



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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OFFICE OF  
PREVENTION PESTICIDES AND  
TOXIC SUBSTANCES

DATE: November 13, 2000

MEMORANDUM

SUBJECT: *IMAZALIL*: Re-define the Short Term Dermal Exposure for Assessing Seed Treatment Exposure Scenario

FROM: Abdallah Khasawinah, Ph.D., Toxicologist  
Reregistration Branch 4  
Health Effects Division (7509C)

*A. Khasawinah* 11/13/2000

THROUGH: Jess Rowland, Ph.D. Co-Chair  
Hazard Identification Assessment Review Committee  
Health Effects Division (7509C)

*Jess Rowland* 11/13/00

TO: Sanjivani Diwan, Ph.D., Senior Toxicologist  
and  
Susan V. Hummel, Ph.D., Branch Senior Scientist  
Reregistration Branch 4  
Health Effects Division (7509C)

*Sanjivani Diwan*  
11/14/00

*Susan V. Hummel*

P.C. Code: 111901

The HIARC document (HED No. 013539) dated June 29, 1999 for Imazalil selected a NOAEL from a 21-day dermal study in rabbits for short term dermal exposure of 1-7 days and a NOAEL from a 90 day oral dietary study in rats for intermediate term dermal exposure scenario of one week to several months. On July 12, 2000, imazalil registrant, Janssen Pharmaceutica (DP Barcode D267829) requested to use duration of 10 days for on farm seed treatment and 15 days for commercial seed treatment. Imazalil application rate for these two scenarios are at a minimum of 0.00391 lb ai/100 lb of seed to a maximum of 0.01 lb ai/100 lb of seed. Janssen is requesting to use a short-term NOAEL from the 21 day dermal study to assess for these two scenarios.

During the October 24, 2000 meeting, HIARC members considered the Janssen Pharmaceutica request. The above use pattern exhibits an exposure period of not more than 15 days. The HIARC recommended that it would be appropriate to use the 21-day dermal study for assessing risks from this exposure because the treatment regime in the study (21 days) approximates exposure scenarios of concern and redefined short term exposure duration to include exposure ranging from 1-30 days. This change is applicable only for assessing the specific seed treatment exposure scenarios.