1-16-79

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Caswell 454BB

DATE: January 16, 1979

SUBJECT: EPA Reg. No. 241-243; PP 5F1556. PROWL Herbicide. American Cyanamid Co. "Twenty-Four Month Oral Study".

FROM: Roland A. Gessert, D.V.M.; Toxicology Branch R. Gessert, WSW

TO: Mr. Robert Taylor, Product Manager # 25.

In a review of a special report by pathologist Robert F. McConnell, D.V.M., resulting from re-examining pathology slides, Dr. Engler requested an expansion of the report by Dr. McConnell "stating whether or not he has examined the tissues of intermediate and low dose animals and whether or not the conditions he describes were present at the lower levels." The submission being reviewed resulted.

LIVERS: The present submission indicates that the livers of the low, intermediate, and control rats were again reviewed, and that the hepatocellular alteration described in 6/10 high dose male rats was not present in the control, low, or intermediate dose animals.

THYROID: An increase in secretory globules was observed in the follicular epithelial cells of the thyroid in both the high dose and intermediate dose males and females when compared to controls. This increase appears to be physiologic in nature and related to decreased secretory function or increased production of thyroglobulin, and therefore is not a degeneratave change.

CONCLUSION: The NEL remains as previously assigned for the study (500 ppm).

In another review dated March 26, 1976 (re PP 6F1741 and 6G1740), Dr. Engler stated, "Since this is a dinitro compound, an evaluation of the cataractogenic potential should be done." A 17-day cataractogenic study with PROWL Technical in White Leghorn chicks was conducted by Industrial Bio Test Laboratories and reported to American Cyanamid in a report dated January 5, 1977.

The study was conducted with 4 groups of 15 chicks each, beginning at 10 days of age. Two groups were fed PROWL Technical at levels of 1000 or 3000 ppm in the diet. One positive control group was fed 3000 ppm 2,4-dinitrophenol in the diet, and an untreated control group received only the diet of Purina Chick Startena.

Gross changes in the lens, indicative of potential cataracts, were observed in 12 of the 15 birds fed 2,4-dinitrophenol. No such changes were observed in any of the birds receiving PROWL Technical. Since this is an IBT study, it may be subject to a data audit. Otherwise it would meet CORE Guidelines.

EPA FORM 1320-6 (REV. 3-76)