Monsanto

FROM (NAME & LOCATION): G. J. Levinskas - A2SC

DATE: September 25, 1975

SUBJECT: PCBs

REFERENCE:

cc H. S. Bergen - B2SL
D. R. Bishop - B1ND
W. B. Papageorge - B2SK
R. G. Potter - B3SA
W.W. Withers - B2SA

TO:

G. Roush, Jr.
A2SA

The attached represents a final (?) version of the toxicity statement on PCBs. This takes note of all the comments which have been received since the version mailed to you on August 29, 1975.

This was discussed on the phone with Wayne Withers, and he agreed that it was acceptable. Since Wayne was the only one who had comments regarding the August 29 version, this should be satisfactory to all concerned.

G.J.L

George J. Levinskas

/bkp

att.

PCBs

Recently, we were informed that liver carcinomas were observed in female Sherman strain rats fed AROCLOR 1260 for 20½ months. This prompted us to re-examine livers from male and female rats of the Charles River strain which had been fed AROCLOR 1242, AROCLOR 1254 or AROCLOR 1260 for 2 years in earlier studies conducted for Monsanto Company.

There are 4 elements which are closely interwoven in this matter: (1) differences in test procedures, (2) differences in results obtained by various investigators, (3) definition of what is a cancer, and (4) evaluation of potential risks, if any, to man. These will be summarized briefly.

(1) Several animal studies have been conducted with various brands of PCBs. In some studies, the test material has been identified by trade name (AROCLOR, KANECLOR). In others, there was just a general reference to PCB. Consequently, the quality of test material with respect to the amounts and nature of contaminating impurities or by-products cannot be determined in ~~each~~ case. In addition, several strains of test animals were used, the duration of the experimental periods varied, and there was a wide range in the depth of detail with which the observations were reported. Consequently, it is difficult to make comparisons between these studies.

(2) In general, studies have shown mice to be more susceptible than rats and females to be more sensitive than males to the liver effects of PCBs. Beyond these generalizations, the results have not been consistent. Some investigators have

reported liver carcinomas. Others have observed only benign tumors. Several have noted changes in liver tissue without detecting tumor formation. For the reasons just cited, it is difficult to determine the bases for these different results. The most direct comparison can be made between the 2 studies on AROCLOR 1260 since the same high dosage level of the same lot of AROCLOR 1260 was employed in both experiments. In the studies reported to us, liver carcinomas occurred in approximately 8% of female rats of the Sherman strain (the only sex used), In Monsanto's study, none of the liver lesions had progressed beyond the stage of benign tumors (hepatomas) despite a slightly longer duration of feeding of AROCLOR 1260 to rats of Sprague Dawley, Charles River strain. The Monsanto study employed rats of both sex and it did confirm the previously noted greater sensitivity of female rats to liver effects of PCBs.

(3) A review of the liver alterations seen in all 3 AROCLORS in Monsanto's studies shows that the lesions were benign in character in the traditional pathologic sense. An evaluation of all information available to us, including the contradiction between the recent data showing AROCLOR 1260 to be a carcinogen and our earlier negative results on the same product, leads to a conclusion that AROCLOR 1260 is not carcinogenic to all commonly used strains of laboratory test animals.

(4) In 1972, the manufacture of AROCLOR 1260 was discontinued in the United States and the sale of AROCLORs was restricted to a single use, i.e., as dielectric fluids. As such they are used in closed systems which will at least minimize additional environmental contamination. Considering the

high degree of fire risk associated with this use, and recognizing that AROCLOR 1260 may have a weak carcinogenic potency which has not been fully proven and that AROCLORS 1242 and 1254 have not been shown to be carcinogens, it is concluded that the continued use of AROCLORS 1242 + 1254 as dielectric fluids will not present an unreasonable human health hazard.