

# STILLMEADOW

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I N C O R P O R A T E D

**Corr-Ze™ 100**

AMENDED FINAL REPORT

**RABBIT SKIN CORROSION (DOT)**

AUTHOR:

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STUDY INITIATION DATE: 10 January 2012  
STUDY COMPLETION DATE: 28 February 2012  
STUDY AMENDMENT DATE: 07 December 2020

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

LABORATORY STUDY NUMBER:

**15926-11**

PAGE 1 OF 9

SPONSOR:  
**Corrosions Innovations, LLC**  
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**Pasadena, TX 77504**

## TABLE OF CONTENTS

	<u>Page</u>
SUMMARY .....	3
INTRODUCTION .....	3
TEST SUBSTANCE.....	3
TEST SYSTEM .....	4
Experimental Animals .....	4
Animal Husbandry.....	4
PROCEDURES.....	4
Preparation of Animals .....	4
Test Substance Preparation and Application .....	4
Removal of Test Substance .....	4
Observations and Scoring Method.....	5
DOT Corrosion Evaluation.....	5
RESULTS AND DISCUSSION .....	5
Evaluation.....	5
CONCLUSION.....	5
SIGNATURE.....	5
STUDY PERSONNEL .....	5
LEGEND TO TABLES 1 & 2 .....	6
TABLE 1 – Signs of Dermal Corrosion/Irritation .....	7
TABLE 2 – Extended Signs of Dermal Corrosion/Irritation .....	8
APPENDIX A - Amendment.....	9

## SUMMARY

A skin corrosion/dermal irritation study was conducted on three albino rabbits using test substance Corr-Ze™ 100 to determine the skin corrosion potential of the test substance. If the substance was non-corrosive by DOT criteria, the potential for primary dermal irritation was evaluated.

There were three intact skin test sites per animal. Each test site was treated with 0.5 ml of undiluted test substance. The test sites were dosed sequentially to permit removal of test substance and observation of the treated sites for dermal irritation and defects at several predetermined observation times. The first site was dosed, then washed and observed 3 minutes later. A second site was dosed, wrapped for 1 hour, and washed; then both the first and second test sites were observed. A third site was dosed and wrapped for 4 hours. One hour after unwrapping and washing of the third site, all three test sites were observed for signs of skin irritation and/or corrosion. Observations were conducted thereafter at 24, 48 and 72 hours after final unwrap.

Tissue destruction (necrosis or ulceration) was not observed in any animals during the evaluation period. Dermal irritation (erythema) was observed in one animal. No other irritation was observed. The test substance is considered non-corrosive by DOT criteria when applied to the intact skin of albino rabbits.

## INTRODUCTION

The objective of this study was to determine the skin corrosion and/or dermal irritancy potential of the test substance according to US DOT 49 CFR 173.137, Class 8-Assignment of Packing Group. This study was conducted 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 in this study are in compliance with Animal Welfare Act Regulations. The protocol, raw data, and this report are archived at STILLMEADOW, Inc. The animals were treated with the test substance between 0952 and 1100 on 24 Jan 12. The in-life portion of the study was terminated on 27 Jan 12.

## TEST SUBSTANCE

Reference Name:	Corr-Ze™ 100
Label Identification:	CorrLine CorrX Conditioner
Date & Quantity Received:	9 Oct 12; 64.9 g (GW)
Physical Description:	Slightly cloudy liquid
Storage:	Room temperature
Purity:	Not provided to testing facility
Stability:	Not provided to testing facility

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.

## TEST SYSTEM

### Experimental Animals

Species & Strain: Albino Rabbit; New Zealand White  
Justification of Species: The rabbit is a representative species preferred by various regulatory agencies for use in skin corrosion testing.  
Source: Rich-Glo II, Inc; Wills Point, TX  
Date Born/Date Received: 21 Oct 11 / 18 Jan 12  
Quantity & Sex: 1 male, 2 female (nulliparous & non-pregnant)  
Quarantine Period: At least 5 days  
Animal Identification: Ear tattoos  
Initial Body Weights: 3.575-3.700 kg

### Animal Husbandry

Cage Type: Suspended, wire bottom, stainless steel  
Housing: One per cage  
Environmental Controls  
Set to Maintain: · Temperature  $20^{\circ} \pm 3^{\circ}\text{C}$  · Relative Humidity 30-70%  
· 12-hour light/dark cycle · 10-12 air changes/hour  
Actual Temp/Rel. Humidity: 19-22°C / 36-92%  
Food: PMI Feeds Lab Rabbit Diet #5321, in measured amounts  
Water Type: 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 which would have interfered with or affected the results of the study.

