3-23-82

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

001543

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

DATE: March 23, 1982

SUBJECT: Bolstar; Registration Standard Chemical; EPA Reg.#3125-321, 3125-328; Teratology Study in Rats
CASWELL#453AA Accession#246733

FROM: William Dykstra, Toxicologist
Toxicology Branch/HED (TS-769)

WRD JDC 3/23/82

TO: Jay Ellenberger (12)
Registration Division (TS-767)

Recommendations:

1) The teratolcgy study is acceptable as Core-Minimum Data. Bolstar was not teratogenic at dosages up to 30 mg/kg/day.

Review:

1) Embrotoxicity and Teratogenicity Study with NTN 9306 (Bolstar) in Rats (Bayer AG Report No. 80018; July 1981)

Test Material: NTN 9306

Groups of 25 mated Wistar rats were orally intubated with 0, 3, 10 or 30 mg/kg/day of test material from day 6 through day 15 of pregnancy. On day 21 of pregnancy, dams were killed and fetuses removed by cesarean section.

Ovaries and uterine content were examined. The fetuses were sexed, weighed and examined externally. One-third of the live fetuses were subjected to visceral examination by the Wilson technique. The remaining fetuses were examined for skeletal malformations and variations.

1.3.1

Results:

One female at 3 mg/kg/day and 12 females at 30 mg/kg/day died. At 30 mg/kg/day, the rats displayed toxic signs evidenced as exophthalmus, kyphosis and tremors. Body weight and food consumption was reduced in the 30 mg/kg/day group. Implantations and resorptions were unaffected by treatment. Fetal body weight was reduced in the 30 mg/kg/day group.

One fetus in one litter with omphalocele was found in the 30 mg/kg/day group. Dilated kidney pelvises were found in 2 fetuses in two litters of the control group, 1 fetus of one litter in the 3 mg/kg/day group and 2 fetuses of two litters of the 10 mg/kg/day group. Two fetuses in two litters of the 3 mg/kg/day group and 2 fetuses of two litters of the 30 mg/kg/day group had wavy-ribs. An increase in the number of fetuses with unossified sternebrae was present at 10 and 30 mg/kg/day groups.

Conclusions:

Bolstar technical was not teratogenic at dosages up to 30 mg/kg/day. The fetotoxic NOEL is 3 mg/kg/day. The maternal toxic NOEL is 10 mg/kg/day.

Classification: Core-Minimum Data

TS-769:th:TOX/HED:WDykstra:3-23-82:card 8