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W Mahfouz

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

DEC 7 1983

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MEMORANDUM

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Oftanol; A Request for Delayed Neurotoxicity Studies.  
CASWELL#447AB

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

FROM: Amal Mahfouz, Toxicologist  
Section V, Toxicology Branch  
Hazard Evaluation Division (TS-769)

*Amal Mahfouz 12/1/83*

*LD 12/2/83*

THRU: Laurence D. Chitlik, Section Head  
Section V, Toxicology Branch  
Hazard Evaluation Division (TS-769)  
and  
William L. Burnam, Chief  
Toxicology Branch  
Hazard Evaluation Division (TS-769)

*WLB*

I have been asked by Larry Chitlik to assess the status of the neurotoxicity data previously available on Oftanol in the Caswell file. The following is a summary of our evaluation.

A. The available neurotoxicity data on hens were submitted with PP#8G2025 and were reviewed by Bill Greear in his memo of 3/16/78. This review indicated that no delayed neurotoxic effects were noted in the submitted data.

However, due to the fact that the data obtained from this study reflected only effects of a single dose administration, and in view of the new findings reported by the State of California (see attached materials), the Toxicology Branch requests that the registrant submit the following studies/data:

1. All raw data for the submitted neurotoxicity study in hens (Institut-Fur Toxicologie, Report #34025, 3/30/72 and Huntingdon Research Center, Report #53881, 7/19/72).
2. A new Acute Delayed Neurotoxicity Study in Hens.
3. A Subchronic 90-Day Neurotoxicity Study in Hens.
4. Any additional information available to, or in possession of the registrant relative to Oftanol toxicology and specifically, neurotoxicity.

B. Adequate antidotal protection was reported for hens (see the above mentioned review by Greear). However in rats, antidotal protection was only noted in one study ( Bayer AG Intitut, Report #46135, 10/24/75), but no significant protection was noted in a previous study (Bayer AG Institut Fur Tox.; Report #34160, 5/15/72). Thus, the registrant should also submit any additional information available to him on this subject.

Attachments:

1. News Release; California Department of Food and Agriculture, 1220 N Street, Sacramento 95814; November 22, 1983.
2. Isofenphos Antidote Project. A Memo dated November 21, 1983 by Barry W. Wilson of the University of California at Davis to Rex Magee of the California Department of Food and Agriculture.
3. Proposed Registration of 1.5% Granules. A memo dated November 14, 1983 by Keith T. Maddy of the California Department of Food and Agriculture at Sacramento to George Reese also of CDFA.

See also the following two newspaper articles:

4. Oftanol Safety Tests Questioned; and State Issues Ban on Oftanol Use, Animal Nerve Damage; both by Thom Akeman of the Sacramento Bee.