2,4-D/TOX

(18)

3/5 Releasable

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: October 11, 1977

SUBJECT: Summary Sheet Petition 7E1980

FROM: Toxicology Branch
R. Engler Ph.D. 10/11/77

TO: Special Registration Section
Mr. C. Fletcher

For detail review see review by Mr. R. Coberly, of 11, October 1977.

1. Data considered.

Oral LD_{50} rat 300-470 mg/kg
113 day rat feeding study NEL 300 ppm
90 day dog feeding study NEL 400 ppm
2 year rat feeding study NEL 1250 ppm
2 year dog feeding study NEL 500 ppm
rat 3 generation reprod. study NEL 500 ppm
rat teratology no terata at 25 mg/kg
hamster teratology no terata at 40 mg/kg
teratology on 2,7-dichloro dibenzo
dioxin (rat and hamster) no terata at 2 mg/kg
22 week cattle feeding NEL 50 mg/kg
carcinogenicity screen (mice)
Bionetics no carcinogenicity

2. data desired:
a) carcinogenicity study in second species
b) mutagenicity testing

3. action taken to obtain information
none

4. other tolerances:
granted under 180.142 on about 80% of total human diet.

5. Theoretical Maximum Residue Contribution (TMRC). The TMRC for 2.4-D is 0.903 mg/day (computer calculation) or 0.795 mg/day (calculated by Mr. Coberly). The ADI is not exceeded, only about 12% of the ADI is represented by these figures. The TMRC is not affected by the present tolerance on millet, which is an animal feed item in the United States. The safety for dometic animals is demonstrated by feeding studies with laboratory animals and cattle.

6. ADI and MPI.
The ADI was calculated based on the dog 2 year feeding study, using a safety factor of 100. The ADI is 0.125 mg/kg b.w./day, thus the MPI for a 60 kg man is 7.5 mg/day. The dog study was used since the NEL in the dog study and the rat reproduction study was 500 ppm, quite lower than the NEL of 1250 ppm in the life time feeding study in rats.

7. Pending actions:
   None of which TB is aware.

8. No additional comments.