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Submitting Organization					
CONFIDENTIAL					
Contractor					
Document Title					
INITIAL SUBMISSION: LETTER FROM [] TO USEPA, SUMMARY OF DOSE RANGE-FINDING STUDY FOR EFFECTS ON EMBRYO-FETAL DEVELOPMENT OF [] IN PREGNANT RATS, DATED 120299 (SANITIZED)					
Chemical Category					
CONFIDENTIAL					

**INITIAL  
SUB-  
MISSION**

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PR 24565

SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam,

(" ") is submitting certain data which we believe to be reportable under TSCA 8(e). This information concerns an experimental insecticide and miticide, identified as , an experimental insecticide and has been assigned CAS Number . has recently imported solely for R&D testing purposes on behalf of (" ").

Summary of Dose Range-Finding Study for Effects on Embryo-fetal Development of in Pregnant Rabbits.

Testing facility: (contract laboratory)

Materials & Methods

- (1) ANIMALS: Kbl.JW rabbits
- (2) ADMINISTRATION METHODS:

Route: Oral administration by gavage  
 Volume: 5ml/kg  
 Vehicle: 0.5% aqueous solution of methylcellulose  
 Doses: 0, 50, 100, & 150 mg/kg of was administered to pregnant rabbits (4-6 animals per group)  
 Period: Gestational days 6-28

(3) OBSERVATION ITEMS:

Clinical signs, Body weight, Food consumption, Necropsy and Caesarian section (Day 29 of gestation), Fetal body weight, Fetal Examination (External, Visceral, and Skeletal examinations)

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**Results**

Dosage Group	Control (0.5% methylcellulose)	(50mg/kg)	(100mg/kg)	(150mg/kg)
<b>Dams</b>				
No. of pregnant animals	6	5	4	6
No. of dead animals	0	0	0	0
No. of animals with abortion (Gestational days 22, 23, 24, & 29)	0	1	0	0
Clinical signs/no. animals	-	-	-	4
				Scant loose stool (2)
				Scant feces (6)
				No feces (5)
				Scant/no urine (4)
				Loss of fur (1)
				Deep respiration, prone position, sluggish startle reaction, emaciation (1)
Body weight	-	-	-	Decreased
Food intake	-	-	-	Decreased
Necropsy/no. animals	-	-	-	Liver: pale color (2)
				Heart: pale color (2)
				Cecum: retention of dark green liquid (4)
				Stomach: retention of large amount of hair (1)
				Adrenals (both): enlargement (1)
				Gallbladder: mucosal surface (1)

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Dosage Group	Control (0.5% methylcellulose)	(50mg/kg)	(100mg/kg)	(150mg/kg)
<b>Litter Data</b>				
No. of corpora lutea	11.3	10.5	13.0	11.5
No. of implantations	9.2	10.3	9.8	9.0
No of live fetuses	8.7	9.5	7.5	6.5
Embryo-fetal mortality	4.7	6.8	18.0	26.3
Sex ratio	36.5	42.2	80.2**	61.9
Fetal body weight (g)				
Male	37.5	34.3	44.0	26.7
Female	41.5	34.3	43.1	24.2*
Placental weight (g)	3.10	3.07	3.62	3.27
<b>Fetuses</b>				
External examination	0 (0.0%)	1 (2.5%)	0 (0.0%)	0 (0.0%)
No abnormal signs or no significant difference from control.				
* Significantly different from control, $p < 0.05$				
** Significantly different from control, $p < 0.01$				

**Comments:**

Abortions were observed in four (4) of six (6) of the animals. It is known that dietary deprivation may induce abortions in rabbits. In this study, abortions occurring on gestational days 22, 23, 24 and 29 followed in those rabbits which had consumed no food for several days prior to the abortions. The study director therefore considered these abortions to be secondary effects of maternal toxicity.

The body weight of the live fetuses was lower in the rabbits receiving the highest dose level of 150 mg/kg. Visceral and skeletal examinations of the fetuses are in progress at the time of this report.

The NOEL was estimated to be lower than 200 mg/kg.

**Substantiation of CBI Claims**

We wish to substantiate claims that certain information on this letter be treated as Confidential Business information ("CBI"). All information which has been deleted from the sanitized version of this letter (copy attached) should therefore be treated as CBI. In substantiation of this claim, we are attaching a copy of our November 30, 1999 letter regarding an earlier TSCA 8(e) submission on

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Should you have questions concerning this submission, please do not hesitate to contact me at  
( ) by telephone, ( ) by telefax or via e-mail through

Sincerely yours,

Enclosure: (1)

cc:

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**CERTIFICATE OF AUTHENTICITY**

THIS IS TO CERTIFY that the microimages appearing on this microfiche are accurate and complete reproductions of the records of U.S. Environmental Protection Agency documents as delivered in the regular course of business for microfilming.

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**END**