SGS U.S. Testing Company Inc.
75 Passaic Avenue
Fairfield, NJ 07004-3833
Tel: 201-575-5252
Fax: 201-244-1823

Skin Sensitization (Kligman) Study in Guinea Pigs
on

NuShield™(Cold Fire)

Conducted for:

NuMar Technologies, Inc.
841 Mountain Avenue
Springfield, NJ 07081

Manufactured by

Firefreeze Worldwide, Inc.

Prepared by:

Joan Breheny, M.S.
Supervisor of Toxicology

SIGNED FOR THE COMPANY BY

Charles C. Tong, Ph.D., D.A.B.T.
Director of Toxicology

Member of the SGS Group

ANALYTICAL SERVICES • PERFORMANCE TESTING • STANDARDS EVALUATION • CERTIFICATION SERVICES

SGS U.S. TESTING COMPANY INC. REPORTS ARE FOR THE EXCLUSIVE USE OF THE CLIENT TO WHOM THEY ARE ADDRESSED. ANYONE RELYING ON SUCH REPORTS SHOULD UNDERSTAND ALL OF THE DETAILS OF THE ENGAGEMENT. REPORTS REFLECT RESULTS ONLY OF THE STANDARDS OR PROCEDURES IDENTIFIED TO THE TESTS CONDUCTED AND ARE LIMITED TO THE SAMPLES TESTED. TEST RESULTS MAY NOT BE INDICATIVE OF THE QUALITIES OF THE LOT FROM WHICH THE SAMPLE WAS TAKEN. SGS U.S. TESTING COMPANY INC. HAS NOT CONDUCTED ANY QUALITY CONTROL PROGRAM FOR THE CLIENT. NEITHER THE NAME, SEALS, MARKS NOR INSIGNIA OF SGS U.S. TESTING COMPANY INC. MAY BE USED IN ANY ADVERTISING OR PROMOTIONAL MATERIALS WITHOUT THE PRIOR WRITTEN APPROVAL OF SGS U.S. TESTING COMPANY INC. THIS REPORT SHALL NOT BE REPRODUCED EXCEPT IN FULL WITHOUT THE WRITTEN PERMISSION OF THE SGS U.S. TESTING COMPANY INC. SAMPLES NOT DESTROYED IN TESTING ARE DISPOSED OF AFTER 30 DAYS.

GLP COMPLIANCE

The characterization of the test substance was the responsibility of the sponsor. To the best of our knowledge, the remaining part of the study was conducted in compliance with 21 CFR 58, FDA Good Laboratory Practices.

Charles C. Tong, Ph.D., D.A.B.T.
Study Director

QAU STATEMENT

Test Substance: (Sponsor's Code)	NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc.
Nature of Study:	Skin Sensitization (Kligman) Study in Guinea Pigs
Study Number:	202536-02
Study Initiation Date:	05/13/96
QAU Review of Protocol:	05/13/96
QAU Review of In-Life Phases:	05/14/96, 05/21/96, 06/07/96
Reported to Study Director:	05/15/96, 05/21/96, 06/07/96
Reported to Management:	05/16/96, 05/21/96, 06/07/96
QAU Review of Raw Data:	08/12/96
QAU Review of Draft Report:	08/12/96
QAU Review of Final Report:	08/16/96
Study Termination Date:	08/16/96

The above study was conducted at SGS USTC Laboratories in accordance with GLP regulations applicable to the Quality Assurance Unit. This study was inspected by the QAU on the dates specified above. The findings of the in-life inspections were reported to the Study Director and Management on the dates listed.

.. Franconeri
Quality Assurance Coordinator

8/16/96
Date

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

REPORT OF TEST

Table of Contents

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

REPORT OF TEST

Summary

When tested as specified, NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc., under the conditions of this experiment, was not considered to be a skin sensitizing agent.

