceptable grades. Dermal = 16 to 31 replicates Inhalation = 27 replicates High confidence in dermal and inhalation data.
Mixing of Liquids for Backpack Sprayer (1c)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Open mixing liquids	Closed mixing liquids	Long sleeved shirt and long pants; chemical resistant gloves	Eight 5-gallon tanks (one worker supporting 5 applicators)	PPE: Dermal and inhalation acceptable grades. Dermal = 59 to 122 replicates Inhalation = 85 replicates High confidence in dermal and inhalation data. Engineering Controls: Dermal and inhalation acceptable grades. Dermal = 16 to 31 replicates Inhalation = 27 replicates High confidence in dermal and inhalation data.
Loading Dusts for Aerial Application (2a)	No data	No data	No data	No data	No data	No data	PPE: No data Engineering Controls: No data

Exposure Scenario (Number)	Data Source	PPE*		Engineering Controls		Standard Assumptions* (8-hr work day)	Comments*
		Clothing Scenario	Equipment	Clothing Scenario	Equipment		
Loading Dusts for Groundboom Application (2b)	No data	No data	No data	No data	No data	No data	PPE: No data Engineering Controls: No data
Applicator Exposure							
Aerial equipment (liquids) (3a)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Aircraft; open cockpit	Aircraft; enclosed cockpit	Long sleeved shirt and long pants; no gloves	800 acres	PPE: Dermal grades A, B, C; inhalation all grades. Dermal = 9 to 17 replicates Inhalation = 17 replicates Low confidence for inhalation and dermal data. Engineering Controls: Dermal grades acceptable; inhalation grades A, B, C. Dermal = 14 to 34 replicates Inhalation = 23 replicates Medium to high confidence in dermal data; medium confidence in inhalation data.
Aerial equipment (dusts) (3b)	No data	No data	No data	No data	No data	No data	PPE: No data Engineering Controls: No data
Groundboom (liquids) (4a)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Open Cab	Enclosed Cab	Long sleeved shirt and long pants; no gloves	80 acres	PPE: Dermal grades A, B, C; inhalation acceptable grades. Dermal = 7 to 29 replicates Inhalation = 22 replicates Medium confidence in dermal data; high confidence for inhalation data. Engineering Controls: Dermal grades A, B, C; inhalation grades acceptable. Dermal = 16 to 29 replicates Inhalation = 16 replicates Medium confidence in dermal data; high confidence in inhalation data.
Groundboom (dusts) (4b)	No data	No data	No data	No data	No data	No data	PPE: No data Engineering Controls: No data
Airblast equipment (5)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Open Cab	Enclosed Cab	Long sleeved shirt and long pants; no gloves	40 acres	PPE: Dermal and inhalation acceptable grades. Dermal = 18 to 48 replicates Inhalation = 47 replicates High confidence in dermal and inhalation data. Engineering Controls: Dermal grades acceptable; inhalation grades A, B, C. Dermal = 20 to 30 replicates Inhalation = 9 replicates High confidence in dermal data; low confidence in inhalation data.

Exposure Scenario (Number)	Data Source	PPE*		Engineering Controls		Standard Assumptions* (8-hr work day)	Comments
		Clothing Scenario	Equipment	Clothing Scenario	Equipment		
Thermal fog generator (6)	No data	No data	No data	No data	No data	No data	PPE: No data Engineering Controls: No data
Ultra low volume cold fog generator (7)	No data	No data	No data	No data	No data	No data	PPE: No data Engineering Controls: No data
Painting heat/steam pipes (8)	PHED VI.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Paint brush	N/A	N/A	1 acre greenhouse	PPE: Dermal grades A, B, C; inhalation grade C. Dermal and inhalation = 15 replicates each Medium confidence in dermal and inhalation data. Engineering Controls: N/A
Hot plane/pan (9)	No data	No data	No data	No data	No data	No data	PPE: No data Engineering Controls: No data
Backpack sprayer (10)	PHED VI.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Backpack sprayer	N/A	N/A	Eight 5-gallon tanks	PPE: Dermal and inhalation grades acceptable. Dermal = 60 to 69 replicates Inhalation = 40 replicates High confidence in dermal and inhalation data. Engineering Controls: N/A
Flagger							
Liquids (11)	PHED VI.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	In treatment area	Enclosed Cab	Coveralls over long sleeved shirt and long pants; chemical resistant gloves.	800 acres	PPE: Dermal and inhalation grades acceptable. Dermal = 2 to 18 replicates Inhalation = 18 replicates Low confidence in dermal data, high confidence in inhalation data. Engineering Controls: Dermal grades acceptable; inhalation grades A, B, C. Dermal = 0 to 10 replicates Inhalation = 45 replicates Low confidence in dermal data, medium confidence in inhalation data.
Dusts (12)	No data	No data	No data	No data	No data	No data	PPE: No data Engineering Controls: No data

