

US EPA ARCHIVE DOCUMENT

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM:

DATE: 7/16/96

SUBJECT: REVISED OCCUPATIONAL AND RESIDENTIAL EXPOSURE
ASSESSMENT AND RECOMMENDATIONS FOR THE
REREGISTRATION ELIGIBILITY DECISION DOCUMENT FOR
PARAQUAT DICHLORIDE

TO: Mary Clock
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

FROM: Tina Manville, Biologist *Tina Manville*
Special Review and Registration Section II

THRU: Mark I. Dow, Ph.D., Section head *Mark I. Dow*
Special Review and Registration Section II
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find the OREB review of paraquat dichloride.

DP Barcode: D224830, D227710

Pesticide Chemical Codes: 061601

EPA Reg. Nos.: 10182-103, 10182-111, 10182-115, 10182-120, 10182-280, 10182-362, 10182-372.

EPA MRID Nos.: 436442-01, 436442-02, 436182-01, 436182-02.

LUIS Report Date: No

PHED: Yes, V1.1

Acute Toxicity

The toxicological data base for paraquat dichloride is adequate and will support reregistration. Studies for acute toxicity, presented in the Toxicology Chapter for the RED, indicate that the end-use product (33 percent paraquat cation) of paraquat dichloride is classified as category II for acute oral toxicity and eye irritation potential, category III for acute dermal toxicity, and category IV for skin irritation potential. It is not classified as a skin sensitizer. Another study for acute toxicity (using crystalline paraquat dichloride presumed to be 99.9 percent pure), also presented in the Toxicology Chapter for the RED, classified paraquat dichloride as category I for acute inhalation toxicity. A vapor pressure of $< < 10^{-8}$ kPa at 25 degrees C was identified for the dried technical salt (99.5 percent w/w paraquat dichloride [MRID 40479001]).

Other Adverse Effects

The *Toxicology Endpoint Selection Document* for paraquat (6/28/96) that discusses the Less-Than-Lifetime/Peer Review Meetings of July 25, August 1, October 10, 1995, and June 28, 1996, indicates that there are toxicological endpoints of concern for paraquat dichloride. The endpoint used in the occupational/residential exposure assessment for short- and intermediate-term exposure is a systemic NOEL of 3.0 mg/kg/day based on a 21-day developmental study in rats (maternal and developmental endpoint). A chronic endpoint has been identified as 0.45 mg/kg/day from a one year feeding study in dogs. However, there are no chronic exposure scenarios for the use of paraquat.

The *Toxicology Endpoint Selection Document* also notes that in previous meetings an inhalation endpoint was selected for short- and intermediate-term exposure assessments. This endpoint was based on the NOEL of 0.01 $\mu\text{g}/\text{l}$ (0.00167 mg/kg/day) based on a 21-day inhalation study in rats (MRID# 00113718). The committee decided that particles used in agricultural practices (400 to 800 μm) are well beyond the respirable range and therefore there is no need for this endpoint. However, it was implied that if particle size is in the respirable range there would be a need for an inhalation endpoint.

Dermal absorption of paraquat is 0.3 percent based on a study using human volunteers (paraquat applied to hands and arms and measured by excretion). The most recent Toxicology Branch Peer Review Committee (March 15, 1989, presented in the Toxicology Chapter for the RED) classified paraquat dichloride as a Category E carcinogen. Cancer risk is not quantifiable.

The following chemical-specific mixer/loader/applicator study was submitted by the registrant:

- *MRID Number: 436442-02. 1995. D. Meier. Paraquat: Worker Exposure During Mixing, Loading, and Application of GRAMOXONE® EXTRA to Pecans Using Vehicle-Mounted Ground Boom Equipment.*

This worker biomonitoring study was completed to support label revisions related to personal protective equipment required for mixers, loaders, and applicators. Paraquat formulated as GRAMOXONE® EXTRA herbicide in water was applied at a maximum application rate of 0.94 lb active ingredient/acre by ground boom spray to pecan orchards in southwestern Georgia and southeastern Alabama in September, 1994. Urinary excretion of paraquat was measured as the indicator of exposure to workers mixing, loading, and applying the herbicide. A total of 17 combined mixer/loader/applicator replicates were monitored. OREB has reviewed this study and considers it acceptable since it adequately meets Subdivision U Guidelines of the Pesticide Assessment Guidelines.

Application of paraquat was conducted on fifteen separate pecan farms using ground boom spray equipment mounted on open-cab tractors. Three pints Gramoxone® EXTRA herbicide were mixed with surfactant and water to 13 to 42 gallons/acre spray mixture. Workers either poured the formulated product directly into the spray tank or measured it into a calibrated container before transferring it to the spray tank.

Although the study sponsor requested that the workers comply with label requirements for personal protective equipment (PPE), they did not interfere with the individual subject's typical practices. As a result, a wide variety of PPE was employed. This ranged from only eight wearing gloves while mixing, and the remainder wearing only normal work clothing, and three wearing face/eye protection, and an apron in addition to protective gloves. Two workers wore Tyvek suits during application. The time spent mixing and loading ranged from 14 to 104 minutes, and the total time of exposure from 230 to 660 minutes. Activities relevant to exposure were reported. Total amount of paraquat handled varied from orchard to orchard, with a range of 9.5 to 69 pounds active ingredient

The Limit of Quantification (LOQ) was stated to be 10 ng/ml for a 1 ml urine sample. The level of Detection was given as 5 ng/ml. The study results showed that six of the 17 urine samples collected contained detectable paraquat. All were in the Day 1 (application exposure day) samples. Absorbed paraquat was estimated using a referenced excretion rate of 59% from a paraquat pharmacokinetics study in monkeys. The pharmacokinetics of paraquat have been verified by Toxicology Branch I¹.

Table 1. Short- and Intermediate-Term Risk From Paraquat, Derived From Biological Monitoring Data.

Exposure Scenario	Unit Dose (mg/kg/lb ai)	Equipment Used	Clothing Scenario Monitored	No. of Obs	Total Daily Dose (mg/kg/day) ^a	Total MOE ^b
Mixer/loader/Applicator Internal Dose						
Ground boom (MRID 436442-02) [Note: 1 lb cation/A and 80 Acres are assumed to calc. daily dose; actual body weights of subjects used to calc. unit dose.]	4.0 x 10 ⁻⁶	Open cab tractor	9 reps no PPE worn; 4 reps gloves worn only when mixing; 2 reps gloves, face shield, and apron; 1 rep respirator, face shield, goggles, apron, gloves, and Tyvek for applying; 1 rep face shield, goggles, apron, gloves, and Tyvek for applying	17	3.2 x 10 ⁻¹	9,100
Aerial [Note: 1 lb cation/A and 350, 900, and 1200 acres are assumed to calc. daily dose; the groundboom unit dose is being used as a surrogate for the aerial applicators.]	4.0 x 10 ⁻⁶	Ground boom tractor surrogate	9 reps no PPE worn; 4 reps gloves worn only when mixing; 2 reps gloves, face shield, and apron; 1 rep respirator, face shield, goggles, apron, gloves, and Tyvek for applying; 1 rep face shield, goggles, apron, gloves, and Tyvek for applying	17	350A: 1.4 x 10 ⁻¹	350A: 2,100
					800A: 3.2 x 10 ⁻¹	800A: 940
					1200A: 4.8 x 10 ⁻¹	1200A: 630

^aTotal Daily Dose (mg/kg/day) = Unit Dose (mg/kg/lb ai) X appl rate (lb ai/A) X acres per day.
^bMOE = NOEL / Total Daily Dose (mg/kg/day). Where: NOEL = 3 mg/kg/day.

PHED V1.1 data are used to estimate short- and intermediate-term exposure, dose, and risk from paraquat for backpack sprayer mixer/loaders and applicators, for flaggers for aerial spray applications, for mixers/loaders/applicators for spot treatments using a backpack sprayer or low pressure wand, and for mixers/loaders/applicators for resin soaking uses using a low pressure wand. These exposure scenarios are presented in Tables 2 and 3. Inhalation exposure and doses were not calculated since spray particles used in applying paraquat are well beyond the respirable range and paraquat has a very low vapor pressure. The potential daily dermal dose is calculated using the following formula:

Potential Daily Dermal Dose (mg/kg/day) =

Dermal Unit Exposure (mg/lb ai) X max. Appl. Rate (lb ai/amount) X Max. area treated (amount/day) X Dermal Absorption ÷ Body Weight (kg)

These calculations of daily dose of paraquat received by handlers are used to assess the risk to those handlers. The dermal Short-Term and Intermediate-Term MOE was calculated using the following formula:

Dermal MOE = NOEL (mg/kg/day) ÷ Potential Daily Dermal Dose (mg/kg/day)

Table 2. Short-Term and Intermediate-Term Exposure and Risk to Paraquat Dichloride Derived From PHED V.1.1 Data.

