8-31-92

PHASE FOUR REVIEW

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

Pesticide: Grotan (hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine
Chem.#/Case#: 0833101/3074
Transmitted to HED
Tox. Chem.#: 481C
Sponsor: Buckman Labs (Triazine Joint Venture)
CRM: Linda Deluise Phone #: 308-8065

Branch: Toxicology I, Section II Reviewer: M. Morrow, D.V.M.
Completed: _____ Concurrence: Karl P. Baetcke 8/3/92
Division Director's Concurrence: Penelope A. Fenner-Crisp 8/3/92

Response by Guideline

Guideline #: 81-1 Description: Acute oral/rat
MRID #: 416752-06, Study #: 3138-47
Discussion/ Recommendation: The study is tentatively acceptable for review.

Guideline #: 81-2 Description: Acute dermal
MRID #: reformatted 93100004, Study #:
Discussion/Recommendations: Based on information provided in the reformat, the study is tentatively acceptable for review.

Guideline #: 81-3 Description: Acute inh/ rat
MRID: , Study #:
Discussion/ Recommendation: A waiver of this requirement was requested based on the fact that the sponsor does not expect respirable particles to be produced. The material is also in a 78.5% aqueous solution and is a viscous material with a low vapor pressure. The request for data waiver is denied. Data is requested because the material may be inspired under.

Guideline #: 81-4 Description: Primary eye
MRID #: 93100005, Study #: 371/8408
Discussion/Recommendation: The study is tentatively acceptable for review.

Guideline #: 81-5 Description: 1° Derm. Irr/ rabbit
MRID #: 93100006, Study #: 317/8505
Discussion/ Recommendation: Although the size of the application site was not specified, the study is tentatively acceptable for review.

Guideline #: 81-6 Description: Dermal sens./Guinea pig
MRID #: 93100007, Study #: Not provided

Discussion/ Recommendation: Study is tentatively acceptable . No positive control was used in this study but this should not compromise results. (No reactions were reported).

Guideline #: 82-1 Description: Subchronic Feeding
MRID #: 93100008, Study #: LEF/3/89
Discussion/Recommendation: This study was reviewed on 9/11/90 and was graded core minimum. The NOEL was 50 mg/kg/d. The DER is acceptable.

Guideline #: 82-3 Description: Repeat dose dermal tox.(90d)
MRID #: 93100009 Study #: LEF/4/89
Discussion/ Recommendation: This study was reviewed on 9/11/90 and was graded core minimum. The systemic NOEL was 250 mg/kg. The DER is acceptable.

Guideline #: 83-3(a) Description: Teratology/ rat
MRID #: Reformatted 93100010, Study #: LEF/8/89
Discussion/ Recommendation: The DER for this study is acceptable. The study was reviewed 1/18/90 and was graded core minimum. The developmental NOPEL was 750 mg/kg (HDT) and the maternal NOEL was 500 mg/kg. The maternal LOEL was 750 mg/kg based on decreases in body weight gain.

Guideline #: 84-2 Description: Salm. typhim. gene mut. assay
MRID #: 412317-02 reformatted 93100011, Study #:
Discussion/ Recommendation: The DER for this study is acceptable. The compound was determined to be negative for gene mutation. The study was reviewed on 1/18/90.

Guideline #: 84-2(b) Description: SCA: Mouse Micronucleus Test

MRID #: 412317-01 reformat -93100012, Study #:

Discussion/Recommendations: The DER for this study is acceptable. The study was reviewed on 1/18/90 and the study was classified as acceptable. The compound was negative when administered at dioses upto 80% of the LD_{50}.

Guideline #: 84-4 Description: Other genotoxic effects

MRID #: , Study #:

Discussion/Recommendations: This study (unscheduled DNA synthesis) was reviewed on 4/10/90 and was unacceptable. Recommendations were made that the study be repeated to determine whether the observed genotoxic effects were reproducible. It was also determined that information on the test material (purity, batch #, analytical data, etc.

GROTAN

Page_____ is not included in this copy.

Pages 4 through 5 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

X The document is not responsive to the request.

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