272E
CASWELL FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OCT 16 1990

OCT 16 1990

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Cyproconazole 40 WG. Waiver request for an acute inhalation study.

TO: Lewis/Chamblis PM 21
Registration Division (H7505C)

FROM: K. Clark Swentzel K. Clark Swentzel 10/2/90
Section Head
Toxicology Branch II (HFAS)
HED (H7509C)

THRU: Marcia van Gemert, Ph.D. Marcia van Gemert 10/10/90
Branch Chief
Toxicology Branch II (HFAS)
HED (H7509C)

and

William Burnam W Burnam 10/17/90
Deputy Division Director
HED (H7509C)

EPA ID No. 55947-RGE
MRID/Acc. No. none
Project No. 0-1912
Caswell No. 272E
Registrant: Sandoz Corp.

Requested action

Review additional data to support waiver request for an acute inhalation study.

Previous submissions

The original data package for this new chemical included a letter to the Agency (S. Janousky to L. Rossi, May 19, 1988) which indicated that acute inhalation testing with the 40 WG formulation is not applicable since the bulk of material consists of large particles not inhalable by man. The submitted data showed the distribution of particles between 425 and 2000 microns; aerodynamic diameters were not discussed. These data indicated that 6.4% of the particles were less than 425 microns. TB II requested a description of

the methodology and examples of findings from tests performed to derive the submitted particle size data (memorandum, Swentzel, HED, to Rossi, RD, January 17, 89). TB also requested data which show the proportion of particles in the range inhalable by man (< 10um). The registrant responded with data which showed that the distribution of particles are between 149 and 840 microns and that 0.28% of the particles are less that 149 um (memorandum, Swentzel to Lewis/ Grable, February 26, 1990). The registrant stated that the submission of data showing the proportion of particles in the range inhalable by man could not be included due to limitations of the dry sieving equipment. Particle aerodynamic diameters were not discussed. The response to this submission indicated that TB II would be willing to waive the acute inhalation study with Cyproconazole 40 WG if the registrant can provide convincing evidence that a very low percentage of respirable particles (< 1 micron) would result from handling and transport.

Current submission

The registrant sent 2 lb. samples to 8 field representatives who performed 15 transportation and handling tests. Samples were transported during a 2 to 4 weeks period at distances of 1066 to 4933 miles under various road conditions (Table II appended). A sample was retained as a control for "time zero" particle size distribution (Table I appended). Following field tests, the samples were submitted to Advance Particle Measurement Inc. for particle size determination on a Malvern Particle Size Analyzer, which the manufacturer claims can measure particles as small as 0.5 microns. Data for particles less than 32 um showed that particle size distribution was comparable between control and test samples, the percent (by weight) of particles less than 32 um was less than 1% and no particles less than 8 um were detected (Table III appended).

Conclusion

TB II is willing to waive test requirements for an acute inhalation toxicity study (81-3) with Cyproconazole WG 40 based on the particle size distribution data in this submission.

2

CYPROCONAZOLE Tox review

Page_____ is not included in this copy.

Pages 3 through 5 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

X A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.