

US EPA ARCHIVE DOCUMENT



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
DP Barcode Nos. 1. D185143, 2. D185163

From: Myron S. Ottley, Ph.D.
Section IV, Toxicology Branch I
Health Effects Division (H7509C)

MS Ottley
12/14/92

To: Portia Jenkins/Dennis Edwards, Jr. (PM19)
Registration Division (H7505C)

Through: Marion P. Copley, D.V.M., D.A.B.T.
Section Head
Section IV, Toxicology Branch I
Health Effects Division (H7509C)

Marion Copley
12/16/92

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 (CCBA/ED)

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 21% Formulation 2.5% Formulation	T 2033060* 89-012-DV 89-012-DY*
81-2	Acute Dermal Rat Rabbit	Technical 21% Formulation 2.5% Formulation	T 5033063* 89-025-EB 89-025-DS*
81-3	Acute Inhalation—Rat	Technical 21% Formulation 2.5% Formulation	T 2025951* T 3025952* T 4025953* 89-042-EG 89-042-DX*
81-4	Primary Eye Irritation Rat Rabbit	Technical 21% Formulation 2.5% Formulation	T 8025515* 89-335-DZ 89-335-DT*
81-5	Primary Dermal Irritation in the Rabbit	Technical 21% Formulation 2.5% Formulation	T 8025515* 89-325-DU 89-325-ED*
81-6	Dermal Sensitization in the Guinea Pig	Technical 21% Formulation 2.5% Formulation	T 9025651* 89-324-DO 89-324-DN*
82-1	90-Day Feeding Rat Dog	Technical Technical	101949 100176
82-2	21-Day Dermal—Rat	Technical	100688
83-1	Chronic Feeding Rat Dog	Technical Technical	101931 100015
83-2	Oncogenicity Rat Mouse	Technical Technical	101931 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 M 181 0177-5 M 1810175/3 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.