

PHASE FOUR REVIEW

(NOTE: This only contains additions and changes from the phase 2 response.)

Pesticide: Ametryn

Transmitted to HED on: 9-13-90

Chemical#/Case#: 80801 / 2010

Tox. Chem #: 431

Sponsor: Ciba Geigy

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Phone#: 557-2558

Branch: TOX-I

Reviewer: John E. Whalan

Completed: 09/25/90

Concurrence:

Are there any changes from the reviews in phase 2?

NO XX
YES
(See below)

Response, by Guideline

Guideline #: 81-1

Acute oral/rat

MRID 40995814 Study #5567-88

Discussion/Recommendation:

No change.

NOTE: The purity of the test article which was missing in the original report was reported in the summary.

Guideline #: 81-2

Acute dermal/rabbit

MRID 40995815 Study #5567-88

Discussion/Recommendation:

No change.

NOTE: The purity of the test article which was missing in the original report was reported in the summary.

Guideline #: 81-3

Acute inhalation/rat

MRID 40995816 Study #5571-88

Discussion/Recommendation:

No change.

NOTE: The purity of the test article which was missing in the original report was reported in the summary.

Guideline #: 81-4

Primary eye irritation/rabbit

MRID 40995817 Study #5568-88
Discussion/Recommendation:

No change.

NOTE: The purity of the test article which was missing in the original report was reported in the summary.

Guideline #: 81-5

Primary dermal irritation/rabbit

MRID 40995818 Study #5569-88
Discussion/Recommendation:

No change.

NOTE: The purity of the test article which was missing in the original report was reported in the summary.

Guideline #: 81-6

Dermal sensitization/Guinea Pig

MRID 40995819 Study #5570-88
Discussion/Recommendation:

No change.

NOTE: The purity of the test article which was missing in the original report was reported in the summary.

Guideline #: 82-2

21 Day dermal/rabbit

MRID 41067902 Study #882215
Discussion/Recommendation:

Although a study has been performed, it has yet to be submitted for review. Study deficiencies recognized by the Registrant include the absence of urinalysis and lung histopathology, and the dosing of less than 10% of the body surface area. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 83-1a

Chronic toxicity/rodent

MRID _____ Study # _____
Discussion/Recommendation:

See Guideline 83-5.

Guideline #: 83-1b

Chronic toxicity/nonrodent

MRID 40349902 Study #842118
Discussion/Recommendation:

No change.

Guideline #: 83-2a

Oncogenicity/rat

MRID _____ Study # _____
Discussion/Recommendation:

See Guideline 83-5.

Guideline #: 83-2b

Oncogenicity/mouse

MRID 40349904 Study #483-128
Discussion/Recommendation:

No Change.

NOTE: The Registrant submitted a summary for a 28-day range-finding study which was used to select doses for the chronic study. The summary only served to demonstrate the failure to select adequate doses.

Guideline #: 83-3a

Teratology/rat

MRID 153215 Study #852054
Discussion/Recommendation:

The summary resolved questions about test article purity, stability, and homogeneity. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 83-3b

Teratology/rabbit

MRID 153214 Study #842107
Discussion/Recommendation:

The summary resolved questions about test article purity, stability, and homogeneity. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 83-4

Reproduction

MRID 92002-026 Study #852048
Discussion/Recommendation:

The summary resolved questions about test article purity, stability, homogeneity, and dose concentration. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 83-5

Chronic Feeding-Oncogenicity/rat

MRID 40349906 Study #842119
Discussion/Recommendation:

No change.

Guideline #: 84-2a

Mutagenicity/Ames

MRID 40995820 Study #840802
Discussion/Recommendation:

No change.

Guideline #: 84-2b Mutagenicity/Struct. Chromosomal Aberration

MRID 41067903 Study #881548
Discussion/Recommendation:

No change.

Guideline #: 84-4

Other genotoxic effects

MRID 41067904 Study #881549
Discussion/Recommendation:

No change.

Guideline #: 85-1

Metabolism

MRID 41463301 Study #RPT0022
Discussion/Recommendation:

This study has not been submitted to HED for review, and it is not listed in the bibliography (dated April 7, 1989). A screen could not be performed because only a brief study summary was provided. Based on a preliminary assessment of the summary, the study is acceptable for review.