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

V. n Ormer 6-27-83

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Evaluation of regulatory impact of two citations on pentachlorophenol (PCP, penta).

Tox Chem No. 641

TO: Paul Lapsley
Chief, Special Review Branch
Registration Division (TS-767)

THRU: Ed Budd, Section Head
Section II, Toxicology Branch
Hazard Evaluation Division (TS-769)

Budd
6/27/83

The two citations are as follows:

1. World Health Organization, "IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans." Vol. 20, pp. 303-325, October 1979.
2. Williams, Phillip L., "Pentachlorophenol, an Assessment of the Occupational Hazard," Am. Ind. Hyg. Assoc. J., 43(11):799-810, 1982.

Conclusion

Toxicology Branch is aware of no impact by the two citations (from the standpoint of toxicology) on current regulatory proposals for penta. All but one of the referenced studies on chronic effects (including oncogenicity and fetotoxicity) have been reviewed by the Agency. The article by Williams implies there is a practical difficulty in maintaining a satisfactory margin of safety for penta, in the occupational setting, with regard to possible fetotoxic effects. Also; the occupational and domestic hazard from acute exposure to penta receives attention. The need for additional mutagenicity testing is suggested by implication.

In neither submission is there a reference to the oncogenicity of the contaminant HCDD.

Comments on the Citations

The IARC Monograph was received from SPRD for comment some years ago. It antedates the hexadioxin NCI bioassay used for oncogenicity risk analysis in PD 2/3. With one exception, all oncogenicity and teratogenicity studies mentioned in the Monograph have received comment in Wood Preservative Position Documents. The previously unreviewed study (NTIS, U.S. Dept. of Commerce, 1968) involved two strains of mice (18 animals of each sex per group) given single s.c. injections of 46.4 mg/kg commercial penta (in corn oil) at 28 days of age. The animals were observed up to 78 weeks of age. The incidence of hepatomas (4/17) in males of the strain (C57BL/6XC3H/Anf) F1 was significantly increased ($p < 0.05$) over that in controls (9/141).

In the article by Williams, all of the referenced studies on chronic, oncogenic, or fetotoxic effects have received comment in Wood Preservatives RPAR Position Documents. The article does not mention the NCI bioassays of HCDD. Inadequacies are itemized for the penta oncogenicity studies, which were termed negative by CAG, as mentioned in PD 2/3.

The article notes, with some justification, that further testing would be needed (according to current testing recommendations) to properly characterize the mutagenic potential of penta.

For inhalation exposure to penta the article presents a calculation showing that if the TLV is reached, "an occupationally exposed female may receive a dose that exceeds the no-effect level of PCP for fetotoxicity, allowing for a standard safety factor." (This calculation uses a somewhat higher NOEL value than accepted in PD 2/3.) The article further states that, "It is thought that no safe level for the exposure of PCP to pregnant women can be established at this time..." and that (occupational) "air concentrations of PCP can reach and exceed the TLV." It would appear that the author of the article discounts the realistic possibility or usefulness either of reducing ambient levels of PCP or of using protective clothing. The article also states, appropriately, that "with regard to acute exposures, the toxicity of PCP itself is of the most concern" (relative to that of the contaminants).



David G. Van Ormer, Ph.D.
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Hazard Evaluation Division (TS-769)

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

Van Ormer

Ed Budd check & see what's needed? Van Ormer

High priority for WAB
for FY83
out put

A complete review may not be needed; just comments

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

JUN 10 1983

MEMORANDUM

Subject: Evaluation of Pentachlorophenol Studies

To: Bill Burnam
Acting Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

Does it suggest or not - That's the question

Please review the two attached studies on pentachlorophenol and indicate any impact on the Agency's current regulatory proposals to conclude the Wood Preservatives RPAR.

The two citations are as follows:

1. World Health Organization, "IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans." Vol. 20, pp. 303-325, October 1979.
2. William, Phillip L., "Pentachlorophenol, an Assessment of the Occupational Hazard," Am. Ind. Hyg. Assoc. J., 43(11):799-810, 1982.

If possible, I would like these reviews by ^{June} ~~July~~ 30, 1983.

Thank you for your attention to this matter.

Paul LaSley
Branch Chief
Special Review Branch
Registration Division (TS-767)

cc: Judy Heckman

Bill, please let me know if you can't make the June 30 date.