Exposure Scenario (#)	Baseline Dermal Unit Exposure ^a (mg/lb caiton)	Maximum Label Application Rate ^b	Daily Maximum Area Treated ^c	Potential Daily Dermal Dose ^a (mg/kg/day)	Dermal MOE ^d	Risk Mitigation ^f	
						[Dermal Unit Exposure] (mg/lb caiton)	Dermal MOE ^e
0							
Mixer/Loader							
Mixing/loading liquids for backpack sprayer application (5)	2.9	1 lb caiton/A	20 acres ^a	0.0029	1000	NA	NA
Applicator							
Backpack Sprayer (6)	483	1 lb caiton/A	4 acres ^a	0.097	31	[234] 0.0468	64
Flagger							
Flagging (liquids) (7)	0.01	1 lb caiton/A	350 to 1,200	0.00018 to 0.0006	17,000 to 5,000	NA	NA
Mixer/Loader/Applicator							
Low Pressure Hand-held Sprayer (Spot Treatment) (8)	104	0.0195 lb caiton/gal	40 gals	0.0041	730	NA	NA
Backpack Sprayer (Spot Treatment) (9)	486	0.0195 lb caiton/gal	40 gals	0.019	160	NA	NA
Low Pressure Sprayer (Resin Soaking) (10)	104	0.4 lb caiton/gal	40 gals	0.083	36	[4.11] 0.0033	910

a Long pants, long-sleeved shirt, no gloves. Mixer/loader assessments are from using open mixing systems.
 b Label Reg No. 10182-103, 10182-111, 10182-120.
 c 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.
 d Potential daily dermal dose (mg/kg/day) = Dermal Unit Exposure (mg/lb caiton) X 0.003 (0.3 percent dermal absorption) X Maximum Application Rate (lb caiton/acre or lb caiton/gal) X Maximum Treated (acres/day or gal/day) + 60 kg BW.
 e Dermal MOE = NOEL/Potential daily dermal dose (mg/kg/day) (short- and intermediate-term NOEL = 3 mg/kg/day)
 f Addition of gloves to long pants & long-sleeved shirt.
 g If 40 gal/day can be applied by a backpack sprayer, then 4 acres will be treated at a finish spray volume of 10 gal/A

Table 3. Exposure Scenario Descriptions of Baseline and Risk Mitigation Measures for Uses of Paraquat Dichloride from PHED Data.

Exposure Scenario (7)	Data Source	Additional PPE	Standard Assumptions* (8-hr work day)	Comments ^b
Mixer/Loader Exposure				
Mixing/loading liquids for backpack sprayer application (5)	PHED V1.1 (including PHED study # 9003)	NA	200 gallons (for 20 acres) mixer/loader supporting five backpack sprayers	Baseline: Dermal acceptable grades & 25 to 122 replicates; High confidence data. PHED data used for baseline; no PF necessary.
Applicator Exposure				
Backpack Sprayer (6)	PHED V1.1 (including PHED study # 9003)	gloves	4 acres as a finish spray volume of 10 gal/acre (therefore 40 gal/day)	Baseline and Additional PPE: Dermal acceptable grades & 60 to 69 replicates; High confidence data. Baseline exposures were calculated from total deposition using a 50% PF for the addition of a single layer of clothing (feet data were deleted). Additional PPE exposure was calculated by adding a 90% PF for the addition of gloves to the baseline exposure.
Flagger				
Flagging (liquids) (7)	PHED V1.1	NA	350 to 1,200 acres	Baseline: Dermal grades acceptable & 16 to 18 replicates; High confidence data. PHED data used for baseline; no PF necessary.
Mixer/loader/applicator Exposure				
Low Pressure Hand-held Sprayer- Spot Treatment (8)	PHED V1.1	NA	40 galb total using two to three gallon hand held wand sprayers	Baseline: Dermal all grades & 25 to 96 replicates; Low confidence data. PHED data used for baseline; no PF necessary.

