

12-7-90

COVER SHEET FOR FIFRA 88 PHASE 4 TOXICOLOGY REVIEW
CHANGES AND ADDITIONS TO PHASE 2 REVIEW

Case No.: 2315 Chemical No.: 043901
Chemical Name: Glutaraldehyde

Reviewer: John E. Whalan Phone: 557-1511
Concurrence: *[Signature]* Date: 12/4/90

Rozin Hatan 12-7-90
Are there any changes from the reviews in Phase 2: Yes

NOTE: The Registrant submitted 14 summaries. Five of these were accompanied by reformatted studies.

PHASE FOUR REVIEW

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

Pesticide: Glutaraldehyde

Transmitted to HED on: 11-5-90 Chemical#/Case#: 043901 / 2315

Tox. Chem #: 468

Sponsor: Union Carbide

CRM: Linda DeLuise

Phone#: 308-8066

Branch: TOX-1

Reviewer: John E. Whalan

Completed: 11/29/90

Concurrence: *Roger Gordon* 12-7-90

Are there any changes from the reviews in phase 2?

XX
NO YES
(See below)

Response, by Guideline

Guideline #: 81-1

Acute oral/rat

MRID 92070-001 Study # 45-124
Discussion/Recommendation:

This is a summary of MRID 41478001. Thus, a screen of the study could not be performed. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 81-2

Acute dermal/rabbit

MRID 92070-002 Study # 48-51
Discussion/Recommendation:

This is a summary of MRID 164183. Thus, a screen of the study could not be performed. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 81-3

Acute inhalation/rat

MRID 92070-003 Study # 47-21

Discussion/Recommendation:

This is a summary of MRID 164462 and related MRID 164654. Thus, a screen of the study could not be performed. Only females were exposed. The 6-hour exposure was static rather than dynamic. Relative humidity attained 100%, and supplemental oxygen had to be added to maintain chamber oxygen at approximately 20%. Based on a preliminary assessment of the summary, the study is not acceptable for review.

Guideline #: 81-3

Acute inhalation/rat

MRID 92070-004 Study # 44-96

Discussion/Recommendation:

This is a summary of MRID 164654 and related MRID 164462. Thus, a screen of the study could not be performed. Chamber temperature ranged from 21 to 26° C. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 81-4

Primary eye irritation/rabbit

MRID 92070-005 Study # 47-33

Discussion/Recommendation:

This is a summary of MRID 164474. Thus, a screen of the study could not be performed. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 81-5

Primary dermal irritation/rabbit

MRID 92070-006 Study # 47-33

Discussion/Recommendation:

This is a summary of MRID 164463. Thus, a screen of the study could not be performed. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 82-1a

90-day feeding/rodent

MRID 92070-007 (summary); 92070-015 (reformatted study) Study # 48-107

Discussion/Recommendation:

The Registrant submitted both a summary and a reformatted report of MRID 164181 and related MRID 164181. Deficiencies include the lack of alkaline phosphatase, creatinine kinase, lactic dehydrogenase, and cholesterol measurements (all are supplemental), and histopathological evaluations of the oviduct and some lungs. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 82-1a

90-day drinking water/rodent

MRID 92070-022 (summary); 92070-023 (reformatted report) Study # 52-1

Discussion/Recommendation:

The Registrant submitted both a summary and a reformatted report of MRID 41089601. Deficiencies include the lack of creatinine kinase, lactic dehydrogenase, and cholesterol measurements (all are supplemental), and histopathological evaluations of the oviduct. Based on a preliminary assessment, the study is acceptable for review.

Guideline #: 82-1b

90-day drinking water/nonrodent

MRID 92070-008 Study # 52-93

Discussion/Recommendation:

The Registrant submitted both a summary and a reformatted report of MRID 41480501. Deficiencies include the lack of lactic dehydrogenase (supplemental), and histopathological evaluation of the oviduct. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 82-4

90-Day inhalation/rat

MRID 92070-009 (summary); 92070-017 (reformatted report) Study # 46-101

Discussion/Recommendation

The Registrant submitted both a summary and a reformatted report of MRID 164178 and related MRID's 164188 and 164365. There were a large number of deficiencies. Weekly mean chamber temperature was 26° C (compared to 20-24°C). Five randomly selected rats/sex/group were evaluated for clinical pathology (instead of 10 rats/sex/group). Platelet counts, inorganic phosphorus, and sodium (all required), and cholesterol, creatinine, potassium, and chloride (all supplementary) were not measured. Histopathologic evaluations were not performed for aorta, eyes, cecum, colon, duodenum, skin, ileum, jejunum, stomach, mammary gland, muscle, epididymis, urinary bladder, peripheral nerve, esophagus, oviduct,

pancreas, rectum, spinal cord, salivary glands, thymus, uterus, and accessory sex organs. Lungs, liver, and kidneys were not evaluated for all low and mid-dose rats. The brains were not weighed. Based on a preliminary assessment of the summary, the study is not acceptable for review.

Guideline #: 84-2a

Mutagenicity/Ames

MRID 92070-010 (summary); 92070-018 (reformatted report) Study # 44-131
Discussion/Recommendation:

The Registrant submitted both a summary and a reformatted report of MRID 164458, an Ames Assay. Based on a preliminary assessment, the study is acceptable for review.

Guideline #: 84-2a

Mutagenicity/Ames

MRID 92070-011 Study # 44-67
Discussion/Recommendation:

This is a summary of MRID 92070-019, a CHO Mutation Test. Thus, a screen of the study could not be performed. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 84-2b

Mutagenicity/Struct. Chromosomal Aberration

MRID 92070-012 Study # 43-16A
Discussion/Recommendation:

This is a summary of MRID 164186, a CHO Mutation Test. Thus, a screen of the study could not be performed. Based on a preliminary assessment of the summary, the study is acceptable for review.

Guideline #: 84-4

Other genotoxic effects

MRID 92070-013 Study # 43-16B
Discussion/Recommendation:

This is a summary of MRID 164186, a Sister Chromatid Exchange study in CHO Cells. Thus, a screen of the study could not be performed. Based on a preliminary assessment of the summary, the study is acceptable for review.