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MEMORANDUM

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: REVISED Oxyflourfen (Goal) Quantitative Risk Assessment (Q_1^*) Based On CD-1 Male Mouse Dietary Study With $^3/_4$'s Interspecies Scaling Factor

P.C. Code 111601

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Summary

The unit risk, Q_1^* $(mg/kg/day)^{-1}$, of Oxyflourfen (Goal) based upon male mouse combined liver tumor (adenomas and/or carcinomas) rates is 7.32×10^{-2} in human equivalents (converted from animals to humans by use of the $^3/_4$'s scaling factor - Tox_Risk program, Version 3.5, K. Crump, 1994)[1]. The dose levels used from the 20-month dietary study were 0, 2, 20, and 200 ppm of Oxyflourfen (Goal). The corresponding tumor rates for the male mouse combined liver tumors (adenomas and/or carcinomas) were 2/47, 0/44, 4/44, and 8/52, respectively.

Background

On May 24, 1989, the Carcinogenicity Peer Review Committee recommended that a quantitative risk assessment for Oxyflourfen (Goal) be estimated for combined liver tumors (adenomas and/or carcinomas) in male mice. A quantitative risk assessment (Oxyflourfen (Goal) - Quantitative Risk Assessment, 20 Month Dietary Study of Charles River CD Male Mice, B. Fisher, 9/18/89) was prepared using the $^2/_3$'s scaling factor. This revised quantitative risk assessment reflects the Division change from use of the $^2/_3$'s scaling factor to the $^3/_4$'s scaling factor in 1994[1].

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

The statistical evaluation (Oxyflourfen (Goal) - Qualitative Risk Assessment - 20 Month Feeding Study - Charles River CD Male Mice, B. Fisher, 10/28/88) indicated that there were significant decreasing trends with either the untreated or vehicular (ethanol) control groups, but no significant pair-wise comparisons, for mortality with increasing doses of Oxyflourfen (Goal). The male mice had a dose-related significant increasing trend with either control group at $p < 0.01$, and a significant difference in the pair-wise comparison of the 200 ppm dose group with the vehicular controls at $p < 0.05$, for combined liver tumors (adenomas and/or carcinomas).

Dose-Response Analysis

The estimate of unit risk, Q_1^*, was based upon combined liver tumors (adenomas and/or carcinomas) observed in male mice.

Since the male mice had no statistically significant incremental changes in mortality with increasing doses of Oxyflourfen (Goal), the estimate of the unit risk, Q_1^*, was obtained by the application of the Multi-Stage model (Tox_Risk program, Version 3.5, K. Crump, 1994).

For the conversion to human equivalents, weights of 0.03 kg for the mouse, 70 kg for humans and the $^3/_4$'s scaling factor were used.

It is to be noted that the 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."