* Clothing represents the exposure estimates used in Table 1.

* Standard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.

* "Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B for dermal and inhalation, and grade C for hand rinse method. All grades that do not meet OREB's SOP are listed individually.

Table 3. Summary Exposure/Risk Values for Non-Agricultural Uses of Naled

Exposure Scenario (Number)	Dermal Exposure ^a (mg/lb ai)		Inhalation Exposure ^b (ug/lb ai)		Maximum Label Application Rate ^c (lb ai/gal)	Daily Max. Treated ^d (gallons)	Daily Dermal Dose ^e (mg/kg/day)		MOE ^f (dermal)	
	Homeowner	Occupational	Homeowner	Occupational			Homeowner	Occupational	Homeowner	Occupational
Applicator Exposure										
Dog/cat collars and tags (10)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Pump Sprayer (Ready-to-use liquid) (11)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Bait (liquid) by hand (12)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Mixer/Loader/Applicator										
Backpack Sprayer (15)	3.4	1.3	30	6.0	4.69 x 10 ⁻²	10 gal 40 gal	2.9 x 10 ⁻²	3.5 x 10 ⁻²	44	29
Low pressure hand wand (18)	103	1.5	31	6.2	4.69 x 10 ⁻²	4 gal 10 gal	2.8 x 10 ⁻²	1.1 x 10 ⁻¹	3.4	99
Sewage system by injection (19)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Hand-held sprinkler can (20)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
High Volume/Low Pressure Lawn Sprayer (21)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data

^a Dermal unit exposures are reported as the best fit mean for workers wearing: Homeowner = long pants and long-sleeved shirts and no gloves; Occupational = Coveralls over long pants, long-sleeved shirts, and chemical resistant gloves.

^b Inhalation Exposure Values are reported as geometric means (lognormal distributions). No respirators for homeowners. A ten fold protection factor for occupational workers was used to simulate workers wearing organic vapor removing respirators.

^c Dibrom 8 Emulsive Label, Reg. No. 59639-15; LUIS Reports for Naled dated 08/30/94 and 08/31/94..

^d Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.

^e Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} \times \text{Max. Appl. Rate (lb ai/acre)} \times \text{Max. Treated}}{70 \text{ kg}}$

^f MOE = NOEL / Daily Dermal Dose (mg/kg/day). NOEL = 1 mg/kg/day, 28 day dermal study.

Table 4. Exposure Scenario Descriptions for Non-Agricultural Uses of Naled

Exposure Scenario (Number)	Data Source	Homeowner*		Occupational		Standard Assumptions* (8-hr work day)	Comments
		Clothing Scenario	Equipment	Clothing Scenario	Equipment		
Applicator Exposure							
Dog/cat collars and tags (10)	No data	No data	No data	No data	No data	No data	Homeowner: No data Occupational: No data
Pump Sprayer (Ready-to- use liquid) (11)	No data	No data	No data	No data	No data	No data	Homeowner: No data Occupational: No data
Bait (liquid) by hand (12)	No data	No data	No data	No data	No data	No data	Homeowner: No data Occupational: No data
Mixer/Loader/Applicator							
Backpack sprayer (15)	PHED V1.1	Long-sleeve shirt and long pants; no gloves	No data	Coveralls over long-sleeve shirt and long pants, chemical resistant gloves	Backpack sprayer	Homeowner: Two 5-gallon tanks Occupational: Eight 5-gallon tanks	Homeowner: No data Occupational: Dermal grades A, B, C; acceptable inhalation grades; Dermal = 9 to 11 replicates, Inhalation = 11 replicates, Low confidence in dermal and inhalation data.
Low pressure hand wand (18)	PHED V1.1	Long-sleeve shirt and long pants; no gloves	1 to 3 gallon capacity low pressure handwands	Coveralls over long-sleeve shirt and long pants, chemical resistant gloves	1 to 3 gallon capacity low pressure handwands	Homeowner: Two 2-gallon tanks Occupational: Five 2-gallon tanks	Homeowner: Dermal and inhalation all grades; Dermal = 25 to 96 replicates, Inhalation = 96 replicates Low confidence in dermal and inhalation data. Occupational: Dermal and inhalation all grades; Dermal = 25 to 96 replicates, Inhalation = 96 replicates Low confidence in dermal and inhalation data.
Sewage system by injection (19)	No data	No data	No data	No data	No data	No data	Homeowner: No data Occupational: No data
Hand-held sprinkler can (20)	No data	No data	No data	No data	No data	No data	Homeowner: No data Occupational: No data
High Volume/Low Pressure Lawn Sprayer (21)	No data	No data	No data	No data	No data	No data	Homeowner: No data Occupational: No data

* Clothing scenario represents exposure data in Table 3.

* Standard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.

* "Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B for dermal and inhalation, and grade C for hand rinse method. All grades that do not meet OREB's SOP are listed individually.

Postapplication Exposures & Assumptions

Postapplication/reentry exposure data for naled and the potential metabolite/contaminant DDVP were required by the Agency in a Data-Call In issued 9/20/91. The following documents pertaining to post-application exposures were submitted to the Agency in support of the reregistration of naled:

Titles:	(1) Dissipation of Dislodgeable Foliar Residues of Dibrom 8 Emulsive Applied to Grapes (2) Validation of Analytical Methods for Naled and Dichlorvos (DDVP) in Worker Exposure and Re-entry Matrices (3) Worker Re-entry Exposure While Harvesting Grapes Treated with Dibrom 8 Emulsive (4) Margin of Exposure Calculations for Workers Reentering Fields Treated with Dibrom 8 Emulsive
Authors:	(1) Leah Rosenheck and Clari J. Cone (Pan-Ag) (2) Clari J. Cone (Pan-Ag) (3) Ian C. Lamb (Pan-Ag) (4) Eric D. Bruce (Valent)
Performing Laboratory:	(1,2,3) Pan-Agricultural Laboratories/32380 Avenue 10/Madera, CA 93638 (4) Valent U.S.A. Corporation/1333 N. California Blvd./Walnut Creek, CA 94596
Identification Codes:	(1) Valent Project 10107-A, Pan-Ag Report 93271-Amended, EPA MRID 432239-01 (2) Pan-Ag Report 93258, EPA MRID 432239-05 (3) Valent Project 10109-A, Pan-Ag Report 93270, EPA MRID 432239-07 (4) Valent Project EDB.494, EPA MRID 432239-06
Sponsor Company:	Valent U.S.A. Corporation 1333 N. California Blvd. Walnut Creek, CA 94596

No major deficiencies were noted in the Agency's review of the studies identified above. The foliar dislodgeable residue study monitored two separate applications (i.e., not sequential and at different sites) of naled to grapes in the Central Valley of California. Concurrent with the second application, human reentry exposure monitoring was conducted using passive dosimetry at 1, 3, and 7 days after the application. The registrant's submission pertaining to Margin of Exposure Calculations (study #4 listed above) was not reviewed; the Agency instead used data from the foliar dissipation and postapplication exposure studies to determine daily exposure levels to naled and DDVP in order to assess the risk to persons entering treated sites at various intervals postapplication. The data submitted indicated that foliar dislodgeable residues and postapplication exposure to DDVP were minimal relative to naled foliar residue and exposure levels. Restricted Entry Intervals (REIs) for naled were calculated based on the data submitted.

