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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Inhalation Study on an Oftanol Product

TO: William Miller (PM-16)
Registration Division (TS-767)

FROM: Byron T. Backus
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HED (TS-769)

THROUGH: William Butler, Head
Review Section III
and
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Products: Oftanol 1.5% Granular, Oftanol 5% Granular, Oftanol 20% Granular

Registration # 3125-330, 3125-331

Tox Chem # 447AB

Registrant: Mobay Chemical Corporation

Action

As a result of a laboratory audit, deficiencies have been found in inhalation LC_{50} studies conducted by Mobay on some granular Oftanol products. These studies were originally accepted as core minimum data, but have now been downgraded to core supplementary.

Conclusions:

The LC_{50} study on 20% granular Oftanol was used to support the registration of a 5% granular product. Since the study as reported indicated a toxicity category IV hazard by the inhalation exposure route the 5% granular product was also accepted as toxicity category IV.

Mobay has submitted a study on a 22% Oftanol product indicating a 1-hr inhalation LC_{50} for males >0.344 mg/L, and for females = 0.329 mg/L. If toxicity is due only to the active, corresponding figures for a 5% Oftanol product would be 1.51 and 1.45 mg/L (toxicity category II). EPA Reg. No. 3125-330 has the

signal word CAUTION, and there are no label statements as to possible inhalation exposure hazards.

An inhalation LC_{50} study should be conducted on the 5% granular Oftanol product (EPA Reg. No. 3125-330). If this study indicates the 5% product is not in toxicity category IV by the inhalation exposure route, an inhalation LC_{50} study would be required on the 1.5% granular product (EPA Reg. No. 3125-331).

Discussion:

On March 17, 1983, a lab audit was conducted at the Mobay Stanley Research Farm on acute oral LD_{50} and inhalation LC_{50} studies conducted on an Oftanol formulation. These studies are in Acc. 243557.

It was found that the inhalation LC_{50} study was conducted using a modified 55-gallon drum. No information could be provided either as to actual (as opposed to nominal) concentration of product and/or actives or as to particle sizes.

Two inhalation LC_{50} studies in Acc. 243557 were reviewed (March 24, 1981) and given core minimum data classification. Formulations tested were a 1.5% granular and a 20% granular; in both cases the LC_{50} was reported as greater than 20 mg/L for 1-hr exposure (toxicity category IV). No signs of toxicity were observed in test subjects during either the exposure or subsequent 14-day observation period.

Results of the data audit were reviewed in IRB/TSS, and the recommendation was made that any inhalation studies that were conducted with the modified 55-gallon drum should not be accepted to support registration actions. A letter was sent to the registrant on October 3, 1983, which indicated the deficiencies. The registrant's response (dated November 4, 1983) was that a new apparatus had been designed and was at the testing laboratory.

This apparatus was apparently in use in early 1982, as the registrant has submitted an inhalation LC_{50} study, dated March 1982, conducted at the Stanley Research Center on a 22% Oftanol formulation which reported a male $LC_{50} > 0.344$ mg/L and a female inhalation $LC_{50} = 0.329(0.289-0.364)$ mg/L for 1-hr exposure, placing the 22% product in toxicity category II by this exposure route. This study is in accession #248241 and has been classified as core minimum.