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

006566

JAN 29 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Propazine Registration Standard - Calculation of Worker Risks Based on EAB Exposure Assessment for Policy Group

Caswell No.: 184

FROM: William Dykstra, Reviewer
Review Section II, Toxicology Branch
Hazard Evaluation Division (TS-769C)

William Dykstra 1/27/88

TO: Jude Andreasen
Product Manager
Special Review Branch
Registration Division (TS-767C)

THRU: Edwin Budd, Section Head
Review Section II, Toxicology Branch
Hazard Evaluation Division (TS-769C)

Budd 1/28/88 1/29/88

In the Exposure Assessment Branch (EAB) memorandum dated January 11, 1988 from M. Firestone to J. Andreasen, EAB estimated the annual exposure to mixer/loaders and applicators handling propazine as a preemergent herbicide for sorghum. The estimates, based on a 70 kg individual wearing commonly used work attire (long-sleeved shirt and long pants) at all times and protective gloves during mixing/loading are presented in Table 1.

Table 1

		Exposure (mg/kg/yr)		
Ground - Grower:	Open Pour M/L	2.7	to	5.3
	Application	0.58	to	1.2
	Combined	3.3	to	6.5
Ground - Commercial:	Open Pour M/L	13	to	80
	Closed System M/L	0.21	to	1.3
	Applicator	3.7	to	22
Aerial:	Closed System Mixer/Loader	0.13	to	1.3
	Pilot	0.04	to	0.4
	Flagger	0.22	to	2.2

Based on 365 days/year, Toxicology Branch (TB) has converted the EAB exposure units to mg/kg/day.

Table 2

		Exposure (mg/kg/day)		
Ground - Grower:	Open Pour M/L	0.0074	to	0.015
	Application	0.0016	to	0.0033
	Combined	0.0090	to	0.018
Ground - Commercial:	Open Pour M/L	0.036	to	0.22
	Closed System M/L	0.00058	to	0.0036
	Applicator	0.010	to	0.060
Aerial:	Closed System Mixer/Loader	0.00036	to	0.0036
	Pilot	0.00011	to	0.0011
	Flagger	0.00060	to	0.0060

The potency estimate, Q^*_1, of propazine is 1.7×10^{-1} $(mg/kg/day)^{-1}$ in human equivalents. This estimate was calculated using the Weibull '82 model and is based upon all mammary tumors combined in female rats (memo of 6/12/87 from C. J. Nelson to W. Dykstra, attached). TB has calculated the worker oncogenic risks by multiplying the Q^*_1 value of 1.7×10^{-1} $(mg/kg/day)^{-1}$ by the exposure estimates in Table 2 expressed in mg/kg/day. Dermal absorption has been based on 100%, since no dermal absorption study is available.

The oncogenic risks are presented in Table 3.

Table 3

		Worker Risks Risk x 10^{-3}		
Ground - Grower:	Open Pour M/L	1.3	to	2.6
	Application	0.27	to	0.56
	Combined	1.5	to	3.1
Ground - Commercial:	Open Pour M/L	6.1	to	37.4
	Closed System M/L	0.099	to	0.61
	Applicator	1.7	to	10.2
Aerial:	Closed System Mixer/Loader	0.061	to	0.61
	Pilot	0.019	to	0.19
	Flagger	0.10	to	1.0

Additionally, it has been TB policy to adjust worker risks for total years of work (30) per average worker lifetime (70) by multiplying worker risks by 30 years/70 years. By utilizing this adjustment, Table 4 presents the range of worker risks. Again, it should be noted that these oncogenic risks have not been adjusted for dermal absorption of propazine, since no dermal absorption study is available. Therefore, dermal absorption has been assumed to be 100%.

Table 4

		Range of Risks
Ground - Grower:	Open Pour M/L	10^{-4} to 10^{-3}
	Application	10^{-4} to 10^{-3}
	Combined	10^{-4} to 10^{-3}
Ground - Commercial:	Open Pour M/L	10^{-3} to 10^{-2}
	Closed System M/L	10^{-5} to 10^{-4}
	Applicator	10^{-4} to 10^{-3}
Aerial:	Closed System Mixer/Loader	10^{-5} to 10^{-4}
	Pilot	10^{-6} to 10^{-5}
	Flagger	10^{-5} to 10^{-4}

Attachment

cc: Amy Rispin, Chief
SIS/HED (TS-769C)

Jim Yowell, PM #25
FHB/RD (TS-767C)

006566

Shaughnessy #: 080808

Due Date: 1/13/88

To: J. Andreasen
Product Manager
Registration Division (TS-767)

From: Michael P. Firestone, Chief
Special Review Section #2
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Thru: Paul Schuda, Chief
Exposure Assessment Branch/HED (TS-769C)

Attached please find the EAB review of...

Reg./File No.: ______

Chemical: Propazine

Type Product: Herbicide

Product Name: ______

Company Name: ______

Submission Purpose: Exposure Assessment for Policy Group

ACTION CODE: ______

Date In: 12/14/87

EAB # None

Date Completed: 01/11/88

Total Reviewing Time: 3 Days

Monitoring Study Requested: ____

Monitoring Study Voluntarily: ____

Deferrals To:

______ Ecological Effects Branch

______ Residue Chemistry Branch

______ Toxicology Branch

1.0 INTRODUCTION

The Registration Division and the Hazard Evaluation Division have requested an exposure assessment for the uses of propazine. The exposure assessment will be utilized to estimate nondietary risk to mixer-loaders and applicators for presentation to the OPP Policy Group. Propazine is a triazine herbicide used to control broadleaf and a few grassy weeds in sorghum, non-crop areas, and lily bulbs (Oregon Special Local Need).

2.0 PROPAZINE USE DATA

James Saulmon, Science Support Branch, Benefits and Use Division, provided "rough, preliminary" use information to the Exposure Assessment Branch (EAB) on December 30, 1987 (Estimates of Exposure Parameters for Propazine Use on Sorghum in the US). Use data were provided for sorghum, which accounts for essentially all the propazine used in the US. Propazine is applied to sorghum as a preplant and preemergent herbicide to control pigweed, cocklebur, green foxtail, lambsquarter, ragweed, kochia, and sunflower. Less than half of the propazine is applied with other herbicides. When propazine is applied with other herbicides, metolachlor is the herbicide of choice although atrazine, alachlor, cyanazine, and terbutryn are also used.

Propazine is applied to sorghum once per year at an application rate of 1.0 to 2.0 lbs a.i./acre. The average acreage of sorghum per farm is 200 acres. Propazine may be applied by ground boom equipment or aerially. When applied by ground boom by the grower, the same individual will perform the mixing/loading and application tasks. The treatment of 200 acres at 1.0 to 2.0 lbs a.i./acre will require 200 to 400 lbs propazine and require 8.8 hours of spraying time over a two day period.

Commercial ground applications are expected to consist of a mixing/loading crew and a seperate application crew. The ground boom application of a preemergent herbicide can cover approximately 100 acres in a day. A commercial crew is estimated to apply propazine for 10 to 30 days annually. The mixer/loader would handle between 1000 lbs a.i. at 1.0 lbs a.i./acre to 100 acres/day for 10 days to 6000 lbs a.i. at 2.0 lbs a.i./acre to 100 acres/day for 30 days. Ground application will require 5.5 hours/day of spraying time.

Aerial crews will consist of a mixer/loader and pilot. A flagger is also possible. Treatment of propazine to 200 acres/day will require 0.8 hours of spraying time. A crew may be contracted to apply propazine 6 to 30 days annually. The mixer/loader would handle between 1200 lbs propazine, based on application of 1.0 lbs a.i./acre to 200 acres daily for 6 days, to 12,000 lbs propazine, based on the application of 2.0 lbs a.i./acre to 200 acres daily over 30 days. Aerial mixer/loaders usually utilize closed loading systems such as "barrel suckers".

3.0 NONDIETARY OCCUPATIONAL EXPOSURE

3.1 MIXER/LOADER EXPOSURE

To estimate the dermal exposure to mixer/loaders, EAB reviewed four studies available in the published literature. To the extent possible, exposure was estimated in which mixer/loaders wore long pants and long-sleeved shirts. The use of protective gloves was also assumed. The exposure to mixer/loaders using closed loading systems or open pouring the concentrated pesticide were calculated separately. A summary of the exposure estimates are provided below:

I. OPEN POUR

Study	Replicates	Exposure (mg/lb ai)	Clothing
Abbott	18	0.93	Long-sleeved shirt, long pants, protective gloves

II. CLOSED LOADING

Study	Replicates	Exposure (mg/lb ai)	Clothing
Dubelman	9	0.0041	Long-sleeved shirt, long pants, protective gloves
Peoples	9	0.025	Long-sleeved shirt, long pants, protective gloves

The 18 Abbott replicates estimate dermal exposure to mixer/loaders open pouring the concentrated pesticide to be 0.93 mg/lb ai handled. The use of closed loading systems reduces the exposure received to 0.015 mg/lb ai handled.

