STILLMEADOW
INCORPORATED

VOLUME __ OF __ OF SUBMISSION

Alcohols, C18-22, distn. residues (CAS No: 1160164-88-4)

FINAL REPORT

ACUTE ORAL TOXICITY STUDY (UDP) IN RATS

OECD 425

AUTHOR:

Janice O. Kuhn, PhD, DABT

STUDY INITIATION DATE: 11 September 2009
STUDY COMPLETION DATE: 2 November 2009

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

LABORATORY STUDY NUMBER:

13292-09

VOLUME 1 OF 1 OF STUDY

SUBMITTED TO:
Sasol Germany GmbH
Anckelmannsplatz 1
Hamburg, Germany 20537

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: Sasol Germany GmbH

Company Agent: _____ Date: _____

Title _____ Signature _____

These data are the property of Sasol Germany GmbH, 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 at STILLMEADOW, Inc. and was conducted in compliance with United States Environmental Protection Agency TSCA 40 CFR 792 with exception of:
Section 792.31(d) and 792.105 (a)(b)(e) The provided Certificate of Analysis was not accompanied by a GLP compliance statement.

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with Organization for Economic Cooperation & Development Principles of GLP, Annex 2, C(98)17 with exception of:
Section II, 1.1 (2)(p), 6.1 (1) and 6.2 (2)(4) The provided Certificate of Analysis was not accompanied by a GLP compliance statement.

This study was designed and performed at STILLMEADOW, Inc. and was conducted in compliance with Japan Ministry of Agriculture, Forestry & Fisheries, Notification No. 11 Nousan 6283, Director-General of Agricultural Production Bureau with exception of:
Article 3.1 (18), 12.5 and 12.7 The provided Certificate of Analysis was not accompanied by a GLP compliance statement.

Janice O. Kuhn, PhD, DABT
Study Director, STILLMEADOW, Inc.

02 Nov 09
Date

Signature of Agent of Sponsor

Date

Agent Name
Sponsor: Sasol Germany GmbH

Signature of Agent of Submitter

Date

Agent Name
Submitter: Sasol NA

QUALITY ASSURANCE STATEMENT

Test Substance: Alcohols, C18-22, distn. residues (CAS No: 1160164-88-4)
Study Title: Acute Oral Toxicity Study (UDP) in Rats

The study report and data have been audited in accordance with Good Laboratory Practice Standards and STILLMEADOW, Inc. Standard Operating Procedures (SOPs). The final report accurately reflects the study data. The Quality Assurance Unit has not been involved in the actual conduct of this study.

The Quality Assurance Unit performed a recent facility inspection on 10 Jul 09. All findings were reported to Management, and the report and responses are kept in the Quality Assurance files.

The findings from any study inspections and audits were reported to the Study Director and Management as follows:

Critical Phase Inspected	Date Inspected	Reported to Study Director	Reported to Management
Protocol Review	08 Sep 09	08 Sep 09	08 Sep 09
Necropsy	13 Oct 09	13 Oct 09	13 Oct 09
Report/Data Audit	29 Oct 09	29 Oct 09	29 Oct 09

Scott Feazell
Quality Assurance, STILLMEADOW, Inc.

30 Oct 09
Date

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SUMMARY

The test substance, Alcohols, C18-22, distn. residues (CAS No: 1160164-88-4), was evaluated for its acute oral toxicity potential in female albino rats when administered as a gavage dose at a level of 2000 mg/kg. The study was terminated following the stopping rules of this procedure. No mortality occurred during the study. Clinical signs included salivation, crusting on muzzle, and polyuria, which were no longer evident by Day 2. There was no effect on body weight gain in animals. The gross necropsy conducted at termination of the study revealed no observable abnormalities. The acute oral LD_{50} was estimated to be greater than 2000 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 OECD 425, OPPTS 870.1100, and Canadian notification. This study was conducted for Sasol Germany GmbH, 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 study was initiated on 11 Sep 09, the pre-dose experimental portion began on 21 Sep 09, and the animals were treated as follows:

Dose Level (mg/kg)	Treatment		Animal Number	In-life Termination Date
	Date	Time		
2000	22 Sep 09	0944	201	06 Oct 09
2000	24 Sep 09	0925	202	08 Oct 09
2000	25 Sep 09	0850	203	09 Oct 09
2000	29 Sep 09	0953	204	13 Oct 09
2000	01 Oct 09	1014	205	15 Oct 09

TEST SUBSTANCE

Label Identification:	Alcohols, C18-22, distn. residues (CAS No: 1160164-88-4); Lot: 03585/MA; Spec: 59B1RN2
Date & Quantity Received:	11 Sep 09; 246.3 g (GW)
Physical Description:	Tan solid
Storage:	Room temperature
Purity:	See attached Certificate of Analysis
Stability:	Exp: Aug 2013 per provided information

Data generated for characterization and stability is the responsibility of the sponsor. Records pertaining to identity, synthesis methods and location of documentation are the responsibility of the sponsor. A copy of the Certificate of Analysis is included as report Appendix A.

