



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

FEB 10 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: SAN-835H: Data requirements for registration

TO: Karen Hicks/Robert Taylor PM 25
Registration Division (7505C)

FROM: K. Clark Swentzel *K. Clark Swentzel 2/3/94*
Toxicology Branch II
HED (7509C)

THROUGH: Marcia van Gemert, Ph.D. *van Gemert 2/7/94*
Branch Chief
Toxicology Branch II
HED (7509C)

SUBMISSION: S-456389

BARCODE: D198345

MRID NO.: none

CASWELL NO.: none

REGISTRANT: Sandoz

CHEMICAL NO.: none 005108

Action Requested

Review the attached letter from the registrant.

Submission

The registrant has asked the agency to consider "a tiered approach" to safety testing while allowing a conditional registration as the data base is being completed.

Response

The registrant has made the noted request based on "the exceptionally favorable SAN 835H toxicological profile to date". It is not clear what is meant by "a tiered approach" since the data requirements in a given tier can be contingent on results of studies completed in a previous tier. Is this the approach that they are proposing?

Regardless of the classification of the compound (herbistat or herbicide), 158 Guideline toxicity data requirements for a food-use



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end-use product (proposed for use on corn) must be satisfied. It should be noted that toxicity data generated to date are from acute, subchronic and developmental and 2-generation reproduction pilot toxicity studies. There has been no assessment of potential long-term adverse effects or genotoxicity.

The proposal regarding conditional registration while a safety data base is being fulfilled should appropriately be addressed by Agency risk managers.

TB II is willing to consider any specific proposal that the registrant might have for satisfying the safety data base, however, this proposal should be submitted in writing for our evaluation.