3.2 GROUND-BOOM APPLICATOR EXPOSURE

To estimate the dermal exposure to ground-boom applicators, six studies available in the published literature were evaluated. The estimated dermal exposure for ground-boom applicators applying 1.0 lb ai/A while wearing the long-sleeved shirt and long pants is presented below. Any deviations from this clothing scenario are also identified.

Study	Replicates	Exposure (mg/hr)	Clothing
Abbott	18	40	Long-sleeved shirt, long pants
Maitlen	21	0.7	Short-sleeved shirt, long pants
Dubelman	12	0.93	Long-sleeved shirt, long pants
Wojeck	23	72	Long-sleeved shirt, long pants
Staiff	20	0.4	Short-sleeved shirt, long pants
Wolfe	7	9.4	Short-sleeved shirt, long pants

The total of 101 replicates yields a weighted geometric mean exposure of 4.6 mg/hr. The large range of 0.4 to 72 mg/hr around this geometric mean reflects the wide range of exposure that can occur to applicators during ground-boom application. Tractor type and boom equipment can greatly affect exposure. Enclosed cabs provide a physical barrier between the applicator and spray. Wojeck found that shielding the boom yielded lower exposures. Wind can blow spray drift across the applicator and increase exposure. It is reasonable to assume that depending on equipment used, weather conditions, and the personal habits of the applicator, the exposure received during any given application can fall anywhere within this range of 0.4 to 72 mg/hr.

3.3 PILOT AND FLAGGER EXPOSURE

To estimate the dermal exposure to pilots and flaggers, EAB reviewed six studies available in the published literature. To the extent possible it was assumed that the pilots and flaggers wore long-sleeved shirts and long pants. In the Maddy, Peoples, and Mumma studies the actual residue measured under the clothing was used to estimate dermal exposure. Atallah presented his data as calculated dermal exposures that assumed long pants and short-sleeved shirts that completely eliminated exposure to the covered areas of the body. The pilot exposure from the Lavy-82 study was calculated assuming the pilots wore long-sleeved shirts and long pants that completely eliminated exposure to the covered body areas. The Lavy-82 study had an insufficient number of patches to estimate exposure to the legs.

The estimated pilot exposures adjusted to an application rate of 1.0 lb ai/A are presented below.

Study	Replicates	Exposure (mg/hr)
Lavy-82	3	0.10
Maddy	4	0.021
Peoples	11	0.86
Mumma	6	0.80
Atallah	4	0.38

The exposures ranged from 0.021 to 0.86 mg/hr with a weighted mean exposure of 0.58 mg/hr.

The estimated flagger exposures adjusted to an application rate of 1.0 lb ai/A are presented as follows:

Study	Replicates	Exposure (mg/hr)
Maddy	8	0.36
Peoples	9	1.1
Atallah	3	17.2

The flagger exposure ranged from 0.36 to 17.2 mg/hr with a weighted mean of 3.2 mg/hr. The flagger estimates are for flaggers standing in the open and attempting to remain upwind of the spraying. Wind shifts can, and in the studies did, produce higher exposures.

4.0 ANNUAL NONDIETARY EXPOSURE TO PROPAZINE

As previously discussed, propazine is applied to sorghum at 1.0 to 2.0 lbs a.i./acre. A grower will handle 200 to 400 lbs a.i. in treating 200 acres annually. The required spray time is 8.8 hours. The annual grower exposure, when propazine is applied to sorghum, is as follows:

Low Application Rate

Mixer/Loader-Open Pour-	0.93 mg/lb a.i. x 200 lbs a.i./yr x 1/70 kg = 2.7 mg/kg/yr
Ground Boom Applicator-	4.6 mg/hr x 1 x 8.8 hrs/yr x 1/70 kg = 0.58 mg/kg/yr
Combined-	2.7 mg/kg/yr + 0.58 mg/kg/yr = 3.3 mg/kg/yr

High Application Rate

Mixer/Loader-Open Pour-	0.93 mg/lb a.i. x 400 lbs a.i./yr x 1/70 kg = 5.3 mg/kg/yr
Ground Boom Applicator-	4.6 mg/hr x 2 x 8.8 hrs/yr x 1/70 kg = 1.2 mg/kg/yr
Combined-	5.3 mg/kg/yr + 1.2 mg/kg/yr = 6.5 mg/kg/yr

The commercial applicator will treat 100 acres daily at 5.5 hours/day for 10 to 30 days annually. The mixer/loader will handle 1000 to 6000 lbs of propazine a year. If the mixer/loader open pours propazine, the annual exposure is estimated to range from 13 mg/kg/yr to 80 mg/kg/yr. If the mixer/loader uses a closed loading system, the annual exposure would be reduced to 0.21 mg/kg/yr to 1.3 mg/kg/yr. The applicator's annual exposure would range from 3.7 mg/kg/yr (1.0 lbs a.i./acre, 10 days annually) to 22 mg/kg/yr (2.0 lbs a.i./acre, 30 days annually).

Aerial mixer/loaders are commonly different individuals from the pilot or flagger. Closed loading systems are more common with aerial operations. Therefore, the annual exposure for an aerial mixer/loader handling between 1200 and 12,000 lbs a.i./yr is 0.13 mg/kg/yr to 1.3 mg/kg/yr. The pilot exposure would range from 0.04 mg/kg/yr (0.58 mg/hr x 1 x 0.8 hrs/day x 6 days/yr x 1/70 kg) to 0.4 mg/kg/yr (0.58 mg/hr x 2 x 0.8 hrs/day x 30 days/yr x 1/70 kg). Assuming the flagger is exposed for the same period as the pilot, annual flagger exposure is estimated to range from 0.22 mg/kg/yr (3.2 mg/hr x 1 x 0.8 hrs/day x 6 days/yr x 1/70 kg) to 2.2 mg/kg/yr (3.2 mg/hr x 2 x 0.8 hrs/day x 30 days/yr x 1/70 kg).

5.0 CONCLUSION

EAB estimated the annual exposure to mixer/loaders and applicators handling propazine as a preemergent herbicide for sorghum. The estimates based on a 70 kg individual wearing commonly used work attire that consists of a long sleeve shirt and long pants at all times and protective gloves during mixing/loading are as follows:

Ground - Grower:	Open Pour M/L		- 2.7 to 5.3 mg/kg/yr
	Application		- 0.58 to 1.2 mg/kg/yr
	Combined		- 3.3 to 6.5 mg/kg/yr
Ground - Commercial:		Open Pour M/L	- 13 to 80 mg/kg/yr
		Closed System M/L	- 0.21 to 1.3 mg/kg/yr
		Applicator	- 3.7 to 22 mg/kg/yr
Aerial :	Closed System Mixer/Loader		- 0.13 to 1.3 mg/kg/yr
	Pilot		- 0.04 to 0.4 mg/kg/yr
	Flagger		- 0.22 to 2.2 mg/kg/yr

The above estimates have not been adjusted for the dermal absorption of propazine. The estimates are subject to revision upon receipt from BUD of the comprehensive follow-up use report planned for late February 1988.

Curt Lunchick 11 Jan 88

Curt Lunchick
Special Review Section
Exposure Assessment Branch/HED (TS-769C)

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

12/30/87

MEMORANDUM

Subj: Estimates of exposure parameters for propazine use on sorghum in the US

From: James G. Saulmon, Botanist
Plant Biology Section
Science Support Branch
Benefits and Use Division (TS-768-C)

To: Michael P. Firestone, Chief
Special Review Section I
Exposure Assessment Branch
Hazard Evaluation Division (TS-769-C)

Thru: Janet L. Andersen, Acting Chief
Plant Biology Section
Science Support Branch
Benefits and Use Division (TS-768-C)

Attached is a very rough, preliminary report of telephone-generated data on exposure parameters for propazine use on sorghum in the US. These are preliminary estimates which are subject to change and are based on a few contacts. A more comprehensive follow-up report is planned for the last of February, 1988.

Also, attached are copies of two other related reports. These include the following:

(1) a February 21, 1986 report, titled: Use Data for Exposure Analysis of Terbutryn. [Note that terbutryn is also used on sorghum.]

(2) December 11, 1987 memorandum, titled: Transmittal of Propazine materials for BUD Division Review.

If there are questions I can be reached at 557-1774 in room 1024A.

