



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

PP# OF 3918

JUL 29 1992

EXPEDITE

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: SAN 582H: Supplemental Product Chemistry Data.

DP Barcode: 176087. CBTS #'s 9629, 9630.
MRID #'s 422388-01, -02, -04.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

THROUGH: Debra F. Edwards, Ph.D., Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

TO: Cynthia Giles-Parker/James Stone, PM 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Albin Kocialski, Head
Registration Section
Chemical Coordination Branch
Health Effects Division (H7505C)

This review is being expedited at the request of the
Registration Division. The due date is 7/31/92.

Sandoz Agro, Inc. has submitted supplemental product chemistry information for its 96.9% technical product. Four studies have been submitted: explodability, storage stability of the TGAI, storage stability of SAN 582H 900 EC (MRID # 422388-03), and a discussion of the potential for nitrosamine impurities. The review of the end use product, SAN 582H 900 EC, is the responsibility of the Registration Division; so MRID # 422388-03 will not be reviewed.

Guideline Number 63-16. Explodability.

Sandoz has submitted the following report:

"Explodability of SAN 582 H, Technical," Z. Srnak, 9/26/91,



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Lab ID No. 414103-51. (MRID # 422388-01)

The performing laboratory was Stresau Laboratory Inc., Spooner, WI. According to the registrant, this laboratory does not have a formal GLP program, and there are currently no laboratories in compliance with 40 CFR Part 160 capable of conducting this study.

The study was conducted using Stresau Laboratory Inc. # F0305 Impact Sensitivity Test with Bureau of Explosive Impact Tester (attached as Appendix 1 of the report). Explosion or ignition was not observed in 10 trials when a weight of 8 lbs was dropped from 10 inches, nor was it observed during repeated tests when the sample was first absorbed in a filter paper.

§63-16 has been satisfied.

§63-17 -- Storage Stability.

Sandoz has submitted the following report:

"Storage Stability of Technical SAN 582H," R.S. Jones, 12/18/91, Lab. I.D. No. 414106-9. (MRID # 422388-02)

SAN 582H 96.7% T was shown to be stable in glass at 25±5°C for a period of one year. SAN 582H 91.8% T is stable in a 55 gallon high density polyethylene drum at warehouse temperatures for two years.

This submission does not satisfy the requirements of §63-17. There is no discussion of the sensitivity of the active ingredient to metal ions and metal or the sensitivity of the active ingredient to sunlight. At this time we will not require testing of the 96.7% technical at warehouse temperatures.

Discussion of Possible Formation of Nitrosamines

Sandoz has submitted the following report:

"SAN 582H Process Nitrosamine Potential," B. Belkind, 3/4/92, Lab. I.D. No. 10582-05 suppl a. (MRID # 422388-04)

The report is discussed in the Confidential Appendix to this review. CBTS concludes that nitrosamine formation is unlikely during the manufacture and storage of SAN-582H. Sample analyses for nitrosamines are not necessary at this time.

2

Attachment: Confidential Appendix

cc: with Attachment: PP#0F3918, SAN 582H Reg. Std. File, M.
Flood.

cc: without Attachment: RF, SF, Circu.

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):7/27/92.
RDI:BranchSeniorScientist:RALoranger:7/27/92.

DIMETHENAMID

Page _____ is not included in this copy.

Pages 4 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.
- ☐ 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.

X CONFIDENTIAL APPENDIX

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.