Exposure Scenario (f)	Data Source	Additional PPE	Standard Assumptions* (8-hr work day)	Comments*
Backpack Sprayer - Spot Treatment (9)	PHED V1.1 (liquid m/l unit exposure + backpack appl. unit exposure [2.9 + 483 mg/lb cation])	NA	40 gals	<p>Baseline: Dermal acceptable grades & 60 to 69 replicates, High confidence data.</p> <p>Baseline exposures were calculated from total deposition using a 50% PF for the addition of a single layer of clothing (test data were deleted).</p>
Low Pressure Sprayer (Resin Soaking) (10)	PHED V1.1	gloves	40 gals total using two to three gallon hand held wand sprayers	<p>Baseline and Additional PPE: Dermal all grades & 15 to 96 replicates; Low confidence data.</p> <p>PHED data used for baseline and additional PPE; no PF necessary.</p>

* 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. All grades that do not meet OREB's SOP are listed individually.
 * Baseline is defined as long pants, long-sleeved shirt and no gloves

Post-Application Exposures & Assumptions

EPA has determined that there is potential exposure to persons entering treated sites following: (1) preemergent/early-season treatments, particularly in crop areas; (2) directed spray treatments, particularly in orchard or vegetable-crop sites with heavy weed density; and, (3) desiccant/harvest-aid treatments particularly when performing harvesting-related tasks, such as removal or compacting (i.e. trampling) of desiccated foliage and stems on crops such as cotton, dry beans, potatoes, sunflowers, and sugar cane.

Post-application exposure data were required during Phase IV of the reregistration process, since, at that time, one or more toxicological criteria had been triggered for paraquat dichloride.

The following post-application study was submitted by the registrant:

- *MRID Number - 436182-02. Tak Iwata and Malcolm Findlay, 1994. Worker Exposure During Re-Entry into Paraquat-Treated Cotton Fields: Biological Monitoring in Georgia in 1994.*

This worker biomonitoring study measured urinary excretion of paraquat as a indicator of exposure to workers reentering the treated fields for the purpose of **scouting**. Cotton fields were treated with STARFIRE, a product normally used by growers as a harvest aid, at a rate of 0.55 lb active ingredient/acre. Scouting activities started at 4 hours (12 replicates) and 24 hours (13 replicates) post-application. Scouting activities consisted of walking into the field, handling and cracking a few bolls, and bending foliage and stems for a total field exposure of 2.5 hours. Complete 24 hour urine samples were collected from each subject on the reentry exposure day and on the next 5 days.

The study results showed that only one urine sample contained detectable paraquat. This was from a Day 1 (reentry exposure day) urine sample from a subject in the 4 hour reentry test group. Based on a reported urinary level of 6 ng/ml and a sample volume of 400 ml, a total amount of paraquat excreted was estimated as 0.0024 mg. An exposure of 0.00004 mg/kg/day was calculated for this subject using a 204 pound body weight and a referenced excretion rate of 59% from a paraquat pharmacokinetics study in monkeys (see MRID No. 436182-01). All other (non-detect) data points were treated as containing no (0) paraquat.

The authors also present an exposure assessment in a separate submission (MRID No. 436182-01) which contains an estimate of a Margins of Exposure (MOE). Using a NOEL value of 0.6 mg/kg for a 90 day feeding study in dogs (from the 1987 registration standard, which identifies this level as 0.5 mg/kg/day), a MOE of 15,000 was derived. Based on this value and the stated "worst case" conditions of the study, the authors suggest that workers could safely reenter paraquat-treated fields (cotton as

well as other crops) 4 hours after application (when sprays have dried).

Toxicology Branch I has confirmed the pharmacokinetic data used in this study¹. As reported in the Toxicology Chapter for the RED (9/95), a single dose of paraquat dichloride administered subcutaneously to rats was excreted mostly in urine (73-96%) as unchanged paraquat within 24 hours after dosing. Therefore adequate time was allowed in this experiment for urine collection.

