SEP 23 1968

C. Paton - General Offices

September 23, 1968

AROCLOR 5460/FDA PETITION

→ ~~Dr. R. E. Kelly~~/Dr. W. H. Hunt
Dr. R. E. Keller
W. F. Waychoff

H. L. Williams - Anniston
G. W. Miller - Anniston

Further to our conversation, I am sending you several pieces of correspondence.

1. The letter from the FDA to Dr. Kelly indicating the deficiencies in our petition on Aroclor 5460.

2. The section of our 1968 petition on Aroclor 5460 (pages 10-13) which deals with the biphenyl and chlorinated biphenyl content of Aroclor 5460.

3. The GC and IR curves we attached to the 1968 petition.

4. The section of our 1966 petition on Aroclor 5460 which we withdrew without prejudice because we needed more feeding data.

5. The GC curve on Aroclor 5460 which was attached to the 1966 petition.

You will note:

1) Our manufacturing procedure has been described differently in the two petitions. After today's conversation, I understand the 1968 is the more correct of the two descriptions. The percentage biphenyl is determined on the Santowax R fed to the chlorinator. On distilling the chlorinated Santowax R, Montar 9 and Aroclor 5460 is obtained. No top-cut is taken in this distillation.

2) The questions raised by the FDA in their letter were answered, I think, by the GC curve submitted with the 1966 petition. The GC curve submitted with the 1968 petition does not give column details and other analytical conditions. It omits the factors necessary to calculate the percentage of each of the components. Can you let me have this information please.

DSW 312450

STLCOPCB4072436

With regard to the polyphenyl composition, what maximum can we live with because we'll have to specify.

This will also be true for biphenyl content in the Santowax R. Can you live with 0.5%, 1.0% or what.

3. We need copies of the methods we could actually use for:

   Softening point
   Chlorine content
   Refractive index

   Bob Keller is attempting to determine a test method for chlorinated biphenyl content in Aroclor 5460.

4. I understand that AI 43 was the lot used in the feeding studies and we don't have a retained sample.

   Do we have any samples of lots prior to AI 43 and just after AI 43 so that we can determine:

   a) biphenyl content of Santowax R

   b) chlorinated biphenyl content of Aroclor 5460.

We must reply to the FDA by October 12 so these requests are rather urgent.

Cumming Paton

CP:dbw

DSW 312451

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