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

Procedure: Skin Sensitization Test

Animals and Husbandry:

Young adult Hartley strain guinea pig initially weighing between 250 and 350g were the laboratory animal model for the skin sensitization test. Animals were purchased from a registered USDA supplier and housed in groups of 5 or 6 in a stainless steel solid bottom caging with wooden shavings bedding. Female test animals were non-pregnant and nulliparous. Water and guinea pig ration were available ad libitum. Animals were ear-tagged upon arrival and monitored for 7 days prior to initiating tests.

Test animal groups should be comprised of an equal number of each sex, if possible. Ten (10) animals were selected for the test article group and 10 additional animals were selected for the control sample. Additional animals might be used to screen for primary skin irritation, if necessary.

Procedure

Preparation of Test Animals, Sample and Induction Period:

The hair was clipped from the appropriate area of the trunk of test animals using electric clippers with a fine (No. 40) surgery prep blade. Care should be taken to avoid abrading the skin when shaving. Only one flank of the animals was shaved for the induction period.

Sample Preparation:
Preliminary irritation screening indicated that submitted sample was not irritating. Test article was administered neat.

Step (1) Induction (Week 1):

A) For Injectable Test Articles:

The backs (shoulder region) of the guinea pigs received intradermal injections of a) Freunds adjuvant; b) test article or control sample mixed with Freunds adjuvant (v/v); c) test article or control sample. Duplicate injections were made; the quantity injected was 0.1ml.

REPORT OF TEST

Procedure: Skin Sensitization Test (continued)

B) For Non-Injectable Articles: (Not applicable in this study)

The backs of the guinea pigs received an intradermal injection of Freunds adjuvant. Next, the test article was topically applied to the back under an occlusive patch. The skin, however, was either pre-irritated with a dilution of SLS for 24 hours, or a percentage of SLS was incorporated with the test article during skin contact. The time of topical contact was 48 hours.

The occlusive patch consisted of a ca. 2x4cm pad (i.e. Webril pad, filter paper etc.) covered by surgical tape. The body of the guinea pig was then overwrapped with an elastroplast bandage.

Step (2) Induction (Week 2):

The same skin site previously injected or treated in Step 1 was treated again by topical patch administration.

The test article or control sample was applied to skin pre-irritated with a dilution of SLS for 24 hours, or a percentage of SLS was incorporated with the test article during skin contact. The test article or control sample was administered under the occlusive patch (described above) for a 48 hour period.

Step (3) Challenge Application (Week 4):

The challenge for sensitivity required that a new site on the guinea pig's body to be exposed to the test article:

The previously unused flank or belly of the guinea pig received the final topical application of the test article administered under an occlusive patch. This time, the skin site was not irritated intentionally by SLS treatment. Both the test animals and the control received the test sample in this challenge application.

After 24 hours of contact, the skin exposed to the challenge patch was evaluated for reactions. Readings were made at 1, 24 and 48 hours.

REPORT OF TEST

Criterion for Evaluation:

After previous contact with the skin, an allergen, e.g., "sensitizer" will cause a skin reaction upon a repeated application of the substance. This can occur at a site on the body which has not been exposed. If the substance is both irritating and sensitizing, repeated contact will cause an exacerbation of the irritating effects even at a minimal concentration.

The eruption of a skin response after contact with the sub-irritating doses of the test article on the guinea pig belly was graded using the following rating scale:

Dermal Reaction	Score
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

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

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

Results:

Test Animals:

Strain: Hartley albino Guinea pigs
Source: Ace Animals, Boyertown, PA
Date Received: 05/07/96

Test Materials:

Test article - NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc.

Test Parameters:

Test Group Animals	Sample Administration
10 - test article	Induction Regime - Intradermal Injection at day 0 and Topical occluded patch for 48 hours at day 7 on irritated skin.
10 - control sample	Challenge Regime - Topical occluded patch, 24 hour exposure on day 21.
	Dermal Reaction Readings - 1, 24 and 48 hour post-challenge doses.

Observations:

All test animals and control animals appeared normal and showed progressive weight gain during the induction phase of the study.

