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TOXICOLOGY ENDPOINT SELECTION DOCUMENT

TO: James Kariya, DRES
Larry Dorsey, OREB
Esther Saïto, CCB
Caswell File

Debra Edwards, CBTS
Edward Zager, CBRS
William Burnam, SAB
George Ghali, RfD Secretary

Chemical Name: Alachlor

PC Code: 090501

Based upon a review of the toxicology database for the chemical listed above, toxicology endpoints and dose levels of concern have been identified for use in risk assessments corresponding to the categories below. A brief capsule of the study is presented for use preparation of risk assessments.

Where no appropriate data have been identified or a risk assessment is not warranted, this is noted. Data required to describe the uncertainties in the risk assessment due to the toxicology database are presented. These include but are not limited to extrapolation from different time frames or conversions due to route differences. If route to route extrapolation is necessary, the data to perform this extrapolation are provided.

Reviewer: _____ Date: _____

Branch Chief: M. van Gemert Date: 3/21/94

Dermal Absorption Data (If available)

Accession No. 256624, Percutaneous Absorption Study of Lasso MCB/C9 in Rhesus Monkeys

Accession No. 256624, Percutaneous Absorption Study of Lasso MicroTech in Rhesus Monkeys

% absorbed: 24

Acute Dietary Endpoint (One Day)

Study Selected - Guideline No.: None

MRID No.: None

Summary (Enter Standard Executive Summary or equivalent):

Not Applicable

Endpoint and dose for use in risk assessment.

None

Comments about study and/or endpoint:

None

This risk assessment is not required. Based upon a review of the available data for alachlor, no endpoint indicating the potential for acute toxicity from a one-day dietary exposure was identified.

Short Term Occupational or Residential Exposure (1 to 7 Days)

Study Selected - Guideline No.: Developmental Toxicity Study - Rats (IRDC, 3/21/80)

MRID No.: 00243506, 00043645

Summary: Rats were given 0, 50, 150 or 400 mg alachlor/kg BW/day for days 5 to 16 of gestation (inclusive). The NOEL for maternal and fetotoxicity were 150 mg/kg/day based upon maternal hair loss, soft stools, anogenital staining, increased mortality, increased post-implantation loss and a reduced number of live fetuses. The developmental NOEL was 400 mg/kg/day.

Endpoint and dose for use in risk assessment: None.

Comments about study and/or endpoint: The NOEL for the only appropriate study exceeds the 100 mg/kg/day cutoff for requiring an exposure assessment.

This risk assessment is not required.

Intermediate Term Occupational or Residential (1 Week to Several Months)

Study Selected - Guideline No.: Six Month Dog Study - Dietary (82-1(b))

MRID No.: 246292, 246293, 247376

Summary: Beagle dogs were given 0, 5, 25, 50 or 75 mg alachlor/kg BW/day in diet for six months. No NOEL was established. The LOEL was the lowest dose tested, 5 mg/kg/day, based upon increased absolute and relative liver weights in males.

Endpoint and dose for use in risk assessment: LOEL = 5 mg/kg/day based increased relative and absolute liver weights in male dogs, with a dermal absorption factor of 24%.

Comments about study and/or endpoint: The results of a one-year study in dogs (Acc. No. 255953) support the validity of this endpoint. The liver effects occur at lower dose levels when the period of dosing increases.

This risk assessment is required.

Cancer Classification and Basis: B₂ based upon increased nasal tumors in CD mice and Long-Evans rats.

Q₁* = 8.0E-2

R_fD and basis: 0.01 mg/kg/day based upon the results of a one-year feeding study in dogs. The NOEL was 1.0 mg/kg/day with an uncertainty factor of 100. The LOEL was 3.0 mg/kg/day based upon hemosiderin storage in kidney and spleen in males.

NOEL for critical study: 1.0 mg/kg/day

Study Type - Guideline No.: One year dog dietary (83-1(b))

MRID: 255953
