

US EPA ARCHIVE DOCUMENT



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

DEC 17 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORADUM

SUBJECT: Exposure Assessment for New Chemical, Prodiamine, Using Surrogate Data. (HED Project # 2-0123, Intra Project # 0221)

TO: Joanne Miller, PM 23
Fungicide - Herbicide Branch
Registration Division H7505C

FROM: Ameesha Mehta, Chemist *Ameesha Mehta 12/13/91*
Special Review and Registration Section
Occupational and Residential Exposure Branch
Health Effects Division H7509C

THRU: Curt Lunchick, Section Head *Curt Lunchick*
Special Review and Registration Section
Occupational and Residential Exposure Branch
Health Effects Division H7509C

Charles Trichilo, Ph.D., Chief
Special Review and Registration Section
Occupational and Residential Exposure Branch
Health Effects Division H7509C *Charles Trichilo*

I. INTRODUCTION

A. Background:

Prodiamine (BARRICADE) is a selective preemergence herbicide manufactured by Sandoz Crop Protection Corporation that provides residual control of many grass and broadleaf weeds as they germinate in turf and landscapes. The current formulation which is 65% Wettable Granular contains 10.4 oz a.i./lb. The toxicity for both the end-use product and the technical grade are Category III for dermal and inhalation. The no observed effect level (NOEL) determined from a life-time feeding study in male and female rats, is 7.2 and 9.1 mg/kg/day. EPA has classified

Prodiamine as a Category C carcinogen without risk quantification. Efforts are underway by Sandoz to register this new herbicide.

B. Purpose:

RD has requested OREB to provide an exposure assessment for mixer/loader/applicator using the fungicide Cyproconazole as a surrogate. OREB has also been asked to provide a residential or bystander exposure assessment for this chemical.

C. Method of Application:

Applications of Prodiamine, according to the label, are to be made using calibrated, low pressure sprayers with 50 mesh or coarser screens attached to either a broadcast boom or hand held wand. The label provides different application rates according to the turf species and expected weed species (see Prodiamine Label). This herbicide may be applied as a single application or as sequential applications to control turf and weed species. The maximum annual rate is 2.30 lbs product/acre (1.50 lbs ai/acre). A maximum of three applications, the sum of which does not exceed 1.50 lbs ai/acre, may be used in a year.

D. Routes of Absorption:

Routes of absorption for Prodiamine are primarily via dermal exposure, and some inhalation exposure.

II. DETAILED CONSIDERATIONS

A. Basis for Using Surrogate Chemical:

EPA Pesticide Assessment Guidelines, Subdivision U, specify when surrogate studies can be used to conduct exposure and risk assessments of new chemicals. The following considerations should be addressed when choosing a study to be used as a surrogate to estimate exposure:

1) Similar method of application, 2) Similar use pattern, 3) Similar type of formulation, and exposure measured during each separate application cycle of a work day.

The study entitled "Risk Assessments from Mixer/Loader and Application Exposure to Cyproconazole During Turf Treatment" was chosen to estimate the risk associated with applying Prodiamine on turf and landscape. The study was reviewed

by OREB and found to be acceptable according to EPA's Subdivision U Guidelines. (Memo from A. Mehta to S. Lewis on 4/19/91)

B. Data Used:

The above study monitored fifteen mixer/loader and applicators who were exposed to 0.8 lb ai when they handled a 2 lb 40 WDG formulation in 100 gallons of finished spray at 50 gallons/acre. Applications were made to turf using ground boom sprayers mounted on golf cart type equipment. Workers were monitored for both dermal and respiratory exposure. Multilayer dosimeter were used to estimate bodily exposure for workers wearing Tyvek coveralls, baseball caps, full face respirators, neoprene gloves, and rubber boots. Each worker was suited with 10 cm x 10 cm alpha-cellulose patches (non-protected), and 10 cm x 10 cm alpha cellulose patches (protected). Respiratory exposure was measured using personal air sampling pump drawing air (2.0 l/min) from interior of the full face respirator.

Average values for the non - protected mixer/loader/applicator will be used in assessing the exposure since it does not assume that workers will wear long sleeves shirt and pants when using this chemical; thereby, providing a worst case scenario.

C. Assumptions:

In order to calculate exposure estimates, OREB made the following assumptions.

OREB assumes that a 70 kg body weight to represent average body weight, and that a worker has standard body surface areas as outlined in EPA's: Subdivision U.

Since inhalation as a route of exposure may be of concern; OREB assumes that workers while performing light tasks have a inhalation rate of 29 liters/min. Activities associated with turf application were assumed to be light tasks. 100% inhalation absorption assumed by OREB.