Attachments

Table I. PROPAZINE USE ON SORGHUM - Estimates of Exposure Given by [illegible] Registrants

Parameter [For]	Ground Grower	Ground Commercial	Aerial
1. % propazine applied (basis: 1987 acreage from agricultural statistics)	1,200,000 to 1,500,000 acres	320,000 to 400,000 acres	80,000 to 100,000 acres
2. average size farm	200 acres	200 acres	200 acres
3. most common formulation used	Max 90 (= 90% a.i.) 4L (= 4 lbs a.i. per gallon)	Max 90 4L	Max 90 4L
4. Av. application rate/acre	1 to 2 lb a.i. per acre	1 to 2 lb a.i. per acre	1 to 2 lb a.i. per acre
5. Av. # applications/year	1 per year	1 per year	1 per year
6. Typical work hours per day	8 hours	8 hours	6 hours
7. Is mixer/loader = applicator?	yes	no, use a separate crew	no, use a separate crew
8. # days/yr applied propazine	2 days	10 to 30 days	6 to 30 days
9. protective clothes worn by mixer/loader	gloves, coveralls, dust mask, goggles, some wear no suits, a few wear plastic suit.	gloves, coveralls, dust mask, rubber boots, coats, some use total body covering	gloves, coveralls, dust mask
10. protective clothes worn by applicator	jeans, coveralls, dust mask, driver wears gloves, goggles	gloves, coveralls, dust mask, goggles	gloves, coveralls, dust mask goggles, respirator
11. closed or open system used by applicator	varies from use of no closed system to use of closed system by 1/2 of growers	varies from 80% open system to 95% closed system	80% open, as most are in closed cockpit of airplane
12. total exposure time for applicator(s) per day			
a. ferry time per day	1.8 hours	1.0 hours	3.0 hours
b. turning time per day	0.2 hours	0.3 hours	0.4 hours
c. treatment time per day	4.2 hours	5.2 hours	0.4 hours
d. herbicide pouring time per day	0.2 hours	0.1 hours	0.4 hours
e. filling tank & transfer per day	1.8 hours	2.1 hours	1.9 hours
f. total operation time/day	8.2 hours	8.8 hours	6.1 hours

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

006566

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

December 11, 1987

MEMORANDUM

SUBJECT: Transmittal of Propazine Briefing Materials for BUD Division Review

TO: Paul R. Lapsley, Deputy Director
Benefits and Use Division (TS-768-C)

FROM: William G. Phillips, Chief
Science Support Branch
Benefits and Use Division (TS-768-C)

Arnold Aspelin, Chief
Economics Analysis Branch
Benefits and Use Division (TS-768-C)

Attached is a copy of the Propazine Briefing Materials package for review and concurrence.

cc: Jack Housenger/Jud Andreasen
Al Jennings

Bill/Arnie,
Nice job! Please hand it to Jim and Art, and forward to AD.
Paul L
12/15

RECEIVED
DEC 14

BRIEFING MATERIALS

Propazine Usage and Benefits Overview

Usage Summary

Propazine is a selective, preplant and preemergent herbicide registered for control of weeds in sorghum, for control of vegetation in areas where no crops are grown, and control of weeds in lily bulbs (Oregon, Special Local Need). Essentially all of the propazine used is applied to sorghum. The Agency is not aware of any data which indicate significant current usage of propazine on non-crop land or for control of weeds in lily bulbs in Oregon.

Yearly use on sorghum ranges from 1,700,000 to 2,600,000 pounds of active ingredient. Acres of sorghum treated have ranged from 1,600,000 to 2,000,000 acres with a typical treatment of about one pound active ingredient per acre. Propazine accounts for somewhat less than ten percent of all acre-treatments of herbicides on sorghum. The majority of propazine use occurs in Texas and Kansas where it provides thirty-five percent of herbicide acre-treatments of Texas sorghum and eight percent of herbicide acre-treatments of sorghum in Kansas. Small amounts of propazine are used in Colorado, Oklahoma and Nebraska.

Biological Overview

Propazine controls a number of broadleaf weeds and a few grasses. In the sorghum growing regions of the US, these weeds include pigweed, cocklebur, green foxtail, lambsquarter, ragweed, kochia and sunflower.

Less than one-half of the propazine is applied with other herbicides. The herbicide most commonly applied with propazine is metolachlor, but atrazine, alachlor, cyanazine and terbutryn are also tank-mixed with propazine. These tank mixes are used to provide control of a greater number of weed species for a longer period of time than could be achieved with the use of a single herbicide.

There are limitations to each of most widely used alternatives to propazine. Atrazine is the preferred herbicide on sorghum acreage except on alkaline (high pH) soils where atrazine may be phytotoxic (cause injury) to young sorghum plants. About one-sixth of the US sorghum crop is grown on these alkaline soils. Propazine can also be phytotoxic on these soils, but this occurs less often than with atrazine.

Other herbicides are used to a lesser degree on sorghum. Alachlor and metolachlor control some of the same weeds as propazine, but are phytotoxic to sorghum unless a seed safener (a coating that partially neutralizes the effect of these herbicides) is used. Even if a safener is used, when cold wet weather occurs after planting, phytotoxicity may result because the sorghum seed both germinates more slowly in cold soil and grows more slowly through the pesticide layer and because the safener is diluted more in wet soil. Alachlor and metolachlor are mainly used for control of annual grasses and are also less effective than propazine against broadleaf weeds. Terbutryn controls some of the same weeds as propazine, but retains effectiveness against weeds for a much shorter period. There are registered herbicides other than the alternatives discussed above but they tend to be used less and it is unclear how well they would substitute for propazine.

Cultivation could be a possible substitute for propazine usage on sorghum, but would cost more and would probably not totally substitute for use of the chemical. Cultivation may also cause some injury and yield loss from this injury.

Economic Analysis

As discussed above, alternative herbicides to propazine can be used although there is some risk of phytotoxicity. Phytotoxicity from alternative herbicides would not occur every year, but when it occurs yields are reduced. The exact amount of yield reduction is unknown; estimates by contacts in the affected states range up to forty percent for the sorghum acreages on alkaline soils. Forty percent is probably an extreme estimate of the possible yield loss. Even if a loss of this magnitude occurred it would be unlikely that it would occur on all sorghum acreage formerly treated with propazine. Rather, it is probable that yields on some acres would be only slightly reduced while other acres might experience a severe yield loss.

Propazine costs about $2.00 per acre. Alternative herbicides would range in cost from about $2.00 to as much as $20.00 per acre. Cultivation would cost $4.00 per acre per cultivation.

If the extreme case occurs, and if yields on the affected acres are presently equal to average sorghum yields, then a forty percent yield loss would be a reduction of yield from 60 bushels per acre to 36 bushels per acre. Gross revenues would fall from $120 per acre to $72 per acre for a revenue loss of $48 per acre. A more probable yield loss of 10 percent on propazine treated sorghum acreage would lead to a yield reduction of six bushels per acre and a reduction in gross revenues of $12 per acre.

A yield loss of this magnitude would be a one percent reduction in total production of sorghum in the United States. Some of the affected farmers might no longer grow sorghum, but instead would plant another crop.

Table 1. Summary of Benefits for Propazine Use

Use (Site/site category)	Region	Extent of Usage: AI/Year (1000 lbs.)	Extent of Usage: Treatment Units (1000 acres)	Key Pests	Availability of Viable Economic Alternatives	Economic Impact of Cancellation (1987 dollars): Type	Extent	Significance
sorghum	Southwest (CO, KS, NE, OK TX)	1,700-2,000	1,[illegible]-2,000	pigweed cocklebur green foxtail lambsquarters kochia sunflower ragweed	Alternatives available but either cost more or could lead to lower yields on high pH soils if cold, wet weather occurs	User lower yields	0 up to 40% possible yield reductions on some soils in some years. Average effect will probably be much less than 40% and would probably be an average of 10% or less on affected acres.	Quite significant losses for some of the affected farmers if weather is unfavorable
						higher costs	0 up to $20 cost increase per acre	
						Consumer meat price increases	zero or very small	not significant
non-crop	OR	no use		n/a	n/a	n/a	n/a	n/a
lily bulbs	US	no use		n/a	n/a	n/a	n/a	n/a
total		1,700-2,000	1,[illegible]-2,000					

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

February 21, 1986

MEMORANDUM

SUBJECT: Use Data for Exposure Analysis of Terbutryn

FROM: George W. Keitt, Jr., Ph.D.
Chief, Plant Biology Section
Science Support Branch
Benefits and Use Division (TS-768-C)

TO: Joe Reinert
Exposure Assessment Branch
Hazard Evaluation Division (TS-769-C)

The attached database represents an updating and reformatting of previous memos from this branch on this subject, in response to your comments. We trust it will allow you to complete your analysis promptly.

