

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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SUBJECT: NAA: Request for Waiver From Requirement
for Second Teratogenicity Study 264-336

TO: Robert J. Taylor (PM-25)
Fungicide-Herbicide Branch, RD (TS-767C)

FROM: *Robert P. Zendzian* 5/10/82
Robert P. Zendzian, Ph.D.
Toxicity Branch HED (TS-769)

THRU: William Butler, Head *William Butler* 5/10/82
Review Section III
William Burnam, Deputy Chief
Toxicology Branch

The registrant of Naphthaleneacetic acid, Union Carbide, has requested a waiver from the requirement for a second teratology study as required in the Registration Standard.

Toxicology Branch recommends that the request for waiver be denied.

Naphthalene acetic acid is used on tree fruits and tolerances for this use have been granted. Because of the possible exposure of pregnant women two teratology studies are required. A study has been performed in rats with negative results and a second study in another species is being required.

The registrant believes that one negative study is sufficient and requests a waiver from the requirement.

Toxicology Branch recommends that the waiver be denied. Tragic experience has taught that teratogens are often species specific. The human teratogen, thalidomide, is inactive in the rat but active in the rabbit. Thus, a single negative study is not considered sufficient to assess the teratogenic potential of a compound. A second teratogenic study can only be waived for such a compound if the first study shows teratogenicity.

A waiver could be granted if the registrant withdrew the food tolerances for the compound.

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