Naled is a broad spectrum insecticide which can be used on a variety of agricultural crops as well as in a variety of other scenarios (e.g., greenhouses and residences). However, the only postapplication/reentry exposure data which were submitted by the registrant were from studies conducted on grapes in California. Although the studies were conducted using the maximum label application rate for grapes (0.9 lbs ai/A), naled labels allow higher maximum application rates on other crops. The highest label application rate is 3.6 lbs ai/A on tree crops (e.g., peaches and citrus). No *acceptable* data exist with which to

calculate REIs for registered crops other than grapes. The Agency is concerned about potential exposure during reentry activities associated with other crops/use sites, including low- and medium-height crops and orchard-type tree crops, outdoor ornamentals and turfgrass, greenhouse-grown ornamentals and vegetable crops, and forestry use sites. In addition to agricultural crop uses, naled can be used on livestock and in industrial and residential settings. The particular crop groups/use sites of concern with respect to potential postapplication/reentry exposure include:

Naled Crop Groups/Use Sites
<u>AGRICULTURAL CROP GROUPS</u> Vine crops (grapes-data submitted) Tree crops (citrus, peaches) Medium-height crops (cotton, tobacco, etc.) Low crops (strawberries, broccoli, etc.) Outdoor ornamentals and turf (sod farms) Indoor ornamental and low crops
<u>USE SITES</u> Forestry uses Outdoor residential (ornamentals, turf, fruit and vegetables) Indoor residential (crack/crevice, houseplants) Nuisance-insect control - residential and livestock areas Industrial and refuse-site uses

RISK CHARACTERIZATION

Occupational and Residential

The toxicological endpoints of concern for occupational and residential exposure are (1) for naled -- a NOEL of 1 mg/kg/day in both dermal and oral 28-day studies in rats and (2) for DDVP -- NOEL values are 0.5 mg/kg/day for acute toxicity, 0.1 mg/kg/day for subchronic toxicity, and 0.05 mg/kg/day for chronic toxicity.

Risks to Handlers (M/L/A)

The calculations indicate that MOEs are unacceptable (all but one exposure scenario have MOEs less than 100; several scenarios have MOEs less than 5) for mixing/loading and application of naled for most exposure scenarios using both baseline and maximum PPE. Thus, even when maximum PPE (engineering controls - closed loading system and enclosed cab with respiratory filtration system) is simulated, the MOEs for mixer/loaders and

applicators are still unacceptable for most exposure scenarios.

RISK-MITIGATION MEASURES FOR HANDLERS OF NALED WILL BE REQUIRED. THE AGENCY WILL DISCUSS THE HANDLER RISK-MITIGATION DECISION IN A MEETING WITH THE REGISTRANT.

Risks From Post-Application Exposures

Based on the foliar dissipation and postapplication/reentry exposure data submitted for grapes, the Agency calculated a Restricted Entry Interval (REI) for grapes as well as interim REIs for all other agricultural crops and WPS uses for which naled is registered. The interim REIs established for crops other than grapes were calculated by the Agency using data submitted for grapes in conjunction with assumptions pertaining to foliar residue and postapplication exposure levels that would be expected on crops treated at rates up to the maximum label application rate (3.6 lbs ai/A). The Agency is establishing the following REIs at this time:

Crop/Crop Group	Restricted Entry Interval (REI)
Grapes/vine crops	3 days postapplication
All other WPS uses*	4 days postapplication (interim REI)

*THESE REIs ARE BASED ON DERMAL EXPOSURE DATA FOR OUTDOOR SETTINGS. INHALATION EXPOSURE DATA FOR GREENHOUSE/INDOOR SETTINGS ARE NOT AVAILABLE. THE REGISTRANT MUST ADDRESS THE ISSUE OF INHALATION EXPOSURE WHEN DEVELOPING AND CONDUCTING ADDITIONAL POSTAPPLICATION EXPOSURE STUDIES FOR GREENHOUSE EXPSOURE SCENARIOS.

ADDITIONALLY, POSTAPPLICATION EXPOSURE DATA ARE NOT AVAILABLE FOR HOMEOWNER/RESIDENTIAL USES OR FOR NUISANCE-INSECT CONTROL USES. THE REGISTRANT MUST ADDRESS THE ISSUES RELATIVE HOMEOWNER/RESIDENTIAL RISKS AND RISKS FROM MOSQUITO AND OTHER INSECT CONTROL PROGRAMS.

OPTIONS PERTAINING TO THE ABOVE ISSUES SHOULD BE IDENTIFIED BY THE REGISTRANT AND SUBMITTED TO/DISCUSSED WITH THE AGENCY.

The Agency is requiring that appropriate data be generated to definitively calculate REIs for all crop groups/use sites for which interim REIs have been established.

Additional Occupational/Residential Exposure Studies

Handler (M/L/A) Studies

HANDLER (M/L/A) EXPOSURE STUDIES (GUIDELINES 231, 232, 233, AND 234) MAY BE REQUIRED AS CONFIRMATORY DATA; HOWEVER, THE DETERMINATION OF THE SPECIFIC EXPOSURE SCENARIOS TO BE ADDRESSED HAS BEEN POSTPONED PENDING THE OUTCOME OF THE HANDLER RISK-MITIGATION DECISION.

Postapplication Studies

Postapplication/reentry exposure studies are required as confirmatory data to determine definitive REIs for all crop groups/use sites on which naled is registered for use. The interim REIs established in this document will be adjusted accordingly upon submission of the additional data. Data requirements for grapes have been satisfied; however, confirmatory data are still required to support the use of naled on the following crop groups/use sites:

- o Tree crops (orchard-type, i.e. citrus, peaches)
- o Medium-height crops (such as cotton, tobacco)
- o Low crops (such as strawberries, broccoli, cauliflower)
- o Greenhouse-grown crops (roses and other ornamental plants)
- o Residential sites (turfgrass)

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
 *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.

THE FOLLOWING TWO SECTIONS OF THE OREB CHAPTER (SUGGESTED LANGUAGE FOR INSERTION INTO SECTIONS IV AND V OF THE RED) HAVE BEEN COMPLETED TO THE EXTENT POSSIBLE. SOME SEGMENTS WILL NEED TO ALTERED PENDING THE OUTCOME OF THE RISK-MITIGATION DISCUSSIONS WITH THE REGISTRANT.

(SECTION IV - REGULATORY POSITION AND LABELING RATIONALE)

Occupational/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, 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 the plants are (or will be) grown in.

Currently registered uses of naled include some uses within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) as well as some uses outside the scope of the WPS. Those that are outside the scope of the WPS include:

- on pastures or rangelands,
- on livestock or other animals (including collars and tags), or in or around animal premises,
- on plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses;
- 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; and
- 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 and structural pest control, such as termite control and wood preservation.

- for mosquito abatement or nuisance-insect control that is part of a government-sponsored wide-area public pest control program,
- on the portions of agricultural plants that have been harvested, such as in cull piles of discarded vegetables.

Compliance With The WPS

Any product whose labeling reasonably permits 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, all products within the scope of those notices must bear WPS PR Notice complying labeling when they 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, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

Personal Protective Equipment/Engineering Controls for Handlers

Occupational-Use Products (WPS and NonWPS Uses)

For each end-use product, PPE/engineering control requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute 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 will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.
2. If EPA has special concerns about an active ingredient due to 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 or engineering-control requirements that pertain to all or most occupational 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 each 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.

There are special toxicological concerns about naled that warrant the establishment of active-ingredient-based handler PPE/engineering-control requirements.

THE SPECIFIC LABEL REQUIREMENTS FOR HANDLER PPE/ENGINEERING CONTROLS WILL BE DETERMINED UPON COMPLETION OF THE HANDLER RISK-MITIGATION DECISION.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted Entry Interval:

Under the Worker Protection Standard (WPS), interim restricted entry intervals (REIs) 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.

For occupational end-use products containing naled as an active ingredient, EPA is establishing a 3-day restricted-entry interval for uses on grapes and a 4-day restricted-entry interval for each other use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The basis for this decision is the post-application data on grapes, the range-finder estimate for non-grape crops, the lack of crop-specific data (other than grape data) pertaining to post-application exposures, and low MOE's for certain applications of naled.

In addition, due to concerns about post-application exposures to naled/DDVP in

greenhouses following applications where naled is painted on heating/steam pipe or applied by heating in a hot plate/pan, EPA is establishing additional entry restrictions following those uses. For those uses, EPA is **prohibiting** entry by **any person** -- other than a correctly trained and equipped handler who is performing a WPS-defined **handler** task -- into the entire enclosed treated area from the start of application until one of the WPS ventilation criteria has been met. After ventilation is completed, workers are not allowed into the entire enclosed area during the remainder of the restricted-entry interval, except for worker entry as allowed by the WPS.

