



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

#447AB

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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Oftanol, EPA Reg. #3125-326. A Protocol for a 90-Day Subchronic Delayed Neurotoxicity Study in Hens.

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

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THRU: Laurence D. Chitlik, DABT  
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and  
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*Amal Mahfouz*  
*11/6/84*  
*LOC*  
*11/6/84*

The submitted protocol for the 90-day subchronic delayed neurotoxicity study in hens for Oftanol appears to be adequate (copy attached). Although the study has been initiated before the submission of this protocol for review, this reviewer notes that the following points may need to be addressed by the registrant:

(1) The choice of solvent (water) as a vehicle for the test compound. Oftanol has a solubility of 20 ppm in water. It is known that a major reason for lack of sensitivity of a test animal to a test compound is failure of absorption of the neurotoxin. This reviewer needs to know to what extent the registrant considered this factor before his choice of water as the vehicle in this study.

(2) A large range is noted in the age of hens used in this study (12 to 18 months old, they weighed 1.0 to 2.5 kg). This reviewer notes that a more uniform age and weight would have been more adequate for the comparison of results.

(3) It is not clear from the protocol if the acclimation period of 3 to 4 months was included in the above mentioned bird's age of 12 to 18 months. The registrant should clarify this issue when the study is submitted for review.