## PROCEDURES

### Preparation of Animals

Healthy albino rabbits were released from quarantine. Each animal was prepared on the day prior to treatment by clipping the dorsal area of the trunk free of hair to expose an area at least 8 x 8 cm. Care was taken to avoid abrading the skin. Only those animals with exposure areas free of pre-existing skin irritation or defects were selected for testing. There were three intact skin test sites per animal.

### Test Substance Preparation and Application

Each test site was treated by applying 0.5 ml of undiluted test substance beneath a 4 ply, 2.5 x 2.5 cm surgical gauze patch. Each patch was secured in place with a strip of non-irritating adhesive tape. With the exception of dosing for the 3-minute observation, the entire trunk of each animal was then wrapped with clear plastic film to retard evaporation of volatile substances and to prevent possible ingestion of the test substance. The wrappings were held in place with non-irritating adhesive tape.

### Removal of Test Substance

The wrappings were removed at the end of the 1 and 4 hour exposure periods. All test sites (including the 3 minute exposure site) were washed with room temperature tap water and a clean cloth to prevent further exposure.

#### Observations and Scoring Method

The scoring scale used for the evaluation of skin reactions is presented in the Legend to Tables 1 and 2. Test sites were observed and scored for signs of skin irritation, necrosis, or other defects after patch removal at 3 minutes and 1 hour for the 3-minute and 1-hour exposure sites, respectively. All test sites were observed at 1, 24, 48 and 72 hours, and on Days 7, 10 and 14 after last patch removal.

#### DOT Corrosion Evaluation

Corrosion under DOT criteria is considered to have occurred if the test substance in contact with the intact skin of the rabbits causes destruction or irreversible alteration of the skin on any rabbits tested at any time. Tissue destruction is considered to have occurred if there is ulceration or necrosis at any observation time. Tissue destruction does not include erythema, edema, flaking of the epidermis, or shallow lateral fissuring. The Packing Group is determined by the shortest exposure time producing tissue destruction (Legend to Tables 1 and 2).

### RESULTS AND DISCUSSION

#### Evaluation

Observations for dermal corrosion/irritation through 24 hours after dosing of the 4 hour test site are presented in Table 1. Observations for dermal corrosion/irritation from 48 hours after final dosing through study termination are presented in Table 2. Very slight erythema was present in one animal at the 4-hour test site. Edema was not observed in any animals. No other signs of irritation were observed. Tissue destruction (necrosis or ulceration) was not observed in any animals during the entire period.

### CONCLUSION

The test substance Corr-Ze™ 100 is considered non-corrosive by DOT criteria when applied to the intact skin of albino rabbits.

Study Director: \_\_\_\_\_

Andrew Doig, MS  
Toxicologist, STILLMEADOW, Inc.

07 Dec 20  
Date

### STUDY PERSONNEL

Technical Staff: Carol Morris, BA  
Hector Fuentes

Paul Siemens, BA  
Nancy Casajuana, LAT, AS

Data Services: Connie Pavatte, Report Preparation

**LEGEND TO TABLES 1 & 2**  
Rabbit Skin Corrosion (DOT)

Evaluation of Skin Reactions

<u>Erythema Formation</u>	<u>Score</u>
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Maximum Possible	4

<u>Edema Formation</u>	<u>Score</u>
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4
Maximum Possible	4

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Classification of Test Substance

Classification of Corrosive Materials into DOT Packing Groups\*:

**PACKING GROUP I** - Substances that cause full thickness destruction of intact skin tissue within an observation period of up to 60 minutes starting after the exposure time of 3 minutes or less.

**PACKING GROUP II** - Substances, other than those meeting Group I criteria, that cause full thickness destruction of intact skin tissue within an observation period of up to 14 days starting after the exposure time of more than 3 minutes but not more than 60 minutes.

