

TRADE SECRET

Study Title

FRD-903: Corrositex[®] *In Vitro* Test

AUTHOR: Carol Carpenter, B.A.

STUDY COMPLETED ON: September 25, 2007

PERFORMING LABORATORY: E.I. du Pont de Nemours and Company
DuPont Haskell Global Centers
for Health & Environmental Sciences
P.O. Box 50
Newark, Delaware 19714
U.S.A.

LABORATORY PROJECT ID: DuPont-24019

WORK REQUEST NUMBER: 17473

SERVICE CODE NUMBER: 1302

SPONSOR: E.I. du Pont de Nemours and Company
Wilmington, Delaware 19898
U.S.A.

CERTIFICATION

We, the undersigned, declare that this report provides an accurate evaluation of data obtained from this study.

Reviewed by: Denise Hoban 25 Sept 2007
Denise Hoban, B.A., MLT (ASCP)
Staff Medical Technologist and Supervisor
Date

Issued by Study Director: Carol Carpenter 25 Sept 2007
Carol Carpenter, B.A.
Senior Staff Toxicologist
Date

TABLE OF CONTENTS

	Page
CERTIFICATION	2
STUDY INFORMATION	4
SUMMARY	5
INTRODUCTION.....	6
MATERIALS AND METHODS	6
A. Test Substance	6
B. Principles of the Method.....	6
C. Corrositex Assay	7
RESULTS	9
CONCLUSION	9
RECORDS AND SAMPLE STORAGE	9

STUDY INFORMATION

Substance Tested:

- FRD-903
- 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid
- 13252-13-6 (CAS Number)
- H-28307

Haskell Number: 28307

Composition: 99% FRD-903
Less than or equal to 1% Water
14 ppm PFOA
0.02 ppm HFPO trimer acid

Purity: See composition, above

Physical Characteristics: Clear and colorless liquid

Study Initiated/Completed: August 29, 2007 / (see report cover page)

Experimental Start/Termination: September 17, 2007 / September 17, 2007

SUMMARY

FRD-903 was evaluated for skin corrosion potential using the *In Vitro* International Corrositex[®] assay. The results of the assay were used to determine the United Nations and Department of Transportation corrosive packing group. Corrositex[®] is a standardized and quantitative *in vitro* corrosivity test. The model is based on the time required for the test substance to pass through a biobarrier membrane and produce a change in a chemical detection system.

An aliquot of 500 µL of FRD-903 was applied to each of 4 membrane discs. The test substance passed through all 4 of the membranes. The mean breakthrough time for all 4 vials was 1 hour, 8 minutes, and 13 seconds.

Under the conditions of this test, FRD-903 is corrosive and is assigned to Packing Group III (minor danger).

INTRODUCTION

The purpose of this study was to determine skin corrosion potential of FRD-903 using the *In Vitro* International Corrositex[®] assay kit. The results of the assay were used to determine the United Nations (UN) and Department of Transportation (DOT) Packing Group for transport of the test substance.

MATERIALS AND METHODS

A. Test Substance

The test substance, FRD-903, was supplied by the sponsor. The pH was 0, according to information provided by the sponsor. The test substance appeared to be stable under the conditions of the study. No evidence of instability, such as a change in color or physical state, was observed.

B. Principles of the Method

Corrositex[®] is an *in vitro* assay used to determine the skin corrosion potential of a test substance. The assay is based on the ability of a corrosive test substance to pass through a biobarrier membrane and to cause a color change in the liquid Chemical Detection System (CDS). The proprietary biobarrier membrane consists of a reconstituted collagen mixture. The CDS is composed of water and pH indicator dyes. Corrositex[®] is conducted in three steps:

1. Qualification Step

The test substance is pre-qualified to establish compatibility with the assay. The test substance is placed directly into a vial containing the CDS. If a change in color or consistency occurs, the test substance can be tested by using this assay.

2. Categorization Step

This step establishes the category of the test substance for use in the classification step. The test substance is placed into Vial A (containing an acid buffer) and Vial B (containing a base buffer), and the vials are observed for a color change. A color change observed in either vial is matched to a color chart. The test substance is assigned to either Category 1 or Category 2 based on the color change in each vial. Category 1 and Category 2 are indicative of the time scales used in the classification step.

