

Supplement to Document No. 004853 - DER for Accession No. 000258128: Oral Embryotoxicity and Teratogenicity of Imazalil in Cobs Mice. This supplement provides an Executive Summary to upgrade the original DER.

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Reregistration Branch 4 (7509C)
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DATA EVALUATION RECORD

STUDY TYPE: Prenatal Developmental Study - Mouse; OPPTS 870.3700
[§83-3a]

DP BARCODE: D262725
P.C. CODE: 111901

SUBMISSION CODE: S548748
TOX. CHEM. NO.: 497AB

TEST MATERIAL (PURITY): Imazalil Sulphate (R27180)

SYNONYMS: None reported

CITATION: Sanz, G. and Gillardin, JM. 1985. Oral Embryotoxicity and Teratogenicity of Imazalil in Cobs mice. Study number 85-02. Research Department, Laboratories Janssen, France. March 25, 1985. Accession No.000258128. Unpublished.

SPONSOR: Janssen Pharmaceutica N.V., 2340 Beerse, Belgium

EXECUTIVE SUMMARY:

In a developmental toxicity study (Accession No. 000258128), imazalil (purity not specified) was administered to 24 female cobs mice/dose by oral gavage in Arabic gum solutions at dose levels of 0, 2.5, 10 or 40 mg/kg/day from days 6 through 16 of gestation.

No maternal toxicity was observed at any level. There were no treatment related mortalities. Body weight gains and food consumption were comparable to controls. Pregnancy was comparable in all groups.

There was no fetal toxicity either. All measured parameters (number of live fetuses per litter, number of dead fetuses per litter, litter size, number of resorptions, number of implantations, weight of living pups) were similar in all groups.

No fetal abnormalities related to treatment were reported.

The maternal systemic and Fetotoxic NOAEL is >40 mg/kg/day, the highest dose tested.

This developmental toxicity study in the mouse is classified as **Unacceptable and not upgradable**. It does not satisfy the guideline requirement for a developmental toxicity study (83-3) in rodents. The highest dose tested did not produce any evidence of maternal or fetal toxicity. No information on the test material purity was provided.

COMPLIANCE: Signed and dated GLP, Quality Assurance, Data Confidentiality, and Flagging statements were not provided.

IMAZALIL

Developmental Study OPPTS 870.3700 (\$83-3a)

SignOff Date:	2/8/00
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