

CODING FORMS FOR SRC INDEXING

Microfiche No.		
OTS0560000		
New Doc ID		Old Doc ID
88010000068S		8EHQ-0101-14856S
Date Produced	Date Received	TSCA Section
01/25/01	01/30/01	8E
Submitting Organization		
CONFIDENTIAL		
Contractor		
Document Title		
INITIAL SUBMISSION: LETTER FROM [] TO USEPA REPORTING PRELIMINARY TERATOLOGY STUDY OF [], AN EXPERIMENTAL PYRETHROID INSECTICIDE, IN RABBITS, DATED 1/25/2001 (SANITIZED)		
Chemical Category		
EXPERIMENTAL PYRETHROID INSECTICIDE (CONFIDENTIAL)		

There were no effects to the embryos or fetuses of dams dosed with

Materials & Methods

Animals: Primary group (0, 10, 50, 100, and 200 mg/kg)
Kbl:NZW rabbits, 19-week old males and 20-week old females (body weight range 3.47-4.42kg at the start of dose administration).

Additional group (300 mg/kg)
Kbl:NZW rabbits, 24 week old males and 25 week old females (body weight range 4.19-5.13kg at the start of dose administration)

The males in this study were used only for impregnating the females and received no doses of the test substance.

Administration: route: oral gavage
frequency: once daily
volume: 0.5ml/kg based on most recent body weight
vehicle: corn oil
period: gestational days 6 through 27

Animals observed for: clinical signs, maternal body weight, body weight changes, and food consumption

Other procedures: caesarian section and necropsy on gestational day 28 in the dams, followed by fetal examinations consisting of determination of sex, fetal body weight, and observation of skeletons and viscera for adverse effects

Results: The results of this study are summarized in the Table 1 overleaf on page 3 of this report.

Table 1 Preliminary Teratology Study with in Rabbits

Dosage (mg/kg)	Control (Corn oil only)	10	50	100	200	300
No. animals artificially inseminated	5	5	5	5	5	5
No. animals not pregnant	0	1	0	0	0	1
No. animals excluded (Gestational day)	0	1 ^a (15)	0	0	0	0
No. animals found dead (Gestational day)	1 ^b (19)	0	0	0	1 (8)	1 ^b (19)
No. aborted fetuses (Gestational day)	1 (22)	0	0	0	1 (23)	0
No. litters totally resorbed	0	1	0	0	0	0
Clinical signs	-	--	--	--	clonic convulsions observed in animal which subsequently died	-
Body weights	-	-	-	-	-	↓ on gestational day 6
Body weight changes	-	-	-	-	-	↘
Body weight change adjustment for pregnancy	-	-	-	-	-	↘
Food consumption	-	-	-	-	-	↘
Effects on embryos or fetuses	-	-	-	-	-	--

Interpretation of symbols in table above:

- ^a: Animal excluded due to dosing procedure
- ^b: Death caused by dosing error
- : No abnormal findings observed OR no significant difference from control
- ↓: Significantly different from control (p<0.05)
- ↘: "Tended to be lower"

Substantiation of CBI Claims

All information deleted from the sanitized version of this letter (copy attached) should be treated as CBI because [redacted] wishes to protect its confidential business plan for the possible commercial development of this compound. Disclosure of this information would harm [redacted]'s efforts to commercialize this compound. Please refer to the attached copy of our letter to [redacted] of the [redacted] regarding the substantiation of these CBI claims.

Should you have questions concerning this submission, please do not hesitate to contact me at () - by telephone or () - by telefax. If preferred, you may email me at

Sincerely yours,

Enclosure: (1)
cc: