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

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AUG 12 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Imazalil Reregistration; Reregistration Case No. 2325; Review of Supplemental Data Related to Carcinogenicity Study in Mice and to 3-Month Oral Mechanistic Toxicity Study in Mice

DP Barcode D204243
Case 819449
Submission S467630

Tox. Chem. No. 497AB
PC Code No. 111901
MRID No. 432424-01
432424-02

FROM: Edwin R. Budd, Toxicologist
Review Section III
Toxicology Branch I
Health Effects Division (7509C)

TO: Kathryn Davis/Ron Kendall/Kathleen Depukat
Chemical Review Manager Team 52
Reregistration Branch
Special Review and Reregistration Division (7508W)

THRU: Karen Hamernik, Ph.D., Section Head
Review Section III
Toxicology Branch I
Health Effects Division (7509C)

The registrant of Imazalil, Janssen Pharmaceutica, has provided additional information related to the carcinogenicity study in mice using Imazalil Base as the test material (MRID No. 429720-01) and also to the 3-month oral mechanistic toxicity study in mice using Imazalil Base as the test material (MRID No. 432226-01 and 432024-02). Both studies were recently reviewed by Toxicology Branch I [see memoranda from Edwin R. Budd to Kathyrn Davis, dated June 8, 1994 (carcinogenicity study) and dated about July 29, 1994 (mechanistic study)].

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The additional information is identified as follows:

1) Supplement to MRID 429720-01
Carcinogenictiy Study in Swiss Mice:
Imazalil Base
Study No.: 2194
[MRID 432424-01]

2) Supplement to MRID 432226-01
Three-Month Oral Mechanistic Tosicity
Study With One MOnth Interim Sacrifice in
SPF Albino Swiss Mice
Study No.: 3140 (Supplement)
[MRID 432424-02]

The supplemental data for the carcinogenicity study consisted of the following: 1) identification of Aerosil (a component of the 50% premix used in diet preparation) as being amorphous silicon dioxide, together with certain physico-chemical data on this chemical, and 2) additional information on the concentration analysis, stability and homogeneity of imazalil base used in the carcinogenicity study, which showed that stability and homogeneity of the test material in the pelleted diets used in this study were satisfactory. The additional information does not affect the previous Core classification for this study (Core Minimum).

The supplemental data for the mechanistic study consisted of the following: 1) the purity (98.5%) of the Imazalil Base used in the study, and 2) additional information on the concentration analysis, stability and homogeneity analysis of imazalil base used in the mechanistic study, which showed that stability and homogeneity of the test material in the pelleted diets used in this study were satisfactory. The additional information does not affect the previous Core classification for this study (not classified).

The submitted information on both studies is acceptable.

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