DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

January 9, 1967

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Dr. William H. Hunt
Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166

Re: Food Additive Petition No. 7B2117

Dear Dr. Hunt:

This replies to your letter of December 28, 1966, requesting a copy of any data we may have available regarding past toxicity studies conducted by this Administration concerning 60 percent chlorinated terphenyl (Arochlor 5460) which is the subject of the above referenced petition.

In response to your request we have prepared the following summary of some results obtained in our testing of various Arochlors using the AOAC bioassay method for chick edema factor (Official Methods of Analysis, 10th Ed., Association of Official Agricultural Chemists, 26.087-26.091):

Sample	No. of Chicks	Level In Diet ppm	Heart fluid, ml (or incidence of hydropericardium)	Early Deaths	Remarks
Arochlor 1268	12	200	0.25 (1/12)	5	Hemorrhages(4/12)
Arochlor 1268	12	400	0.21 (3/12)	3	Hemorrhages(6/12)
Arochlor 5460	12	50	(0/12)	0	None
Arochlor 5460	12	200	(0/12)	4	Hemorrhages(5/12)
Arochlor 5460	12	400	0.26 (1/12)	4	Hemorrhages(3/12)
Arochlor 1242	10	100	(2/9)	1	Enlarged heart Group Score 2+
Arochlor 1242	6	349	(1/12)	4	Group Score 3+ (toxic)

MONS 087993

Arochlor 1242 was distilled in a spinning band column; 28 fractions and a small amount of residue were obtained. The higher boiling fractions were more toxic than the early fractions. Some of the results of chick bioassay are as follows:

Sample	No. of Chicks	Level In Diet ppm	Incidence	Hydropericardium Group Score	Remarks
Fraction 1	6	100	0	0	1 early death; no edema
Fraction 21	6	100	0	0	no edema
Fraction 25	6	100	2	2+	toxic
Fraction 28	6	100	3	5+	6 early deaths; toxic
Residue	6	100	5	5+	6 early deaths; toxic
Fraction 25	10	50	0	0	2 early deaths; no edema
Fraction 28	7	10	0	0	no edema
Fraction 28	10	50	7/7	15+	3 early deaths 5 hemorrhages

Fraction 28, molecular weight 324, represents 4.2% by weight of Arochlor 1242. Microcoulometric gas chromatograms (6 ft. column, instrument programmed at 4° C/minute beginning at 150° C) show the presence of 3 major and 2 minor peaks.

Sincerely yours,

William F. Randolph
Petitions Control Branch
Bureau of Science

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