TOX

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

Caswell #840

MEMORANDUM

DATE: November 28, 1980

SUBJECT: EPA File Symbol 3876-REA
Betz ER-23

FROM: Sherell A. Sterling
FHB/TSS

12-5-80
E 12/15/80

TO: John H. Lee
Product Manager (31)

Applicant: Betz Laboratories, Inc.
4636 Somerton Road
Trevose, PA 19047

Active Ingredients:
3,5-Dimethyl tetrahydro-2H-1,3,5
thiadiazine-2-thione.....21.0%
Inert Ingredients.....79.0%

Background:

This review is in response to the Product Manager's request for reconsideration. No new data were evaluated in the preparation of this review. The "cite all" method of support was chosen.

Recommendations:

1. The Acute Oral study is considered Core Supplementary Data and, therefore, not acceptable for registration purposes. Please see the previous review (Sterling, 4/11/80) for details.

2. The Acute Dermal study is considered Core Supplementary Data and, therefore, not acceptable for registration purposes. Please see the previous review (Sterling, 4/11/80) for details.

3. The Acute Inhalation study is considered Core Supplementary Data and, therefore, not acceptable for registration purposes. Please see the previous review (Sterling, 4/11/80) for details.

4. The Eye Irritation study is Core Supplementary Data and, as such, is not acceptable for registration purposes. Please see the previous review (Sterling, 4/11/80) for details.

5. The Skin Irritation study is acceptable for conditional registration purposes. Please see previous review (Sterling, 4/11/80) for details.

6. Since similar products are registered and the method of support is "cite all," TSS has no objection to the conditional registration of this product. However, please note the additional data may be required in the future.

The following labeling revisions are necessary.

Labeling Recommendations:

1. The statement "Harmful or fatal if swallowed..." must be revised to "Harmful if swallowed...."

2. The heading "FIRST AID" must be changed to "Statement of Practical Treatment."

3. Enclosed you will find a list with required "Storage and Disposal" statements. These statements must replace the statements appearing on current draft labeling.

4. No further labeling recommendations can be made at this time.

Notes to the PM:

1. Current draft labeling does not include the statement "Keep out of reach of children." If it is DIS Branch's policy that products with the words "For Industrial Use Only" on the labeling do not require this statement, it will not be required. Otherwise, applicant must seek a waiver or include the statement on the labeling.

2. An [redacted] which bears the signal word WARNING. However, due to the known ocular irritation caused by this type of product, TSS can agree with the registrant that DANGER is an appropriate signal word for this product. Data submitted for screening and reviewed by Sterling (4-11-80) showed minimum corneal irritation in some eyes; therefore, a retest of this substance will not be required at this time.

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3. Please note that the Acute Oral, Acute Dermal, Acute Inhalation and Eye Irritation studies submitted for this product are inadequate. TSS is not aware of any other available and acceptable data on this formulation. Conditional registration is sought under the "cite all" method of support and, therefore, conditional registration may proceed without additional data.

DAZOMET SCIENTIFIC REVIEWS

Page 4 is not included in this copy.

Pages _____ through _____ are not included in this copy.

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 product 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 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.
