

US EPA ARCHIVE DOCUMENT

September 30, 2006



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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dear Reader,

The Reregistration Eligibility Decision (RED) document for dicofol was signed in September, 1998. At that time, revised occupational re-entry intervals (REIs) were not established as the Agency was awaiting additional data. This additional data has been received and reviewed, the occupational risk assessment was revised, and an addendum to the dicofol RED was issued for public comment. The revised risk assessments, benefit assessments, and public comments can be found on the EPA EDOCKET system (www.epa.gov/edocket) under docket number OPP-2005-0220. After assessing the data that was submitted by the registrant, and consultation with the U.S. Department of Agriculture, stakeholders, and the public, the Agency has established revised REIs for crops that dicofol is used on. Attached with this letter is the Addendum to the Dicofol RED. This addendum establishes REIs for dicofol and presents rationale supporting these REIs.

In addition, included in the docket are supporting documents that the Agency used to determine the REIs. The Addendum contains a complete list of documents that are available.

If you have questions on the dicofol RED or any of the revisions listed in the attached amendment, please contact Anne Overstreet at (703) 308-8068. For questions about product reregistration and/or the Product Data Call-In that accompanies this document, please contact Venus Eagle at (703) 308-8045.

Sincerely,

A handwritten signature in cursive script, appearing to read "Debra Edwards", is written over a horizontal line.

Debra Edwards, Ph.D.

Director

Special Review and Reregistration Division

Attachment

Addendum to Dicofol RED

Purpose of Addendum

September 30, 2006

The United States Environmental Protection Agency (hereafter referred to as EPA or Agency) is issuing this document as an addendum to the 1998 Reregistration Eligibility Decision (RED) for dicofol. This update reflects subsequent recalculations based upon new data received and reviewed as well as required label changes to ensure that currently registered uses of dicofol meet appropriate standards.

At the time the RED was signed, the Agency was concerned with occupational exposure and risk. Most short-term and all intermediate-term exposure scenarios for mixers, loaders, and applicators were of concern to the Agency. However, the Agency believed that the default assumptions that were used to arrive at these conclusions led to an overestimate of risk (e.g., the default assumption of 100% dermal absorption). To improve the estimation of risk, the registrant agreed to submit a dermal toxicity study. Additionally, the registrant submitted a dislodgeable foliar residue study. This information was submitted to the Agency and a revised occupational risk assessment was conducted. After completing the revised risk assessment, potential short- and intermediate-term risk to mixers/loaders/applicators and field workers was still a concern for most crops. The Agency addresses these potential risk areas of concern as specified below and is issuing this document to address these concerns. The required restricted entry intervals (REIs) for all registered uses are included in this addendum.

Dicofol Overview

Dicofol is an organochlorine miticide which is registered for use on beans (dry, lima, and green), cotton, hops, mint, peppers, tomatoes, citrus, pecans, walnuts, tree nuts, cucurbits, grapes, pomefruit, stone fruit, strawberries, melons, and non-residential lawns and ornamentals. Special Local Need registrations are currently active for use on alfalfa and cane berries. At the time the RED was signed, dicofol was an important component of mite control programs. Today there are many alternatives to dicofol that are equally efficacious and cost effective, resulting in an overall decrease in dicofol use.

According to EPA resources, usage on three major use sites (cotton, grapefruit, and oranges) has significantly declined since 1998. For example, publicly available U.S. Department of Agriculture National Agricultural Statistic Service (NASS) data show a 75% decrease in dicofol use on cotton (approximately 400,000 pounds active ingredient in 1998 and approximately 100,000 pounds active ingredient in 2003). The 1998 RED cites that dicofol was used on approximately 22% of grapefruit grown in the U.S. at that time. Currently, the Agency's resources show that on a national scale, approximately 7% of grapefruit is treated with dicofol and annual pounds of active ingredient applied have decreased 94% since 1995. Additionally, the 1998 RED cites that dicofol was used on approximately 13% of oranges grown in the U.S. at that time. Currently, the Agency's resources show that less than 5% of oranges grown in the U.S. are treated with dicofol and annual pounds of active ingredient applied have decreased 97% since 1995.

Registered end-use products are formulated as emulsifiable concentrates or wettable powders. These formulations may be applied as concentrates or dilute sprays using aircraft or ground spray equipment. Several currently registered products were registered after the RED was signed, but these must also be modified to follow the mitigation set forth in the RED and Addendum to the RED. In addition, compliance with this mitigation is also required for three Special Local Need (SLN) products.

Work the Agency has done since the completion of the RED

Since the issuance of the RED, the Agency received and evaluated a 90-day dog dermal toxicity study (MRID 44720501) and a chemical specific dislodgeable foliar residue study (MRID 45290602). The review of the 90-day dermal study resulted in the revision of selected endpoints. Changes and discussion of changes are presented in the Revised Report of the Hazard Identification Assessment Review Committee, dated September 9, 1999. The Agency used the newly submitted information and re-evaluated post-application occupational exposures. Most post-application exposure scenarios continued to be of concern to the Agency. This addendum also addresses the need for early entry personal protective equipment (PPE) and specific label language as appropriate for these scenarios.

The Agency has concluded that revised, longer REIs are needed. For crops on which dicofol is used, workers may be required to work in fields for extended periods of time. The Agency is concerned that certain activities, including hand harvesting and moving from one treated field to the next, will potentially put workers at risk. Crops in this category include citrus (grapefruit, oranges, nectarines, and tangelos), stone fruits (apricots, nectarines, and peaches), tree nuts, mint, tomatoes, peppers, cucurbits, pomefruit (apples and pears), grapes, beans, strawberries, cane berries, and non-residential lawns and ornamentals. However, the Agency believes increasing REIs for these crops will not likely impact production of these crops because adequate alternatives are available and dicofol applications can be made when field activities are not required for some time following treatment.

In order to determine the economic and biological impact of imposing longer REIs, EPA's Office of Pesticide Programs Biological and Economic Analysis Division (BEAD) provided benefit assessments for selected crops. BEAD examined crops/crop groups that have 5% or more percent crop treated with dicofol, on a national basis. The crops that were included in the assessment are: citrus (grapefruit, oranges, and tangelos), stone fruits (apricots, nectarines, and peaches), and tree nuts (pecans). The complete results of the benefits assessments are provided with this addendum as supporting documents.

At present, all dicofol labels require REIs of 12 hours. The Agency is increasing REIs for most crops in order to protect post-application occupational workers. For cotton and alfalfa, which are largely mechanically harvested, the Agency believes that post-application exposures will be minimal, eliminating a major source of potential exposure. Therefore, the Agency has concluded that the restricted entry interval of 12 hours can remain the same for cotton and alfalfa.

Revised Restricted Entry Intervals

The Agency has determined that dicofol labels need to be revised to incorporate longer REIs for the following crops: citrus, pecans, walnuts, stone fruit, cucurbits, pomefruit, beans, grapes, non-residential turf and ornamentals, tomatoes, peppers, strawberries, cane berries, mint, and hops. To determine the biological and economical impact of increasing REIs for crops that have more than 5% crop treated nationally, the Agency conducted benefits assessments. As discussed previously, these crops include citrus, pecans, and stone fruit. The Agency has received information from USDA to help inform this decision. A brief summary of the rationale used by the Agency for these crops is included below and complete assessments are included as supporting information.

To protect workers, the Agency will require that new labels include the following REIs for the specified crops:

- Citrus (oranges, tangelos, tangerines, grapefruit) - 87 days
- Stone fruit (apricots, peaches, nectarines) - 33 days
- Pecans/Walnuts/Tree Nuts - 49 days (applications must be made before shuck split)
- Cucurbits - 21 days
- Pomefruit (apples, pears) - 35 days
- Beans - 33 days
- Grapes - 39 days
- Sod/Turf (surrogate for non-residential turf) - 29 days
- Tomatoes/Peppers - 25 days
- Strawberries (and Cane Berries)- 31 days
- Mint - 32 days
- Hops - 29 days
- Ornamentals – 34 days
- Bermuda grass grown for seed – 20 days
- Christmas trees – 41 days

Specific Crop Analyses

Citrus

Dicofol is applied to citrus to control a complex of mites including spider mites and rust mites. Currently, dicofol is not significantly used on oranges, tangelos, or tangerines. In Texas approximately 25% of grapefruit is treated with dicofol.

Dicofol labels currently specify a 12 hour REI for citrus. The Agency is concerned that an REI of 12 hours is not restrictive enough, and that residue levels of dicofol may be present that could potentially harm workers who are participating in field activities. Therefore, a new REI of 87 days will be established for citrus.

The Agency believes that there will not likely be a negative impact on grapefruit production in Texas if REIs are extended, as dicofol will be shifted in the rotational spray

program to a period where field activities will not be restricted. In addition, even with a longer REI, dicofol application would still be an option during the non-harvest period (June-September). Further, numerous alternative miticides are available which are both efficacious and cost effective. Alternatives include, but are not limited to: abamectin, formetanate hydrochloride, diflubenzuron, pyridaben, propargite, and fenbutatin oxide. These alternatives have REIs that range from 12 to 48 hours. A more complete list of alternative miticides, as well as a discussion of alternatives, is included in the "Benefits Assessment for Dicofol on Citrus: Oranges, Grapefruit, Tangerines, and Tangelos", dated April 13, 2005.

Stone Fruit

Dicofol is applied to stone fruits to control several types of mites, including web-spinning mites. Over the past four years, national use of dicofol on stone fruit has declined.

Dicofol labels currently specify a 12 hour REI for stone fruit. The Agency is concerned that a 12 hour REI is not restrictive enough to protect field workers from post-application exposures to dicofol. Therefore, a new REI of 33 days will be established for stone fruit.

While the extended REI might impact timing of applications, other miticides are available which are as efficacious and economical as dicofol for mite control. Since the alternative miticides are currently used to treat more acres annually than dicofol, there is not likely to be either a biological pest control impact or economic impact on producers. Alternatives include, but are not limited to: abamectin, bifenazate, esfenvalerate, fenbutatin oxide, and insecticidal oils. A more complete list, as well as a discussion of alternatives, is included in the "Benefits Assessment for Dicofol on Apricots, Peaches, and Nectarines", dated March 23, 2005. In addition, dicofol can still be used but producers will need to schedule field activities around new REIs.

Pecans (Tree Nuts)

Dicofol is applied to pecans to control mites, primarily the leaf scorch mite. Dicofol use on pecans is highest in Georgia and Louisiana, where approximately 34% and 21% of pecans are treated, respectively.

Dicofol labels currently specify a 12 hour REI for pecans. The Agency is concerned that a short REI would allow workers to re-enter treated fields when residue levels are of concern and field activities could result in extended periods of exposure. Therefore, a new REI of 49 days will be established for tree nuts.

Because the application schedule for dicofol is July through October and field activities requiring contact with treated foliage are minimal during this time, extending REIs will not likely impact pecan production. To further ensure that workers do not come in contact with treated foliage and nuts for long periods of time, labels need to specify that dicofol can only be applied before pecan shuck split and that, following treatment, pecans need to be harvested mechanically.

Potential Intermediate-Term Exposure

Based upon the use pattern and toxicological profile of dicofol, the Agency believes that potential intermediate term exposures are not likely. As stated in the 1998 RED, it is not feasible for dicofol applications to be made more than once per growing season and these applications are more likely to be performed earlier in the season due to the incorporation of the longer REIs required for most crops. The development of resistance to the miticide, dicofol, is yet another concern which may limit usage during growing season. Furthermore, toxicological effects based on the LOAEL of 10 mg/kg/day are not seen until week 11 of continuous treatment with dicofol. Continued application of dicofol for this duration of time is unlikely to occur. Therefore, the Agency believes it is unlikely that a worker would be exposed for a duration long enough for an effect to be manifested.

Additional Labeling Updates Needed Since the RED:

The PPE and Engineering Control sections appearing in the Dicofol RED require revisions and updating as follows to bring them up to today's standards:

Double Notification Statement Needed

It should be noted that REI's of greater than 7 days trigger the following double notification text that must be added to the label:

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

Early Entry PPE Label requirements:

No early entry personal protective equipment (PPE) was specified in the Dicofol RED. This addendum also addresses the need for this equipment and specific label language as appropriate for these scenarios. The additional label language is as follows:

"Early Entry PPE:

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-sleeve shirt and long pants,
- Chemical-resistant gloves made of any waterproof material,
- Chemical-resistant footwear plus socks,
- Chemical-resistant headgear (if overhead exposure)."

Handler PPE for Liquids

Some materials that are chemical-resistant to this product are made of XX. If you want more options, follow the instructions for category X on an EPA chemical-resistance category selection chart.

