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

JUL 26 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: List A Chemical, Data Call-In (48-Hour Review)
SIMAZINE (#80807; Case #0070)

TO: Amy S. Rispin, Ph.D., Chief
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The Branch has reviewed the Draft of the Data Call-In for the herbicide SIMAZINE (PC #80807; Case #0070) prepared by SRRD. Corrections and/or additions for previously imposed data have been made directly on the text of the DCI draft. The new requirements imposed by EFGWB at this time appear in a separate sheet of paper attached to the DCI.

A. ENVIRONMENTAL FATE REQUIREMENTS PREVIOUSLY IMPOSED: Clarification

163-1: The registrant was requested in the 7/19/90 review (batch-equilibrium adsorption/desorption studies with parent simazine and its major degradates, additional information on the USDA Soil Series Names for the soils used in the studies. EFGWB is also requesting at the present time data on the solubility of the degradates in aqueous media since solubility data (parent and degradates) are needed in most of the models currently used at the Branch.

164-1: New terrestrial field dissipation studies are required. The registrant may choose to conduct these studies in conjunction with the required field leaching monitoring studies (see below). However, if the registrant chooses this option, the terrestrial field dissipation part must conform to current guidelines/SEP for this kind of study (that is, the study must address both the pattern of formation/decline of degradates and the movement of parent and/or degrade residues through the soil profile). Protocols must be submitted and approved prior initiation of the studies; the protocol should follow SEP for Terrestrial Field Dissipation studies (NTIS No. PB90-208935; EPA No. 540/09-90-073).

165-1: EFGWB is not requesting a new Confined Rotational Crop study since the data in-house already indicate the tendency of simazine (parent and metabolites) to accumulate in rotational crops when planted one year after treatment. Based on this observation, EFGWB recommended petitioning tolerances for rotated crops (Second Round Review of SIMAZINE; 7/11/89). In the Second Round Review, additional information was requested for that study (40614423) which, if acceptable, could upgrade the study; however, the study would not support uses at application rates greater than 2 lb ai/acre.

B. NEW DATA REQUIREMENTS: Rationale for Imposing the Data Requirements

Groundwater Monitoring Studies

Monitoring studies are being imposed by EFGWB for SIMAZINE in this DCI for the first time.

From environmental fate data reviewed by EFGWB, it is known that SIMAZINE has the potential to leach to and persist in ground water (See attached Table); refer also to the 7/11/89 Second Round Review). Moreover, from the Agency's "Pesticides in Ground Water Data Base" (1988) there are documented findings of simazine in ground water as a result of registered applications in several states including California, Connecticut, Maryland, Nebraska, and Pennsylvania; some of the detections approach or exceed the Office of Drinking Water Maximum Contaminant Level Goal of 4 ppb. From a limited monitoring study submitted by Ciba-Geigy for atrazine, it was found that simazine was detected at 0.25 ppb or greater in 6 of the 11 sites monitored across the country.

The preponderance of data indicating the leaching of atrazine to ground water suggests that simazine (which has a structure, physical/ chemical parameters and environmental fate chemistry behavior closely related to atrazine) will also have the tendency to leach to ground water.

Because of all these reasons, EFGWB is requesting small-scale field leaching studies (166-1). The studies must be conducted in three different locations (sites). These studies must be conducted according to protocols submitted and approved by EFGWB prior to initiation of the studies.

If the registrant chooses to conduct terrestrial field dissipation studies in conjunction with the monitoring studies, the 164-1 part of the study must conform to current 164-1 guidelines/SEP (see above).

C. RESERVED STUDIES- Rationale

Field Run-off and Surface Water Monitoring Studies:

The Field Run-off (167-1) and Surface Water Monitoring (167-2) studies are being held in RESERVE pending an EFGWB review of literature containing surface monitoring data on simazine.

<u>PARAMETER/CHARACTERISTIC</u>	<u>LEACHING CRITERIA</u>	<u>SIMAZINE</u>
Water Solubility	> 30 ppm	3.5 ppm
Henry's Law Constant	< 10^{-2} atm-m ³ /mol	3.2×10^{-10} atm-m ³ /mol
Hydrolysis half-life	> 25 weeks	> 30 days
Photolysis half-life	> 1 week	Data gap, but appears to be > 30 days
Soil adsorption: K _d	< 5 (usually < 1-2)	0.65 - 4.3
Soil adsorption: K _{oc}	< 300-500	103 - 152
Aerobic soil metabolism half-life	> 2-3 weeks	> 100 days
Field dissipation half-life	> 2-3 weeks	44 to 231 days have been reported
Depth of leaching in field dissipation study	> 75-90 cm	Data gap in field studies.

