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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 02 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Review of Acute Oral Toxicological Studies for Different
Sulfluramid Formulations [REDACTED]

TO: Phil Hutton/Michael Mendelsohn, PM-18
Registration Division (H-7505C)

FROM: David S. Liem, Ph.D. *David Liem 7/27/92*
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THROUGH: K. Clark Swentzel, Section Head *K. Clark Swentzel 7/27/92*
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and
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DP BARCODE NO.: D164368

SUBMISSION NO.: S396021

CASWELL NO.: 454E

HED PROJECT NO: 1-1257

MRID NO.: 417994-02 (Acute Oral LD₅₀ in the Rats with Sulfluramid
Test Articles : MRD-89-567 through MRD-89-471)

417994-03 (Acute Oral Toxicity Test in the Rats with
Sulfluramid Test Articles : MRD-89-512
(Sulfluramid [REDACTED] and MRD 89-513
(Sulfluramid [REDACTED])

ACTION REQUESTED

To review acute oral LD₅₀ toxicity studies for different
Sulfluramid isomeric [REDACTED] mixtures [REDACTED]
administered once by gavage to rats and observed for a period of 14
days.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED



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- D. Sulfluramid [REDACTED] isomers)/MRD 89-469
 Acute oral LD₅₀ = 1354 mg/kg for both sexes combined
 Acute oral LD₅₀ = 1554 mg/kg for the males
 Acute oral LD₅₀ = 1192 mg/kg for the females
 This study satisfies the data requirement for Subdivision F
 Guideline No. 81-1. Toxicity Category III.
- E. Sulfluramid [REDACTED] isomers,
 purified) - MRD-89-512
 Acute oral LD₅₀ = 1934 mg/kg for both sexes combined
 Acute oral LD₅₀ = 2359 mg/kg for the males
 Acute oral LD₅₀ = 1580 mg/kg for the females
 This study satisfies the data requirement for Subdivision F
 Guideline No. 81-1. Toxicity Category III.
- F. Sulfluramid [REDACTED] isomers)/MRD 89-468
 Acute oral LD₅₀ = 2349 mg/kg for both sexes combined
 Acute oral LD₅₀ = 2296 mg/kg for the males
 Acute oral LD₅₀ = 2376 mg/kg for the females
 This study satisfies the data requirement for Subdivision F
 Guideline No. 81-1. Toxicity Category III.
- G. Sulfluramid [REDACTED]/MRD 89-467
 Acute oral LD₅₀ > 5000 mg/kg for both sexes combined
 Acute oral LD₅₀ > 5000 mg/kg for the males
 Acute oral LD₅₀ > 5000 mg/kg for the females
 Since the maximum limit dose of 5000 mg/kg was used, this study
 is acceptable and it satisfies the data requirement for
 Subdivision F Guideline No. 81-1. Toxicity Category IV.

Classification

- o Core-minimum for studies with sulfluramid [REDACTED] (MRD 89-467), [REDACTED] (MRD 89-468), [REDACTED] (MRD 89-469), [REDACTED] purified (MRD 89-512), and [REDACTED] purified (MRD 89-513).
- o Core-supplementary for studies with Sulfluramid [REDACTED] (MRD 89-471) and Sulfluramid [REDACTED] (MRD 89-470) pending the receipt of the identity of the chemical formula of the [REDACTED] in the formulations.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

CONCLUSIONS AND RECOMMENDATIONS

Based on the results of the LD₅₀ values presented in the two study reports (MRID# 417994-02 and 417994-03), Sulfluramid [REDACTED] (MRD 89-470) is the most toxic and Sulfluramid [REDACTED] (MRD 89-467) is the least toxic among the seven Sulfluramid formulations tested. The presence of [REDACTED] isomer increases the toxicity of the Sulfluramid formulation. The addition of the [REDACTED] in the formulation also increases the toxicity of the formulation. The Sulfluramid [REDACTED] and Sulfluramid [REDACTED] formulations were more toxic than the other Sulfluramid formulations tested.

The LD₅₀ for Sulfluramid [REDACTED] could not be determined accurately because there was less than 50% mortality in the high dose group. But since the maximum limit dose of 5000 mg/kg was used, this study is acceptable and it satisfies the data requirement for an Acute Oral Toxicity Study in rat, Subdivision F Guideline No. 81-1.

It should be noted that although the acute oral LD₅₀ toxicity studies for Sulfluramid [REDACTED] and Sulfluramid [REDACTED] were acceptable, these studies are classified as core-supplementary pending the receipt on the identity of the chemical formula of the salts in these formulations.

The acute oral LD50 of the seven Sulfluramid formulations tested listed in descending order of toxicity are as follows:

A. Sulfluramid [REDACTED] isomers)/
MRD 89-470

Acute oral LD₅₀ = 717 mg/kg for both sexes combined

Acute oral LD₅₀ = 602 mg/kg for the males

Acute oral LD₅₀ = 803 mg/kg for the females

This study is classified as core-supplementary pending the receipt on the identity of the chemical formula of the [REDACTED] in the formulation. Toxicity Category III.

B. Sulfluramid Salt [REDACTED] isomers)/
MRD 89-471

Acute oral LD₅₀ = 792 mg/kg for both sexes combined

Acute oral LD₅₀ = 621 mg/kg for the males

Acute oral LD₅₀ = 903 mg/kg for the females

This study is classified as core-supplementary pending the receipt on the identity of the chemical formula of the [REDACTED] in the formulation. Toxicity Category III.

C. Sulfluramid [REDACTED] isomers,
purified) - MRD 89-513

Acute oral LD₅₀ = 1001 mg/kg for both sexes combined

Acute oral LD₅₀ = 772 mg/kg for the males

Acute oral LD₅₀ = 1571 mg/kg for the females

This study satisfies the data requirement for Subdivision F Guideline No. 81-1. Toxicity Category III.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED