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

DEC 17 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

# MEMORANDUM

Subject: 1. ID No. 003125-UEE: Confidor 2 Flowable
2. ID No. 003125-UEG: Confidor 2.5% Granular
New Chemicals Screen: NTN 33893 21.4% and NTN 33893 2.5% Formulations

Tox. Chem.No. 497E
PC Code No. 129099
Submission Nos. 1. S430176, 2. S430227
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## CONCLUSIONS

NTN 21.4% and 2.5% Formulations pass the pre-review toxicology screen for food use chemicals, as evaluated by the registration Acceptance Criteria.

## ACTION REQUESTED

Toxicology Branch I has been requested to review data submitted by Miles Corp. to determine whether they meet the criteria for pre-review toxicity screen for a food use chemical. The following data are required to be present and acceptable for review:

CC Rose Kearns (EFED)
Nan Gray (CCB/HED)

TABLE 1 DATA REQUIREMENTS

| Guideline No. | Description | Test Substance |
|---|---|---|
| 81-1 | Acute Oral—Rat | EP* & TGAI** |
| 81-2 | Acute Dermal | EP & TGAI |
| 81-3 | Acute Inhalation—Rat | EP & TGAI |
| 81-4 | Primary Eye Irritation—Rat | EP & TGAI |
| 81-5 | Primary Dermal Irritation | EP & TGAI |
| 81-6 | Dermal Sensitization | EP & TGAI |
| 82-1 | 90-Day Feeding Rodent/Non-Rodent | TGAI |
| 82-2 | 21-Day Dermal | EP & TGAI |
| 83-1 | Chronic Feeding Rodent/Non-Rodent | TGAI |
| 83-2 | Oncogenicity—2 Species | TGAI |
| 83-3 | Developmental Toxicity 2 species | TGAI |
| 83-4 | Reproduction, 2-generation | TGAI |
| 84-2 | Gene Mutation Structural Chromosomal Aberration | TGAI |
| 84-4 | Other Genotoxic Effects | TGAI |
| 85-1 | General Metabolism | TGAI |

* End-Use Product ** Technical Grade Active Ingredient

## RESULTS

Table 2 lists the studies included in the present submission by Miles Corporation in a effort to complete the screen on NTN 33893 Formulations. Study numbers and Guideline numbers are indicated. Studies not required, but included in this submission for support and/or comment purposes were not screened. A list of all data submitted in this action is attached.

As indicated in Table 2, some data were submitted under a separate action. The Technical Grade and 2.5% Formulation were previously evaluated. After considering the

previously evaluated studies, and taking into account the data screened in this submission, it appears that sufficient data have been submitted to satisfactorily meet the Acceptance Criteria for the Subdivision F pre-review screen.

**TABLE 2.** STUDIES EVALUATED AND JUDGED ADEQUATE FOR REVIEW UNDER SUBDIVISION F ACCEPTANCE CRITERIA

| Guideline No. | Study Type | Technical/ Formulation | Study Numbers |
|---|---|---|---|
| 81-1 | Acute Oral—Rat | Technical | T 2033060* |
| | | 21% Formulation | 89-012-DV |
| | | 2.5% Formulation | 89-012-DY* |
| 81-2 | Acute Dermal | | |
| | Rat | Technical | T 5033063* |
| | Rabbit | 21% Formulation | 89-025-EB |
| | | 2.5% Formulation | 89-025-DS* |
| 81-3 | Acute Inhalation—Rat | Technical | T 2025951* |
| | | | T 3025952* |
| | | | T 4025953* |
| | | 21% Formulation | 89-042-EG |
| | | 2.5% Formulation | 89-042-DX* |
| 81-4 | Primary Eye Irritation | | |
| | Rat | Technical | T 8025515* |
| | Rabbit | 21% Formulation | 89-335-DZ |
| | | 2.5% Formulation | 89-335-DT* |
| 81-5 | Primary Dermal Irritation | Technical | T 8025515* |
| | in the Rabbit | 21% Formulation | 89-325-DU |
| | | 2.5% Formulation | 89-325-ED* |
| 81-6 | Dermal Sensitization | Technical | T 9025651* |
| | in the Guinea Pig | 21% Formulation | 89-324-DO |
| | | 2.5% Formulation | 89-324-DN* |
| 82-1 | 90-Day Feeding | | |
| | Rat | Technical | 101949 |
| | Dog | Technical | 100176 |
| 82-2 | 21-Day Dermal—Rat | Technical | 100688 |
| 83-1 | Chronic Feeding | | |
| | Rat | Technical | 101931 |
| | Dog | Technical | 100015 |
| 83-2 | Oncogenicity | | |
| | Rat | Technical | 101931 |
| | Mouse | Technical | 101929 |

TABLE 2. STUDIES EVALUATED AND JUDGED ADEQUATE FOR REVIEW UNDER SUBDIVISION F ACCEPTANCE CRITERIA

| Guideline No. | Study Type | Technical/ Formulation | Study Numbers |
|---|---|---|---|
| 83-3 | Developmental Toxicity | | |
| | Rat | Technical | 083496 |
| | Rabbit | Technical | 083518 |
| 83-4 | Reproduction 2-generation—Rat | Technical | 100647 |
| 84-2 | Gene Mutation | Technical | 100668, 101276, T 6030111, 100661, 100662, 98584, 99676, 102655, 99262 |
| | Structural Chromosomal Aberration | Technical | 100666, 100678, 99257, 100021 |
| 84-4 | Other Genotoxic Effects | Technical | 100665, 102613, 101275, 98573 |
| 85-1 | General Metabolism | Technical | M 182 0176-5<br>M 181 0177-5<br>M 1810175/3<br>M 31819004 |

* Studies reviewed under previous action and found to be acceptable to support regulation.

Not all of the Mutagenicity studies evaluated under this screen met Acceptance Criteria. However, sufficient studies of similar design did meet the Acceptance Criteria to avoid invalidating screen in this area. Following is a list of cytogenetics (84-2) studies, conducted on the Technical, which did not meet Acceptance Criteria:

| Report Number | MRID Number |
|---|---|
| 102652 | 422563-47 |
| 102654 | 422563-48 |
| 100664 | 422563-66 |
| 100663 | 422563-68 |

## DATA REVIEW AND ACCEPTANCE

Acceptance of the data in this submission, at this stage, does not constitute a Core Classification. This is an Acceptance Criteria Screen only. Detailed review of each study

and the supporting documents is required before final conclusions can be drawn on the acceptability of the data.

Acceptance Criteria forms for each study submitted and evaluated are currently in the possession of the Reviewer. They will eventually be stored in the Caswell file as a group, or attached singly to individual DERs.