Monsanto

FROM (NAME & LOCATION) Mr. J. E. Smith - General Office

DATE: July 9, 1970

CC: Messrs.
M.W. Farrar S. 2nd St.
W.F. Waycheff
W.S. Clark
E. Emery Org. Res.

SUBJECT: AROCLOR 5460 - FDA APPROVAL

REFERENCE

TO: J.L. Corder/H.L. Williams
Anniston Plant

Earlier this week, the Business Group reviewed status and plans relative to FDA approval of Aroclor 5460. Our plans are to request approval for use in hot melt adhesives only. Several actions need to be completed before we can submit a petition. Those of direct concern to the plant include the following:

1. We need to demonstrate the pending low color process amendment. This apparently has been transmitted but I have not seen it yet. I understand the field demonstration is targeted for August. Marketing's position is that they would like to submit petition based on a low color product. Low color is not mandatory to submitting the petition however.

2. We need better definition of PCB level in routine 5460 production. Ed Emery's memo of 6/22/70 outlined plans to analyze five sets of samples taken during routine production from late March and early April. This information should be forthcoming. In January funds were approved for purchase of chromatograph to enable PCB analysis to be performed at Anniston. What is the status of this program?

3. Once we have a better fix on the PCB level of current production from the new system, we need to outline an appropriate program to reduce and/or control PCB content at a level which will give reasonable assurance of FDA approval of the petition. This obviously is subjective at this point but if at all possible, I'd like to shoot for a level of less than .5%. With the improvements incorporated in the new 5460 system and use of this system as the sole source of 5460 "normal" PCB content should relate directly to biphenyl content in the Santowax-C and Santowax-R in turn. Conceivably better biphenyl/Santowax-C separation efficiency may be required.

Will you please outline a program and time schedule for completion of the necessary plant support work relative to the FDA petition. Will Clark incidentally will be coordinating this activity.

J. E. Smith

JES:md

0357798

IN-10 REV 11-65

TOWOLDMON0057567