STILLMEADOW
INCORPORATED

VOLUME __ OF __ OF SUBMISSION

ALKA VITA (ALKAHYDROXY®) (2%)

FINAL REPORT

ACUTE ORAL TOXICITY STUDY (UDP) IN RATS

OPPTS NO. 870.1100

AUTHOR:

Janice O. Kuhn, Ph.D., DABT

STUDY INITIATION DATE: 14 April 2005
STUDY COMPLETION DATE: 20 June 2005

CONDUCTED BY:
STILLMEADOW, Inc.
12852 Park One Drive
Sugar Land, TX 77478

LABORATORY STUDY NUMBER:

9017-05

VOLUME 1 OF 1 OF STUDY

SUBMITTED TO:
Cisne Enterprises Inc.
3535 W. 16th Street
Odessa, TX 79763

STATEMENT OF NO DATA CONFIDENTIALITY CLAIM

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10 (d) (1) (A), (B) or (C).

Company: Cisne Enterprises Inc. _____

Company Agent: _____ Date: _____

Title _____ Signature _____

These data are the property of Cisne Enterprises Inc., and as such, are considered to be confidential for all purposes other than compliance with FIFRA § 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other statute or in any other country.

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was designed and performed in STILLMEADOW, Inc.'s laboratory and was conducted in compliance with:

- United States Environmental Protection Agency FIFRA 40 CFR 160 with exception of Sec. 160.31 (d), and 160.105 (a) (b) (e) characterization and stability information was not provided in a Certificate of Analysis
- United States Environmental Protection Agency TSCA 40 CFR 792 with exception of Sec. 792.31 (d), and 792.105 (a) (b) (e) characterization and stability information was not provided in a Certificate of Analysis
- Organization for Economic Cooperation & Dev. Principles of GLP, Annex 2, C(98)17 with exception of Sec. 1.1 (2) (p), 6.1 (1), and 6.2 (2) (4) characterization and stability information was not provided in a Certificate of Analysis
- Japan Ministry of Agriculture, Forestry & Fisheries, Notification No. 11-Nousan-6283, Director-General of Agricultural Prod. Bureau with exception of Art. 3.1 (18) and 12.5, and 12.7 characterization and stability information was not provided in a Certificate of Analysis

Janice O. Kuhn

20 Jan 05

Janice O. Kuhn, Ph.D., DABT
Study Director, STILLMEADOW, Inc.

Date

Signature of Agent of Sponsor

Date

Agent Name
Sponsor: Cisne Enterprises Inc.

Signature of Agent of Submitter

Date

Agent Name
Submitter: Cisne Enterprises Inc.

QUALITY ASSURANCE STATEMENT

Test Substance: ALKA VITA (ALKAHYDROXY®) (2%)
Study Title: Acute Oral Toxicity Study (UDP) in Rats

The study report and data have been audited in accordance with STILLMEADOW, Inc. Standard Operating Procedures (SOPs). The final report accurately reflects the study data. The findings from the inspections and audit were reported to the Study Director and Management as follows:

Study Phase Inspected	Inspection Type	Date Inspected	Reported to Study Director	Reported to Management
Protocol Review	Study-based	5 Apr 05	5 Apr 05	5 Apr 05
Facility inspection	Facility-based	29 Dec 04 – 6 Jan 05	6 Jan 05	6 Jan 05
Body weights	Study-based	28 Apr 05	28 Apr 05	28 Apr 05
Report/Data Audit	Study-based	27 May 05	27 May 05	27 May 05

Richard L. Martin

Richard L. Martin, B.S., M.S., C.Ph.T.
Quality Assurance, STILLMEADOW, Inc.

20 Jun 05
Date

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SUMMARY

The test substance, ALKA VITA (ALKAHYDROXY®) (2%), was evaluated for its acute oral toxicity potential in albino rats when administered as a gavage dose at a level of 5209 mg/kg. The study was terminated following the stopping rules of this procedure. No mortality occurred during the study. There were no clinical signs of toxicity during the study. There was no effect on body weight gain. The gross necropsy conducted at termination of the study revealed no observable abnormalities. The acute oral LD_{50} was estimated to be greater than 5000 mg/kg.

INTRODUCTION

The objective of this study was to assess the acute oral toxicity potential of the test substance when administered by gavage to rats in accordance with US EPA OPPTS 870.1100, which is intended to meet testing requirements of FIFRA 7 USC 136, *et seq*, and TSCA 15 USC 2601. This study was conducted for Cisne Enterprises Inc., according to the approved protocol and STILLMEADOW, Inc. SOPs. There were no deviations from the protocol that affected the quality or outcome of the study. All procedures used in this study are in compliance with Animal Welfare Act Regulations. The protocol, raw data, this report and a sample of test substance are archived at STILLMEADOW, Inc. The pre-dose experimental portion began on 18 Apr 05, and the animals were treated as follows:

Dose (mg/kg)	Treatment		Animal Number	In-life Termination Date
	Date	Time		
5209	19 Apr 05	0915	101	3 May 05
5209	21 Apr 05	0942	102	5 May 05
5209	21 Apr 05	0943	103	5 May 05

TEST SUBSTANCE

Label Identification:	ALKA VITA (2%) Mineral Supplement Lot No. 008244 Purity: 99.99%
Date & Quantity Received:	13 Apr 05; 166.2 g (Gr.Wt.)
Physical Description:	Clear liquid
Storage:	Room temperature
Density:	0.8950 g/mL
Purity & Composition:	Certificate of Analysis not provided by sponsor
Stability:	Not provided by sponsor

Records pertaining to stability, characterization, identity, synthesis methods and location of documentation are the responsibility of the sponsor.