Please contact me on 557-7361 if you have any questions.

Attachment

cc: W. Phillips

006566

USE DATABASE
FOR
EXPOSURE ANALYSIS
OF
TERBUTRYN
ON
WINTER WHEAT AND BARLEY
GRAIN FALLOW LAND
GRAIN SORGHUM

Prepared by

James G. Saulmon, Ph.D.
Botanist
Plant Biology Section
Science Support Branch

George W. Keitt, Jr.
Chief, Plant Biology Section
Science Support Branch

U.S. Environmental Protection Agency
Office of Pesticide Programs
Benefits and Use Division
Washington, DC 20460

February, 1986

Introduction

This biological database was developed to support the exposure analysis of terbutryn (080813) uses. Terbutryn is manufactured by Ciba-Geigy and marketed as an 80% wettable powder under the trade name Igran 80W. The chemical name is 2-(tert-butylamino)-4-(ethylamino)-6-(methylthio)-s-triazine (2).

Terbutryn is registered for use on winter wheat, winter barley, grain sorghum, fallow grain lands, and non-crop land areas (10, 11).

Wheat use is limited to Washington, Oregon, Idaho, and Utah. Barley use is limited to Washington, Oregon, and Idaho. Fallow land use has the following limitations: wheat/sorghum/fallow, none; wheat/corn/fallow, Kansas and Nebraska; wheat/fallow/wheat, Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, and Wyoming; wheat/fallow/wheat or sorghum/fallow/wheat, Great Plains, including Oklahoma and northern Texas. It may be applied preemergence or postemergence. Preemergence activity requires moisture to move terbutryn into the soil where it is taken up by the roots of germinating weeds. Postemergence activity involves uptake through the leaves of young weed seedlings, and prevention of growth of later-germinating weeds (2).

When a range of rates is given (e.g., for terbutryn alone), the lower is used on soils that are coarse textured or low in organic matter. The higher rate is to be used on relatively fine-textured soils or those high in organic matter (2).

About one-third of the terbutryn used in the U.S. is applied to winter wheat or winter barley, in the northwest, and about two-thirds is applied to grain sorghum (1). The leading sorghum producing states are Nebraska, Kansas, Oklahoma, and Texas, which together account for about 75 percent of the U.S. production. Usage on non-crop sites is very small (34).

Igran 80W is registered for the following tank mixes:
- Winter wheat and barley: metribuzin; 2,4-D; MCPA; bromoxynil; dicamba; or chlorsulfuron.
- Grain sorghum: atrazine; propazine; atrazine + paraquat,
- Fallow land, (wheat-fallow-wheat): atrazine; 2,4-D; paraquat; cyanazine; metribuzin.
- Non-crop sites: atrazine; simazine (2).

For aerial application, terbutryn is to be applied with low-drift nozzles at a maximum pressure of 40 psi, from a height not above 10 feet, at a spray volume of at least 5 gal/A (2).

For ground application, terbutryn is to be applied with fan-type nozzles at 35-40 psi in a spray volume of at least 20 gal/A. Screens in nozzles and in suction equipment and in-line strainers should be no finer than 50-mesh (2).

MIXING/LOADING DIRECTIONS:

Label directions for applying terbutryn alone or with atrazine or propazine to grain sorghum are the same as for wheat and barley in regard to the spray volume per acre: at least 5 gal./A for aerial, and 20 gal./A for ground spray (2). The tank mix of terbutryn and atrazine + paraquat calls for dilution to 20-40 gal./A. A nonionic surfactant such as X-77® is required at 1-2 pts./100 gal. of diluted spray. Water or nitrogen fertilizer solutions may be used as a carrier. Therefore, a value of 20 gal/A would represent the most efficient dilution as well as the "worst case" exposure (2).

For all uses, mixing directions call for continual agitation in the tank during mixing. If the agitation depends upon the forward motion of the spray rig, then the Igran 80W should be premixed with a small amount of water in a separate container; the resulting slurry is then added to the spray tank partially filled with clean water, and the rest of the water added. [The directions do not mention rinsing the slurry container, but this is obviously desirable in order not to waste herbicides and to prevent disposal problems.] Igran 80W is sprayed as a suspension, and continuous agitation is required until the tank is emptied. If the spray mixture is allowed to stand in the tank, agitation for several minutes is needed in order to assure uniform suspension. The spray rig is to be thoroughly rinsed with clean water immediately after use (2).

Rationale for site selection

Exposure scenarios will be presented for winter wheat/barley, wheat/fallow, and for grain sorghum, as they account for nearly all of usage (1,34). Both aerial and ground applications will be considered, because each is significant. Appplications on "railroad rights-of-way and on other non-crop land sites" are not analyzed herein because information on the extent and variety of such usage is not available at this time. Preliminary indications are that such usage is very slight (1, 34). There is a potential for increased application exposure from the possible use of hand-held equipment on small industrial sites, for example, but we have no data from which to construct a "typical" use scenario, or to show that such usage in fact occurs.

Use Related Exposure Scenarios

1. Winter wheat/barley

Information gathered from extension personnel, company representatives and other sources in Washington, Oregon, and Idaho is summarized in Table 1. Crop acreage values are taken from Agricultural Statistics 1985 (4); farm sizes are estimated from the 1982 Census of Agriculture (3). Ranges of various parameters are indicated, along with our best estimate of the most useful case to use for exposure analysis. It is recognized that there are wide ranges of farm size, equipment size, and personal farming practices to consider. This analysis assumes that for the most part a farmer's equipment is in scale with the size of the farm, and the most efficient practices are used. It also assumes that the largest farms are treated by air, and that commercial ground applicators treat about the same sizes of farms as do private grower applicators. The upper end of the use rate range for terbutryn is assumed to be the "worst case"; however, nearly all terbutryn is applied in tank mixes of various kinds in these crops (22, 34). The label rate for tank mixes is 0.8 lb. ai/A. Ciba-Geigy indicates that the average rate is 1.1 lb. ai/A (34). The gallons/A of spray are taken as the minimum label rates.

Application will usually be made in the fall, mid September - November 1, otherwise in early spring. Therefore, protective clothing can be expected to be worn as far as air temperatures are concerned. We have no data on the extent to which the label-recommended gloves and long-sleeved coveralls are actually used. It is reported (23) that gloves are generally worn while mixing/ loading.

2. Fallow lands

Terbutryn is registered for use on fallow lands used in the following rotations:

Wheat/sorghum/fallow (any state)
Wheat/corn/fallow (KS, NE)
Wheat/fallow/wheat (CO, KS, MT, NE, ND, SD, WY; Great Plains, including OK and northern TX)
Sorghum/fallow/wheat (Great Plains, including OK and northern TX)

The label rate of terbutryn for all these is 1.6 - 2.0 lb. ai/A (2). Actual usage is reported to be close to 1.1 lb. ai/A (34).

ADDENDUM to p. 3, Table 5

E/ 6 Tel. call

Jim Keller

006566

re:
Terbutryn p. 3.

1.1 lb ai

label rate – 5% alm

Table p. 5

Tex p. 3

~~Abate~~

95% – 1.1 lb ai | artificial #

go with label rates.

I recommend: use 2.2# ai rate

(2.2) .6

(2.2 =)

I told her to use for worst case 2.2 lb ai

Don't think very many people will apply it at 1.1 lb ai e.g. if tank mix rate were

The parameters for use of terbutryn alone on fallow land in a wheat/fallow/wheat rotation are the same as for winter wheat and barley, except that application to fallow land is usually made either in the late spring, following winter wheat harvest, or in summer (late July or August) (5) following spring wheat harvest (2, 13). Tank mixes for these fallow treatments may include atrazine, paraquat, 2,4-D, cyanazine and metribuzin, depending on the State in which they are used (2).

3. Grain sorghum

The following information is based on phone contacts with extension and Industry personnel and other sources in NE, KS, OK, and TX. Crop acreages were derived from Agricultural Statistics, 1985 and farm sizes from state specialists for crops and the Census of Agriculture, 1982.

Terbutryn may be applied pre-plant incorporated or preemergence to grain sorghum, either alone or in tank mixes with atrazine or propazine. No-till sorghum may be treated preemergence with terbutryn plus atrazine and paraquat, with the optional addition of 2,4-D (2).

Labelled use rates for terbutryn alone for annual broadleaf and grass weed control range from 1.6 - 2.4 lb. ai/A, and for annual broadleaf weed control only, from 0.8 - 1.6 lb ai/A. The rates depend on soil texture, the higher rates being used on fine-textured soils. Terbutryn rates, when tank-mixed with propazine or atrazine, are 1.6 - 2.0 lb ai/A. Terbutryn rates when tank mixed with atrazine and paraquat (± 2,4-D) for no-till sorghum are 1.6 - 2.0 lb ai/A (2).

