

AUG 25 1983

MEMORANDUM

TO: Douglas D. Campt, Director
Registration Division (TS-767)

THRU: Herbert S. Harrison, Chief
Insecticide-Rodenticide Branch
Registration Division (TS-767)

SUBJECT: Inhalation Studies Conducted by Mobay Stanley
Research Farm -----DECISION MEMORANDUM-----

This memo transmits a recommendation that an examination of all inhalation LC₅₀ studies which were conducted by the Mobay Stanley Research Farm be undertaken. This recommendation is based on results of a lab audit conducted at this lab under the National Laboratory Audit Program and is in accordance with Standard Operating Procedure No. 3050.4.

BACKGROUND:

Under the National Laboratory Audit Program, an audit was conducted at Mobay Stanley Research Farm on an oral LD₅₀ and an inhalation study for the chemical, Amaze (Oftanall). The lab audit report was reviewed by TSS and it was determined that the inhalation study was deficient in that information relative to the actual (as opposed to nominal) concentrations of product and/or active as well as particle size data are lacking. These deficiencies would place the study into a supplementary classification, thus changing the regulatory status of this study. The registrant is to be notified of these deficiencies as per the attached letter. This letter will also notify the registrant that if a modified 55-gallon drum was used as a testing apparatus then this study would be inadequate.

CONCURRENCES

SYMBOL							
SURNAME	<i>Brown</i>						
DATE	8/29/83						

RECOMMENDATION:

It is recommended that an examination of all inhalation LC50 studies which were conducted by this laboratory be undertaken until such time as more adequate inhalation exposure equipment were put into operation. As cited on the attached copy of the TSS review, all inhalation studies run using this type of exposure system would be inadequate.

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

CONCUR 

DO NOT CONCUR _____

DATE

SEP 01 1983

TS-767:RD:IRB:MAutz:gck:Rm.211,CM-2,557-2600:08-10-83
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