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

JUL 20 1988

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUB.

SUBJECT: Peer Review of Captan, Addendum

FROM: Esther Rinde, Ph.D. E. Rinde 6/16/88
Scientific Mission Support Staff
Toxicology Branch/HED (TS-769c)

TO: Richard Mountford
Product Manager (23)
Registration Division (TS-767c)

The Peer Review Committee met on April 13, 1988 to reevaluate the classification of Captan as a B2 Oncogen, and to determine if the $Q_1$* used in the PD 2/3 is appropriate.

A. Individuals in Attendance:

1. Peer Review Committee: (Signatures indicate concurrence with the peer review unless otherwise stated.)

| | |
|---|---|
| Theodore M. Farber | Theodore M. Farber |
| William L. Burnam | |
| Reto Engler | |
| Judith Hauswirth | Judith W. Hauswirth |
| Kerry Dearfield | |
| Lynnard J. Slaughter | L. J. Slaughter |
| Richard Levy | |
| Marion Copley | Marion P. Copley |
| Jack Quest | John A. Quest |
| Esther Rinde | Esther Rinde |

2. Reviewers: (Non-committee members responsible i data presentation; signatures indicate technical accuracy of panel report.)

Marion Copley Marion Copley

3. Peer Review Members in Absentia: (Committee members who were unable to attend the discussion; signatures indicate concurrence with the overall conclusions of the Committee.)

Anne Barton

Richard Hill

Robert Beliles Robert Beliles

Diane Beal

4. Other Attendees:

Joanna Dizikes (RD) was also present.

B. Material Reviewed:

The material reviewed consisted of: the Toxicology Branch Peer Review Memo on Captan (12/29/86), Captan Task force rebuttal and Agency response; DER for 90 day inhalation study in rats; and review of laboratory audit of Bio/Dynamics 2 year mouse feeding study. All these documents are attached to the file copy of this memo.

C. Classification of Oncogenic Potential:

The Committee reaffirmed the B2 classification based on tumors in two species, mutagenicity and SAR.

On the question of Q1*, it was decided that the geometric mean Q1* should be based only on the tumors in mice, omitting the Q1* based on the rat kidney tumors, also excluding the Q1* based on the low dose study in the mouse (based on the Lab. Audit findings that the dosing was uncertain). The new overall $Q_1$*, $3.6 \times 10^{-3}$ (geometric mean) is thus based only on the high dose study in male and female mice.

The kidney tumors in Charles River rats were discussed in light of the Hyaline Droplet findings in the 90 day study. It was agreed that a lot of work has been done in this area and although future events may lead us to conclude that there may be a threshold for such tumors, the final decision regarding this mechanism has not been made. Until that time the Agency must consider this a non-threshold occurrence and that the mechanism cannot be extrapolated to humans.