**PACKING GROUP III** - Substances, other than those meeting Group I or II criteria, that cause full thickness destruction of intact skin tissue within an observation period of up to 14 days starting after the exposure time of more than 60 minutes but not more than 4 hours.

Note: None of the above = Non-corrosive

\* - 49 CFR 173.137 Class 8 - Assignment of packing group

**TABLE 1 – Signs of Dermal Corrosion/Irritation**

Test Substance: Corr-Ze™ 100

Rabbit Skin Corrosion (DOT)

Obs. Time after Treatment	Test Site	ERYTHEMA			EDEMA		
		Rabbit Number			Rabbit Number		
		0962-M	0951-F	0953-F	0962-M	0951-F	0953-F
3 min	RA	0	0	0	0	0	0
1 Hr	RA	0	0	0	0	0	0
1 Hr	RP	0	0	0	0	0	0
5 Hr	RA	0	0	0	0	0	0
5 Hr	RP	0	0	0	0	0	0
5 Hr	LA	0	0	0	0	0	0
*24 Hr	RA	0	0	0	0	0	0
*24 Hr	RP	0	0	0	0	0	0
*24 Hr	LA	0	0	1	0	0	0
DOT CLASS =				Non-corrosive			
RA - Right Anterior; RP - Right Posterior; LA - Left Anterior							
* - Observations were made 24 hours after final unwrap.							
M - Male; F - Female							

Obs. Time after Treatment	Test Site	OTHER OBSERVATIONS		
		Rabbit Number		
		0962-M	0951-F	0953-F
3 min	RA	-	-	-
1 Hr	RA	-	-	-
1 Hr	RP	-	-	-
5 Hr	RA	-	-	-
5 Hr	RP	-	-	-
5 Hr	LA	-	-	-
*24 Hr	RA	-	-	-
*24 Hr	RP	-	-	-
*24 Hr	LA	-	-	-
Note: A dash (-) is used if there are no other signs of dermal irritation.				

**TABLE 2 – Extended Signs of Dermal Corrosion/Irritation**

Test Substance: Corr-Ze™ 100

Rabbit Skin Corrosion (DOT)

Animal Number	Test site	ERYTHEMA					EDEMA				
		Hours		Days			Hours		Days		
		48	72	7	10	14	48	72	7	10	14
0962-M	RA	0	0				0	0			
	RP	0	0				0	0			
	LA	0	0				0	0			
0951-F	RA	0	0				0	0			
	RP	0	0				0	0			
	LA	0	0				0	0			
0953-F	RA	0	0				0	0			
	RP	0	0				0	0			
	LA	0	0				0	0			
RA - Right Anterior (3 min site); RP - Right Posterior (1 hr site); LA - Left Anterior (4 hr site)											
M – Male; F – Female Study Duration: 72 Hrs											

Animal Number	Test site	OTHER OBSERVATIONS				
		Hours		Days		
		48	72	7	10	14
0962-M	RA	-	-			
	RP	-	-			
	LA	-	-			
0951-F	RA	-	-			
	RP	-	-			
	LA	-	-			
0953-F	RA	-	-			
	RP	-	-			
	LA	-	-			
Note: A dash (-) is used if there are no other signs of irritation.						



**APPENDIX A - Amendment**

Rabbit Skin Corrosion (DOT)

Corr-Ze™ 100

Study 15926-11

Sponsor: Corrosion Innovations, LLC

**Final Report Amendment**

This amendment modifies Test Substance name throughout the final report (excepting Label Identification):

To change: from CorrLine CorrX Conditioner to Corr-Ze™ 100

This amendment modifies Sponsor information on cover of the final report:

To change: from	Trigenex of Texas Inc dba CorrLine	to	Corrosions Innovations, LLC
	20523 Whiteberry Court		4020 Strawberry Road
	Humble, TX 77346-1338		Pasadena, TX 77504

Reason for amendment: Sponsor request dated 14 Sep 20.

Amendment Approval:

  
\_\_\_\_\_  
Andrew Doig, MS  
Study Director, STILLMEADOW, Inc.

07 Dec 20  
\_\_\_\_\_  
Date