

US EPA ARCHIVE DOCUMENT



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

497AB

MAR 2 1993

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

MEMORANDUM:

SUBJECT: The Requested Reevaluation of The RFD for Imazalil  
(ID#s 5F03250, 7F03530, 4F03096, 4H05434)

BARCODE D 177305 5415876  
BARCODE D 177309 5415892  
BARCODE D 177306 5415877  
BARCODE D 177308 5415885

PCCODE 111901  
CASWELL# 497AB

TO: Clarence Lewis  
PM Team # 22  
Fungicide Branch  
Registration Division (H7505C)

FROM: Henry Spencer, Ph.D. *Handwritten: HS 7/23/92*  
Pharmacologist  
Review Section 3  
Toxicology Branch 1  
Health Effects Division (H7509C)

THRU: Karen Hamernik, Ph.D. *Handwritten: K. Hamernik 2/8/93*  
Acting Section Head  
Review Section 3  
Toxicology Branch 1  
Health Effects Division (H7509C)

ACTION REQUESTED:

The registrant, Janssen Pharmaceutica, submitted a letter to the Registration Division of OPP on 3/30/92, requesting an increase in the reference dose for Imazalil based on more current animal (dog and rat) feeding studies.

COMMENTS:

In the Janssen Pharmaceutica letter written by William Goodwine, dated March 30, 1992, it is stated that "The RFD for imazalil fungicide should be increased, using studies which meet current guidelines under reregistration."

The change of the RFD is not a simple task as the letter would propose, in that many people are required to evaluate the data package, meet and discuss the chemical and come to a consensus of

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opinion about the appropriate NOEL to be used in the RFD. However, the registrant should be informed that he does not have to ask for a reevaluation of the RFD for Imazalil since HED has already established a mechanism to reevaluate the RFDs when new data are reviewed. Additionally, HED's RfD Committee is being requested to review the RfD for Imazalil and this review will be conducted as the Committee's scheduling permits.

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**JANSSEN**  
PHARMACEUTICA

March 30, 1992

Cynthia Giles-Parker  
Office of Pesticide Programs (H7505C)  
U.S. Environmental Protection Agency  
Registration Division (Team 22)  
401 M Street S.W.  
Washington, D.C. 20460-0001

SUBJECT: Imazalil Fungicide  
Reconsideration of Reference Dose (RFD)

Dear Cynthia:

Currently, the reference dose for imazalil fungicide (Caswell #497AB, A.I. Code: 111901) is based on a NOEL of 1.25 mg/kg established in a two year chronic feeding study in dog. Since the study (MRID 00081172), dated April 12, 1977, did not satisfy the reregistration acceptance criteria, it is no longer used to support imazalil registration.

A repeat dog study (MRID 41328802), dated November 6, 1989, has been accepted to satisfy data requirement 83-1 for chronic feeding - nonrodent; a NOEL of 2.5 mg/kg was established. The data requirement for chronic feeding in rats has also been satisfied under reregistration (MRID 00162412); the NOEL for rats is 5.0 mg/kg body weight.

The RFD for imazalil fungicide should be increased, using studies which meet current guidelines under reregistration.

Please advise me of the disposition of this request and when final action may be expected.

Sincerely,

William R. Goodwine  
Manager  
Plant Protection Division  
(908) 524-9116  
(908) 524-9895 Fax

WRG/mp  
cc: B. Duytschaever  
G03302

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