

CODING FORMS FOR SRC INDEXING

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Contractor			
Document Title	SUPPORT: LETTER FROM [] TO USEPA REPORTING ADD'L INFORMATION FROM 4-WEEK DIETARY ADMINISTRATION STUDY IN RATS W/[], EXPER INSECTICIDE & MITICIDE, DATED 1/12/2001 (SANITIZED)		
Chemical Category	CONFIDENTIAL		

OFFICE OF TOXIC SUBSTANCES
CODING FORM FOR GLOBAL INDEXING

REV. 7/27/82

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SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam,

(" ") is submitting additional data which we believe to be reportable under TSCA 8(e). This information concerns , an experimental insecticide and miticide, identified as a which has been assigned CAS Number . has recently imported solely for R&D testing purposes on behalf of (" ").

Earlier TSCA 8(e) Report: TSCA Control Number needed

We submitted information regarding adverse effects of to rats in a four-week dietary administration study performed by for to your agency under cover of our letter. We are now providing additional information on this study as required by TSCA 8(e) regulations. In we reported decreased body weights in the rats in this study as well as increased absolute liver weights. To date we have not received a TSCA Control Number for this report; we would appreciate receiving such a number.

Four-week study of by dietary administration to rats

is conducting a four-week study of the oral toxicity, with in Crj:CD (SD) rats, for was administered daily by mouth to these rats by mixing the test substance into their diet at 0, 100, 1000, 5000, and 10000 ppm. There

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were 12 rats/sex/dose group. These animals were sacrificed after the 30-day treatment period. An additional 6 rats/sex were assigned to control, 5000 and 10000 ppm groups as 14-day recovery groups. The histopathological part of this study has now been completed.

Additional findings

Centrilobular necrosis of hepatocytes was observed in one female dosed with 10000 ppm of

On the basis of all observations, the NOEL is now expected to be 1000 ppm. This is equivalent to 62 mg/kg/day for male rats and 66 mg/kg/day for female rats.

Substantiation of CBI Claims

All information deleted from the sanitized version of this letter (copy attached) should be treated as CBI. _____ wishes to protect its confidential business plan for the commercial development of this substance. Disclosure of this information would harm _____'s efforts to commercialize it. Please refer to the attached copy of our _____ letter to Mr. _____ of your Agency which substantiates _____'s CBI claims.

Should you have questions concerning this submission, please do not hesitate to contact us at _____ by telephone, _____ by telefax or via e-mail at _____

Sincerely yours,

Enclosure:

cc: