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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY CASWELL FILE

WASHINGTON, DC 20460

FEB 26 1990

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

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

TO: Lewis/Grable PM 21
Registration Division (H7505C).

FROM: K. Clark Swentzel K. Clark Swentzel 2/22/90
Section Head
Toxicology Branch II (HFAS)
HED (H7509C)

THRU: Marcia van Gemert, Ph.D. Marcia van Gemert 2/22/90
Branch Chief
Toxicology Branch II (HFAS)
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EPA ID No. 55947-RGE
MRID/Acc. No. none
Project No. 9-1600
Caswell No. 272E
Registrant: Sandoz Corp.

Requested action

Review response

Background

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 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).

Response

The present submission shows the distribution of particles between

149 and 840 microns. These data show that 0.28% of the particles are less that 149 um. The registrant stated that the submission of data showing the proportion of particles in the range ihalable by man can not be included due to limitations of the dry sieving equipment. They added that the limit for mechanical screens is approximately 37um. The registrant's assessment was based on a Roto-Tap sieve analysis which, evidently, was meant to simulate the milling process that occurs during handling and transport. The Roto-Tap is generally recognized as a particle sizing apparatus rather than a mill. Also, sieve sizing has no direct correlation to aerodynamic diameter.

Conclusion

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.

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