

US EPA ARCHIVE DOCUMENT

The Toxicology Review has identified only one stray that does not meet Agency requirements. The following information is needed for the rat teratology study:

7-15-85

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James W. Allen  
7/15/85

Rat Teratology Study - (OMMAW)

HISTORICAL CONTROL DATA FOR AW NOTED MAJOR AND MINOR MALFORMATION, SKELETAL VARIATION FOR RATS STUDIED IN THE FANC LAB FROM 1982 THROUGH 1984.

SAMPLE: Study No. 682

<u>MAJOR MALFORMATION</u>	$\frac{\# \text{ FETUSES}}{\# \text{ FETUSES EXAMINED}}$	$\frac{\# \text{ LITERAL OFFENSES}}{\# \text{ LITERAL EXAMINED}}$
- ACENTRIC etc.	$\frac{3}{160}$	$\frac{1}{20}$
<u>MINOR MALFORMATION</u>		
- MALFORMED TAIL etc.	$\frac{4}{160}$	$\frac{2}{19}$
<u>SKELETAL VARIATION</u>		
- WASH RIBS	$\frac{6}{160}$	$\frac{3}{20}$
- MISSING #5 STERNAL RIB etc.	$\frac{10}{160}$	$\frac{2}{20}$

...

WE CANNOT BE MORE SPECIFIC BECAUSE THE REPORTED RAT TERATOLOGY STUDY HAD NO MAJOR MALFORMATIONS REPORTED; THE RAT REPRODUCTION HAS SEVERAL UNSUAL TERATOGENIC RESPONSES (NO AXIAL OPENING, ETC) AND THEREFORE PROVIDES SOME ~~AN~~ IMPROVISED FOR FURTHER EXAMINATION OF THE RAT TERATOLOGY STUDY. XX 453

IN ADDITION, IN ORDER TO ESTABLISH THE ADEQUATE WORKING RANGE OF THE TERATOLOGY SYSTEMS 1985/16 G

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AND TECHNIQUES EMPLOYED BY FMC, "POSITIVE CONTROL" DATA ARE REQUESTED. THESE DATA SHOULD BE REPORTED IN THE SAME MANNER AS DISCUSSED PREVIOUSLY WITH IDENTIFICATION OF THE "TEST COMPOUND".

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