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CASWELL

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

Releasable
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 3 1986

MEMORANDUM

SUBJECT: Trichlorfon - Company Response Dated October 7, 1985 to Previous Toxicology Branch (TB) Reviews of Submitted Studies, and Additional Data, Accession No. 259968.

Caswell #385

FROM: Irving Mauer, Ph.D.
Toxicology Branch
Hazard Evaluation Division (TS-769C)

1-23-86

TO: Gary Otakie
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

William Miller, PM 16
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

THRU: Jane E. Harris, Ph.D.
Head Section VI
Toxicology Branch
Hazard Evaluation Division (TS-769C)

JEH 1/24/86
for WBB 2/3/86

Registrant: Mobay

Action Requested:

Review and comment upon company response to certain previous evaluations of submitted trichlorfon data.

3 pages

Background:

The following additional data were requested to support previously submitted studies (see Memo, Mauer to Otakie, June 27, 1985, TB Doc. No. 004509):

1. Subacute inhalation (Mobay Report No. 45160, Accession No. 256446), provisionally CORE-graded MINIMUM pending submission of urinalysis as well as histopathological data.

2. Tests for skin and eye irritation (Mobay Report No. 80616, Accession No. 256446), CORE-graded SUPPLEMENTARY because dose employed was not specifically stated in the original report.

TB Recommendations/Conclusions:

1. Subacute inhalation (Mobay Report 45160)

The registrant has provided in this response the missing histopathological data for controls (as ADDENDUM 1) as well as the missing urinalysis data for all dosage groups (as ADDENDUM 2), both of which are briefly summarized below.

ADDENDUM 1, entitled: "L13/59: Subakute Inhalation an Ratten. Histopathologische Befunde" (L13/59: Subacute Inhalation in Rats. Histopathological Findings), consisting of the raw data sheets for the control group (5 males, 5 females). No histopathological lesions or tissue alterations are reported for any control animal, as indicated in the data sheets (as "0" entries) for lungs, liver, spleen, kidneys, adrenals, stomach, ovaries, testes, eyes, or bones.

ADDENDUM 2, entitled: "Harnbefunde bei Ratten. Einzelwerte." (Urinary Findings in Rats. Individual Values), consisting of raw data sheets for the 4 dosage groups (5 animals/sex/dose). The values for individual animals provided in these data sheets indicate no significant differences from controls for any test group for pH, glucose, protein (albumen), blood, urobilinogen, or casts (sediment).

Both these submissions are acceptable to TB, and the original "provisional" status assigned to this study is removed.

CORE-MINIMUM DATA.

2. Tests for skin and eye irritation (Mobay Report 80616)

The registrant has provided dosage schedules for the primary skin/eye irritation studies in this response (as ADDENDUM 3). ADDENDUM 3 consists of machine copies of the following documents, which detail the methods the registrant stated were followed in these studies:

For skin reactions: (i) *Federal Register*, Vol. 38, No. 187, p. 27019, 1973 (issued by the U.S. Department of Agriculture); (ii) J.H. Draize, Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics (Association of Food and Drug Officials of the U.S.A., 46, 1959).

For ocular reactions: The Table of Ocular Reaction Grades in the *Federal Register* 37, No. 83, 8534-5, 1972 (issued by the U.S. Department of Health, Education, and Welfare, Food and Drug Administration).

As stated in the covering letter of October 7, 1985, the (limit) doses used for these studies were:

skin (USDA):	0.5 gram/animal
(Draize):	0.5 gram/animal
eye (USDHEW):	0.1 milliliter by volume/eye,

which are acceptable to TB. Hence, both these studies (primary skin irritation, primary eye irritation) are upgraded to CORE-MINIMUM DATA.