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DATA ACCESSION NO(S). 265011

PRODUCT MANAGER NO. R. Mountfort (23)

PRODUCT NAME(S) Simazine

COMPANY NAME Ciba-Geigy Corporation

SUBMISSION PURPOSE Submission of data in response to Registration Standard.

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Ciba-Geigy Corporation Submission of Data in Response to Registration Standard

FROM: Thomas M. Armitage Thomas M. Armitage 10-30-86
Fisheries Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

THRU: Raymond W. Matheny Raymond W. Matheny 10-31-86
Head, Section I
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

THRU: Michael W. Slimak, Chief 11/6/86
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

TO: Richard F. Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Ecological Effects Branch (EEB) has reviewed the following studies submitted to fulfill data requirements identified in the reregistration guidance package for simazine.

1. One Generation Reproduction Study with Technical Simazine and Bobwhite Quail. EPA Accession No. 265011. Wildlife International Project No. 108-245.

   EEB Conclusions: The study is scientifically sound. It indicated that dietary concentrations of 20 and 100 ppm did not affect reproductive parameters. At a dose level of 500 ppm, there was an observed reduction in the number of eggs laid, and there appeared to be a possible reduction in the number of eggs set. The study fulfills the Guidelines requirement for an avian reproduction study.

2. Acute Toxicity of Technical Aquazine (Simazine) to Rainbow Trout. EPA Accession No. 265011. ABC Static Bioassay Report No. 30452.

   EEB Conclusions: The study documents a 96-hour LC_{50} > 10 mg/L for rainbow trout exposed to technical simazine. The study does not, however, fulfill the Guidelines requirement for a freshwater fish LC_{50} determination using a coldwater species. This is because a statistically calculated LC_{50}, with 95 percent confidence limits and the slope of the dose-response line, is not reported. At the highest dose level tested, 10 mg/L, no effect was observed. A definitive LC_{50} need not be reported only if it has been demonstrated that a chemical will have an LC_{50} greater than 100 mg/L. This conclusion must be reached by testing at least 30 animals at a dose concentration of 100 mg/L or greater.

   In order to fulfill the Guidelines requirement, the study must be repeated using dose levels high enough to report a definitive LC_{50} and 95 percent confidence limits. The requirement could also be fulfilled by demonstrating that the 96-hour LC_{50} is greater than 100 mg/L. In this case, at least 30 test animals must be tested at exposure levels of 100 mg/L or greater.

3. Acute Toxicity of Aquazine 80W (Simazine) to Rainbow Trout. EPA Accession No. 265011, AES Project No. 7636-500.

   EEB Conclusions: The study documents a 96-hour LC_{50} = 40.5 mg/L (95% c.i. = 34.0 to 48.4) for rainbow trout exposed to the 80W formulation of simazine. It does not, however, fulfill the Guidelines requirement for a coldwater fish LC_{50} determination using formulated product. This is because a precipitate appeared in the upper concentration 48 hours after the start of the test. An additional deficiency of the study is that the amount of solvent used was not reported.

   In order to fulfill the Guidelines requirement, the study must be repeated using different solvents to eliminate precipitation of the test material. A flow-through system, and analytically measured concentrations of toxicant, must be used if the chemical cannot be dissolved in a static system.

4. Acute Toxicity of Aquazine 80W to the Rainbow Trout at 7.0 °C. EPA Accession No. 265011, AES Project No. 7637-500.

   EEB Conclusions: The study documents a 96-hour LC_{50} = 60.0 mg/L (95% c.i. = 49.8 to 72.3 mg/L). It does not, however, fulfill the Guidelines requirement for a coldwater fish LC_{50} determination using formulated product. This is because the study was conducted using a test water temperature of 7.0 °C. The recommended test temperature for rainbow trout is 12.0 °C. The study is also unacceptable because a precipitate formed in the three highest test concentration chambers 24 hours after introduction of the toxicant. An additional study deficiency is the failure to report the amount of solvent used.

   In order to fulfill the Guideline requirement, the study must be repeated using a test water temperature of 12.0 °C. Different solvents should be used to eliminate the problem of test material precipitation. A flow-through system, and analytically measured concentrations of toxicant, must be used if the chemical cannot be dissolved in a static system.

5. Acute Toxicity of Aquazine 80W to the Rainbow Trout at 17 °C.

   EEB Conclusions: The study documents a 96-hour LC_{50} = 44.6 mg/L (95% c.i. = 37.6 to 52.9 mg/L). It does not, however, fulfill the Guidelines requirement for a coldwater fish 96-hour LC_{50} determination. This is because the study was conducted using test water at 17 °C. The recommended test temperature for rainbow trout is 12.0 °C. The study is also unacceptable because a precipitate formed in the three highest test concentrations approximately 24 hours after introduction of the test material. An additional deficiency is that the amount of solvent used was not reported.

   In order to fulfill the Guidelines requirement the study must be repeated at a test water temperature of 12.0 °C. Different solvents should be used to eliminate the precipitate. A flow-through system with analytically measured concentrations of toxicant must be used if the chemical cannot be dissolved in a static system.

EEB notes that data to fulfill requirements identified in the Registration Standard for Simazine should have been submitted to the Agency no later than April 1985. The reason for an 18-month delay in submission of these data is questioned.

EEB has reviewed the studies submitted to support registration of simazine and has determined that the following studies remain to be submitted in order to fulfill the requirements for reregistration.

1. Freshwater fish 96-hour LC_{50} using a species of coldwater fish and technical grade of test material. Guidelines reference 72-1.

2. Freshwater fish 96-hour LC_{50} using typical end-use product or formulated product.

In addition to the studies listed above, additional data will be required to describe residues of simazine on vegetation and soil following its application at the maximum rate of 40 lb ai/acre. These data are required under Guidelines reference 70-1. The study is required because submitted avian reproduction studies indicate that birds could be exposed to residues high enough to produce chronic reproductive effects. The bobwhite quail no-effect level of 100 ppm, and the mallard duck no-effect level of 20 ppm suggest that chronic exposure resulting from high application rates of simazine could provide a hazard to avian species.

Results of a residue monitoring study must be submitted to provide a clear indication of chronic avian exposure to simazine. Simazine is applied to uncultivated areas and rights-of-way at 10 to 40 lb ai/acre. Residues on various types of vegetation must be measured following application at the maximum rate (40 lb ai/acre). Following application, residues should be measured on a weekly basis in order to provide an indication of exposure in the field. The registrant may already have residue data available from completed studies. If data are available, they should be submitted to EEB for review. If data are not available, a protocol must be submitted for review prior to initiation of the study. This study must be submitted within 12 months.