3. Classification Step

This step determines if the test substance is a skin corrosive according to UN and DOT regulations and classifications. The test substance is applied on top of the proprietary biobarrier membrane. A color change or consistency change in the CDS beneath the membrane indicates that the test substance has passed through the membrane. The determination of

corrosive/non-corrosive and the Packing Group assigned are based on the amount of time it takes the test substance to pass through the membrane. The time scales differ for Category 1 and 2.

The category assigned and the mean value of the breakthrough time for all 4 sample replicate vials determine the packing group. The following table is used to assign the appropriate Packing Group by category and breakthrough time.

PACKING GROUP DESIGNATION

Corrositex® Times

Category 1	0 to 3 minutes	> 3 to 60 minutes	> 60 to 240 minutes	> 240 minutes
Category 2	0 to 3 minutes	> 3 to 30 minutes	> 30 to 60 minutes	> 60 minutes
	Packing Group I	Packing Group II	Packing Group III	Non-Corrosive

> = greater than

C. Corrositex Assay

The biobarrier membrane discs provided by the manufacturer were stored in a refrigerator (2-8°C) until the biobarrier membranes were prepared. The biobarrier membranes were prepared 4 days prior to conducting the assay. A thermometer was inserted into a water bath container that was placed on a hot plate/magnetic stirrer. The water bath container was filled with approximately 1 inch of water and heated to 68-70°C. While the water bath was warming, the membrane discs were removed from the refrigerator. The tray lid was removed to prevent condensation. The entire contents of the biobarrier diluent were added to the vial of biobarrier matrix powder. The vial was then placed inside the water bath. The mixture was stirred at medium speed until the biobarrier matrix powder was completely dissolved (approximately 20 minutes). The stir knob and heat were turned off. The solution remained in the water bath for 5 minutes to allow any air bubbles to rise to the surface.

Two hundred microliters of biobarrier solution was pipetted into each membrane disc, ensuring the entire membrane was covered and no air bubbles had formed. The filled tray containing the biobarriers was wrapped with plastic wrap and immediately stored in a refrigerator (2-8°C).

1. Qualification

The test substance was first tested to determine if the sample was compatible with the Corrositex® system. A 150 µL aliquot of the test substance was added to the Qualify test tube, shaken, and allowed to stand for 1 minute. A change in color or consistency was observed qualifying the test substance for use in the Corrositex® system.

2. Categorization

A 150 µL aliquot of FRD-903 was added to Vial A (containing an acid buffer) and Vial B (containing a base buffer). The vials were capped and shaken. A color change was noted. The

color was matched to the colors on the color charts. The color change placed the sample in Category 1.

3. Classification

The filled tray containing the biobarriers was put onto crushed ice. A membrane disc containing the biobarrier matrix was placed into a chemical detection system (CDS) vial. The CDS vials were at room temperature (17-25°C). Within 2 minutes, an aliquot of 500 µL of FRD-903 was evenly applied on top of the disc and a timer was started. This procedure was followed for each of the 4 test vials (vials 1-4). One vial was similarly treated with 500 µL of a positive control [(vial labeled "+") containing sulfuric acid] and another was similarly treated with 500 µL of a negative control [(vial labeled "-") containing citric acid]. A vial labeled C served as a CDS color control. The vials were then observed for a change in the CDS. The first indication of the test substance in the CDS was a narrow stream of color change beneath the biobarrier disc. The time it took for the test substance to break through the membrane was documented. The mean value of the breakthrough time for all 4 test vials was used in determining the packing group. The time it took for the positive control to break through the membrane was also documented.

RESULTS

Breakthrough of the biobarrier occurred as follows (hour:minute:second):

Vial 1 (Test Substance):	1:03:58
Vial 2 (Test Substance):	1:02:46
Vial 3 (Test Substance):	1:12:58
Vial 4 (Test Substance):	1:13:10
Mean Value:	1:08:13

Vial 5 (Positive Control):	0:01:09
Vial 6 (Negative Control):	<u>No breakthrough</u>

The positive control and negative control performed as anticipated.

CONCLUSION

Under the conditions of this test, FRD-903 is corrosive and is assigned to Packing Group III (minor danger).

RECORDS AND SAMPLE STORAGE

Specimens (if applicable), raw data, the protocol, amendments (if any), and the final report will be retained at DuPont Haskell, Newark, Delaware, or at Iron Mountain Records Management, Wilmington, Delaware.