Note: Anaerobic metabolism is considerable slower than aerobic metabolism.
Half-life under anaerobic conditions is ca. 660 days

Dealkylated degradates of simazine are more mobile than parent simazine.
Two of these degradates are also degradates of atrazine and have been found in ground and surface waters.

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★ COMMENTS FOR GUIDELINE REQUIREMENTS

Case # and Name
 0070 Simazine
 Chemical # and Name
 080807 Simazine

GUIDELINE COMMENT

123-1(a) Tier II plant protection testing required of all herbicides for all terrestrial nonfood and aquatic uses.

EEB QUESTION: PLEASE VERIFY FOOTNOTE.

123-1(b) Tier II plant protection testing required of all herbicides for all terrestrial nonfood and aquatic uses.

EEB QUESTION: PLEASE VERIFY FOOTNOTE.

123-2 Tier II plant protection testing required of all herbicides for all terrestrial nonfood and aquatic uses.

EEB QUESTION: PLEASE VERIFY FOOTNOTE.

133-3 All exposure data must comply with Subdivision U Applicator Exposure Monitoring of the Pesticide Assessment Guidelines. A protocol must be submitted and approved prior to study initiation. Data required for domestic turfgrass outdoor use. Not required for commercial turfgrass use.

OREB QUESTION: (1) PLEASE CONFIRM FOOTNOTE AND PROTOCOL REQUIREMENT. (2) PLEASE CHECK FOR CONSISTENCY WITH ATRAZINE REQUIREMENTS. (3) PLEASE CONFIRM THAT GUIDELINE 133-4 IS SATISFIED.

(00143171)

161-2 The cited study provides supplemental information only. Several deficiencies were noted in the study: a) test solutions were not buffered and the pH of the unbuffered water was

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*** COMMENTS FOR GUIDELINE REQUIREMENTS**

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GUIDELINE COMMENT

not specified; b) the test substance was incompletely characterized; c) the temperature of the samples was not specified; d) the spectral energy distribution to the artificial light source (mercury vapor lamp) was inadequately described; e) the intensity and wavelength of the artificial light source were not compared to natural sunlight. This study is not upgradeable and a new study is required for which use of natural sunlight irradiation is recommended. Submittal of a protocol is recommended.

00143171

NOTE: MRID # ~~00158629~~ ONLY PARTIALLY FULFILLS GUIDELINE 161-2.

EFGWB QUESTION: SRRD HAS ADDED THAT THIS STUDY CANNOT BE UPGRADED, PLEASE CONFIRM.

161-3

Study 00158629 is an unacceptable Interim Report to the final report 40614410. Only the portion of 40614410 conducted under natural sunlight irradiation was considered to provide supplemental information. Identification of degradates (by TLC using only one solvent) was unsatisfactory. The temperatures at which the study was conducted (Fall-Winter; Madison, WI) were unacceptably low and not comparable to temperatures that are usually found following simazine application under field conditions. This study cannot be upgraded. A new study is required and submittal of a protocol is recommended. O.K.

NOTE: MRID # 40614410 ONLY PARTIALLY FULFILLS GUIDELINE 161-3.

EFGWB QUESTION: SRRD HAS ADDED THAT THIS STUDY CANNOT BE UPGRADED, PLEASE CONFIRM. O.K.

162-1

Study 00158638 provides supplemental information only. Not all the degradates detected above 0.01 ppm were identified. The study was conducted with foreign (Swiss) silt soil and the registrant did not show the properties of the soil were characteristics of

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*** COMMENTS FOR GUIDELINE REQUIREMENTS**

163-1 The Branch is requesting information on the solubility in water of the degradates G-28473, G-28279, and G-30414.

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GUIDELINE COMMENT

typical agricultural USA soils. Also, it was not clear from the report if the incubation of samples was done in the dark. This study cannot be upgraded, a new study is required. ok.

NOTE: MRID # ~~00158639~~ ⁰⁰⁴⁴³⁴⁷¹
00158638 OK.

EFGWB QUESTION: SRRD HAS ADDED THAT THIS STUDY CANNOT BE UPGRADED, PLEASE CONFIRM. ok.

162-4 The reviewed study (00158639) was considered unacceptable. Therefore, a new study is required and MRID number 00158639 cannot be cited to fulfill guideline 162-4.