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

Results: (continued)

Skin Sensitization Reactions

Test Group I # Animals/Sex	Incidence					Score Average
1 Hour						
5 F	1/0	0/0	0/0	0/0	1/0	0.4/0[1]
5 M	0/0	0/0	0/0	1/0	1/0	0.4/0
24 Hours						
5 F	0/0	0/0	0/0	0/0	0/0	0/0
5 M	0/0	0/0	0/0	0/0	0/0	0/0
48 Hours						
5 F	0/0	0/0	0/0	0/0	0/0	0/0
5 M	0/0	0/0	0/0	0/0	0/0	0/0

Observations:

At one hour after a 24 hour challenge exposure, 4 of the 10 guinea pigs showed slight erythema. By 24 hours after exposure, there was a complete recovery. No gross changes were observed in these animals at necropsy at the completion of the study.

[1]: Grading was Erythema/Edema

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

REPORT OF TEST

Results: (continued)

Skin Sensitization Reactions

Control Group I # Animals/Sex	Incidence					Score Average
1 Hour						
5 F	0/0	0/0	1/0	1/1	1/1	0.6/0.4
5 M	0/0	0/0	0/0	0/0	0/0	0/0
24 Hours						
5 F	0/0	0/0	0/0	0/0	0/0	0/0
5 M	0/0	0/0	0/0	0/0	0/0	0/0
48 Hours						
5 F	0/0	0/0	0/0	0/0	0/0	0/0
5 M	0/0	0/0	0/0	0/0	0/0	0/0

Observations:

At one hour after a 24 hour challenge exposure, 3 of the guinea pigs showed slight erythema. Two of these guinea pigs also showed slight edema. By 24 hours after exposure there was a complete recovery. No gross changes were observed in these animals on necropsy at the completion of the study.

[1]: Grading was Erythema/Edema

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

Conclusion:

When tested as specified, the submitted sample, NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc., was not considered to be a skin sensitizing agent. There did not appear to be a significant difference between the skin irritation scores of the test and control animals one hour after challenge.

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

Individual Body Weight

Test Group	Initial Wt (g)	Final Wt (g)
5 Female	300	466
	315	490
	305	461
	323	467
	280	390
Average	305	455

Individual Body Weight

Test Group	Initial Wt (g)	Final Wt (g)
5 Male	330	503
	307	494
	321	553
	312	523
	302	486
Average	314	512
Group Average	310	484

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

Individual Body Weight

Control Group	Initial Wt (g)	Final Wt (g)
5 Female	293	459
	316	468
	296	428
	288	453
	298	492
Average	298	460

Individual Body Weight

Control Group	Initial Wt (g)	Final Wt (g)
5 Male	310	516
	287	436
	335	527
	322	510
	316	544
Average	314	507
Group Average	306	484

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

ANALYSTS' SIGNATURES

Investigators and analysts for the mammalian toxicology study of NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc.:

Study Director:

Charles C. Tong, Ph.D., D.A.B.T.

Quality Assurance:

R. Franconerii

Analyst:

Joan Brehény, M.S.

Analyst:

Stefania Giobbe, M.S.

Analyst:

Suzanne Poppe

Client: NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

ARCHIVAL OF RAW DATA

SGS U.S. Testing Company policy regarding GLP studies is to inventory and archive a copy of the final report and all original test data and records generated in support of the study for a period of five years following the date of the final report of test. Upon completion of the five year period, all inventoried original test data and study records (or where applicable, photocopies of the originals), shall be transferred to the sponsor (client) of the study. The appropriate agency shall be notified in writing of such a transfer, as required under current guidelines.

SGS U.S. Testing Company Inc.

NuMar Technologies, Inc.