Mixers, loaders, applicators, flaggers, and other handlers using engineering controls must wear:

- Long-sleeved shirt and long pants, and
- Shoes plus socks.
- In addition, mixers and loaders must wear chemical-resistant gloves and a chemical-resistant apron.

See engineering controls for additional requirements.

All other handlers must wear:

- Coveralls over long-sleeved shirt and long pants,
- Chemical-resistant gloves,
- Chemical resistant footwear plus socks,
- Chemical-resistant headgear, if overhead exposure, and
- Chemical-resistant apron, for mixing and loading and when cleaning equipment or applying as a dip,
- A NIOSH-approved respirator with
 - 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), or
 - an organic-vapor cartridge or canister with any N, R or P or HE prefilter.”

Engineering Controls for Liquids

“Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].

Applicators using motorized ground equipment and flaggers must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:

- wear the personal protective equipment required in the PPE section for applicators using engineering controls,
- either wear the type of respirator specified in the PPE section of this labeling or use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling,
- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, chemical-resistant headgear, if overhead exposure, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling,

- take off any PPE that was worn in the treated area before reentering the cab, and
- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.

When handlers use closed systems, enclosed cabs, or cockpits 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.”

Handler PPE for Wettable Powders

“Some materials that are chemical-resistant to this product are made of XX. If you want more options, follow the instructions for category X on an EPA chemical-resistance category selection chart.

Mixers, loaders, applicators, flaggers, and other handlers using engineering controls must wear:

- Long-sleeved shirt and long pants, and
- Shoes plus socks.
- In addition, mixers and loaders must wear chemical-resistant gloves and a chemical-resistant apron.

See engineering controls for additional requirements.

All other handlers must wear:

- Coveralls over long-sleeved shirt and long pants,
- Chemical-resistant gloves,
- Chemical resistant footwear plus socks,
- Chemical-resistant headgear, if overhead exposure, and
- Chemical-resistant apron, for mixing and loading and when cleaning equipment or applying as a dip,
- A NIOSH-approved respirator with
 - 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), or
 - an organic-vapor cartridge or canister with any N, R or P or HE prefilter.”

Engineering Controls for Wettable Powders

“Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must :

- wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders,
- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear, and
- A NIOSH-approved respirator with

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), or an organic-vapor cartridge or canister with any N, R or P or HE prefilter.

Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].

Applicators using motorized ground equipment and flaggers must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:

- wear the personal protective equipment required in the PPE section for applicators using engineering controls,
- either wear the type of respirator specified in the PPE section of this labeling or use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling,
- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, chemical-resistant headgear, if overhead exposure, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling,
- take off any PPE that was worn in the treated area before reentering the cab, and
- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.”

When handlers use closed systems, enclosed cabs, or cockpits 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.”

Attachments:

1. Dicofol- Revised Report of the Hazard Identification Assessment Review Committee, dated September 8, 1999.
2. Dicofol. Revised Refined Post-Application Exposure Estimates (Citrus, Stonefruit, Tree-nut crops), dated July 29, 2004.
3. Dicofol: Revised Refined Post-Application Exposure Estimates (Apples, Pears, Beans, Cotton, Cucurbits, Grapes, Sod/Turf), dated August 29, 2005.
4. Dicofol: Crop-Specific Refined Post-Application Exposure Estimates: Pecans, dated December 9, 2004.
5. Dicofol. Revised Refined Post-Application Exposure Estimates for Hops, Mint & Strawberries, dated August 29, 2005.

6. BEAD Dicofol Crop Usage, dated June 25, 2004.
7. Benefits Assessment for Dicofol on Citrus: Oranges, Grapefruit, Tangerines, and Tangelos, dated April 13, 2005.
8. Pecans Benefits Assessment for Dicofol, dated March 23, 2005.
9. Benefits Assessment for Dicofol on Apricots, Peaches, and Nectarines, dated March 23, 2005.
10. Dow AgroSciences Response to Error-Only Comment Period, dated August 17, 2005.
11. Dicofol: Revisions to the Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision, dated February 6, 2006.
12. Dicofol Response to Comments Document, dated September, 2006.
13. Dicofol Revised Occupational Exposure Assessment, dated November 19, 1999.