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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Subject: Reregistration Eligibility Decision for Oxycarboxin

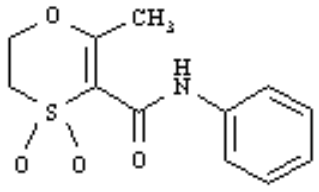
Dear Registrant:

The Reregistration Eligibility Decision (RED) document for the active ingredient carboxin (PC code 090201) was completed in September 2004 as part of Reregistration Case 0012. Reregistration Case 0012 also includes another active ingredient, oxycarboxin (PC code 090202), that was inadvertently omitted. The Environmental Protection Agency (EPA or Agency) has since reviewed the occupational exposure to oxycarboxin fungicide from use on ornamentals grown in enclosed commercial structures such as greenhouses, which is the only registered use. The Agency has determined that oxycarboxin containing products are eligible for reregistration provided that the required confirmatory data are submitted.

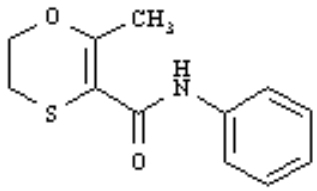
CHEMICAL OVERVIEW

Oxycarboxin (5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide-4,4-dioxide) is a member of the oxathiin class of systemic fungicides. The structural formulae for oxycarboxin and carboxin are shown below in Figure 1.

Figure 1: Chemical Formulae of Oxycarboxin and Carboxin.



Oxycarboxin



Carboxin

REGULATORY HISTORY

Oxycarboxin was first registered as an active ingredient in the United States (US) in 1971 for control of rust on carnations. A major metabolite of carboxin, oxycarboxin was initially developed and registered because it was one of a few very systemic rust control agents. Due to low sales and the limited disease spectrum, oxycarboxin has not been marketed in the US since 2003.

When the carboxin Registration Standard was issued in 1981, oxycarboxin should have been included but was inadvertently omitted. Oxycarboxin data requirements were issued through separate data call-ins (DCI) on February 24, 1994 and October 6, 1995. Based on the similarity to carboxin and occurrence as a major metabolite, data requirements were limited to those which may impact worker risk: Acute toxicity battery, mutagenicity battery, and a 21-day dermal study in rats. In a May 24, 1994 response, the registrant, then Uniroyal, deleted terrestrial non-food outdoor uses and indicated that labels would be limited to ornamentals grown in enclosed commercial structures.

USES

In the US, there are two products containing oxycarboxin: A technical product and an end-use product. Both products are supported by Crompton Corporation. The single oxycarboxin end-use product (Plantvax 75W, EPA Registration Number 400-144) is a wettable powder fungicide to be used as a foliar spray for control of rust diseases of ornamentals grown in enclosed commercial structures such as greenhouses, shadehouses and interiorscapes. It can only be applied by commercial applicators utilizing hand held equipment.

RESIDENTIAL RISK

Since the use of oxycarboxin is limited to enclosed commercial greenhouses and since there is no residential use of oxycarboxin, no dietary, residential, or environmental risk assessment was performed. However, the Agency recognizes that very limited residential exposure may be possible if treated ornamentals are obtained from an enclosed commercial structure such as a nursery or greenhouse and then brought back to a residence. The Agency has determined that residential risk of exposure from oxycarboxin does not exceed levels of concern for the following reasons: Oxycarboxin is believed not to persist on plants post-application; there is little likelihood of sustained potential exposure; the occupational margin of exposure (MOE) is not exceeded assuming baseline levels of protection; and a 12 hour REI is protective for applicators and handlers.

When applied as a foliar spray, oxycarboxin is believed not to persist on plants post-application: Oxycarboxin is rapidly taken up by plants and in aqueous solutions carboxin and oxycarboxin are degraded rapidly in the presence of light. There is little likelihood of sustained potential exposure because oxycarboxin is registered for use only in enclosed commercial structures. The target

MOE is not exceeded for commercial applicators wearing baseline levels of protection applying 1000 gal/day. Residential exposure to oxycarboxin residue on ornamentals is far less than 1000 gal/day, and therefore not of concern. Finally, the Agency has determined that a restricted entry interval (REI) of 12 hours is protective for oxycarboxin handlers and applicators; thus, any residential post-REI exposure is not of concern.

The Agency concludes that residential exposure to oxycarboxin does not exceed levels of concern.

AGGREGATE RISK

The Agency did not consider residential exposure from oxycarboxin in the carboxin RED. There are no registered residential uses of carboxin or oxycarboxin. Aggregate chronic exposure to carboxin in food and drinking water is below the Agency's level of concern. Very limited residential exposure to oxycarboxin may be possible if treated ornamentals are obtained from an enclosed commercial structure such as a nursery or greenhouse and then brought back to a residence; however, this residential exposure does not exceed levels of concern. The Agency has determined that aggregate chronic exposure to carboxin in food and drinking water and oxycarboxin in plants treated in enclosed commercial structures is not of concern.

OCCUPATIONAL RISK

Based on the close structural similarity of carboxin and oxycarboxin (see Figure 1), oxycarboxin is assumed to be toxicologically equivalent to carboxin for this assessment. Oxycarboxin is a metabolite of carboxin and, as such, has been evaluated in situ through the carboxin toxicology studies. Furthermore, separate evaluations of oxycarboxin and carboxin have shown similar toxicology profiles. Accordingly, endpoints selected for carboxin are used to estimate occupational exposure and risk from oxycarboxin. A discussion on selection of toxicity endpoints for dermal and inhalation exposure is provided in the Carboxin HED Risk Assessment for Reregistration Eligibility Decision, PC code 090201 dated December 17, 2003 (DP288406).

The occupational exposure scenario assessed for the greenhouse use is conservatively assumed to be mixing, loading, and applying the fungicide using high pressure handwand equipment. The label-specified maximum application rate of 0.011 pound active ingredient per gallon (lb ai/gal) is assumed. Only short and intermediate term exposures are assessed based on the label-specified use pattern. A target MOE of 100 for the dermal and inhalation routes is considered adequate for the occupational exposure assessment. For short- and intermediate-term occupational exposure assessment, the dermal and inhalation exposure routes cannot be combined because toxicity endpoints for these exposure routes are based on different effects (i.e., kidney effects vs body weight change). The table below presents the occupational assessment for oxycarboxin.

Oxycarboxin Occupational Exposure Assessment Mixing Loading and Applying with High Pressure Handwand				
Crop	Application Rate [1] (lb ai/gal)	Daily Area Treated [2] (gallon/day)	Dermal MOE[3]	Inhalation MOE[4]
greenhouse ornamentals	0.011	1000	1000	530

[1] Crops and use patterns are from oxycarboxin label (EPA Reg No. 400-144).
[2] Amount treated is based on the area or gallons that can be reasonably applied in a single day for each exposure scenario of concern based on the application method and formulation/packaging type. (Standard EPA/OPP/HED values).
[3] Dermal MOE = dermal no observed effect level (NOEL) (400 mg/kg/day) / Daily Dermal Dose. Target Dermal MOE is 100.
[4] Inhalation MOE = inhalation NOEL (10 mg/kg/day) / Daily Inhalation Dose. Target Inhalation MOE is 100.

The current label requires baseline levels of protection: Long pants, long-sleeved shirts, shoes, and socks. When use of dermal and inhalation baseline levels of protection and no respirator is assumed, margins of exposure for both dermal and inhalation occupational exposure are not of concern. Estimated occupational post-application exposures are well below handler exposures and are therefore also not of concern. For a complete discussion please see the Oxycarboxin Occupational Exposure and Risk Assessment PC Code 090202 dated November 19, 2004.

REGULATORY DECISION

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing oxycarboxin as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing oxycarboxin.

The Agency has completed its assessment of the occupational risk associated with the use of pesticide products containing the active ingredient oxycarboxin. Based on a review of these data, the Agency has sufficient information on the human health of oxycarboxin to make decisions as part of the reregistration process under FIFRA. The Agency has determined that oxycarboxin containing products are eligible for reregistration provided that the required confirmatory data are submitted. No label change is necessary for oxycarboxin.

Based on its evaluation of oxycarboxin, the Agency has determined that oxycarboxin products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA.

WHAT IS REQUIRED OF REGISTRANTS

For oxycarboxin technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Lance Wormell at (703) 603-0523 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Lance Wormell
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Lance Wormell
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

For end use products containing the active ingredient oxycarboxin, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);
2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
3. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and
4. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

5. the product-specific data responding to the PDCI.

Please contact Barbara Briscoe at (703) 308-8177 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Barbara Briscoe
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Barbara Briscoe
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of oxycarboxin for the above eligible uses has been reviewed and determined to be substantially complete. However, the following data requirement listed in the table below is necessary to confirm the reregistration eligibility decision documented in this document.

Generic Data Requirement for the Reregistration Eligibility Decision on Oxycarboxin

Guideline	Study Title
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture

ADDITIONAL PRODUCT-SPECIFIC DATA REQUIREMENTS

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A generic and product-specific data call-in, outlining specific data requirements, will be issued at a later date.

If you have any questions on oxycarboxin or carboxin, please contact the Chemical Review Manager, Lance Wormell, at (703) 603-0523.

Sincerely,

Debra Edwards, Ph.D.
Special Review and Reregistration Division