TEST SYSTEM

Experimental Animals

Species & Strain:	Albino rat; Sprague-Dawley
Justification of Species:	The rat is a representative rodent species preferred by various regulatory agencies for use in an acute oral study.
Source:	Texas Animal Specialties, Humble, TX
Date Received:	7 Apr 05
Quarantine Period:	5 days
Quantity & Sex:	3 females (nulliparous and non-pregnant) were selected for testing
Group Identification:	Cage cards
Animal Identification:	Ear punch
Fasted Wt on Dosing Day:	178-184 g
Date of Birth:	14 Feb 05

Animal Husbandry

Cage Type:	Suspended, wire bottom, stainless steel
Housing:	1 per cage
Environmental Controls Set to Maintain:	· Temperature Range 22°C±3° · Humidity Range 30-70% · 12-hour light/dark cycle · 10-12 air changes/hour
Food:	PMI Feeds Inc.™ Formulab #5008; available *ad libitum* except for approximately 16 hours before dosing
Water:	Municipal water supply analyzed by TCEQ Water Utilities Division; available *ad libitum* from automatic water system.

Animal husbandry and housing at STILLMEADOW, Inc. comply with standards outlined in the "Guide for the Care and Use of Laboratory Animals" (NRC Publ.). No contaminants were expected to have been present in the feed or water that would have interfered with or affected the results of the study.

PROCEDURES

Test Substance Administration

The test substance was administered as received and was not diluted. An individual dose was calculated for each animal based on its fasted body weight and administered by gavage at a volume of 5.82 mL/kg. Each dose was administered using an appropriately sized syringe and stainless steel ball-tipped intubation needle. The animals were returned to their cages immediately after dosing.

In-life Observations

Observations for mortality and clinical/behavioral signs of toxicity were made at least three times on the day of dosing (Day 0) and at least once daily thereafter for 14 days. Individual body weights were recorded just prior to dosing and on Days 7 and 14.

Postmortem Observations

On Day 14 after dosing, each animal was euthanized by an overdose of CO_2. All study animals were subjected to gross necropsy and all abnormalities were recorded.

RESULTS AND DISCUSSION

Mortality/Estimated Lethality Values

There was no mortality during the study. The estimated acute oral LD_{50}, as indicated by the data, was determined to be greater than 5000 mg/kg.

Body Weights

Individual body weights are presented in Table 1. Body weight gain was unaffected by the administration of the test substance.

Clinical Signs

Clinical signs are presented in Table 2. All animals appeared normal for the duration of the study.

Necropsy Findings

Individual necropsy findings are presented in Table 1. The gross necropsy conducted at termination of the study revealed no observable abnormalities.

CONCLUSION

The test substance, ALKA VITA (ALKAHYDROXY®) (2%), was evaluated for its acute oral toxicity potential when administered to albino rats. The acute oral LD_{50} is estimated to be greater than 5000 mg/kg in females.

Study Director: Janice O Kuhn — 20 Jun 05
Janice O. Kuhn, Ph.D., DABT — Date
Senior Toxicologist, STILLMEADOW, Inc.

STUDY PERSONNEL

Technical Staff: Carol Morris, B.A.
Paul Siemens, B.A.
Robert Preston
Stephanie Wadley, B.S.

Data Services: Connie Pavatte, Report Preparation

TABLE 1
ACUTE ORAL TOXICITY STUDY (UDP) IN RATS
Body Weights, Time of Death, and Gross Necropsy
Test Substance: ALKA VITA (ALKAHYDROXY®) (2%)

Dose Level: 5209 mg/kg (5.82 mL/kg)

Animal Number	Date of Dosing	Body Weights (g)			Time of Death*	Gross Necropsy Findings
		Day 0	Day 7	Final		
101-F	19 Apr 05	178	212	231	Day 14	NOA
102-F	21 Apr 05	184	221	240	Day 14	NOA
103-F	21 Apr 05	178	222	230	Day 14	NOA

* - Day of dosing is Day 0; Hr is after Day 0 dosing; Day 14 is terminal sacrifice.
F - Female; NOA - No Observable Abnormalities

TABLE 2
ACUTE ORAL TOXICITY STUDY (UDP) IN RATS
Pharmacologic and/or Toxicologic Signs
Test Substance: ALKA VITA (ALKAHYDROXY®) (2%)

Dose Level: 5209 mg/kg (5.82 mL/kg)

Animal No.	Reaction and Severity	Time After Treatment: DAY 0 1st	DAY 0 2nd	DAY 0 3rd	DAYS 1	2	3	4	5	6	7	8	9	10	11	12	13	14
101-F	Animal appeared normal for the duration of the study.																	
102-F	Animal appeared normal for the duration of the study.																	
103-F	Animal appeared normal for the duration of the study.																	

F = Female