



# R.E.D. FACTS

## Pesticide Reregistration

## Paraquat Dichloride

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

Under the Food Quality Protection Act of 1996, EPA must consider the increased susceptibility of infants and children to pesticide residues in food, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with a common mechanism of toxicity in establishing and reassessing tolerances.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0262, paraquat dichloride (commonly referred to as paraquat).

## Use Profile

Paraquat dichloride is a herbicide currently registered to control weeds and grasses in many agricultural and non-agricultural areas. It is used preplant or preemergence on vegetables, grains, cotton, grasses, sugar cane, peanuts, potatoes, and tree plantation areas; postemergence around fruit crops, vegetables, trees, vines, grains, soybeans, and sugar cane; during the dormant season on clover and other legumes; as a desiccant or harvest aid on cotton, dry beans, soybeans, potatoes, sunflowers, and sugar cane; and as a post harvest desiccant on staked tomatoes. It also is applied to pine trees to induce resin soaking. Paraquat dichloride is also used on non-crop areas such as public airports, electric transformer stations and around commercial buildings to control weeds.

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Paraquat dichloride is applied aerially, by groundboom, backpack sprayer, and low pressure handwand.

A soluble concentrate/liquid (SC/L) is the sole paraquat formulation type registered for all uses. This formulation may be applied to crops pre-plant, at planting, pre-emergence (broadcast or band), post-emergence (broadcast, band, split, directed, or spot), post-harvest (as a pre-harvest desiccant or harvest aid), and for suckering and stripping of hops.

## **Regulatory History**

Paraquat dichloride was first registered as a pesticide in the U.S. in 1964. EPA issued a Registration Standard for paraquat dichloride in June 1987 (NTIS# PB88-217005). A December 1991 Data Call-In (DCI) required additional ecological effects, environmental fate and residue chemistry data.

Currently, 7 pesticide products are registered which contain the active ingredient paraquat dichloride. All paraquat products are classified as Restricted Use Pesticides.

## **Human Health Assessment**

### **Toxicity**

In acute toxicity studies using laboratory animals, paraquat has been shown to be highly toxic by the inhalation route and has been placed in Toxicity Category I (the highest of four levels) for acute inhalation effects. However, the Agency has determined that particles used in agricultural practices (400 to 800um) are well beyond the respirable range and therefore inhalation toxicity is not a toxicological endpoint of concern. Paraquat is moderately toxic (Category II) by the oral route and slightly toxic (Category III) by the dermal route. Paraquat will cause moderate to severe eye irritation and minimal dermal irritation, and has been placed in Toxicity Categories II and IV for these effects.

In a subchronic toxicity study using rats, paraquat caused changes in the lungs. A dermal toxicity study using rabbits resulted in scabbing and inflammation when tested at the two highest doses (2.6 mg cation/kg group and 6.0 mg cation/kg group). In an inhalation toxicity study, rats were exposed to respirable aerosols (particle size - less than 2 um in diameter) of paraquat dichloride which resulted in lung changes and extensive sores and swelling in the larynx.

A chronic toxicity study using dogs resulted in an increase in the severity and extent of chronic pneumonitis in the mid dose and high dose male and female dogs. Two chronic toxicity/carcinogenicity studies using rats were conducted with paraquat. In the first chronic toxicity study, paraquat did not appear to be carcinogenic in the lungs or the head region (middle ear, hard palate, head tissue and skin) of the rat. In the second study, paraquat resulted in non-tumor lesions in various organs and no evidence of carcinogenicity. Two chronic toxicity/carcinogenicity studies using mice were also conducted with paraquat. The first study resulted in

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decreased body weight gain, kidney changes and no evidence of carcinogenicity. The second study using mice also resulted in no evidence of carcinogenicity. Based on these studies, paraquat was classified as a “Group E” chemical--one showing evidence of noncarcinogenicity for humans.

Four developmental/maternal toxicity studies were evaluated for paraquat. Treatment-related effects were seen (i.e., delayed hardening [ossification] in the forelimb and hindlimb digits, or retarded ossification of the posterior portion of the skull) in the fetuses only at the same or higher dose levels than effects in the mother. Therefore, the no-observed effect dose levels (NOEL) for maternal toxicity are at least or more conservative (protective) than the NOEL based on developmental toxicity.

There is no evidence that paraquat is associated with reproductive effects. In a reproduction study using rats, paraquat had no effect on body weight gain, food consumption/utilization, fertility or length of gestation. Paraquat also shows no evidence of causing mutagenicity.

### **Dietary Exposure**

People may be exposed to residues of paraquat through the diet. Tolerances or maximum residue limits have been established for well over 80 raw agricultural commodities, processed foods and feed (please see 40 CFR 180.205(a), (b); 185.4700; 186.4700). EPA has reassessed the paraquat tolerances and found that numerous revisions are necessary. Most of these revisions will be handled administratively.

