

10-17-79

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: October 4, 1979

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SUBJECT: EPA File No. 1021-1060, D-Trans Allethrin: teratogenic evaluation
CASWELL#25A

FROM: John Doherty *John Doherty 10/17/79* *Bidd 10/17/79*
Toxicology Branch/HED (TS-769)

TO: Franklin Gee
Product Manager#17/RD (TS-767)

Conclusion:

The teratology study in rats has been reviewed and it is concluded that d-trans allethrin is not a teratogen in rats at doses as high as 195 mg/kg/day (highest level tested).

However, at all test levels there was a significantly increased number of fetuses with rudimentary 14th ribs. This is considered a possible fetotoxic effect and no NOEL is established for this effect.

Toxicology Branch requests information on the detailed history of this lesion (rudimentary 14th ribs) in the strain of rats used for this study to determine if this effect is allethrin dependent.

Teratologic Evaluation of D-Trans Allethrin in Sprague Dawley Rats.

Food and Drug Research Laboratories, April 20, 1979, Lab. No. 6059. (In EPA accession No. 238638)

6 groups of female rats (28-34 per group) were used in this experiment. The doses of d-trans allethrin (92.5%) used were 50, 125, 195 and 300 mg/kg/day. The group receiving 300 mg/kg/day was terminated after the first few doses because this dose was lethal to the dams. Vehicle control and positive control (aspirin, 250 mg/kg/day) groups were also run.

The dams were impregnated and treated by gavage on days 5-15 of gestation. The rats were sacrificed on day 20 and the uterine contents and the pups subjected to thorough examination.

Results (for controls, 50, 125 and 195 mg/kg/day d-trans allethrin)

- 1) The dams gained weight normally and were reported as not having changes in general appearance and behavior. There were 6 deaths in the high dose group (195 mg/kg).
- 2) There were no differences in pregnancy, implantation, numbers of dead or live fetuses, or number of resorption sites/dam reported.

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(2)

- 3) There were no reported soft tissue anomalies in fetuses from d-trans allethrin treated dams.
- 4) The single statistically significant abnormality reported for skeletal development was a significant increase in the % of litters with rudimentary 14th ribs at all doses of d-trans allethrin tested.

<u>Vehicle Control</u>	<u>Aspirin</u>	<u>D-Trans Allethrin</u>		
		<u>50 mg/kg</u>	<u>125 mg/kg</u>	<u>195 mg/kg</u>
10/5	58/17*	18/10*	38/19*	34/15*

upper = number of fetuses affected.
lower = number of litters affected.
* significantly different from control.

There was also an increased incidence of incomplete ossification of the vertebrae at all levels of d-trans allethrin, but this was not statistically significant.

This is a CORE-GUIDELINES study.

TOX/HED:th:RD Initial EBUDD:9-21-79 Rewrite:Budd:sb:10/5/79

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7/6
N. Budd*

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