RD-594
TXR-4919

MEMORANDUM

004919

SUBJECT D P X - F 6025

TO: Taylor / Walter PM 25

Registration Division (TS 767)

FROM : Alex Arce
Toxicology Branch
HED (TS- 769)

Feb 4-86

Through : Clint Skinner Ph.D.
Head Section lll

ackat 2/4/86
(for CS)

Theodore Farber , Ph. D. CHIEF
Toxicology Branch (T S 769)

Compound : D P X

Tox Chemical # 193 B PP # 5E 3186/ 352 UGA

Accession # 260553

Registrant # E. I. du Pont de Nemours

Action Requested

1- Review of new label

2- Additional data to upgrade Mutagenicity study previously reviewed , Study "Unscheduled DNA Synthesis Assay of D P X - F 6025 Herbicide (H L R-208-83)"

Recommendation or Conclusion

1- The label is accepted

2- The additional submitted data is sufficient to upgrade the study to acceptable .

1 of 3

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Background Information

Data submitted by the registrant were previously reviewed and accepted , Study No 208-83 Unschedulled D N A synthesis required explanation regarding justification for selection of

Information Submitted

the highest dose level , since apparently no toxic dose was tested (Coppy Attached)

Acc # 260553 , volume containing new label and justification for use of doses in Unschedulled D NA synthesis study

Discussion

The submitted explanation is acceptable , the doses used are justifiable

Enclosure

Several other documents not related to the Tox Branch

DERs

No assigned

2

References

None

(5) Teratology, rabbit.
Not teratogenic.
Maternal toxicity
NOEL: 60 ppm. LEL: 300 ppm (decreased weight gain)
Fetal toxicity
NOEL: 15 ppm. LEL: 60 ppm (delayed ossification)

Two of the three mutagenicity studies which previously were considered to be not fully adequate have (because of comments and additional information) been upgraded to the Core Classification status, Acceptable. The studies are: (1) in vivo bone marrow study (No. 201-615), No clastogenic, chromasomal, or chromatid effect was seen. (HDT:5000 mg/kg). (2) Ames test. Cytogenicity data provided which indicated that no mutagenicity was found at the cytotoxic dose level.

The Unscheduled DNA Synthesis study, No.208-83, although apparently conducted according to adequate procedures, has an omission. The choice of highest dose was not justified. No toxic dose was tested. Unless 10 m M represents the limit concentration for such studies, ie. 5000 micrograms, cytogenic data is needed. Pending the receipt of such data or appropriate information, the study is inconclusive. However, when toxicity data (or limit dose) or solubilityy criterion information has been provided, the study may be upgraded to Acceptable.

Inerts have been cleared.

Additional data is needed before registration.