The Agency considers this study acceptable since the EPA-approved protocol was followed. After the protocol was approved, the Agency exempted certified or licensed crop advisors and their employees from the Worker Protection Standard requirements, except for obtaining pesticide safety training, based partially on the assumption that such activities result in low exposures (FR, Vol. 60, No. 85, 5/3/95). In addition, the duration of exposure of 2.5 hours calls into question whether this study was in fact a worst-case scenario relative to other crops and cultural practices.

(RISK)

Occupational and Residential

Risk From Handler Exposures

Based on biological monitoring data, the margins of exposure (MOEs) are acceptable (greater than 100) for: (1) mixing/loading to support ground applications; (2) mixing/loading to support aerial applications; (3) applying using ground boom equipment; and (4) applying using aerial equipment (ground boom data were used as a surrogate for aerial). Surrogate exposure data from PHED indicate that: (1) mixing/loading liquid formulations to support several applicators using backpack sprayers; (2) flagging; (3) mixing/loading/applying for spot treatments using low-pressure sprayers or backpack sprayers are acceptable; and (4) with the addition of gloves mixing/loading/applying for resin soaking uses using low-pressure sprayers (MOEs greater than 100).

Based on exposure data from PHED, the MOE for backpack applicators (non-spot treatment) is unacceptable (MOE less than 100) when applicators are wearing long pants and long sleeved-shirt, and chemical-resistant gloves. EPA is concerned about the practicality of adding another layer of PPE (woven material), due primarily to heat stress considerations and the "wicking" affect of multiple layers. EPA wishes to discuss possible risk-mitigation measures for backpack applicators with the registrant. Possible risk-mitigation measures would be modifying all labels to specify that backpack applications should be made as spot treatments only at application rates no higher than 0.0195 lb cation/gal (or 0.23% cation wt/wt spray solutions).

THE REGISTRANT NEEDS TO SUGGEST TO EPA POSSIBLE RISK MITIGATION MEASURES FOR BACKPACK APPLICATORS.

Risk From Post-Application Exposures

Based on the postapplication biological monitoring study EPA has determined that a 12-hour restricted-entry interval is adequate for the uses of paraquat for preemergent or early-season weed control. In these use-situations, the paraquat is directed at the soil and weeds (if present) that are generally less than six inches tall and the workers' degree and duration of contact with treated surfaces is likely to be similar to or less than that for the scouts in the biological monitoring study.

Based on the postapplication biological monitoring study, EPA also has determined that a 12-hour restricted-entry interval is adequate for the uses of paraquat for weed control in orchard and vegetable crops where the spray is directed solely at the weeds (not broadcast over the entire crop area). In these directed-spray use-situations where the paraquat is directed at the weeds, entering workers' degree and duration of contact with treated surfaces are likely to be similar to or less than that for the scouts in the biological monitoring study.

For desiccation and harvest aid applications of paraquat, EPA is establishing a 24-hour restricted-entry interval. EPA believes that such uses may result in exposures to workers of greater degree and duration than that for the scouts in the biological monitoring study, particularly when the workers are performing harvesting-related tasks, such as removal or compacting (i.e. trampling) of desiccated foliage and stems on crops such as cotton, dry beans, potatoes, sunflowers, and sugar cane. It is well documented that paraquat is rendered biologically inactive² upon contact with the soil. However less is known about its residues on leaves. After 21 days, 66% of paraquat is lost from plant surfaces³. The agency does not have any foliar dissipation curves for paraquat to better quantify post-applicator exposure. Personal protective equipment is required for workers who enter the treated area before the REI is expired.

The 12-/24-hour post-application entry restriction for paraquat dichloride does not apply to uses outside the scope of the Worker Protection Standard for Agricultural Chemicals. The predicted frequency, duration, and degree of exposure by such uses do not warrant the same risk mitigation measures required for users covered by the WPS who are engaged in agriculture for commercial or research purposes. However, EPA is concerned about exposures immediately following applications while the sprays are still wet.

Additional Occupational/Residential Exposure Studies

Handler Studies

None are necessary.

Post-Application Studies

If the registrant believes that a restricted-entry interval of less than 24 hours is appropriate for the desiccation/harvest-aid uses of paraquat, an additional study is required. Requirements for post-application exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. The required data include: Guideline 132-1(a): Foliar Residue Dissipation

(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 the plants are (or will be) grown in.

