



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

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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID. No. 010308-RR, Sumilarv, Information to Upgrade 28-Day Inhalation Study in Rats

Tox. Chem. No.: 129032  
DP Barcode #: D218442  
Record No.: S4921101

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CONCLUSIONS:

Toxicology Branch I has reviewed the comments provided by the registrant in regard to deficiencies in the 28 day inhalation study in rats. The information provided in the submission will be made a part of the record for Sumilarv. The 28 day inhalation study will be classified as supplementary because there are no established data requirements for an inhalation study of this duration. However, the information obtained in the study (NOEL, LOEL) can be used for regulatory purposes.

BACKGROUND:

The original 28 day inhalation study was classified as supplementary based on the following findings:

- stability was not characterized
- characteristics of exposure atmosphere were not characterized
- failure to provide dynamic air flow rates

In spite of these deficiencies, a NOEL of 482 mg/m<sup>3</sup> and a LOEL of 1000 mg/m<sup>3</sup> were determined. The LOEL was based on the



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observation of salivation in both sexes and decreased body weight in males (significant at only two reporting intervals). In a memo of August 1, 1995 (Morrow to Tavano), it was concluded that the 90 day inhalation study was not warranted based on the fact that the concentration of active ingredients on the representative labels of Sumilarv products would not result in exposure concentrations that are likely to be toxic.

The following information has been provided by the registrant:

1. Stability. Sumilarv has been demonstrated to be stable in corn oil for one year.
2. Test atmosphere, Temperature and Relative Humidity. The following table provides information on the mean concentration of test material and mean particle size in the chamber.

Group*	Mean Conc. (mg/m <sup>3</sup> )	Mean Part. Size (microns)
I	--	0.88
III	269	0.84
IV	482	0.84
V	1000	0.71

\* Group II was untreated.

The particle sizes reported in this submission suggest that the particles were within the recommended respirable range of 1 to 3 microns for repeat exposure studies. The reported temperature and relative humidity were within an acceptable range, with temperatures not exceeding 27.3° and the relative humidity ranging from 40 to 70% for all groups.

### 3. Airflow

The registrant acknowledges that airflow was less than that which was specified in the guidelines for a subchronic inhalation study; however, the reduced airflow should not adversely affect the results obtained from whole body exposure to the test material.

### 4. Additional Comments

Additional comments pertaining to the statistics used in this study were provided. The registrant stated that the methods used in this study were routinely used in toxicology studies; however, these routine methods were not identified.

The information provided in this submission will be made a part of the file. The 28-day inhalation study will remain supplementary; however, the results can be used for regulatory purposes.