Monsanto Company
St. Louis, Missouri

November 9, 1966

cc: R. E. Bilger - RBILG
M. W. Farrar - 2nd St.
J. D. Early - Washington DC
S. A. Heininger
W. H. Hunt - WHUNT
R. G. Pastorino - RPAST
W. F. Waychoff - WWAYC
df: Plasticizers, Toxicity

DEVELOPMENT DEPARTMENT CALL REPORT NO. 4719

Food and Drug Administration
Washington, D. C.

Date of Call: November 3, 1966

For FDA: Bill Randolph
Joe McLaughlin
Herb Blumenthal
Dr. Misra

For Monsanto: R. W. Bucknell
J. D. Early
R. G. Pastorino
R. M. Parks

Purpose of call: A telephone call to Dr. Early alerted us to the fact that FDA was about to reject our petition on Aroclor 5460 for use in EVA and PVAc hot melt because they had recently uncovered data of their own involving the chicken feeding of 5460, knowledge of which was not transmitted to us, nor remembered by FDA personnel during our earlier three petition meetings. This call was made to determine why the 5460 petition was being rejected and what could be done about it.

Summary of Results: 1. In reviewing our 5460 petition, Bill Randolph suddenly remembered that 5460 was fed to chickens by FDA at the time of the Swift petition on Aroclors in general in EVA hot melts. Since those feeding results indicated development of a cardiac hemorrhage at 200 ppm they red-flagged our petition and had contacted Dr. Early indicating to him that the petition would be rejected on this basis. All FDA personnel were

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red-faced because none had remembered these feeding results during our two preliminary discussions with FDA prior to submitting the 5460 petition.

2. FDA suggested that if we want to go ahead with a petition on 5460 they would require 90-day two species feeding and metabolic studies, plus a no-effect test level with the chicken, and finally a means of characterizing 5460.

Letter sent to W. E Randolph Petition Control Branch FDA Nov. 11, 1966 Copy with Petition Withdrawn as per letter from Randolph 11/16/66 ←

3. They suggested that we withdraw the petition without prejudice to future filing and indicate to them that we are considering the 90-day and chicken feeding studies.

Filed in Petition File 7B2117 60% Aliphatic Terphenyls

Action: Development or Others

1. Medical Department will request the withdrawal of the 5460 petition without prejudice.

2. Marketing/Development will determine whether feeding studies are justified and the cost of those studies.

Details:

1. Embarrassingly, FDA informed us that they recently remembered they had performed feeding studies on Aroclor 5460 which showed cardiac hemorrhages at 200 ppm of the chicken's daily diet. 5460 and other Aroclors were tested as a result of the several-years-ago Swift petition.

2. FDA was embarrassed that no personnel remembered these tests during either of our preliminary discussions prior to submitting the 5460 petition. In fact, during our last discussion, FDA had stated that it looked like smooth sailing for 5460 re our petition.

3. In view of the foregoing test results, FDA suggested that the minimum we would require to submit an amended petition would include data on the no-effect level with the chicken, plus 90-day feeding and metabolic studies on two species. Finally, they would need a means of characterizing Aroclor 5460 versus other chlorinated paraffins and biphenyls or terphenyls.

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4. FDA suggested that we withdraw our 5460 petition without filing to avoid prejudice to future filing, and while we consider whether 90-day feeding and metabolic and chick studies are justifiable.

5. Development will review cost with Industrial Bio-Test and the justification with Marketing and the Product Director.

R. M. Parks

/sn

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