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INITIAL SUBMISSION: LETTER FROM [] TO USEPA REGARDING REPRODUCTIVE TOXICITY STUDIES ON RABBITS WITH SUBSTITUTED SODIUM BENZOATE WITH COVER LETTER DATED 102992 (SANITIZED)			
[Hatched]			
Chemical Category			
SUBSTITUTED SODIUM BENZOATE			

8EHAQ-1092-85555

COMPANY SANITIZED
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92 NOV -3

October 29, 1992

Express Mail - Return Receipt Requested

Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460

8EHAQ 92 8555 init
PP9300000 37

Dear

Substituted Sodium Benzoate

In our letter of October 2, 1992, we reported the preliminary results of a developmental toxicity study in rats. This letter is to inform you of the preliminary results of a recently completed developmental toxicity study in rabbits.

Groups of 20 rabbits were dosed by gavage with solutions of the test material in deionized water equivalent to 0, 30, 100, 300, or 1000 mg/kg on days 7-19 of gestation (the day of insemination was termed Day 0 of gestation). Surviving females were sacrificed on day 29 of gestation and the live fetuses examined for external, visceral and skeletal alterations.

Fetal toxicity was demonstrated by a slight, but significant decrease in mean fetal weight at the 1000 mg/kg/day dose level. There was also a slight but statistically significant increase in the mean number of early resorptions per litter at this dose level. While this finding does meet TSCA 8(e) criteria for reporting developmental toxicity, we do not consider this to be biologically significant since the actual incidence was within the range of recent historical control values. A third finding was the occurrence of two does with totally resorbed litters at the 1000 mg/kg/day dose level. However, this finding is typically considered to be indicative of maternal toxicity. No effects on the incidence of fetuses with developmental variations, variations due to retarded development or the incidence of fetal malformations were detected.

Additional signs of maternal toxicity in the form of mortality, decreased weight gain and decreased feed consumption were observed in the 1000 mg/kg dose group. Clinical observation incidence was significantly increased for this group during the dosing and postdosing periods as well.

We will forward a copy of the final report to EPA when it is available.

Sincerely,

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[]

CBI Substantiation

Support for [] of confidential business information for the information claimed as CBI is provided.

1. Yes.
2. Confidential treatment should be afforded for ten years. Information should remain confidential until that time []
3. No.
4. All documents relating to [] are stored in locked, limited-access facilities and designated as proprietary, trade secret or confidential. [] having access to the information are contractually prohibited from disclosing [] proprietary/ confidential information outside the []. The compound also has been [] in many instances to prevent undesired disclosure of information.
5. Yes, []
6. No.
7. No.
8. []. Disclosure of the C.B.I information would permit a competitor to specifically know and understand [] efforts with this compound and to forego the necessary time and expense to identify/develop this compound, thus capitalizing on []. [] believes that a competitor's knowledge of the chemical identity [] interest in this compound would give a competitor several year's advantage [] and would allow it to forego much of the R&D costs that it would otherwise have to bear. [].
9. Yes.
10. No. []

11. Yes, by knowing the final structure, a synthesis chemist could identically recreate the substance.

12. a. No.

b. No.

c. Yes. Disclosure of [] would reveal the identity and source of the [].

13. []

14. No.

CERTIFICATE OF AUTHENTICITY

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