Monsanto

FROM (NAME & LOCATION) ST. LOUIS - GENERAL OFFICES

TO: Paul Graham

FDA - Aroclor 5460

DATE NOVEMBER 27, 1968

SUBJECT AROCLOR 5460/FDA APPROVAL

REFERENCE

J. R. DARBY - 2ND STREET
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TO : DR. E. EMERY - JFQ RESEARCH
V. R. HAUPT - ANNISTON
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G. W. MILLER - ANNISTON
R. W. PETERSON
J. E. SMITH
H. L. WILLIAMS - ANNISTON

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Attached are the letters from FDA which explain why we decided to withdraw our petition for approval of Aroclor 5460 without prejudice.

We face several problems:

1. What was the chlorinated biphenyl content of the A-5460 used in the feeding studies? That level will be the maximum the FDA would permit if they grant our petition.

2. A test method that the FDA accepts as being accurate and reproducible for determining chlorinated biphenyl in A-5460.

3. The quarterphenyl content of terphenyl. The FDA is not too specific on that as yet, but one gets a feeling we'll hear more about that.

4. Even if we come up with test methods and A-5460 samples that satisfied FDA, there still remains the question: Can our present plant and our proposed plant meet what are likely to be stringent specifications on A-5460? Lot AI-43 was used for feeding studies for the A-5460 petition that has just been withdrawn. The feeding studies were "clean" on chick edema factor, 90-day rat feeding, etc. etc. So we can be somewhat

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optimistic about the future outcome. The fact, however, is that no sample of Lot AI-43 remains. As near as can be determined from plant records, the level of biphenyl in the Santowax R stream if it came from the storage tank was:

	Biphenyl
1/30/67	0.13%
1/31/67	0.05
2/ 1/67	<0.01
2/ 2/67	0.01
2/ 3/67	0.03
2/ 4/67	<0.01

Lot AI-43 was made on 2/1/67. But the possibility exists that the Santowax R came from the receiver and not the storage tank in which case the Santowax R could have come from:

Receiver Batch	Biphenyl
# 99	0.04%
#100	0.07
#101	0.33
#102	0.42

So Lot AI-43 could have had <0.01-0.42% biphenyl before chlorination. If we believe the figure of 0.42%, we can say our feeding study results are excellent and give us leadway in production. If we are in the FDA we are likely to believe a figure of < 0.01% which makes production's job somewhat tricky downroad.

Dr. [redacted] have done an excellent job of analyzing chlorinated biphenyl and chlorinated terphenyl on samples submitted by G. W. Miller of Anniston. The problem of getting a quantitative test method is not resolved as yet.

Several problems remain:

1. The overlap of some chlorinated biphenyl peaks in GLC with mono-chloroterphenyl peaks. Attempts are being made by mass spectrograph to determine just how much the

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presence of mono-chloroterphenyl peaks "inflates" the chlorinated biphenyl peaks.

2. Recently we have been producing a lot of low-soluble A-5460 and this is believed to be due to therminol leaking into the terphenyl chlorinator. (The therminol may be possibly chlorinated to A-1268 or 1271 — memo V. R. Haupt to W. A. Kuhn 10/23/68). This obviously throws a complete unknown into the picture even if we could consistently guarantee virtually zero biphenyl in the Santowax R stream before chlorination.

3. Up to now, Dr. Emery has been working with A-5460 and A-1260. He can state that after a certain elution time no more peaks appear on the GLC column from A-1260. Any peaks from A-5460 on the GLC appearing after that point will be due to chlorinated ter-/quarterphenyls provided A-5460 contains no chlorinated biphenyl higher than A-1260.

4. The possible questions FDA may pose on quarter- and higher polyphenyls have yet to be faced.

So much for the problems, now for the action:

1. (Dr. Emery/Dr. Keller)

Try to determine via mass spectrograph which peaks in A-5460 GLC curve are overlaps of chlorinated biphenyl/lower chlorinated terphenyls.

2. (G. W. Miller)

Send duplicate samples of recent production Aroclor 1268 to Dr. Emery and C. Paton with complete analytical values. Retain samples at Anniston.

3. (Dr. Emery)

Run GLC curves on A-1268 to determine how much more extensive "overlapping" peaks will be if A-1268 type material was present in A-5460.

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4. (Manufacturing/Process Research/C.E.D.)

a) Determine <u>minimum</u> biphenyl contents that can be consistently expected in Santowax OMP.

b) Determine steps that can be taken to prevent leakage of therminol into chlorinator cooling lines plus fail-safe detection system.

c) "Top-cut" retained batches of A-5460 in the laboratory (known to be therminol free and with an accurate record of biphenyl in the Santowax R) to see if this can remove chlorinated biphenyl from A-5460. (This may be one solution to the problem). Send samples to Dr. Emery.

d) Carry out a plant trial of "top-cutting". Send samples to Dr. Emery.

It is suggested that after steps 1, 2, 3, 4 are carried out a meeting be held between Messrs. Hunt/Emery/Paton and Anniston and CED/Manufacturing personnel to determine if we have enough data to go to FDA to discuss further steps.

Hopefully, if we can get FDA to agree that our proposed production, test methods and analyses are satisfactory from a control standpoint, they will indicate that chick edema factor determinations will be sufficient for us to re-submit our petition. (Chick edema tests take 27 days to run). It should be pointed out, however, that FDA may require more feeding studies. Time is important.

We would like to be able to meet with FDA again before January 31.

About 36% of A-5460 sales go to hot melt adhesives where FDA approval is required in many applications. Several potential customers are staying away from A-5460 until it gets FDA clearance because they want to use only FDA approved R.M. regardless of applications. (This prevents the wrong formulation being used in an FDA application). All existing customers say their A-5460 consumption will grow when it gets FDA approval.

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The above action plan was drawn up after a discussion between Messrs. Hunt/Emery/Keller/Paton. It is suggested that we immediately proceed with items 1/2/3. On item 4 we would appreciate feed-back from Manufacturing/CED/ Process Research. Please let me stress once again the need for giving this priority and also the need to retain samples and records.

C. PATON

ms

P.S.

We note that recent lots of A-5460 sent to Dr. Emery had high biphenyl levels in the Santowax R stream.

AK-189	:	0.87% biphenyl
AK-261	:	0.17% biphenyl

The statement in Randolph's letter of October 21 on the biphenyl content of A-5460 was based on statements from Production to R. M. Parks.

C. P.

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