MEMORANDUM


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THRU: Edward Zager, Section Head
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TO: Lois Rossi, PM 21
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M & T Chemicals Inc has submitted storage stability studies on TPTH residues in crops in response to RCB reviews dated 9/1/87 and 9/2/87 (F. Suhre).

The above storage stability data on potatoes, sugar beets, carrots, and soybeans were initially presented to RCB members (F. Suhre and S. Hummel) at a recent meeting with the applicant. According to the 9/23/87 memo of conference, data showed rapid degradation of TPTH to other organotins and inorganic tins, the rates being dependent on the type of crops and fortification levels.

The entire submission consists of summary tables and bar graphs (in addition to a cover letter). No information as to the storage temperature, type of tin compound spiked, amount of added material expressed in parts per million, method of analysis, etc is provided. Furthermore, data reflecting up to only one month storage were provided. Yet the field samples were held in frozen storage for as long as 9 months before residue analysis (see memo of conference cited above).

CONCLUSIONS AND RECOMMENDATION

The submitted storage stability studies are not acceptable. The applicant should provide all relevant information to the conduct of these stability studies: storage conditions, method of analysis, weight of TPTH added, weight of substrate tested, and sample chromatograms, etc. Finally, the duration of
the studies must cover the entire storage period of the field samples prior to residue analysis.

cc:Circ, RF, TPTH SF, Spec Rev F (Hummel), Reg Std F, Cheng, PMSD/ISB
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