Report Number: 202536-02
Date: 08/16/96

Addendum 1

4.	ROUTE OF ADMINISTRATION:	1 intradermal and 2 dermal
5.	EXPOSURE GROUPS:	1 group receiving test substance.
6.	CONTROL GROUP:	1 group receiving vehicle if appropriate
7.	ANIMALS PER GROUP:	5 males and 5 females
8.	SPECIES/STRAIN:	Guinea Pigs, Hartley
9.	SEX/AGE/WEIGHT:	Male & female - 250 to 350 grams
10.	SOURCE:	Ace Animals, Boyertown, PA 19512
11.	RANDOMIZATION OF ANIMALS:	Randomly selected from large pool of healthy subjects maintained at USTC
12.	MEANS OF IDENTIFICATION:	Ear Tags
13.	FOOD & WATER:	Guinea Pig Diet 5025, PMI Feeds, Inc. St. Louis, MO and municipal filtered water. Analysis at least once a year for specific microorganism, heavy metals (water); for specific heavy metals and pesticides (feed). None of these contaminants are reasonably expected to be present at levels sufficient to interfere with this study.
14.	JUSTIFICATION OF TEST SYSTEM:	Guinea pigs historically have been used in safety evaluation studies and are recommended by appropriate regulatory agencies. No alternatives to animal use are currently available. This protocol will be reviewed by the U.S. Testing IACUC for compliance with regulatory guideline concerning the care and use of animals. If not in compliance, modification will be required.

15. TEST MEASUREMENTS:

PRE-TEST	
QUARANTINE	- observations only, 7 days
	- body weights & physical examinations, on test day 0
POST EXPOSURE	
SURVIVAL CHECKS	- at least once daily
CLINICAL OBSERVATIONS	- once daily, 7 days per week
PHYSICAL EXAMINATION	- pretest and test day 7, 14 and 24
BODY WEIGHTS	- pretest and test-day 7, 14 and 24
FOOD CONSUMPTION	- not required
CLINICAL CHEMISTRY	- not required
HEMATOLOGY	- not required
URINALYSIS	- not required
OPHTHALMOLOGY/ DERMATOLOGY	- dermatology, after each exposure and 1 hr, 24 hrs, 48 hrs post day 21 exposure
NECROPSY	- selected test animals
HISTOPATHOLOGY	- not required

16. STATISTICAL METHODS : (IF APPLICABLE)

17. RECORD MAINTENANCE: Equipment maintenance\calibration records, test\control article records, environmental records, specimen, raw data, QA\QC reports, communication and final reports will be archived in secured file at USTC

SGS

18. REGULATORY COMPLIANCE:

This study will be conducted in accordance with the Good Laboratory Practice Regulations as set forth in 21 CFR Part 58, Dec. 22, 1978 (effective June 20, 1979) and any applicable amendments (FDA-GLP), 40 CFR Part 160, Subpart F (EPA-FIFRA-GLP) and 40 CFR Part 792 Subpart F (EPA-TSCA-GLP)

Upon approval of this protocol, the sponsor assumes the responsibility of performing, documenting and maintaining documentation that test, control and reference substance are properly characterized in accordance with the guidelines set forth in the following: 40 CFR 160, Subpart F - Test, Control and Reference Substances (EPA-FIFRA); or 40 CFR 792 - Subpart F - Test, Control and Reference Substances (EPA-TSCA); or 21 CFR 58, Subpart F - Test and Control Articles (FDA-GLP), as applicable to this study.

All data generated in support of this study shall be archived at USTC for a period of five years from the date of the final report of test. Upon completion of this time period, the original data (or where applicable, photocopies of the original data) shall be inventoried and transferred to the sponsor who shall then assume responsibility for archiving the data in accordance with appropriate GLP guidelines. Concurrently, the inventory of the study and a notice that the files have been transferred to the custody of the sponsor shall be sent to the FDA or EPA, as applicable.

Submitted by:

5/13/96

Charles C. Tong, Ph.D., D.A.B.T.
Director of Toxicology

Reviewed by:
(reserved)

5/13/96

Tina Nuccitelli
Quality Assurance Auditor

Approved by:
(Sponsor)

5/13/96

Guy F. Falzarano
Executive Vice President
NUMAR TECH, INC.