EPA notes that the WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. EPA believes that these existing WPS protections are sufficient to mitigate post-application exposures of workers who contact surfaces treated with naled.

The WPS REI in effect until now was 24 hours. A 24-hour reentry interval was established by the June 1983 Registration Standard for naled. That reentry interval was converted into a 24-hour **restricted-entry interval** through labeling modifications specified in PR Notice 93-7, which implemented the labeling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides. EPA found no reason to retain the 24-hour interim REI placed on naled products by PR Notice 93-7.

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 the requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.
2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since naled is classified as category II for acute oral toxicity, category II for acute dermal toxicity, category II for acute inhalation toxicity, category I for eye irritation potential, and category I for dermal irritation, and EPA has special concerns about other adverse effects, the PPE required for early entry is: coveralls over long-sleeve shirt and pants, chemical-resistant footwear plus socks, chemical resistant headgear for overhead

exposures, protective eyewear, and chemical resistant gloves. PPE for entry by handlers into vapor-treated greenhouses before the WPS ventilation criteria have been met is the PPE required for handlers.

The Agency will not require a respirator for early-entry workers, since the WPS places very specific restrictions on early entry and these existing WPS protection are sufficient to mitigate post-application inhalation exposures of workers. EPA notes that following vapor treatments in greenhouses, entry by anyone other than a correctly trained and PPE-equipped (including organic-vapor-removing respirator) handler, is prohibited until one of the WPS ventilation criteria has been met.

WPS Notification Statement:

Since the sufficient post-application data are not available to establish permanent restricted-entry intervals (REIs) and the available post-application data indicate that fairly lengthy REIs may be necessary (at least 3-4 days) and EPA has concerns about inadvertent exposures to naled, EPA is specifying that a statement requiring such "double" notification be placed on the labeling of all naled end-use products which contain uses within the scope of the WPS.

Entry Restrictions for Occupational-Use Products (Non-WPS Uses)

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

Homeowner-Use Products (NonWPS Uses)

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

Other Labeling Requirements

The Agency is requiring additional labeling statements to be located on all end-use products containing naled. For the specific labeling statements, refer to Section V of this document.

(RED SECTION V - LABELING REQUIREMENTS)

LABELING REQUIREMENTS FOR END-USE PRODUCTS

Occupational/Residential Labeling

PPE Requirements for Pesticide Handlers

Sole-active-ingredient end-use products that contain {active ingredient} must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain {active ingredient} must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

WPS and nonWPS uses

Minimum (baseline) PPE requirements -- TO BE DETERMINED BASED ON OUTCOME OF RISK-MITIGATION DISCUSSIONS WITH REGISTRANTS

Exception: When applying to hot pipes in greenhouses or entering vapor-treated greenhouses during application or before ventilation is complete, the protective eyewear must be goggles, unless a full-face respirator is worn.

* The glove statement for naled is the statement established through the instructions in Supplement Three of PR Notice 93-7.

** The word "mixing" may be removed if the product is formulated as "ready-to-use."

Actual end-use product PPE requirements -- The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the 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 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 -- TO BE DETERMINED BASED ON OUTCOME OF RISK-MITIGATION DISCUSSIONS WITH REGISTRANTS

Actual end-use product PPE requirements -- TO BE DETERMINED BASED ON OUTCOME OF RISK-MITIGATION DISCUSSIONS WITH REGISTRANTS

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

Entry Restrictions

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

Multiple-active-ingredient end-use products that contain naled must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. 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 --

Entry Restrictions for End-Use Products That Do NOT Contain Greenhouse Vapor Treatments --

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 days. Exception: the restricted-entry interval for uses on grapes is 3 days.

Entry Restrictions for End-Use Products That Contain Greenhouse Vapor Treatments -- The following is the entry-restriction statement for naled end-use products that contain directions for use as a vapor-treatments in greenhouses (i.e., directions for painting naled on heat/steam pipes or heating naled in a hot plate/pan):

Entry Restrictions:

Outdoors and NonVapor Treatments in Greenhouses: Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 days. Exception: the restricted-entry interval for uses on grapes is 3 days.