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 Born/Date Received:	27 Jul 09 / 17 Sep 09
Quarantine Period:	5 days
Quantity & Sex:	5 females (nulliparous and non-pregnant)
Animal/Group Identification:	Ear punch / Cage cards
Day -1 Wt/Day 0 (fasted) Wt:	180-191 g / 163-176 g

Animal Husbandry

Cage Type:	Suspended, wire bottom, stainless steel
Housing:	1 per cage
Environmental Controls Set to Maintain:	· Temperature 22°± 3° C · Relative Humidity 30-70% · 12-hour light/dark cycle · 10-12 air changes/hour
Actual Temp/Rel. Humidity:	20-22° C / 50-95% Protocol deviation: Relative humidity was outside protocol range but did not affect study outcome.
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 Preparation and Administration

The test substance was mixed with corn oil (Parade; Exp Apr, 2010) to produce a 40% w/v concentration. An individual dose was calculated for each animal based on its fasted body weight and administered by gavage at a volume of 5.00 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 2000 mg/kg.

Body Weights

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

Clinical Signs

Clinical signs are presented in Table 2. The only clinical signs were salivation, crusting around the muzzle, and polyuria in one animal on Days 0 and 1.

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, Alcohols, C18-22, distn. residues (CAS No: 1160164-88-4), was evaluated for its acute oral toxicity potential when administered to albino rats. The acute oral LD_{50} is estimated to be greater than 2000 mg/kg in females.

Study Director: _____ 02 Nov 09
Janice O. Kuhn, PhD, DABT — Date
Senior Toxicologist, STILLMEADOW, Inc.

STUDY PERSONNEL

Technical Staff: Carol Morris, BA; Paul Siemens, BA; Nancy Casajuana, LAT; Hector Fuentes; Robert Preston; Jacinda Chatman, BS

Data Services: Jeanne Poorman, BS
Report Preparation

TABLE 1 - Body Weights, Time of Death, and Gross Necropsy
ACUTE ORAL TOXICITY STUDY (UDP) IN RATS
Test Substance: Alcohols, C18-22, dstn. residues (CAS No: 1160164-88-4)

Dose Level: 2000 mg/kg (5.00 mL/kg)

Animal Number	Dose Amt (mL)	Date of Dosing	Body Weights (g)			Time of Death *	Gross Necropsy Findings
			Day 0	Day 7	Day 14		
201	0.880	22 Sep 09	176	211	215	Day 14	NOA
202	0.835	24 Sep 09	167	207	215	Day 14	NOA
203	0.830	25 Sep 09	166	207	227	Day 14	NOA
204	0.815	29 Sep 09	163	187	202	Day 14	NOA
205	0.820	01 Oct 09	164	193	204	Day 14	NOA

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

TABLE 2 - Pharmacologic and/or Toxicologic Signs
ACUTE ORAL TOXICITY STUDY (UDP) IN RATS
Test Substance: Alcohols, C18-22, distn. residues (CAS No: 1160164-88-4)

Animal		Time After Treatment																
		Day 0			Day													
No.	Reaction/Severity	1st	2nd	3rd	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Dose Level: 2000 mg/kg (5.00 mL/kg)																		
201	Salivation	m	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Crust around muzzle	-	p	p	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Polyuria	-	-	-	m	-	-	-	-	-	-	-	-	-	-	-	-	-
202	Normal at each observation																	
203	Normal at each observation																	
204	Normal at each observation																	
205	Normal at each observation																	

v = very slight; s = slight; m = moderate; e = extreme; p = present; - = observation not present

APPENDIX A - Certificate of Analysis

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Brunsbuettel, 9/09/2009

C E R T I F I C A T E O F A N A L Y S I S

Product: Alcohols, C18-22, distn. Residues (59B1RN2)
Lot No.: 03585/MA
Manufacturing date: 25/08/2009
Expiry date: 08/2013

Tests	Unit	Result
Hydroxyl - Number	[mg KOH/g]	50,
Ester No.	[mg KOH/g]	41,17
Acid No.	[mg KOH/g]	0,09
Water	[wt.%]	0,02
Iodine No.	[mg I/100mg]	5,34

Sasol Germany GmbH
P.O. Box 1160
D-25534 Brunsbuettel
Phone: 049 (0)4852/392-0 Fax: 049 (0)4852/3285

Best regards
Works inspector
M. Sprung