MRID 0502-228 CONFIDENTIAL BUSINESS INFORMATION
DOES NOT CONTAIN
NATIONAL SECURITY INFORMATION (EO 12065)

DATA EVALUATION RECORD

TRICHLORFON

REPRODUCTION/TERATOLOGY

CITATION: Ivanova-Chemishanska L, Petrova-Vergieva T, Mirkova E. 1975. Embryotoxic and teratogenic action of some pesticides. Exper. Med. and Morphol. XIV(1):29-33.

REVIEWED BY:

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Signature: 25 July 83

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DATA EVALUATION RECORD

STUDY TYPE: Reproduction/teratology in the rat.

CITATION: Ivanova-Chemishanska L, Petrova-Vergieva T, Mirkova E. 1975. Embryotoxic and teratogenic action of some pesticides. Exper. Med. and Morphol. XIV(1):29-33.

ACCESSION NUMBER: Not available.

MRID NUMBER: 05022287.

LABORATORY: Hygiene Center, Sofia, Bulgaria.

TEST MATERIAL: Trichlorfon, purity and source not stated. Trichlorfon was referenced in the report as Dipterex (dimethylhydroxytrichloroethyl-phosphonate).

PROTOCOL:

- 1. Dipterex (dimethylhydroxyltrichloroethylphosphonate) was studied for its reproductive toxicity and teratogenic potential. The purity and sources of the dipterex were not stated. [Dipterex is a chemical synonym for trichlorfon.]
- 2. An unspecified number of pregnant rats were utilized in the study. The strain, age, weight, and number of animals per group were not reported.
- 3. The route of exposure, amount of test article administered, and the duration of dosing were not clearly stated. Two dosing methods were described as, "1) singly in the period of organogenesis and at the 'critical moment from the 95hr to the 13th day of gestation at a dose of 1/2 LD50 and lower until determination of a single nonacting dose; 2) over the course of the entire pregnancy at a dose from a determined single threshold until the minimally acting given multiple applications and nonacting teratogenic dose given the same conditions are reached."
- 4. An unspecified percentage of the animals were sacrificed on day 22 of gestation. The animals were caesarean sectioned and the number of corpora lutea, resorptions, "autolysis" [dead fetuses], and live fetuses, were observed. The fetuses were examined for external appearance and fetal weight and crown-to-rump lengths were obtained.

The placentas were weighed. Skeletal examinations were performed on fetuses stained with alizarin red by the method of Dawson (1926, reference not given) and visceral examinations were performed on fetuses utilizing Wilson's techinque. The number of fetuses per litter assigned to skeletal or visceral examinations was not provided, nor was the method of preparing the fetuses that were viscerally examined. "Other animals" were allowed to deliver their offspring. The rat pups were observed for 45 days post-partum. The following indices were recorded at unspecified intervals; number of live and dead pups, pup body weight [unspecified as to individual or litter], and "a biological test for reproduction."

RESULTS:

"Study of the teratogenic and embryotoxic action of dipterex...did not show a fetus damaging effect." No data pertaining to dipterex were provided, nor were other references to dipterex data provided in the text.

CONCLUSIONS:

The omission of any data pertaining to dipterex prevents this reviewer from making any conclusions regarding the reproductive toxicity or teratogenicity of dipterex. The authors stated that dipterex "did not show a fetus damaging effect."

CORE CLASSIFICATION: Invalid.

The following major deficiencies were noted:

- o No data were provided on the effects of dipterex in either the dam, fetus, or offspring.
- o The dose levels administered, the route of administration, and the duration of dosing could not be determined.
- o The strain, age, weight, and number of rats used were not specified.
- o The purity and source of the test article were not stated.