OREB assumes 100% dermal absorption of the herbicide.

Due to the lack of use information, OREB assumes the number of acres treated on an average size (18 hole) golf course to be 48 acres (fairways treated only). Current use label recommends a maximum of three applications not exceeding the sum of 1.5 lbs ai/acre or one application a year at 1.5 lbs ai/acre. It is also assumed that golf courses have full time personnel for year round pest control and maintenance. Hence, a mixer/loader and applicator are assumed to treat approximately 50 acres in two 8 hr days. OREB assumes that at least two workers are involved. (Memo from J. Saulmon (BUD/BEAD) to D. Jaquith, 8/19/87).

Worst case scenario is assumed whereby use of 1 application/year at the maximum label rate of 1.5 lbs ai/acre would involve 2 eight hour days of application of Prodiamine. Note, since have limited use information for Prodiamine or Cyproconazole, BEAD should validate this information.

D. Worker Exposure:

TABLE 1. Calculated Exposure Values for Non- Protected M/L/A

	Avg. Exp. ^a (mg/kg ai)	ADE ^b (mg/kg/day)	AADE ^c (mg/kg/day)	LADE ^d (mg/kg/day)
Mixer/Loader	6.00	1.46	8.0×10^{-3}	4.5×10^{-4}
Applicator	0.749	1.8×10^{-1}	9.9×10^{-4}	5.6×10^{-4}

^a The average exposure in mg/kg ai determined from the study assessing Cyproconazole exposure.

^b The average daily exposure (ADE) assumes the exposure duration to be 50 acres/2 days.

^c The annual average daily exposure (AADE) assumes the exposure duration to be a maximum of 2 days/year at the label maximum rate of 1.5 lbs ai/acre.

^d The lifetime average daily exposure (LADE) assumes that the worker is exposed the concentration for 40 working years/70 year life span.

1. Sample Calculation:

ADE (mg/kg/day) for mixer/loader =

$$(6.0 \text{ mg/kg ai}) * (0.68 \text{ kg ai/acre}) * (50 \text{ acres/2 days}) * (1/70 \text{ kg})$$

$$= 1.46 \text{ mg/kg/day}$$

E. Residential/Bystander Exposure:

Since Prodiamine does not have quantifiable carcinogenic risk, and it does not involve repeated or chronic exposure; OREB, assumes the exposure and risk to residents/bystanders to be negligible. Therefore, OREB, at the present time, will not provide an exposure assessment for the residential/bystander population.

III. CONCLUSION/RECOMMENDATION

OREB has provided estimates of the potential worker exposure to the herbicide Prodiamine using exposure data for the fungicide, Cyproconazole. Prodiamine has a

maximum of either 3 applications/year not exceeding the sum of 1.5 lbs ai/acre or 1 application/year at 1.5 lbs ai/acre. Since Prodiamine is classified as a Class C carcinogen without quantification, margins of exposure (MOE) are calculated to determine the potential risk to this herbicide. However, the values should be deferred to Tox Branch II for validation.

TABLE 2. Calculated Margins of Exposure for Non - Protected M/L/A

	LADD (mg/kg/day)	NOEL ^a (mg/kg/day)	MOE
Mixer/Loader	4.6 x 10 ⁻³	7.2	1565
Applicator	5.6 x 10 ⁻⁴	7.2	12857

^a The no observed effect level determined from a life time feeding study in male and females rats, is 7.2 and 9.1 mg/kg/day respectively. The value for males is used.

Since the assessment is conducted using surrogate data for Cyproconazole, and there were data gaps present with that chemical; therefore, there are limitations present with the extrapolation. OREB recommends that the label should contain the following statement in order to reduce the potential dermal exposure:

During mixing and loading of the concentrate material wear chemical-resistant gloves. Wash nondisposable gloves thoroughly with soap and water before removing.

IV. REFERENCES

EPA (1987). Pesticide Assessment Guidelines: Subdivision U- Applicator Exposure. NTIS Number PB87 - 133286.

Mehta, A. (4/19/91). EPA Memorandum from OREB/HED to S. Lewis of RD titled, " Review of Exposure in Risk Assessments from Mixer/Loader and Applicator Exposure to Cyproconazole During Turf Treatment." (HED # 0-0802).

Saulmon, J. (8/19/87). EPA Memorandum from BUD/BEAD to D. Jaquith (EAB/NDEB) titled "Response to HED's request for information on Human Exposure Scenarios for 1471 - EUP - 82, Cutless 50W (E2-500, Flurprimidol) use on Turf."