UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 18 1995

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: REQUIRED EXPOSURE DATA FOR REGISTRATION OF CLIPPER 2SC TREE GROWTH REGULATOR

FROM: Tina Manville, Biologist
Special Review and Registration Section II

TO: James Stone/Cynthia Giles-Parker
PM Team 22
Registration Division (7505C)

THRU: Mark I. Dow, Ph.D., Section Head
Special Review and Registration Section II

Larry C. Dorsey, Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find below, the OREB review of:

DP Barcode: D214442

Pesticide Chemical Code: 125601

EPA Reg. No.: 10182-267

EPA MRID No.: N/A

Registration Division (RD) has requested OREB to determine if Zeneca by joining the Outdoor Residential Exposure Task Force (ORETF) and the Agricultural Re-entry Task Force (ARTFA) still needs to provide the exposure data for Clipper 2SC requested in the December 29, 1994 letter from Cynthia Giles-Parker to S. K. Theodorakis of Zeneca.

Clipper 2SC tree growth regulator is undergoing the registration process and contains the active ingredient paclobutrazol which is a plant growth regulator. Clipper 2SC is formulated as a soluble concentrate and contains 21.8% active

ingredient. The product label states that Clipper will be applied to trees by soil injection or basal drench methods. Clipper will be used to slow down the regrowth of ornamental trees after they have been trimmed. Use sites are restricted to established non-food crop trees growing in linear patterns such as, electric power line right-of-ways, urban/suburban street median strips and street side trees. Another Clipper formulation, Clipper E 20 UL, is registered as a growth regulator for application to trees via trunk injection.

The end-point of concern for the occupational/residential intermediate term exposure assessment, chosen by the Less than Lifetime Committee, is 2.5 mg/kg/day from the 2-generation reproduction study in rats (MRID 407343-03). In the letter mentioned above Ms. Giles-Parker stated that because of tox concerns the Agency is concerned about the lack of exposure information. The registrant was asked to provide EPA with "a conclusive demonstration of negligible exposure from the soil injection or soil drench uses or submit appropriate exposure data pursuant to 40 CFR 158.390."

CONCLUSIONS:

Joining the ORETF and ARTFA does not provide the requested data information for several reasons. ORETF deals almost exclusively with turf mixer/loader/applicator and reentry studies and therefore would not have data for scenarios where a pesticide is applied to trees via soil injection or soil drench. ARTFA deals with agricultural reentry studies and also would not have the appropriate data. In addition, all task force participants have to conduct foliar dissipation studies since these are end-use product formulation specific. The Pesticide Handlers Data Base (PHED) does not contain applicator data for soil injection or basal drench scenarios but it does contain data that are similar, for example termiticide injection. If the registrant wanted to conclusively demonstrate low mixer/loader and applicator exposure, PHED data could be used with the understanding that if the risk is too high they would need to generate their own data.

It is Zeneca's responsibility to demonstrate negligible exposure or submit appropriate exposure data for this use scenario of Clipper 2SC.

cc: T. Manville
Chemical File: PACLOBUTRAZOL (125601)
Correspondence