

7-15-94



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUL 15 1994

MEMORANDUM:

SUBJECT: EXPOSURE ASSESSMENT FOR USES OF SIMAZINE EC, WP AND WDG FORMULATIONS USING THE PESTICIDE HANDLERS EXPOSURE DATABASE

TO: Walter Waldrop
Product Manager 71
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THRU: Mark Dow Ph.D. Section Head *Mark Dow*
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Health Effects Division (7509C)

Please find below review of:

DP Barcode: D200938

Pesticide Chemical Code: 080807

EPA Reg. 100-526,437,603

EPA MRID No.: 431590-02

PHED: YES- Version 1.01



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I INTRODUCTION:

A. BACKGROUND:

Ciba-Geigy has submitted data on handler exposure to simazine in response to a Data Call-In notice of 9/12/91. The DCI requested exposure monitoring studies for hand-held (directed) spray applications to orchard crops, right-of-way, and tree nurseries; aquatic applications; and all uses of the granular formulation. The response by Ciba-Geigy did not include data for hand-held directed applications which were claimed to be rare or for aquatic applications or rights-of-way. (Aquatic and right-of-way uses have been canceled or withdrawn). Data for the water-dispersible granular formulation, WDG, were included. An exposure assessment for the use of the granular formulation, Princep 4G, is provided in the report "Worker Mixer/Loader and Applicator Exposure to Atrazine" (MRID #430165-06) submitted November 16, 1993. The data submitted contains studies on three products containing simazine applied by ground boom equipment: Princep Caliber 90 WDG, Princep 4L, and Princep 80W. Princep Caliber 90 WDG is a water-dispersible granular formulation containing 90% simazine as active ingredient. Princep 4L is an emulsifiable concentrate formulation containing 41.9% simazine, and Princep 80W is an 80% active ingredient wettable powder formulation.

An Agency memorandum of 5/22/89 (C. Lunchick/HED to E. Saito/HED) stated that data gaps exist for handler exposure during orchard, aquatic, rights-of-way and tree nursery uses of simazine and for the granular formulation. In a memorandum of 10/26/93 (J. Evans/OREB to J. Mitchell/SRRD) OREB stated that surrogate data would be acceptable to fulfill requirements for guideline 231 and 232 for simazine by relying on the Pesticide Handlers Exposure database (PHED). The memo also stated that turf data requirements would be fulfilled by using surrogate data from a study using atrazine. The memo further stated: Surrogate data from PHED are acceptable to the Agency providing there are adequate replicates (15) for the use scenario, formulation type, and the label required PPE. The PPE must also be consistent with the Worker Protection Standard (WPS). The surrogate data from PHED must be at least grade B.

Simazine has been identified as a Group C carcinogen with a $Q^* = 1.2$ (mg/kg/day)⁻¹. Actual dermal absorption has been estimated to be 1% and potential adsorption determined at 32%.

Label precautionary statements for Princep 4L and Princep Caliber 90 require applicators and other handlers to wear long-sleeved shirt and long pants, gloves, and shoes and socks. The label for Princep 80W does not specify use of gloves. This may have been an oversight; use of suitable gloves should be required for this formulation also.

B. PURPOSE:

Review of exposure data for uses of simazine EC, WP and WDG formulations.

II DETAILED CONSIDERATIONS:

In response to the DCI, no data on hand-held application were submitted, since it is claimed that this method of application is not used for the uses identified. It is noted, however, that product labels mention use of spot treatments at least for fruit and nut crops. This implies that application methods by other than ground-boom equipment may be used. The aquatic and right-of-way uses have been canceled or withdrawn. Surrogate data for use of the granular formulation of simazine are provided by the atrazine report: "Worker Mixer/Loader and Applicator Exposure to Atrazine" (MRID #430165-06) submitted November 16, 1993.

In response to Agency memos of 5/22/89 and 10/26/93, Ciba-Geigy has submitted worker exposure data (Subpart U 231 and 232) for orchard, tree nursery and other uses of simazine for several formulation types based on the PHED. The data on turf (sod farms, lawns and fairways etc.) submitted by the registrant are not shown in the Tables for this review as data from the atrazine study are to be considered for this use as indicated in OREB memo of 10/26/93 (J.Evans/OREB to J. Mitchell/SRRD). The reported exposures for these uses may be found in the attached Appendix.

The data submitted are addressed below in the order that they were presented by Ciba-Geigy in MRID# 431590-02, January 4, 1994.

Mixer/loader exposure to the emulsifiable concentrate formulation.

