Tim Gardner

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

JAN 14 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Classification of Azadirachtin

TO: Willie Nelson, Assistant Product Manager
Registration Division (TS-767)

HED has evaluated the information you provided on Azadirachtin in view of your request to classify this "substance" as a conventional or biochemical pesticide.

The information you provided included published literature that stated Azadirachtin is both an insect feeding retardant and an insect growth regulator (e.g., Skatulla and Meisner stated that it bears a "chemical resemblance to ecdyson, the moulting hormone of insects". We also know that the substance is naturally occurring - it is extracted from the seeds of the neem tree.

HED recommends that an entomologist in RD, familiar with efficacy evaluations, review the available literature to determine whether it is adequate to support the assertion that Azadirachtin is a feeding deterent and/or growth regulator. If the RD entomologist(s) conclude that the insecticidal mode of action(s) is as claimed, HED will classify the product as a biochemical.

Please note the following information is needed before HED can provide any further guidance on what data are required to support registration and/or whether an exemption from the requirement of a tolerance may be warranted:

(1) A clear statement of the quantity of a.i. to be applied per acre, the number of applications per season, and the time of these applications relative to plant maturity.

(2) A concise definition of the active ingredient to be claimed. Is it the entire material that is extracted (e.g., azadirachtin and related substances) or is it only azadirachtin as specified by the chemical structure provided.

HED/OLS
Failure to Classify
Neem Extract

Finally, we also note that the studies conducted to date were all performed on a total seed extract containing 0.3% "active ingredient(s)". Future studies should be performed using a concentrated extract in order to more properly assess the toxicological properties of the active ingredient(s). Using the available toxicity test results and extrapolating to 100% ai, it appears that azadirachtin may be acutely toxic. If this is born out in tests conducted with concentrated test material then tier II studies would probably be required.

Please keep me informed of the conclusions drawn by your entomologists concerning the mode of action of azadirachtin in insects.

Fred Betz

Fred Betz, Biologist
Science Integration Staff (TS-769)

cc: Tim Gardner
Hoyt Jameson
Amy Rispin
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