

Monsanto

FROM (NAME & LOCATION) Cumming Paton - St. Louis General Offices

DATE June 17, 1969
SUBJECT AROCLOR 5460/FDA APPROVAL
REFERENCE
TO J. E. Smith - JSMIT
M. W. Farrar - JFQ Research

cc → Dr. E. Emery/Dr. R. E. Keller
V. R. Haupt - Anniston
Dr. W. H. Hunt/Dr. R. E. Kelly
R. M. Kountz - RKOUN
W. A. Kuhn - WKUHN
J. C. Landwehr - Anniston
G. W. Miller - Anniston
W. E. Schalk - WSCHA
W. F. Waychoff
H. L. Williams - Anniston

The latest developments on Aroclor 5460 are:

1. Recent "polution" publicity on PCBs (Aroclor 1262 being specifically named) may make our task of getting FDA approval much harder.
2. Dr. Emery has found differences in two lots of Aroclor 5460 which may make it more difficult to set a low chlorinated biphenyl level unless we consider fractional distillation of Aroclor 5460.

Leading from these developments are the following suggestions:

1. Consideration of a name change from Aroclor 5460 to Santicizer 5460. If agreed, when should we change-prior to re-approaching FDA or after we get approval.
2. Manufacturing/CED stated at one time they could keep the biphenyl in Santowax below 0.1% (0.18% chlorinated biphenyl). Is this still correct. Has it been demonstrated.
3. How feasible is fractional distillation of Aroclor 5460. How low could this take the chlorinated biphenyl level.
4. #3 will lead to higher costs. In order to turn this to our advantage, I suggest we consider having a low color Aroclor 5460 coincide with our FDA efforts. We could then offer an FDA grade which is available only as a white material at 2-3 cents/pound premium.

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5. A decision would need to be reached on the timing of low color material. It might help our case with the FDA if we could say that our product for FDA use would be white, thus eliminating problems of discriminating between non-FDA, yellow product.

Ed Emery's work is near completion. We have requested Marv Gibb's assistance in fractionally distilling five gallons Aroclor 5460 for Ed Emery's analysis.

I would like to recommend that once Ed and Marv have completed their work, we convene a meeting of Medical/Research/Manufacturing/CED/Marketing in St. Louis to consider how we proceed. I would like to shoot for the week of June 30. Does everyone agree.

Cumming Paton

CP:dbw

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