



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

CASWELL FILE

MAR 18 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Review of Supplemental Information on Historical Control Skeletal Variations in the Metam Sodium Rat Teratology Study Addendum to MRID 41577101

TO: Tom Myers PM 52
SRRD (H7508C)

FROM: K. E. Whitby, Ph.D. *for [signature] 3/13/92*
Section, II
Toxicology Branch II/(HED) (H7509C)

THRU: K. Clark Swentzel *K. Clark Swentzel 3/13/92*
Section Head
Toxicology Branch II/(HED) (H7509C)

and

Marcia van Gemert, Ph.D. *M. van Gemert 3/13/92*
Chief, Toxicology Branch II/(HED) (H7509C)

HED Project # 2-1248

Caswell No. 780

Action Requested:

Please review the attached historical control data on skeletal variations for developmental toxicity in the rat as requested by the peer review committee. This information is an addendum to MRID 41577101, Rat Teratology Study.

ICI Americas Inc., has submitted on behalf of the Metam Sodium Task Force, supplemental information on historical control data for skeletal variations in the metam sodium rat teratology study. The data which has been submitted does not provide information on the species, strain, source, vehicle treatment, number of studies used to generate the data, the inclusive dates, or the number of fetuses and litters. In addition, the data does not indicate whether it was generated using day 20 or 21 cesareaned fetuses (assuming the day of a confirmed mating was day 0) which would affect the degree of skeletal ossification. In conclusion, this submission is inadequate to alter the decision of OPP's Health Effects Division, Developmental Peer Review Committee regarding the NOEL.