OREB was unable to reproduce exactly all of the summary statistics for calculated exposures that were included in the registrant's submittal by using the indicated subsets. However, this did not cause significant differences in the unit exposure values that were ultimately generated. The registrant summary statistics for total deposition showed only 12 replicates for six of the body parts. Dermal grade uncovered was A and B. The estimation of total dermal exposure from the difference of total dermal "best fit" data and the geometric mean of the hand data may introduce some uncertainty. The inhalation estimates are acceptable (14 replicates). The unit exposures proposed by the registrant for mixer/loader/EC can be considered as marginally acceptable because they are based on fewer than 15 replicates (six of the body parts had 12 replicates) and because of the indirect method used to estimate body exposure.

Mixer/loader exposure to the wettable powder formulation.

The proposed dermal and inhalation exposure assessments for the WP formulation are not acceptable since none of the replicates used were grade A or B. In addition there were only 4 or 5 replicates for six body parts including only 4 replicates for hand exposure.

Mixer/loader exposure to the water-dispersible granular formulation

Using the dry flowable formulation solid type on PHED, the dermal and inhalation unit exposures estimated by the registrant are acceptable with sixteen replicates of A data for a worker wearing protective coveralls over no clothing and gloves.

Applicator exposure to the emulsifiable concentrate formulation.

The dermal and inhalation unit exposure estimates for open cab application are acceptable. The dermal scenario is for total deposition (no clothing) using only A and B data. There are 14 or 16 replicates for most body parts including hands, but only eight replicates for the upper arms. The 50 foot boom length may not be appropriate for all uses. The unit exposures are used for both EC, WP and WDG formulations.

Applicator exposure to the wettable powder formulation.

Unit exposure used was the same as for the emulsifiable concentrate.

Applicator exposure to the water-dispersible granular formulation.

Unit exposure used was the same as for the emulsifiable concentrate.

III CONCLUSIONS/RECOMMENDATIONS:

OREB finds the exposure estimates presented in Tables I, II, III and IV below to be acceptable. Use information is based on the 1987 Census of Agriculture. Unit exposures were estimated by use of PHED. Estimates based on "Total deposition(no clothing scenarios)" can be considered as overestimates of true exposure.

TABLE I- Average Daily Exposure (ADE) to workers applying Princep 4L (emulsifiable concentrate) for various uses		
USE/TASK	Inhalation ADE mg/kg/day	Dermal ADE mg/kg/day
CITRUS		
Mixer/loader	2.0×10^{-6}	1.5×10^{-4}
Applicator	3.4×10^{-6}	2.3×10^{-4}
BLUEBERRIES		
Mixer/loader	1.1×10^{-7}	7.6×10^{-6}
Applicator	1.9×10^{-7}	1.1×10^{-5}
CANE BERRIES		
Mixer/loader	1.5×10^{-7}	9.6×10^{-6}
Applicator	2.5×10^{-7}	1.4×10^{-5}
CRANBERRIES		
Mixer/loader	3.4×10^{-7}	2.5×10^{-5}
Applicator	5.6×10^{-7}	3.8×10^{-5}
STRAWBERRIES		
Mixer/loader	3.7×10^{-8}	3.2×10^{-6}
Applicator	6.3×10^{-8}	4.8×10^{-6}
TREE NURSERIES		
Mixer/loader	3.7×10^{-7}	2.8×10^{-5}
Applicator	6.3×10^{-7}	4.2×10^{-5}

ADE-Average Daily Exposure = yearly exposure (mg/kg/year) ÷ 365 days/year = mg/kg/day

Exposure values are for Mixer/loader open pour -Total deposition (no clothing except gloves) and Applicator-open cab- Total deposition (no gloves).

TABLE II- Average Daily Exposure (ADE) to workers applying Princep 80W (simazine-wettable powder) for various uses		
USE/TASK	Inhalation ADE mg/kg/day	Dermal ADE mg/kg/day
CITRUS		
Mixer/loader	No Data	No Data
Applicator	3.4×10^{-6}	2.3×10^{-4}
BLUEBERRIES		
Mixer/loader	-----	-----
Applicator	1.8×10^{-7}	1.2×10^{-5}
CANEBERRIES		
Mixer/loader	-----	-----
Applicator	2.2×10^{-7}	1.4×10^{-5}
CRANBERRIES		
Mixer/loader	-----	-----
Applicator	5.2×10^{-7}	3.8×10^{-5}
STRAWBERRIES		
Mixer/loader	-----	-----
Applicator	7.7×10^{-8}	4.7×10^{-6}
TREE NURSERIES		
Mixer/loader	-----	-----
Applicator	6.5×10^{-7}	4.2×10^{-5}

ADE-Average Daily Exposure = yearly exposure (mg/kg/year) ÷ 365 days/year = mg/kg/day

Exposure data proposed for Mixer/loader were not of acceptable quality grade. Applicator-open cab- Total deposition (no gloves).

TABLE III- Average Daily Exposure (ADE) to workers applying Princep Caliber 90 WDG (water-dispersible granular) for various uses		
USE/TASK	Inhalation ADE mg/kg/day	Dermal ADE mg/kg/day
CITRUS		
Mixer/loader	7.4×10^{-6}	8.7×10^{-4}
Applicator	3.5×10^{-6}	2.3×10^{-4}
BLUEBERRIES		
Mixer/loader	4.1×10^{-7}	4.5×10^{-5}
Applicator	1.9×10^{-7}	1.2×10^{-5}
CANE BERRIES		
Mixer/loader	4.7×10^{-7}	5.6×10^{-5}
Applicator	2.3×10^{-7}	1.4×10^{-5}
CRANBERRIES		
Mixer/loader	1.2×10^{-6}	1.5×10^{-4}
Applicator	5.8×10^{-7}	3.8×10^{-5}
STRAWBERRIES		
Mixer/loader	1.4×10^{-7}	1.8×10^{-5}
Applicator	6.4×10^{-8}	4.7×10^{-6}
TREE NURSERIES		
Mixer/loader	1.4×10^{-6}	1.6×10^{-4}
Applicator	6.4×10^{-7}	4.2×10^{-5}

ADE-Average Daily Exposure = yearly exposure (mg/kg/year) ÷ 365 days/year = mg/kg/day

Exposure data are for Mixer/loader-open loading-wearing protective overall over no clothing and gloves. Applicator-ground boom/open cab- Total deposition (no gloves)

TABLE IV- Total Average Daily Exposure (ADE) to workers who perform both mixing/loading and application tasks.		
USE/FORMULATION	Inhalation ADE mg/kg/day	Dermal ADE mg/kg/day
CITRUS		
EC Formulation	5.5×10^{-6}	3.8×10^{-4}
WDG Formulation	1.1×10^{-5}	1.1×10^{-3}
BLUEBERRIES		
EC Formulation	3.0×10^{-7}	1.9×10^{-5}
WDG Formulation	6.0×10^{-7}	5.7×10^{-5}
CANE BERRIES		
EC Formulation	4.0×10^{-7}	2.4×10^{-5}
WDG Formulation	7.0×10^{-7}	7.0×10^{-5}
CRANBERRIES		
EC Formulation	9.0×10^{-7}	6.3×10^{-5}
WDG Formulation	1.8×10^{-6}	1.8×10^{-4}
STRAWBERRIES		
EC Formulation	1.0×10^{-7}	8.0×10^{-6}
WDG Formulation	2.0×10^{-7}	2.3×10^{-5}
TREE NURSERIES		
EC Formulation	1.0×10^{-6}	7.0×10^{-5}
WDG Formulation	2.0×10^{-6}	2.1×10^{-4}

ADE-Average Daily Exposure = yearly exposure (mg/kg/year) ÷ 365 days/year = mg/kg/day

WDG = Water dispersible granular formulation

Total exposures for the 80W (wettable powder) formulation are not reported because mixer/loader exposure data for this formulation were not acceptable.

The use information and application rates used in this review are taken from the report as submitted and are generally based on the 1987 Census of Agriculture. Revised and updated use information will be needed from BEAD for simazine and other triazine pesticides.

if special review for these chemicals proceeds. In addition, previous exposure estimates for the use of simazine on corn may need to be revised or updated.

The registrant should be advised that acceptable data are still needed for mixer/loader exposure to the wettable powder formulation. Data are also needed for aerial applications and non-groundboom applications (e.g. spot treatments) of simazine products if these methods are used.

The label for Princep 80W should be amended to include a requirement for wearing appropriate gloves by applicators and handlers.

Attachments: APPENDIX

CC: A.Schlosser/OREB
Chemical file-Simazine-080807
Correspondence

APPENDIX

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED				Obs.
		Median	Mean	Coef of Var	Geo. Mean	
HEAD (ALL)	Other	.52	6.8972	259.4241	1.081	90
NECK.FRONT	Other	.1575	14.1995	646.0284	.3082	82
NECK.BACK	Other	.044	.6563	347.5849	.0796	81
UPPER ARMS	Other	.291	3.8888	128.3635	1.0602	11
CHEST	Other	.71	22.081	363.7304	2.0088	35
BACK	Lognormal	6.035	13.1857	248.0612	2.9485	21
FOREARMS	Lognormal	3.025	6.4194	135.6139	1.6088	19
THIGHS	Other	.382	4.4371	139.7737	1.2413	13
LOWER LEGS	Lognormal	.357	3.0147	130.3911	.9258	12
FEET						0
HANDS	Lognormal	4.1739	6.5207	117.3678	2.0666	39
TOTAL DERM:		9.6542	15.6954	81.3004	13.3288	

95% C.I. on Mean: Dermal: [-1083.8618, 1246.4626]

Number of Records: 95

Data File: MIXER/LOADER

Subset Name: MIXCLA1.MLOD

*Some subsets used as for PRINCEP 4L.MLOD
Page 21 of Report.*

SRRD review dated 7/15/94

Page _____ is not included in this copy.

Pages 12 through 20 are not included.

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