



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

FEB 24 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: ETU (Ethylene Thiourea) Revised Q_1^* , (3/4's Interspecies
Scaling Factor), NTP B₆C₃F₁ Mouse Dietary Study

Caswell No.443AA

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The revised unit risk, Q_1^* (mg/kg/day)⁻¹ of ETU, based upon female (F₁) mouse liver (adenoma and/or carcinoma) tumor rates is 6.01×10^{-2} in human equivalents (converted from animals to humans by use of the 3/4's scaling factor-1994, Tox_Risk, 3.5-K. Crump)^a. The dose levels used in the mouse study were 0, 100, and 330 ppm of ETU. The corresponding tumor rates in female mice were 9/98, 4/27 and 136/150. These doses and rates were obtained from the memorandum "Ethylene Thiourea (ETU) - Q_1^* Calculation Based on Female Mouse Liver Tumors (Pooled Data) from NTP Study, H. Pettigrew, 11/13/91)."

^a See Memo - Deriving Q_1^* 's Using the Unified Interspecies Scaling Factor, P.A. Fenner-Crisp, Director-HED, 7/1/94.

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Dose-Response Analysis

Since the female mice did not have significant differential mortality with incremental doses of ETU, the estimate of unit risk, Q_1^* , was obtained by the application of the Multi-Stage model (Tox_Risk program, version 3.5 - K.Crump).

The estimate of unit risk, Q_1^* , was based upon liver (adenoma and/or carcinoma) tumor rates observed in female mice.

The resulting estimate of unit risk, Q_1^* , is as follows:

Species, Strain, Sex	Tumor	Q_1^* (mg/kg/day) ⁻¹ in Human Equivalents ^a
Mouse, B ₆ C ₃ F ₁ , Female	Liver (Ad &/or Ca)	6.01x10 ⁻²

For the conversion to human equivalents, weights of .0343 kg for the mouse, 70 kg for humans and the 3/4's scaling factor were used. Food consumption was 5.7 g/day as presented in the study.

It is to be noted that Q_1^* (mg/kg/day)⁻¹ is an estimate of the upper bound on risk and that (as stated in the EPA Risk Assessment Guidelines) "the true value of the risk is unknown, and may be as low as zero."