

## DATA EVALUATION RECORD

CHEM 041101

STUDY 1  
Ethoprop

§161-2

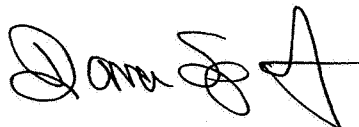
### FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 43833502

Gorman, Mike. 1995. Photodegradation of [ $^{14}\text{C}$ ]Ethoprop in pH 7 Buffered Solution - **Supplemental Study**. ABC Report No. 38139-1. Unpublished study performed by ABC Laboratories, Inc., Columbia, Missouri. Submitted by Rhone-Poulenc Ag Company, North Carolina.

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### CONCLUSIONS:

#### Degradation - Photodegradation in Water - Supplemental Study

1. The purpose of this abbreviated study (day 0 and day 30 sampling only) was to provide confirmatory residue identification. A photodegradation in water study reviewed by EFED on 4/5/90 (M. Carpenter, 1989; 41270702) did not satisfy the data requirement because the study lacked confirmatory residue identification.

The Photodegradation in Water data requirement is **satisfied** by this study together with the Carpenter study.

2. Ethoprop is stable to both direct and indirect photolysis in water. [ $^{14}\text{C}$ ]Ethoprop did not photodegrade in either a sensitized (1% acetone) or a non-sensitized sterile aqueous buffered (pH 7) solution that was continuously irradiated with a xenon arc lamp for 30 days. No degradates greater than 10% were identified. The estimated half-lives, calculated based on the Carpenter study, were 736 days and 603 days for the non-sensitized exposed and dark control samples, respectively. In the sensitized system, half-lives were 277 days for irradiated samples and 1460 days for the dark control.
3. The results demonstrate that photolysis in water is not a significant route of dissipation for ethoprop.

## METHODOLOGY:

[<sup>14</sup>C]Ethoprop (radiochemical purity 99.5%, specific activity 2301 dpm/μg) was added to sterile pH 7 TRIS buffer at a nominal concentration of 16 μg/ml. The study was conducted under direct (non-sensitized) and indirect (sensitized with 1% acetone) conditions. Twelve 10-ml borosilicate culture tubes for the non-sensitized system and another twelve for the sensitized system were filled to capacity with the radiolabeled ethoprop solutions and capped with teflon lined caps. Three tubes served as 0-hour samples. One sample was used to verify sterile conditions. Four tubes were designated as exposed samples, and four tubes were wrapped in aluminum foil and placed in the environmental chamber to serve as non-exposed control samples. The tubes were continuously exposed to a filtered Atlas 6500 watt xenon arc lamp in the environmental chamber at 25°C for 30 days. The study samples were placed so that the irradiation reaching them was approximately one-half the intensity of sunlight.

On day 30, the four exposed and four non-exposed sensitized and four exposed and four non-exposed non-sensitized samples were removed from the environmental chamber. The samples were analyzed by LSC, RP-HPLC, and two-dimensional TLC. LSC was used to determine the total <sup>14</sup>C-radioactivity in samples. HPLC (Waters C18 column, water and acetonitrile mobile phase) was used as a primary method to quantitate and confirm the presence of <sup>14</sup>C-ethoprop and its degradates. 2D-TLC (silica gel, acetonitrile:acetone:water and ethanol:water) was used as a confirmatory method to characterize the <sup>14</sup>C-ethoprop and degradates that exceeded 10% of the applied radioactivity. The samples were transferred to amber vials and stored at 10°C when not in use. Samples were prepared for co-chromatographic analysis by mixing radiolabeled or non-radiolabeled standards with selected samples.

## DATA SUMMARY:

The photolysis half-life in pH 7 buffer was estimated to be 122 days in the exposed system and 416 days in the dark control. In the previous study, values of 736 days and 603 days were calculated. The photolysis half-life in the sensitized (1% acetone) pH 7 buffer was estimated to be 104 days in the exposed system and 2079 days in the dark control. Values of 277 and 1460 days were found in the previous study. Because the current study only involved one sampling interval (30 days), the half-lives determined in the previous study are believed to be more reliable. However, the previously determined half-lives still involve a large amount of extrapolation. In any case, it is clear that photodegradation in water is not a significant route of dissipation for ethoprop.

HPLC analysis of the non-sensitized day 30 samples showed peaks with retention times of 3 minutes (2.60%), 5 minutes (9.97%), and 19 minutes (1.75%). These peaks were not further identified. Ethoprop was the major peak comprising 83% of the applied radioactivity in the exposed sensitized samples and 85% of applied radioactivity in the exposed non-sensitized samples.

In the non-sensitized system, ethoprop comprised an average of 100.02% on day 0 and 84.92% on day 30 in the exposed samples and 95.71% on day 30 in the dark control.

In the sensitized system, ethoprop comprised an average of 99.98% on day 0 and 82.59% on day 30 in the exposed samples and 99.69% on day 30 in the dark control.

The overall material balances averaged  $98.3 \pm 1.39\%$  for the non-sensitized samples and  $99.1 \pm 1.36\%$  for the sensitized samples.

COMMENTS:

1. The UV spectrum of ethoprop in pH 7 TRIS buffer was provided. Ethoprop absorbs primarily below 310 nm.
2. The solubility of ethoprop in water was reported to be 843 mg/L at 21°C.
3. HPLC analysis of the non-sensitized day 30 test solutions showed an unidentified peak, comprising 9.97% of the applied radioactivity, at a retention time of 5 minutes. An attempt should have been made to identify this degradate.

MRI# 43833502

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Pages 4 through 18 are not included.

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