A "worst case" exposure would involve using 2.4 lb. ai/A on fine soils. However, field experts indicate that 2.0 lb. ai/A is the most widely used rate (19,20,21). The tank mix rate is most commonly 1.6 lb. ai/A (18). It is estimated that terbutryn is used alone on about 75 percent of the sorghum acres to which it is applied, and 25 percent in tank mixes (7-10, 17-21,37). Because the maximum tank mix rate for terbutryn is 2.0 lb ai/A, this would justify a 2.0 lb ai/A rate as the most probable one.

5

APPENDIX A

Use estimates for exposure analysis of terbutryn's use on winter wheat and winter barley in Washington, Oregon and Idaho

PARAMETER	AERIAL		GROUND			
	Commercial (all)		Private		Commercial	
	range	best estimate	range	best estimate	range	best estimate
Acres planted	5,300,000A					
Acres treated	53,000A					
% applied air/grd	60		35		5	
Acres/farm in wheat	200-2000	500	50-500	300	50-500	300
applic. rate 5% alone (lb ai/A) 95% TM	1.2-2.2 .6- .8	2.2 .8	1.2-2.2 .6- .8	2.2 .8	1.2-2.2 .6- .8	2.2 .8
gallons/tank	125-150	150	300-500	300	300-700	350
gallons/acre	5-10	5	>20	20	>20	20
flaggers	no	no	N/A	N/A	N/A	N/A
acres/tank	30-50	50	15-50	17	15-70	19
lbs ai/tank	60-110	110	18-110	37	18-154	42
acres treated/day	250-300	300	100-150	150	100-150	150
tank loads/day	5-10	6	2-10	9	2-10	8
hrs worked/day	6-12	8	5-12	10	8-12	12
days/year	1-25	3	.5-3.5	2	1-30	15
open/closed system	open	open	open	open	open	open
protective devices used/load	1/		1/		1/	

1/ Information on actual use of protective clothing and devices was not obtainable.

NOTES ON APPENDIX A

(Winter wheat/winter barley WA, OR, ID)

Acres planted: (harvested)	From the Agricultural Statistics, 1985. Refs. 4, 6 and 22-24.
Acres treated:	Estimated by refs. 6, 22-24 and 34-36.
Acres/farm in wheat:	Estimated from data in the Census of Agricultural, 1982 for Washington, Oregon, and Idaho. Refs. 22-24.
Percent applied, air/ground:	Estimated by refs. 22-24, 34 and 35-36. The proportion of pvt. vs. commercial ground application is based on the assertion that commercial application by ground in that region is not great.
Application rate:	Range is taken from label rates. The maximum values are used to give "worst case". Because label rates are often greater than minimally necessary (to avoid poor performance under conditions of uneveu application, etc.), a lower rate (say 1.1 lb./A on average) might be commonly used. We have at present no confirmation of this. Note that because nearly all is applied as tank mix, the average rate will be close to 1 lb. ai/A. Refs. 2, 6, 22-24, 34 and 36.
Gallons/tank:	Estimated by refs. 6, 12, 16 and 22-24.
Gallons/acre:	Volume of finished spray per acre based on label information (2). The minimum values are assumed to be most efficient and also "worst case". Refs. 6, 12 and 22-24.
Flaggers:	This information was supplied by refs. 6 and 22-24.
Acres/tank:	Derived by dividing gal./tank by gal./A. Refs. 6, 12 and 22-24.
Pound ai/tank:	Derived by multiplying acres/tank by lb. ai/A.

Winter Wheat/Winter Barley

Acres treated/day: Based on these parameters, derived from data on agricultural aircraft (A,B), estimates (F, G, H, I) and calculations (C, D, E, J, K).

			Ground	
		Aerial	Private	Commercial
A.	Boom length, ft.	40	40	60
B.	Speed, mph.	120	5	8
C.	Acres/mile = A X 5280/43,500	4.86	4.86	7.28
D.	Spray hr./A = (1/B)(1/C)	0.0017	0.04	0.017
E.	Spray hr./load = D X A/load	0.086	0.4	0.26
F.	Turn time as % of spray time	100	10	10
G.	Turn time/load	0.086	0.04	0.026
H.	Loading time/load (hr.)	0.10	0.15	0.15
I.	Ferry time/load (hr.)	0.05	0.10	0.10
J.	Total time/load (hr.) (E+G+H+I)	0.322	0.69	0.53
K.	Acres/hr. = A/load divided by hr./load	150	15	28

Tank loads/day: Derived from time per load data in previous table and hr. worked/day. Refs. 6 and 22-24.

No. of hours per day: Aerial applicators are generally limited to a 3-4 hr. windless period each morning. We understand from ref. 6 and 22-24 that sometimes full days are flown when there are no nearby crops on which drift could fall.

Private applicators are assumed generally to work an 8-hr. day because their acreage is treatable in that time in 1-2 days. They could, of course, work longer using headlights, and may do so if operating a large spread. Commercial applicators are assumed to work longer each day to assure that timely applications are made. Refs. 22-24.

No. of days/worked/ yr.:	The range for aerial applicators was derived from the 30-day application window by assuming 25 days would be workable in that period (6). The best estimate assumes that because only 10% of the crop in an area is treated with terbutryn, pilots do not travel more than about 25 miles from their home base, that the use of terbutryn is widely distributed rather than in one area, and therefore, many pilots are applying a little rather than few pilots applying much. Refs. 22-24. The range for private application represents the days needed to cover the smallest to the largest farm likely to be sprayed by a single operator (500A). The range for commercial applicators was taken to cover the entire application window. Considering the small percentage ground-applied by commercial applicators, it was felt that at most one such applicator might apply terbutryn 5 times as many days/yr. as a private applicator would.
Open/closed system:	Information supplied by refs. 6 and 22-24.
Protective devices used:	No information was available as to actual use practices in this regard. Refs. 6 and 22-24.

APPENDIX B

Use data estimates for exposure analysis of terbutryn use on grain sorghum in Kansas, Nebraska, Oklahoma and Texas

PARAMETER	AERIAL		GROUND			
	Commercial (all)		Private		Commercial	
	range	best estimate	range	best estimate	range	best estimate
Acres planted			10,120,000			
Acres treated	(ca 8.5%)	850,000	(includes ca. 150,000 fallow)			
% applied air/ground		33	60		7	
No. acres/farm	100-1000+	350	10-600	150	100-800	200
applic. rate alone (lb ai/A) TM	0.8-2.4 1.6-2.0	2.0 1.6	0.8-2.4 1.6-2.0	2.0 1.6	0.8-2.4 1.6-2.0	2.0 1.6
gallons/tank	200-300	250	200-300	200	200-300	300
gallons/acre	>5	5	>20	20	>20	20
flaggers 1/	2-10%	5%	N/A	N/A	N/A	N/A
acres/tank	40-60	50	10-15	10	10-15	15
lbs ai/tank alone TM	32-144 64-120	110 88	8-36 16-30	20 16	8-36 16-30	30 24
acres treated/day	250-600	450	100-150	125	150-200	150
No. tank loads/day	4-15	9	8-12.5	12.5	10-15	10
No. hrs worked/day	3-10	3-4	4-10	8	4-12	10
No. mixer/loader hours/day	0.7-4	1.7	1.3-3.1	2.1	1.7-2.75	1.7
No. aerial applicators	77-894	77-447	N/A	N/A	N/A	N/A
No. days worked/year	1-25	4-6	1-4	2	1-30	5
open/closed system	90-95%open 5-10%closed	93%open 7%closed	open	open	open	open
protective devices used in loading	2/	2/	2/	2/	2/	2/

1/ No special clothing was reported for flaggers

2/ For mixers/loaders, an estimated 75% use coveralls & gloves, 25% use goggles, 5-10% use masks, 75% use gloves, 50% use coveralls.

NOTES ON APPENDIX B

(Grain Sorghum NB, KS, OK, TX)

Acres planted: (harvested)	USDA Crop Reporting Service, 1985 data. Refs. 4, 14 and 15.
Acres treated:	Estimated from regional contacts, refs. 17-21 and 33,34,37.
No. acres/farm:	Estimated from farm size distribution data in U.S. the Census of Agriculture, 1982. The ranges and best estimate assume the sizes of farms likely to be treated by each mode. Refs. 3, 7-9, 14, 17-21.
Percent applied by air vs. ground:	Estimated by refs. 7, 9, 17-21 and 33.
Application rates:	Ranges are from lowest to highest labeled rates. Best estimate is based on Ciba-Giegy's informal estimate (34, 37). This may reflect not only considerable usage on coarse soils, but also the fact that label rates are often somewhat higher than minimally necessary, to assure good weed control despite uneven application, etc.
Gallons/tank:	Based on estimates, from regional experts refs. 7-9, 16 and 17-21.
Gallons/acres:	Lowest label rates are used, as being most efficient. Refs. 7-9, 17-21 and 34.
Flaggers:	The percent values represent the proportion of flights involving living flaggers. Most operators use mechanical markers (17-21).
Acres/tank:	The values are derived by dividing the gallons per tank by gallons per acre Refs. 7-9, 17-21.
Pounds ai/tank:	The range extends from the lowest concentration (0.8 lb. ai/A) in the smallest tank to the largest concentration in the largest tank (2). The best estimate values are derived by multiplying the best estimates of lbs. ai/A value by the acres/tank value.

Grain Sorghum

Acres Treated/day: Based on these parameters derived from data on agricultural aircraft (A, B), estimates (F, G, H, I) and calculations (C, D, E, J, K).

		Aerial	Ground Private	Ground Commercial
A.	Boom length, ft.	40	40	60
B.	Speed, mph.	120	5	8
C.	Acres/mile = A X 5280/43,500	4.86	4.86	7.28
D.	Spray hr./A = (1/B)(1/C)	0.0017	0.04	0.017
E.	Spray hr./load = D X A/load	0.086	0.4	0.26
F.	Turn time as % of spray time	100	10	10
G.	Turn time/load	0.086	0.04	0.026
H.	Loading time/load (hr.)	0.10	0.15	0.15
I.	Ferry time/load (hr.)	0.05	0.10	0.10
J.	Total time/load (hr.) (E+G+H+I)	0.322	0.69	0.53
K.	Acres/hr. = A/load divided by hr./load	150	15	28

Aerial applicators, limited to several hrs. of morning flight, may cover 450 acres in 3 hours, or 600 acres in 4 hrs. The low estimate of 250 considers that the applicator applies terbutryn to one farm only in the course of the day, whereas the larger value assumes applying only terbutryn that day. The 450 figure allows for working more than one farm; it would be possible to cover 600 acres on one farm in a half day (4 hr). Refs. 17-21.

Private ground applicators can cover 15 A/hr. which means it takes 8 1/3 hrs. to do 125 acres. If 2 meal breaks of 1-hr. each are added, this can be done in one work day of 10 1/3 hrs. To do an entire 150 acres requires 10 hrs. Since the applications will be made in the shorter days of fall or spring, the work may be divided into two 5-hr. sessions, or 8 hrs. plus 2 hrs. A meal break needs to be added (use 1 hr.) for full days (e.g. 9 hr. in the field). Refs. 17-21.

Grain Sorghum

No. of hours worked per day: Aerial applicators are generally limited to a 3-4 hr. windless period each morning. We understand from refs. 7-9 and 17-21 that sometimes full days are flown when there are no nearby crops on which drift could fall.

Private applicators are assumed generally to work an 8-hr. day because their acreage is treatable in that time in 1-2 days. They could, of course, work longer using headlights, and may do so if operating a large spread. Commercial applicators are assumed to work longer each day to assure that timely applications are made. Refs. 7-9 and 17-21.

No. of aerial applicators: Calculated per refs. 25-32.

No. of days/worked/yr.: The range for aerial applicators was derived from the 30-day application window by assuming 25 days would be workable in that period. The best estimate assumes that because only 10% of the crop in a area is treated with terbutryn, pilots do not travel more than about 25 miles from their home base, that the use of terbutryn is widely distributed rather than in one area, and therefore, many pilots are applying a little rather than few pilots applying much. Refs. 6 and 22-32.

Open/closed system: This information came from refs. 7-9 and 17-21.

Protective devices: This information was supplied by refs. 7-9 and 17-21.

No. of mixer-loader hr./day: Calculated per ref. 7-9 and 17-21.

2/12/86 006566

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15. Gary Nelson, 1/16/86. USDA, Crop Reporting Service, Washington, DC (202) 447-9526.

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17. Dr. Erick B. Nilson, 10/31/85. Manhattan, KS. grain Sorghum. (913-532-6011). [see also ref. #7].

18. Dr. Alex Martin, 10/30/85. Lincoln, NB. grain Sorghum. (402-472-1527). [see also ref. #7].

19. Dr. Howard Greer, 10/31/85. Stillwater, OK. grain Sorghum (405-624-6420). [see also ref. #7].

20. Dr. Allen Wiese, 10/31/85. Buckland, TX. grain Sorghum (806-378-5710). [see also ref. #7].

21. Dr. Dave Weaver, 10/30/85. College Station TX. grain Sorghum (409-845-4808). [see also ref. #7].

22. Dr. Dean Swan, 11/14/85. Pullman, WA. Winter Wheat/Winter Barley (509-335-2961). [see also ref. #6].

23. Dr. Russ Karrow, 11/14/85. Corvallis, OR. Winter Wheat/Winter Barley (503-754-2771). [see also ref. #6].

24. Dr. Steve Dewey, 11/15/85. Logan, UT. Winter Wheat/Winter Barley (801-750-2256). [see also ref. #6].

25. Mrs. Beardsley, 1/17/86. Federal Aviation Administration (FAA), Washington, DC (202-426-3791)

26. William Steward, FAA, 11/17/86. Lincoln, NB (FTS; 541-5485; Comm: 402-471-5485).

27. Gerald Mertens (or Mr. Richardson), 1/17/86. FAA, Wichita, KS. (FTS: 752-7016; Comm: 316-946-4462).

28. John Hammert (or Charlie Taylor) 1/17/86. FAA, Oklahoma City, OK. (FTS: 736-4196; Comm: 405-789-5220).

29. Phillip Cramer, 1/17/86. FAA, Dallas, TX. (FTS: 729-8479; Comm: 214-357-0142).

30. George Masterson, 1/17/86. FAA, Houston, TX. (FTS: 526-5882; Comm: 713-643-6504).

31. Ray Terry, 1/17/86. FFA, Lubbock, TX. (FTS: 738-7675; Comm: 806-762-0335).

32. Walter Ernst, 1/17/86. FAA, San Antonio, TX. (530-5121 (discontinued)); Comm: 512-824-9535)

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36. Vern Neilsen, 2/10/86. Ciba-Geigy Corp. Oregon. Winter Wheat/Winter Barley. (503-666-3528)

37. Stan Cruitt, 2/11/86. Ciba-Geigy Corp. Greensboro, NC. Grain Sorghum. (1-800-334-9481)

006566

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

JUN 12 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Propazine: Quantitative Risk Assessment of Two-Year Chronic Oral Study in Female Rats (IRDC Report No.382-007; April 28, 1980). Caswell # 184.

FROM: C.J. Nelson, Statistician
Scientific Mission Support Staff
Toxicology Branch, HED (TS-769)
cjnelson 6/12/87

TO: William Dykstra, Ph.D., Toxicologist
Section III
Toxicology Branch, HED (TS-769)

THRU: Richard Levy, M.P.H.,Leader-Biostatistics Team
Scientific Mission Support Staff
Toxicology Branch, HED (TS-769)
Richard Levy 6-12-87

and

Reto Engler, Ph.D., Chief
Scientific Mission Support Staff
Toxicology Branch, HED (TS-769)
Reto Engler

Summary:

The potency estimate, Q_1^*, of Propazine [C(q)] is 1.7×10^{-1} $(mg/kg/day)^{-1}$ in human equivalents. This estimate was calculated using the Weibull '82 model and is based upon All+ mammary tumors combined in female rats.

\+ Mammary Gland: Adenoma and/or Adenocarcinoma, Papillary Adenoma and/or Adenomacarcinoma, Fibroadenoma, Cystadenoma, Ductular Adenoma.

Quantitative Risk Assessment:

Since there were significant survival disparities between control and dose groups in the two-year chronic oral study of female rats fed propazine, the potency estimate, Q_1^*, was obtained using the Weibull '82 time-to-tumor model for extra risk. (Reference memo on Qualitative Risk Assessment of Propazine - R. Levy 4/87). The resulting potency estimate in $(ppm)^{-1}$ of Propazine was converted to $(mg/kg/day)^{-1}$ for rats by using Lehmannn's Tables and then to human equivalents in $(mg/kg/day)^{-1}$ on the basis of an interspecies surface area adjustment as recommended by the EPA Cancer Guidelines.

The potency estimate based on all mammary tumors combined in female rats fed propazine for 105 weeks was 1.7×10^{-1} $(mg/kg/day)^{-1}$ human equivalents. A potency estimate was also calculated for malignant tumors combined and was 5.9×10^{-2} $(mg/kg/day)^{-1}$ human equivalents. For comparison, the human equivalent potency estimate on all mammary tumors combined was 1.3×10^{-1} $(mg/kg/day)^{-1}$,and the human equivalent potency estimate on malignant mammary tumors combined was 5.3×10^{-2} $(mg/kg/day)^{-1}$ using the Crump multistage procedure.

006546

DRAFT

PROPAZINE

OUTLINE

DRAFT

I. ISSUE

Based on data submitted to the Agency showing that propazine is a potential human oncogen, should a Special Review be initiated at this time?

II. BACKGROUND

A. Description and Use

Propazine (2-chloro-4,6-bis (isopropylamino)-s-triazine) is a selective, pre-emergent herbicide used to control grassy and broadleaf weeds on sorghum. It is manufactured by Ciba-Geigy under the trade names Milogard, Milocep (propazine and metolachlor) and Maxx 90. Other names are Milo-Pro and Tide Weed and Feed. Formulations include 80% and 90% wettable powders, a 90% water dispersible granule (Maxx 90), an 18.7% (1.7 lb/gal. a.i.) flowable concentrate (Milocep), and 43 - 44.5% (4 lb/gal. a.i.) flowable concentrates and wettable powders formulated with atrazine, simazine, linuron and norea. More than half of the propazine is marketed as a single active ingredient product.

Virtually 100% of the propazine used in the U.S. is for weed control on sorghum. It is also registered as a preemergence application (SLN) on lily bulbs in Oregon, and as a general application in non-crop areas. 90% - 95% of propazine use on sorghum occurs in Texas and Kansas, which collectively produce 50% - 60% of the U.S. sorghum crop. Small amounts of propazine are used in Colorado, Oklahoma and Nebraska, and the Agency is unaware of any recent non-crop use.

Yearly use on sorghum ranges from 1.7 to 2.6 million pounds of active ingredient on 1.6 to 2.0 million acres, with a typical treatment of about 1 lb a.i./acre. Propazine accounts for 10% to 15% of all acre-treatments of herbicides on sorghum, primarily on alkaline soils where it can be used with less phytotoxic effects than other herbicides. About 1/6 of the U.S. sorghum crop is grown on these alkaline soils.

B. Regulatory History

There are nine registrants of products containing propazine, which has been in use in the U.S. since 1958. Currently, there are approximately 22 products, of which 7 are herbicide mixtures. There are 4 intrastate registrations, all of which are herbicide mixtures. Tolerances were established in 1968 for 0.25

ppm propazine in sorghum grain, forage and fodder. New analytical methodology now permits the detection of mono-dealkylated and di-dealkylated chloro metabolites G-30033 and G-28273. Consequently, the registrant has proposed a revised tolerance of 1.0 ppm for the combined residues in fodder and forage. Also proposed are tolerances in meat, milk, poultry and eggs. The established tolerance of 0.25 ppm for grain was maintained.

There have been 2 data call-in (DCI) letters on propazine. All data had already been submitted for the general chronic DCI issued on 3/31/83, but many studies were reviewed and found to be unacceptable. Additional studies are required by the Registration Standard. The second was an environmental fate DCI on 7/18/84 to address ground water concerns. All required data were submitted in 1985 by Ciba-Geigy, have been reviewed, and are acceptable. By late February 1988, a third DCI will be issued calling for a small-scale, retrospective ground water monitoring study.

III. BASIS FOR CONCERN

A. Toxicity

1. Oncogenic Effects

Two acceptable studies are available to determine propazine's oncogenicity, one each on mice and rats. The mouse study indicated no evidence of tumorigenic effects at dietary concentrations up to and including 3000 ppm, but the rat study was positive for oncogenicity.

a. Rat Study

OPP reviewed a 2-year chronic feeding study on rats conducted in 1980 by International Research and Development Corporation (IRDC). Sixty male and 60 female CD rats/dose were selected randomly and given 0, 3, 100 and 1000 ppm of propazine in their diets for 2 years. Gross necropsy showed an increase in subcutaneous masses and nodules in females of the 1000 ppm dose group, which correlated with an increase in mammary neoplasms. These neoplasms included ademonas, adenocarcinomas, fibroademomas, and papillary adenomas. The increase in tumor-bearing animals was statistically-significant and considered compound-related. The percent incidence (37.7%) of malignant mammary tumors at 1000 ppm in female rats exceeds the upper limit of the range in the historical controls for carcinoma and fibrosarcoma (21.4% and 1.7% respectively), and the percent incidence (76.4%) of all mammary tumors at 1000 ppm in female rats exceeds the percent incidence of all mammary gland tumors in the controls (48.3%). The systemic/oncogenic NOEL is 100 ppm.

b. Mouse Study

The same test was done on 60 male and 60 female CD-1 mice/dose (IRDC, 1980), at dose levels of 0, 3, 1000 and 3000 ppm, and propazine was not found to be oncogenic. There were significant incidences of non-neoplastic lesions in high-dose males, and myocardial degeneration in high-dose females. The oncogenic NOEL is > 3000 ppm and the systemic NOEL is 1000 ppm for mice.

c. Other Evidence of Oncogenicity

Triazine compounds related structurally to propazine are atrazine, terbutryn, cyanazine and simazine. Like propazine, atrazine and terbutryn test positive for mammary tumors in the rat. Oncogenic studies for cyanazine and simazine are in progress (due 1990 and 1988, respectively). The lowest effective cancer dose (LECAD) for the 3 triazines known to be carcinogens are: atrazine 70 ppm, terbutryn 3000 ppm, and propazine 1000 ppm.

d. Oncogen Classification/Potency

In January of 1987, the cacinogenicity of technical propazine was reviewed by the EPA Carcinogen Assessment Group/Office of Research and Development (CAG). They concluded that the propazine data imply a sufficiently positive effect in the female rat to suggest that such an effect is possible in humans similarly exposed to propazine in the diet. Propazine was classified as a Group C oncogen, a possible human carcinogen.

In August of 1987, the HED Peer Review Committee unanimously agreed that propazine should be classified as a Group C oncogen, based on the findings for oncogenicity in one species (rat). They also agreed that a quantitative risk assessment should be performed on propazine, based on the progression to malignant tumors, the strong structural-activity relationships of propazine to symmetrical triazine herbicides, and the positive response in one of the mutagenicity assays (Chinese hamster). The human equivalent potency estimate (Q_1*) of propazine is 1.7×10^{-1} (mg/kg/day)$^{-1}$, calculated using the Weibull '82 model, and is based on all mammary tumors combined in female rats. The human equivalent potency on malignant mammary tumors only was 5.3×10^{-2} (mg/kg/day)-1.

2. Other Effects

Technical propazine is classified in Toxicity Category IV for acute oral toxicity, and Category III for acute dermal toxicity. In 2 rat oral gavage studies, propazine did not produce any frank teratogenic effects at the high dose levels (500, 600 mg/kg/day). In a 3-generation rat reproduction study, no compound-related effects in fertility, gestation or survival were observed from propazine administration.

Propazine produced a mixed response in a battery of mutagenicity tests. In a gene point mutation study (V79 Chinese hamster cells) propazine induced a dose-related, positive mutagenic response (without metabolic activation), and a weak non-dose related response with activation. It was not found to be mutagenic on hamsters in a Nuclear Anomaly assay, nor on rat hepatocytes in a DNA damage/repair assay.

B. Exposure and Risk

1. Dietary

Dietary exposure to propazine can occur from residues in or on sorghum, or from residues in meat, milk, poultry and eggs which result from feeding livestock propazine-treated sorghum grain, forage and fodder. There are existing tolerances for propazine on sorghum grain, forage and fodder (0.25 ppm). However, because new analytical methodology exits which permits detection of propazine metabolites, the registrant has proposed new tolerances. These proposed levels do not reflect any change in the current use pattern for propazine, but rather inclusion of the metabolites in the tolerance expression. These levels (petition #2F2618, 12/14/81) are as follows:

sorghum grain	0.25 ppm
sorghum forage and fodder	1.0 ppm
milk and eggs	0.02 ppm
meat and meat by-products	0.05 ppm
poultry	0.05 ppm
kidney and liver	0.1 ppm

In March 1987, the Toxicology Branch ADI Committee established a Provisional Acceptable Daily Intake (PADI) of 0.02 (mg/kg/day) for propazine. The decision was based on the 2-year rat feeding/oncogenicity study in which in which the systemic NOEL was set at 100 ppm, based on significant depression in body weight of both males and females at the high dose of 1000 ppm. The safety factor was 300 based on an uncertainty factor of 100 to account for inter- and intraspecies differences, and an additional factor of 3 to account for the incompleteness of the chronic data base (gaps for chronic dog and rabbit teratology studies).

