Monsanto

OCT 2 1968

FROM (NAME & LOCATION) Anniston, Alabama

DATE : September 30, 1968

SUBJECT :

REFERENCE :

cc: R. E. Kelly
W. H. Hunt
W. F. Waychoff
H. L. Williams

TO : Cumming Paton

There is little doubt that communications problems associated with the FDA petition for Aroclor 5460 have caused most of the zero blurs in getting the petition approved. It would have been beneficial if we at the plant were informed as to what information was needed and in general terms, why.

The description of the manufacturing process included in the 1968 petition is adequate. In answer to subsequent questions:

I.

A. No distillation forecut is taken during the distillation process.

B. It was realized initially that a product yield of only 75% is realized in the conversion of Aroclor 5060 to Aroclor 5460. The original statement—1% maximum chlorinated biphenyl in Aroclor 5460—made to Bob Parks in January 1968 took into account the concentrating effect realized during distillation. In actual numbers the biphenyl content of Santowax R can be held below 0.75%.

II.

A. GC curves submitted in 1966 and 1968 are analyses of Santowax R. You imply that the 1966 curve was on Aroclor 5460. It is impossible to perform GC analyses on chlorinated terphenyl products.

B. The conditions of analysis were not specified directly on the example GC chart. The chromatogram was specially prepared to show relative location of the peaks, and does not reflect an actual analysis.

C. Polyphenyl Composition

I have discussed this area with Vince Haupt and we agree that the following statements can be made with reasonable surety.

1. In Santowax R
   (a) Biphenyl content will be less than 0.75%.
   (b) Terphenyl content will be greater than 80%.
   (c) Quaterphenyl and higher polyphenyls will be less than 20%.

2. In Aroclor 5460
   (a) Chlorinated biphenyl content will be less than 1%.
   (b) Chlorinated terphenyl content will be greater than 95%.
   (c) Chlorinated quaterphenyls and higher polyphenyls will be less than 5%.

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C. Polyphenyl Composition (continued)

The Santowax R statements can be verified by past operating data. The Aroclor 5460 statements: (a) is deduced from the process material balance and (b) and (c) are based on process research and development studies performed at the plant.

III.

I have inclosed our standard analytical methods for (1) Softening Point and (2) Total Organically Bound Chlorine Content. I have attached a copy of Method 161 Santowax Isomer Distribution (Internal Standard Method) which is now used for the analysis. The methodology and techniques remain essentially unchanged with the exception that an internal standard is now added to increase the accuracy of the method. The internal standard improvement was not incorporated into the method when the chromatograms submitted with the 1966 and 1968 petitions were prepared. In addition, the old style of peak integration has been discontinued in favor of electronic integration. The new chromatogram, with test conditions and electrically integrated peak areas, is attached.

We do not have a written method for refractive index of solid materials because of no requirements for the analysis. In the past we have employed the technique recommended by Bausch and Lamb Company, as outlined in the Instruction Manual accompanying the Abbe 3L Refractometer.

IV.

We do not have any lots of Aroclor 5460 produced at approximately the same period as AI-43. AI-43 was produced February 3, 1967, and the reserve sample was held until February 3, 1968, at which time it was discarded. Standard procedure calls for twelve months retention of all solid Aroclor production lots. The sample submitted for feed testing was requested by R. M. Parks on April 25, 1967, against shipper 575500 with no advance notice as to need for (1) Aroclor 5460 with a specified chlorinated biphenyl content or (2) special retentions of the particular lot shipped for feed testing.

I have gone back through plant operating data and pieced together the history of Lot AI-43 as best possible. The chlorinator batch which produced Lot AI-43 was charged on February 1, 1968, and if my correlation is correct, contained approximately 0.1% biphenyl. Allowing for a 25% concentration factor during the distillation, the chlorinated biphenyl content of Lot AI-43 is $0.1 \pm 0.02\%$.

I hope this helps.

G. W. Miller

/bs

Attachment

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