At this time some of the registered uses of paraquat 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 pastures or rangelands,
- 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.
- 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 non-crop 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 paraquat. Even though the MOE's were greater than 100 for occupational mixers, loaders, and applicators (except backpack applicators and resin-soaking uses) without personal protective equipment requirements beyond long-sleeve shirt, long pants, shoes, and socks. EPA notes the relatively significant epidemiological evidence of poisonings from accidental swallowing and prolonged dermal exposures and the lack of a specific antidote for systemic poisoning. These considerations have led to the determination that active ingredient-based minimum PPE should be required for all occupational paraquat handlers. The requirement for a face shield for all mixers and loaders reflects EPA's particular concern about accidental swallowing in case of a spill or splash-back.

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 all occupational uses of paraquat (specified in Section V). These requirements must be followed in the labeling of all paraquat end-use products intended primarily for occupational use.

NOTE: THE RISK MITIGATION MEASURES FOR BACKPACK APPLICATORS HAVE YET TO BE DETERMINED. THIS SECTION MAY CHANGE SUBSTANTIALLY IF PPE IS ADDED FOR SUCH APPLICATORS.

Homeowner-Use Products

There are no registered homeowner-use products.

Post-Application/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.

During the reregistration process, EPA determined that the restricted-entry interval (REI) for all occupational-use products that contain paraquat and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) should be 12 hours for preemergence and directed-spraying uses and 24 hours for desiccation and harvesting uses.

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 personal protective equipment 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.*

EPA is establishing PPE for dermal protection on the basis of the acute toxicity of the active ingredient. Paraquat is classified as toxicity category III for acute dermal toxicity. Since paraquat is classified as category II for eye irritation potential, 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."

Based on the acute toxicity of the active ingredient, EPA is not requiring double notification.

Occupational-Use Products (NonWPS Uses)

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

Homeowner-Use Products

There are no registered homeowner-use products.

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 paraquat. 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 paraquat, 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 paraquat, 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 not establishing minimum (baseline) engineering controls for any occupational uses of paraquat end-use products.

NOTE: THE RISK-MITIGATION MEASURES FOR BACKPACK APPLICATORS HAVE YET TO BE DETERMINED. THIS SECTION MAY CHANGE SUBSTANTIALLY IF PPE IS ADDED FOR SUCH APPLICATORS.

EPA is establishing the following minimum (baseline) PPE for all occupational uses of paraquat end-use products:

"Mixers and loaders must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--shoes plus socks,
--chemical-resistant apron,
--face shield"

"Applicators and other handlers (other than mixers and loaders) must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--shoes plus socks"

* For the glove statement, use the statement established for paraquat 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

There are no registered homeowner-use products

Entry Restrictions

For **sole-active-ingredient** end-use products that contain paraquat 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.

For **multiple-active-ingredient** end-use products that contain paraquat 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:

"For preplant or preemergence (broadcast or banded) applications, post-emergence directed-spray applications, dormant-season applications, and "between cutting" alfalfa

applications: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."

"For harvest-aid and desiccation applications: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:

- coveralls,
- chemical-resistant gloves*,
- shoes plus socks,
- protective eyewear.

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

WPS Notification Statement:

Not required on label.

Placement in labeling:

The REI statements must be inserted into the Agricultural Use Requirements box as 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. The double notification statement must be placed into the Agricultural Use Requirements box as required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions:

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

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

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:

There are no registered homeowner-use products.

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 paraquat that are intended primarily for occupational use.

Application Restrictions

"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."

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 washable, use detergent and hot water. Keep and wash PPE separately from other laundry."

**"DO NOT USE AROUND HOMES, SCHOOLS, RECREATIONAL PARKS,
GOLF COURSES, OR PLAYGROUNDS"**

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

There are no registered homeowner-use products.

References

- 1 Memo dated 9/26/95, entitled "Paraquat dichloride formulated as Starfire Herbicide or Gramaxone Extra -- Worker Exposure Studies" from Krystyna K. Locke, Toxicology Branch I, to Mary Clock, RCAB.
- 2 Gunther , Francis A., Ed. Residue Reviews. Residues of Pesticides and Other Foreign Chemicals in Foods and Feeds. Springer-Verlag, New York Inc.: 1968, Vol. 23, p. 97.
- 3 Summers, L.A. Bipyridium Herbicides. Academic Press: 1980.



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