Assuming the proposed tolerance levels, the theoretical maximum residue contribution (TMRC) is 0.0003 mg/kg/day, equivalent to 1.7% of the PADI. The most highly exposed subgroups are non-nursing infants (0.0014 mg/kg/day, equivalent to 7.2% of the PADI, and children 1 - 6 years of age (0.0009 mg/kg/day, equivalent to 4.3% of the PADI).

HED has suggested that the proposed tolerances be used in estimating dietary exposure The lifetime oncogenic risk using these levels and a potency estimate of 1.7 x 10^{-1} (mg/kg/day)$^{-1}$, is 5.1 x 10^{-5}. Adjusting this risk to account for the fact that only 10 to 15 percent of the U.S. sorghum crop is treated with propazine reduces this risk to 7.7 x 10^{-6}. Since tolerances in meat, milk, poultry and eggs are set at the limit of detection, rather than at measurements of actual residues, actual risk is expected to be lower than the calculated estimate.

2. Non-Dietary

Non-dietary exposure to propazine can result from mixing/loading operations and application of the pesticide.

In December 1987, BUD submitted rough, preliminary use data on propazine to update a 1982 assessment. EAB calculated exposure based on the range of typical use data provided by BUD for propazine, and using surrogate data from atrazine and terbutryn studies. Assumptions were that mixer/loaders (M/L) and applicators (A) wear long sleeves and long pants, and M/L wear gloves. The current label does not require any protective clothing for M/L/A or flagmen. The average farm size was assumed to be 200 acres, and exposures to M/L using closed and open pour systems were calculated separately. Commercial ground crews can cover approximately 100 acres/day, and aerial crews can treat appoximately 200 acres/day. The range of exposure is based on the use of 1 to 2 lbs of active material per acre, and it is assumed that a farmer functions as both M/L and A. The exposure range for commercial applicators is based on the number of workdays per year, varying from 10 to 30 for ground boom operators and from 6 to 30 for aerial operators.

The annual exposure estimates were divided by 365 for a daily exposure, and the result multiplied by the Q* value to calculate potential oncogenic risk, and by 30/70 to estimate risk over 30 years rather than a lifetime. HED indicates that applicator and mixer/loader exposures could be reduced by up to 80% and 40%, respectively, by replacing open cabs and loading systems with closed ones.

		ESTIMATED ANNUAL EXPOSURE mg/kg/yr	ONCOGENIC RISK
M/L/A	Farmer	3.3 - 6.5	10^{-3} - 10^{-4}
M/L	Commercial-open	13.0 - 80.0	10^{-2} - 10^{-3}
M/L	Commercial-closed	0.21 - 1.3	10^{-4} - 10^{-5}
A	Commercial-boom	3.7 - 22.0	10^{-3} - 10^{-4}
M/L	Commercial-aerial	0.13 - 1.3	10^{-4} - 10^{-5}
A	Pilot	0.04 - 0.4	10^{-5} - 10^{-6}
Flagger		0.22 - 2.2	10^{-4} - 10^{-5}

In calculating risk, a 100% dermal absorption rate was assumed in the absence of actual data. An acceptable dermal absorption study on a similar triazine, terbutryn, indicated up to 20% dermal absorption. Propazine is much less soluble than terbutryn in both water and organic solvents, hence the dermal absorption rate of propazine is likely to be much less than 20% (personal communication, Dr. Zendzian, TOX/HED). A dermal absorption study is required in the Registration Standard.

3. Ground Water

Data submitted in response to the Ground Water DCI led OPP to conclude that propazine has a potential for contaminating ground water. It is persistent, moderately mobile, and stable to hydrolysis, photolysis and microbial degradation.

In January 1988, the Agency issued Health Advisories (HA) for 50 pesticides, including propazine, to which a tentative lifetime HA level of 14 ppb was assigned. The public comment period ends in April 1988. Propazine has been detected in ground water in California, Nebraska and Pennsylvania at trace levels (<0.1 ppb).

STORET data indicate propazine was found in 132 of 1,231 surface water samples analyzed , and in 20 of 1,056 ground water samples, in a total of 8 states. The maximum concentrations found was 20 ppb in surface water and 300 ppb in ground water. The 85th percentile of all nonzero samples was 2.3 ppb in surface water and 0.2 ppb in ground water samples. However, STORET data are not acceptable for regulatory purposes, since the source of information and the monitoring method are unknown. Another DCI will be issued by late February 1988 requiring monitoring studies for propazine and 14 other potential ground water contaminants.

C. Reported Pesticide Incidents

According to HED data (PIMS, California, and other sources of U.S. vital statistics), no deaths, hospitalizations or illnesses requiring absence from work have been reported due to propazine use.

D. Additional Data Required

The Registration Standard will require additional studies, including the following:

Chronic feeding (nonrodent)
Teratogenicity (nonrodent)
General metabolism
Dermal absorption

IV. ALTERNATIVES

There are a number of alternatives to propazine, including alachlor, atrazine, metolachlor and terbutryn. However, there are limitations to each of the most widely used alternatives. Atrazine is the preferred herbicide on sorghum except on alkaline soils where atrazine may be phytotoxic to young sorghum plants. About one-sixth of the U.S. sorghum crop is grown on these alkaline soils. Propazine can also be phytotoxic on these soils, but less frequently that atrazine. The preliminary report of a 2-year rat study on atrazine shows a dose-related increase in the incidence of adenocarcinoma of female rat mammary glands.

Alachlor and metolachlor control some of the same weeds as propazine, but are phytotoxic to sorghum unless a seed safener is used. Even if the sorghum seeds are coated with a seed safener, phytotoxicity may result if cold, wet weather occurs after planting. Alachlor and metolachlor are less effective than propazine against broadleaf weeds. Both of these chemicals are animal oncogens.

Terbutryn controls some of the same weeds as propazine, but retains effectiveness against weeds for a much shorter period. It is a Class C oncogen.

There are other herbicides registered for use on sorghum, but it is unclear how well they would substitute for propazine. Cultivation could be a possible substitute for propazine usage, but it would be more costly and may also cause some injury and subsequent yield loss.

V. SUMMARY

A. TOXICITY

Oncogenicity	Class C
Oncogenic Potency	1.7×10^{-1} (mg/kg/day)-1
Acute Oral	Category IV
Acute Dermal	Category III
Chronic	Systemic NOEL rats = 100 ppm
Mutagenicity	Positive in mammalian cell assay
Teratogenicity	NOEL maternal and developmental toxicity: 10 mg/kg (low dose)

B. EXPOSURE AND RISK

Dietary

Approved Tolerances: 0.25 ppm in forage, fodder and grain.

Proposed Tolerances:
- 1.0 ppm forage/fodder
- 0.25 ppm grain
- 0.02 ppm milk, eggs
- 0.05 ppm meat
- 0.01 ppm kidney, liver.

Oncogenic Lifetime Risk $10^{-5} - 10^{-6}$

Non-Dietary

	Oncogenic Risk
M/L/A Farmer	$10^{-3} - 10^{-4}$
M/L Commercial-open	$10^{-2} - 10^{-3}$
M/L Commercial-closed	$10^{-4} - 10^{-5}$
A Commercial	$10^{-3} - 10^{-4}$
M/L Aerial	$10^{-4} - 10^{-5}$
A Pilot	$10^{-5} - 10^{-6}$
Flagger	$10^{-4} - 10^{-5}$

VI. RECOMMENDATIONS

It is recommended that propazine not be placed in special review at this time. Concerns regarding the potential danger to mixers/loaders/applicators are based on marginal risks, which are highly likely to be lessened by at least one order of magnitude when the dermal absorption study is completed. This expectation is supported by TOX Branch's comparison of propazine's structure and solubility to that of a similar triazine herbicide, terbutryn, which has a dermal absorption rate of 20%. It is expected that propazine will have a dermal absorption rate of 10% or less, rather than the 100% assumed.

At 100% dermal absorption rate, the unacceptable (ie. > 10^{-4}) risks are for farmers, commercial M/L using open systems and commercial ground boom applicators. Except for open system M/L, these risks will be brought to an acceptable level if dermal absorption proves to be 10%. If dermal absorption proves to be greater than 10%, other risk reduction measures such as protective clothing and closed systems could be required.

If the dermal absorption data, which are required by the Registration Standard (to be issued in the third quarter of FY 88), prove to be higher than expected, a PD 1/2/3 would be issued.

In the absence of dermal absorption data, OPP recommends the following interim risk-reduction measures be included in the Registration Standard: the use of maximum, full-body protective clothing (i.e. protective suit covering the body, chemical-resistant gloves, apron and shoes, goggles or a face mask), and the use of closed systems for commercial M/L.

END