

US EPA ARCHIVE DOCUMENT

Subject: *ETH Registration Number 7501-42*  
*Sustafon Upon - the said Productant*

From: *Dallas J. Irraham*  
*ME/LL E 8/1/74*

005195

To: *Henry Jacoby*  
*Product Manager (21)*

Applicant: *Sustafon, Inc.*  
*P.O. Box 660065*  
*Dallas, Texas 75266-0065*

*Active ingredient:*  
*Methyl: N-(2,6-dimethylphenyl)*  
*-N-(methoxyacetyl) amine methyl*  
*ester* . . . . . *28.35%*  
*inert ingredient* . . . . . *71.65%*

*Examination is submitted in part for*  
*analysis of active ingredients data and 2050*  
*and 7501 and a preliminary report will*  
*be submitted on or about October 30, 1983*  
*Method of support not indicated*

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*Recommendation*

*(1) Based on the 2050 information submitted*  
*for Gen. Biol. Serv. the appropriate priority*  
*category for this drug is II (Patent)*

*193*

48-1-8

(2) Based on the information attached to letter dated March 9, 1984 from the Company and information received on acute inhalation October 20, 1983, it is concluded that there would be minimal exposure through inhalation route.

005195

Label:

No additional labeling comments.

- References:
1. Acute Oral Toxicity Study: Product Safety Labs; Report No. T-3030; May 6, 1983.

Procedure: Five male and five female rats weighing between 200 and 300 grams received a single dose of 5.0 g/kg. Observations were daily for 14 days after treatment. Necropsy performed on all animals.

Results: 2/5 M and 5/5 F died. Lethargy was the only toxic sign noted in the 3/5 M survivors. Necropsy revealed discolored liver and spleen; intestinal hemorrhage; pulmonary hemorrhage. ~~LD50 less than 5.0 g/kg.~~

i.D.S.C. expected to be 2.9 g/kg with 95% confidence limits between 1.8 and 4.6 g/kg.

Med. Classification: Carcinogenic Data -

Toxicity Category: III - (MUTAGEN)

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METALAXYL

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Page 3 is not included in this copy.

Pages \_\_\_\_\_ through \_\_\_\_\_ are not included.

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The material not included contains the following type of information:

- Identity of product inert ingredients.
  - Identity of product impurities.
  - Description of the product manufacturing process.
  - Description of quality control procedures.
  - Identity of the source of product ingredients.
  - Sales or other commercial/financial information.
  - A draft product label.
  - The product confidential statement of formula.
  - Information about a pending registration action.
  - FIFRA registration data.
  - The document is a duplicate of page(s) \_\_\_\_\_.
  - The document is not responsive to the request.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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