163-1 EFGWB QUESTION: PLEASE CONFIRM THAT THIS STUDY CANNOT BE UPGRADED. ok

164-1 Studies submitted in response to the 1984 Standard are unacceptable and cannot be upgraded; new studies are required. To support registration for uses on turf, a study conducted on turf is required (two different, typical-use sites). Submission of protocols for terrestrial field dissipation studies is highly recommended. *Studies should be conducted according to recent SEP (540709-90-073; BB10-208935) and address "Worst-Case" scenarios.*
EFGWB QUESTION: SRRD HAS ADDED THAT THIS STUDY CANNOT BE UPGRADED, PLEASE CONFIRM. ok.

164-2 A) Studies conducted in swimming pools: The study conducted at the Iowa site (40614419) is unacceptable. The study conducted at the Georgia site (40614422) provides supplemental information only. None of the studies were conducted at the maximum application rate recommended for this type of use. B) Studies conducted in ponds: The study conducted at the Iowa site (40614419) is unacceptable. The study conducted at the Iowa site (40614422) provides supplemental information only. C) Other studies: Aquatic field dissipation studies contained in 00025412 and 00025413 are unacceptable.

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• COMMENTS FOR GUIDELINE REQUIREMENTS

Case # and Name	COMMENT
0070 Simazine Chemical # and Name	the requested small-scale field leaching studies (166-1), but the dissipation part of the study must follow current SEP for 164-1 studies (NTIS No. PB901208935, EPA No. 540/99-98-073); patterns of formation and decline and of degradates and the movement of parent/degradates through the soil profile must be addressed. For any of the field studies, the submitted protocols must be approved by EFGWB prior to initiation of the studies.
080807 Simazine	

Therefore, new studies are required. Submission of protocols prior to initiation of the studies is highly recommended. *Studies must be conducted at the maximum application rate with the typical end-use product(s).* The registrant has the option of conducting the 164-1 studies in conjunction with NOTE: MRID NUMBERS 40614419, 40614421, 00025412 AND 00025413 CANNOT BE CITED TO FULFILL GUIDELINE 164-2. NONE OF THESE STUDIES CAN BE UPGRADED AND MUST BE REPEATED.

EFGWB QUESTION: SRRD HAS ADDED THAT THIS STUDY CANNOT BE UPGRADED, PLEASE CONFIRM. *at the time of the Second Round Review by additional information support registration (40614423) may upgrade the study if acceptable the study would not However, in applicant rates on greater than 2560/acre.*

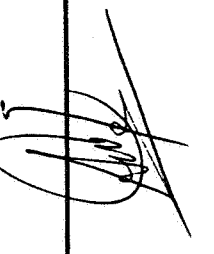
165-1 (parent's degradable metabolites)
The rotational crop data submitted were unacceptable ~~and cannot be upgraded.~~ *Based on these data, residues are likely to occur in all crops rotated one year or more following application of simazine at current use rates. Therefore, appropriate rotational crop intervals for simazine cannot be established at this time.* Tolerances for all crops to be rotated other than crops listed on the label must be requested and supported by appropriate data.

NOTE: MRID # 40614423 IS AN UNACCEPTABLE STUDY AND CANNOT BE UPGRADED. A NEW STUDY IS REQUIRED. *No! No new 165-1 study is required because the registrant was asked to petition for tolerances for rotated crops.*

EFGWB QUESTION: SRRD HAS ADDED THAT THIS STUDY CANNOT BE UPGRADED, PLEASE CONFIRM. CHECK ACCURACY OF FOOTNOTE. *See above.*

171-4(a) Data depicting the total terminal residue of uniformly ring-labeled [14 C]simazine in corn and two additional dissimilar crops (asparagus and a representative citrus fruit are recommended). A completely characterized test substance representative of technical simazine used in commercial formulations must be applied under conditions representing normal cropping practices and at rates high enough to result in sufficient radiolabeled residues for characterization. The identities and quantities of residues in or on all

See attached new data requirements (166-1; 167-1/-2)



NEW DATA REQUIREMENTS

166-1 Small-scale Field Leaching Studies: EFGWB is requiring these studies based on environmental fate data that show that simazine has the potential to leach to ground water as well as on reports on findings of simazine residues in ground waters. The studies must be conducted in three different locations (sites). These studies must be conducted according to protocols submitted and approved by EFGWB prior to initiation of the studies.

167-1 Field Run-off
167-2 Surface Water Monitoring Studies
Both of these studies are being held in RESERVE pending an EFGWB review of literature containing surface water monitoring on simazine.

