



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

RECEIVED

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Telone II -Revised Q_1 , (3/4's Interspecies Scaling
Factor), Mouse ($B_6C_3F_1$) Inhalation Study

Caswell No.324A

From: Bernice Fisher, Biostatistician
and
Hugh Pettigrew, Section Head
Statistics Section
Science Analysis

Bernice Fisher
Hugh Pettigrew 12/19/94
9C)

To: Debra Edwards
Chemical Control

ref + 4

(15)

(7509C)

Thru: William L.
Science Analysis

09C)

W. L. Beringer

The revised unit risk, Q_1 (mg/day)⁻¹ of Telone II, based upon male lung bronchioalveolar adenoma tumor rates is 1.3×10^{-5} in human equivalents (converted from animals to humans by use of the 3/4's scaling factor-1994, Tox Risk, 3.5-K.Crump)¹. The dose levels used in the mouse study were 0, 5, 20 and 60 ppm concentrations of Telone II vapor in air, 6 hours per day, 5 days per week. The corresponding tumor rates in male mice were 9/49, 6/50, 13/49 and 22/50 (these rates did not include interim sacrificed animals). The memorandum, Telone II - Qualitative Risk Assessment, B. Fisher, 7/5/89 contained the underlying data and statistical evaluation that was used for the above revision of the unit risk of Telone II.

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

cc: Caswell file

M.Beringer



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

192

Dose-Response Analysis

The estimate of unit risk, Q_1^* , was based upon lung bronchioalveolar adenoma tumor rates in male mice.

Since the male mice had no significant differential mortality with incremental doses of Telone II, the estimates of unit risk, Q_1^* , were obtained by the application of the Multi-Stage model (Tox_Risk program, version 3.5 - K.Crump).

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 , Male | Bronchiolveolar Adenoma | 5.33x10 ⁻² |

For the conversion to human equivalents, weights of .03 kg for the mice, 70 kg for humans and the 3/4's scaling factor were used.

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."