The available data support the established tolerances on all but sorghum forage, ruminant kidney, oats, rye, soybeans and hops. The tolerance for sorghum forage was reassessed from 0.05 to .1 ppm, while kidney was reassessed from 0.3 ppm to 0.5 ppm, soybeans from 0.05 ppm to 0.25 ppm, and hops from 0.2 ppm to 0.5 ppm. As there are presently no registered uses of paraquat on rye, the tolerances for this commodity will be revoked. Also the tolerance on oats will be revoked, as the registrant has indicated that they do not wish to support this use. Additionally, the tolerances for poultry (except for eggs) will be revoked. Finally, a tolerance for popcorn (0.05 ppm) will be established (See Section IV, Tolerance Reassessment Summary and Table in the paraquat RED for further specifics).

Numerous international Codex maximum residue limits (MRLs) have been established for paraquat. Harmonization of Codex MRLs and U.S. tolerances for paraquat exists for many crops. However, at this time there remain some incompatibilities between U.S. tolerances and Codex MRLs on the following raw plant commodities because of differences in agricultural practices: cottonseed, dry hops, maize, olives, potatoes, rice, sorghum, and dry soya beans.

EPA has assessed the dietary risk posed by paraquat. The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population

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represents 10% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The highest subgroup, non-nursing infants (<1 year old) occupies 31% of the RfD. This fraction of the allowable RfD is considered to be an acceptable dietary exposure risk.

### **Occupational and Residential Exposure**

Exposure to homeowners is not expected since there are no residential uses. Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to paraquat dichloride during and after normal agricultural use. Ground, aerial and backpack application methods were considered. All the dermal and inhalation Margins of Exposure (MOEs) were acceptable (greater than 100) except backpack applicators and resin-soaking uses. The registrant has agreed to reduce the concentration of paraquat dichloride allowed when using a backpack sprayer and make label changes for tree injection (resin soaking) use.

### **Human Risk Assessment**

Paraquat generally is of moderate to high acute toxicity based on inhalation toxicity (Toxicity Category I), oral toxicity, and moderate to severe eye irritation (Toxicity Category II). It is a Group E chemical--one showing no evidence of carcinogenicity.

Although people may be exposed to residues of paraquat in many food commodities, the chronic dietary risk from all uses is considered minimal.

Of greater concern is the risk posed to paraquat handlers, particularly mixers/loaders/applicators. A dermal endpoint--based on maternal toxicity effects-- was used to assess risks to handlers. Margins of Exposure (MOEs) for dermal effects to paraquat are adequate (greater than 100) for all exposure scenarios considered except for backpack sprayer applicators (non-spot treatment) and low pressure sprayer (resin soaking) for mixer/loader/applicators. Even with gloves, the margin of exposure for handlers using a backpack sprayer was too low. Exposure and risk to workers will be mitigated by reducing the concentration of paraquat in backpack sprayers, and through the use of Personal Protective Equipment (PPE) required by the WPS, supplemented by gloves, a chemical-resistant apron and face shield for all occupational uses of paraquat end-use products, as required by this RED. PPE requirements for applicators and other handlers (other than mixers and loaders) include a long-sleeved shirt and long pants, chemical-resistant gloves and shoes plus socks. Based on a biological monitoring study, post-application reentry workers will be required to observe a 12-hour Restricted Entry Interval for the uses of paraquat for preemergent or early-season weed control and weed control for orchard and vegetable crops where the spray is directed solely at the weeds (not broadcast over the entire crop area). A 24-hour Restricted Entry Interval is required for desiccation and harvest aid applications of paraquat

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since the Agency concludes such uses result in a greater degree of exposure to workers.

### **Food Quality Protection Act Considerations**

In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residue.

The Agency considered the appropriateness of an additional uncertainty factor to account for situations where available data indicate increased sensitivity of infants and children and concluded that it is not warranted based on an evaluation of the toxicology database. Regarding aggregate exposure, the Agency only considered dietary exposure because there are no residential or other non-occupational uses of paraquat, and exposure to paraquat in drinking water is not expected. The EPA estimates that paraquat residues in the diet of the general U.S. population account for 10% of the RfD, 24% of the RfD for children aged 1-6 years and 31% of the RfD for non-nursing infants (less than 1 year). Therefore, the Agency has determined that there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to paraquat dichloride residues. Further, based on the available data, the Agency does not believe that the effects produced by paraquat would be cumulative with those of other structurally related compounds. Therefore, based on these conclusions, the Agency considers the tolerances in the RED to be reassessed with regard to FQPA requirements.

### **Environmental Assessment**

#### **Environmental Fate**

Paraquat dichloride was shown to be very immobile in soil. Paraquat does not hydrolyze, does not photodegrade in aqueous solutions, and is resistant to microbial degradation under aerobic and anaerobic conditions. The primary route of environmental dissipation of paraquat is adsorption to biological materials and soil clay particles. Due to the apparent adsorption strength of paraquat for soil clays, these bound residues do not appear to be environmentally available. Nevertheless, since paraquat is persistent, it could potentially be found in surface water systems associated with soil particles carried by erosion. However, detections would not be considered to be representative of normal paraquat use (since it binds so strongly to soil clay particles and becomes environmentally inactive). Therefore, paraquat is not expected or considered to be a groundwater concern from normal paraquat dichloride use patterns.