Vapor Treatment in Greenhouses: Entry by any person -- other than a correctly trained and equipped handler who is performing a WPS-defined handling task -- is PROHIBITED in the entire enclosed area from the start of application until one of the WPS ventilation criteria has been met. After ventilation is completed, do not enter or allow worker entry into the entire enclosed area during the restricted-entry interval (REI) of 24 hours, except as allowed by the WPS.

Early-entry personal protective equipment (PPE)

Early-Entry PPE Requirements for End-Use Products That Do NOT Contain Greenhouse Vapor Treatments --

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves*
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headgear for overhead exposure
- Chemical-resistant apron when cleaning equipment, mixing, or loading

* The glove statement for naled is the statement established through the instructions in Supplement Three of PR Notice 93-7.

Early-Entry PPE Requirements for End-Use Products That Contain Greenhouse Vapor Treatments -- The following are the early-entry PPE requirements for naled end-use products that contain directions for use as a vapor-treatments in greenhouses (i.e., directions for painting naled on heat/steam pipes or heating naled in a hot plate/pan):

PPE for early entry to treated areas (1) outdoors, (2) in non-vapor treated greenhouses, or (3) in vapor-treated greenhouses after ventilation is complete -- that is permitted under the Worker Protection Standard and that involves contact

with anything that has been treated, such as plants, soil, or water, is:

- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves,
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headgear for overhead exposure

PPE for entry by handlers into vapor-treated greenhouses before WPS ventilation criteria have been met is listed in the "Hazards to Humans and Domestic Animals" section of this labeling.

* The glove statement for naled is the statement established through the instructions in Supplement Three of PR Notice 93-7.

Placement in labeling -- The entry restrictions and early-entry PPE requirements must be inserted into the Agricultural Use Requirements box as shown in Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions -- The Agency is establishing the following entry restrictions for nonWPS occupational uses of naled end-use products:

--For spray applications, other than applications to livestock:

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

--For spray applications to livestock:

"Avoid contact with treated animals until sprays have dried."

--For dust applications:

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

--For impregnated tags and livestock/pet collars:

EPA is not establishing an entry restriction for this use.

--For mosquito/nuisance-insect control applications:

EPA is not establishing an entry restriction for this use.

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 restriction in that box.

If no WPS uses are on label: Add the appropriate nonWPS entry restriction to the labels of all end-use products, except products primarily intended for homeowner use, in a section in the Directions For Use with 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 naled end-use products:

--For spray applications, other than applications to pets:

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

--For dust applications, other than applications to pets:

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

--For impregnated tags and pet collars and other applications to pets:

EPA is not establishing an entry restriction for this use.

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 ~~{active ingredient}~~ that are intended primarily for occupational use.

Application Restrictions: (except wide-area government-sponsored pest control programs, such as for mosquito or nuisance-insect control):

"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."

User Safety Requirements:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. 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. As soon as possible, wash thoroughly and change into clean clothing."

Engineering Controls:

TO BE DETERMINED BASED ON OUTCOME OF RISK-MITIGATION DISCUSSIONS WITH REGISTRANTS

"When handlers use closed systems, or 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."

Skin Sensitization Statement:

In addition, because naled is classified as a weak skin sensitizer, EPA is requiring that the following statement be required in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements on the labeling of all end-use products containing naled:

"This product may cause skin sensitization reactions in some people."

WPS Notification Statement:

Double notification requirement -- The following statement must be added to all end-use product labeling that contain directions for one or more WPS uses:

"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."

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

Respirator Type:

The following type of respirator is appropriate to mitigate naled inhalation concerns:

"A respirator with either an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)."

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 requirements

"Follow manufacturer's instructions for cleaning/maintaining protective clothing and equipment. If no such instructions for washables, use detergent and hot water. Keep and wash protective clothing and equipment 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 protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Skin sensitizer statement

"This product may cause skin sensitization reactions in some people."

cc: Walt Waldrop/SRRD (7508W)
Larry Schnaubelt/SRRD (7508W)
Mary Clock/HED (7509C)
Chemical File
Correspondence File
Circulation



13544

R107903

Chemical:	Naled
PC Code:	034401
HED File Code	12000 Exposure Reviews
Memo Date:	05/19/95
File ID:	DPD199395
Accession Number:	412-05-0095

HED Records Reference Center
05/17/2005