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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Metam Sodium-Quantitative Risk, Q_1^*, Two-Year Drinking Water Study in C57BL/10JfCD-1/Alpk Mice

Caswell No. 780

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Summary

The estimated unit risk, $Q_1^*(mg/kg/day)^{-1}$ of Metam Sodium, based upon angiosarcoma rates in male mice, is $1.98x10^{-1}$ 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 carcinogenicity study for their drinking water were 0, 1.6, 6.5, and 27.7 mg/kg/day of Metam Sodium. The corresponding tumor rates in male mice were 7/52, 12/52, 12/55, and 27/52.

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

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Background

In March, 1995, the Carcinogenicity Peer Review Committee recommended that a quantitative risk assessment for Metam Sodium be estimated from male mouse angiosarcoma tumor rates.

The statistical evaluation (Metam Sodium Qualitative Risk Assessment Based on Hsd/Ola: Wistar Tox Rat and C57BL/10JfCD-1/Alpk Mouse Drinking Studies, L.Brunsman 2/95) indicated no significant dose related differential mortality in the male mice.

Male mice had a dose related significant ($p<.01$) increasing trend in liver angiosarcoma tumor rates and also a significant difference in the pair-wise comparison of 27.7 mg/kg and the controls.

Dose-Response Analysis

Since mortality was not affected differentially with increasing doses of Metam Sodium, the estimate of the unit risk, Q_1^*, in human equivalents was obtained by the application of the Multi-Stage model (Tox_Risk program, version 3.5 - K.Crump). An estimate of the risk was calculated from male mouse liver angiosarcoma tumor rates.

The resulting estimates of unit risk, Q_1^*, were converted to human equivalents, by the use of weights of .030 kg for the mice and 70 kg for humans and the 3/4's scaling factor for interspecies extrapolation.

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."