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## **Ecological Effects**

Paraquat is practically non-toxic to honey bees and slightly toxic to fish on an acute basis. Paraquat is moderately toxic to non-endangered and endangered terrestrial animals (birds and mammals), non-target terrestrial and semi-aquatic plants. Acute toxicity to terrestrial animals (birds) and mammals only exists immediately after application.

## **Ecological Effects Risk Assessment**

Paraquat exposure to birds, mammals, non-target terrestrial and semi-aquatic plants including endangered species may result from paraquat spray drift during application.

The Agency levels of concern (LOCs) have been exceeded for acute effects for birds and small (herbivorous and insectivorous) mammals and for acute effects on semi-aquatic and terrestrial plants. However, the risk for birds and small mammals only exists shortly after application. Once the applied paraquat has dried (or becomes bound) its risk is greatly reduced. Therefore, the Agency concludes the registered uses of paraquat are not expected to pose significant risk to birds or mammals. The Agency LOCs have also been exceeded for non-endangered and endangered non-target terrestrial and semi-aquatic plants. Depending on the application method and application rate, the risk quotients ranged from acceptable to acute effects. To mitigate these risks, the registrant has agreed to lower the maximum use rate, amend all paraquat labels to include a warning about possible adverse effects to non-target and semi-aquatic plants due to drift and include spray drift language.

## **Risk Mitigation**

To lessen the occupational and ecological risks posed by paraquat, EPA is requiring the following risk mitigation measures.

○ For all risk concerns:

Reduce the maximum rate of application from 1.6 lb cation/A to 1.0 lb cation/A and maintain the Restricted Use Classification.

○ To protect workers:

Additional PPE are being required for mixers and loaders: gloves, chemical-resistant apron and face shield. PPE requirements for applicators and other handlers (other than mixers and loaders) include: long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks.

Further, the concentration of paraquat in backpack sprayers will be reduced and the resin soaking sections on the paraquat labels amended (i.e., delete plastic acid bottle use) to lessen the exposure and risk to applicators.

○ To protect non-target terrestrial and semi-aquatic plants from drift:

Aerial applications will include the most current spray drift language and all paraquat products must place a statement in the “Environmental Hazard” section of the label that warns the user about possible adverse effects to non-target and semi-aquatic plants due to drift.

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## **Additional Data Required**

EPA is requiring data to establish tolerances for paraquat dichloride on taro foliage, corn and soybean aspirated grain fractions, wheat and hay, cotton and gin byproducts and processed grapes. The Agency is also requiring data to confirm that the existing tolerances for field corn is adequate to cover the specialized use of paraquat as a harvest aid.

Additionally, the Agency is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

## **Product Labeling Changes Required**

All paraquat dichloride end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the paraquat dichloride RED document.

### **Application Rates and Label Deletions for End-Use Products**

In cooperation with the Agency the registrant has agreed to the following application rates and label deletions:

- The maximum paraquat dichloride application rate for all products will be lowered from 1.6 lb cation/A to 1.0 lb cation/A.
  - For broadcast applications of paraquat with backpack sprayers, **non-spot**, the application rate should not exceed 0.625 lb cation/A and the application volume should be no less than 20 gallons per acre.
  - The maximum application rate for **spot spraying** on all paraquat labels will be no more than 0.0195 lbs cation/gallon.
- Delete the plastic acid bottle and the tree injection directions for use from the resin soaking sections of all paraquat dichloride labels.

### **Hazard Statement**

The following hazard statement must be placed in the “Environmental Hazard” section of all paraquat labels to warn the user about possible adverse effects to non-target terrestrial and semi-aquatic plants due to drift:

“Paraquat dichloride is toxic to nontarget crops and plants if off-target movement occurs. Extreme care must be taken to ensure that off-target drift is minimized to the greatest extent possible.”

### **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

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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

Although the MOE's were greater than 100 for all but two scenarios (backpack applicators and resin-soaking uses) without personal protective equipment requirements beyond long-sleeve shirt, long pants, shoes and socks, the Agency notes the relatively significant epidemiological evidence of poisonings from intentional/accidental swallowing and numerous non-systemic skin and eye effects in California (see OREB J. Blondell memo, 12/5/95). These considerations have led to the Agency establishing the following minimum (baseline) PPE is required 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"

Although there is no direct evidence that occupational handlers have ever ingested a lethal amount of paraquat from a splash or spill, the requirement for a face shield for all mixers and loaders reflects the Agency's particular concern about accidental swallowing in case of a spill or splash back.

"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.



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### 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 Occupational 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 - Entry Restrictions and Labeling**

#### 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."

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**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.

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.

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### 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."

### **Spray Drift Labeling**

Please see the paraquat dichloride RED document for the text of this Advisory, which must be contained on each paraquat product label that can be applied aerially.

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## Conclusion

dichloride in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Paraquat products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

## For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for paraquat dichloride during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198, fax 513-489-8695.

Following the comment period, the paraquat dichloride RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the paraquat dichloride RED, or reregistration of individual products containing paraquat dichloride, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.