



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

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BB-1144  
712-3830

*Caswell #*  
*434A*

MEMORANDUM

TO: Robert Taylor, PM #2  
Registration Division, TS-767

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

FROM: Chad B. Sandusky, Ph.D.  
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*Chad B. Sandusky*  
*5/29/84*

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*CF Chaisson*  
*5/29/84*  
*11/16/84*  
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*5/29/84*

SUBJECT: Addendum to the Two-year Mouse 1979 Oncology  
Study on Butylate, Sutan® Technical, T-6341;  
PP# 476-2156.  
Reg. No.

Action Requested:

Additional data on the previously reviewed 1979 mouse study has been submitted by Stauffer Chemical Co. This data was submitted in support of the Butylate Registration Standard. The submission contains information on the butylate compounding and stability in feed. The lack of this information was listed as a deficiency in the butylate support document to the Butylate Registration Standard (J.W. Holder, Tox., 7/6/83, pg. 40).

Data Review:

The compound butylate was analyzed after extraction from the diet media, Purina Laboratory Chow. It was found that:

- 1) Fresh diet was made up weekly, and analyses showed butylate was  $\pm$  5 to 10% of the expected doses.

The expected doses were: 0, 20, 80, 320 mg. a.i./kg. b.w./day.

- 2) Butylate was found to be stable over the period of a week, i.e., the period between new diet preparations.

- 3) The amount of butylate per dose level did not have any effect on butylate stability in the Purina Laboratory Chow.

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Conclusion:

This additional information indicates butylate was stable under test conditions used. This deficiency is now eliminated. Thus, the conclusions of the two-year mouse oncology study remain unchanged.

No changes are necessary for the butylate standard.