REPORT OF TEST

SGS U.S. Testing Company Inc.
75 Passaic Avenue
Fairfield, NJ 07004-3833
Tel: 201-575-5252
Fax: 201-244-1823

Acute Dermal Toxicity Study In Rabbits on NuShield™(Cold Fire)

Conducted for:

NuMar Technologies, Inc.
841 Mountain Avenue
Springfield, NJ 07081

Manufactured by:

Firefreeze Worldwide, Inc.

Prepared by:

Joan Breheny, M.S.
Supervisor of Toxicology

SIGNED FOR THE COMPANY BY

Charles C. Tong, Ph.D., D.A.B.T.
Director of Toxicology

Member of the SGS Group
ANALYTICAL SERVICES · PERFORMANCE TESTING · STANDARDS EVALUATION · CERTIFICATION SERVICES
SGS U.S. TESTING COMPANY INC. REPORTS ARE FOR THE EXCLUSIVE USE OF THE CLIENT TO WHOM THEY ARE ADDRESSED. ANYONE RELYING ON SUCH REPORTS SHOULD UNDERSTAND ALL OF THE DETAILS OF THE ENGAGEMENT. REPORTS REFLECT RESULTS ONLY OF THE STANDARDS OR PROCEDURES IDENTIFIED TO THE TESTS CONDUCTED AND ARE LIMITED TO THE SAMPLES TESTED. TEST RESULTS MAY NOT BE INDICATIVE OF THE QUALITIES OF THE LOT FROM WHICH THE SAMPLE WAS TAKEN. SGS U.S. TESTING COMPANY INC. HAS NOT CONDUCTED ANY QUALITY CONTROL PROGRAM FOR THE CLIENT. NEITHER THE NAME, SEALS, MARKS NOR INSIGNIA OF SGS U.S. TESTING COMPANY INC. MAY BE USED IN ANY ADVERTISING OR PROMOTIONAL MATERIALS WITHOUT THE PRIOR WRITTEN APPROVAL OF SGS U.S. TESTING COMPANY INC. THIS REPORT SHALL NOT BE REPRODUCED EXCEPT IN FULL WITHOUT THE WRITTEN PERMISSION OF THE SGS U.S. TESTING COMPANY INC. SAMPLES NOT DESTROYED IN TESTING ARE DISPOSED OF AFTER 30 DAYS.

Client: NuMar Technologies, Inc.

Report Number: 202536-01
Date: 08/16/96

REPORT OF TEST

GLP COMPLIANCE

The characterization of the test substance was the responsibility of the sponsor. To the best of our knowledge, the remaining part of the study was conducted in compliance with 21 CFR 58, FDA Good Laboratory Practices.

Charles C. Tong, Ph.D., D.A.B.T.
Study Director

REPORT OF TEST

Table of Contents

Summary

When tested as specified, NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc. was not acutely toxic to laboratory rabbits following dermal application at a dose level of 2.0g/kg. Thus, under the conditions of this experiment Cold Fire is practically nontoxic following dermal application.

Client: NuMar Technologies, Inc.

Report Number: 202536-01
Date: 08/16/96

Subject: Sample submitted and identified by the client as:

NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc.

Project: Acute Dermal Toxicity Test

Introduction and Purpose

The purpose of this safety test is to determine if acute health hazards are associated with dermal exposure to the test article. The measure acute toxicity can be expressed as the median lethal dose (LD50), a statistically derived value that estimates the dose that would theoretically kill 50% of the test animal group. Such tests require the dosing of a large number of animals to generate a precise LD50 value.

Often such a precise measurement of lethality is either not required to characterize the test article or may not be practical as the test article may be minimally toxic to animals following dermal application. To minimize the number of animals used in acute dermal toxicity tests without compromising the intent of such safety test, the use of screening test and the administration of a single building limit dose to a groups of animals is often adequate for assessing the inherent acute toxicity of the test article.

The test was conducted in accordance with the procedures as outlined in:

Environmental Protection Agency (EPA) Health Effects Test Guidelines EPA 560/6-82-001 and Pesticide Assessment Guidelines, EPA 540/9-82-025, of the Office of Pesticides and Toxic Substances.

Client: NuMar Technologies, Inc.

Report Number: 202536-01
Date: 08/16/96

Testing Regime:

The Client requested characterization of the acute dermal toxicity of the submitted samples. These data were established through the use of acute dermal toxicity upper limit tests.

Procedure: Acute Dermal Toxicity Test

Ten New Zealand stain albino rabbits each weighing between 2.3 to 3.5kg were selected for each dosage. The animals were housed individually in stainless steel caging with raised flooring in a conditioned animal room. Animals were maintained on a commercial pelleted rabbit food and water was available ad libitum.

On the day of the test, the animals were identified and body weights recorded. The fur from the backs and flanks of the animals was removed with the use of electric clippers. The animals were carefully shaved to avoid abrading the skin. Approximately 20% of the animals' body surfaces were prepared for administering the test article.

The test articles dosages were administered topically to the prepared skin sites. The samples were held in contact with the skin covering the skin site with a single layer of gauze and occluding the trunks of the animals with plastic film. the impervious covering was secured with an elastic wrapping and taped to contain the dosage without leakage during the 24 hour exposure period. After exposure, the animals were thoroughly cleaned of the test articles with water or as specified in submitted protocol whenever appropriate and returned to their cages for observation.

Animals were closely observed for gross toxicological effects immediately after administration of the sample and then daily for a 14-day observation period. Test animals' body weights, a sensitive indicator of toxic insult, were recorded during the observation period and necropsies of dead, morbid or surviving animals were performed if indicated during the progression of the study.

Client: NuMar Technologies, Inc.

Report Number: 202536-01
Date: 08/16/96

Observations:

All animals appeared normal throughout the 14-day observation period. Twenty-four hours after dosing, one of the ten test animals (#5♂) displayed slight blanching and dermal irritation at the test site. By day 14, all ten test animals showed normal skin at the test sites. Individual clinical observations are presented in Appendix 1.

Gross Pathology:

Individual necropsy findings are presented in Appendix 1. At necropsy on day 14, in animal #4 female (#2363), a lobular, red-brown, mottled lesion (4x3x2 cm) on the right lateral lobe of the liver was found. After consulting with Dr. F. R. McConnell, DVM, our consulting veterinarian, it is our opinion that the lesion does not appear to be test related.

Conclusion:

When tested as specified, the liquid test article, NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc., was not acutely toxic to laboratory animals following dermal application and exposure to the test article at 2.0g/kg. Therefore, under the conditions of this experiment TREO Lotion is practically nontoxic following dermal application.

Client: NuMar Technologies, Inc.

Report Number: 202536-01
Date: 08/16/96

ARCHIVAL OF RAW DATA

SGS U.S. Testing Company policy regarding GLP studies is to inventory and archive a copy of the final report and all original test data and records generated in support of the study for a period of five years following the date of the final report of test. Upon completion of the five year period, all inventoried original test data and study records (or where applicable, photocopies of the originals), shall be transferred to the sponsor (client) of the study. The appropriate agency shall be notified in writing of such a transfer, as required under current guidelines.

REPORT OF TEST

Analysts' Signatures

Investigators and analysts for the mammalian toxicology study:

Study Director:

Charles C. Tong, Ph.D., D.A.B.T.

Quality Assurance:

R. Franconeri

Analyst:

Joan Brehedy, M.S.

Analyst:

Stefania Giobbe, M.S.

Analyst:

Suzanne Poppe

SGS U.S. Testing Company Inc.

Client: NuMar Technologies, Inc.

Report Number: 202536-01
Date: 08/16/96

APPENDIX 1

Individual Animal Body Weight
Clinical Observations and Necropsy Findings

Sample: NuShield™(Cold Fire) manufactured by Firefreeze Worldwide, Inc.

Dose (g/kg)	Animals/ Sex	Dose Vol (ml)	Body Weight (kg) Day 0	Day 7	Day 14	Clinical Observation Day 0 - Day 14	Necropsy Findings
2.0	2360-F	5.0	2.5	2.8	2.8	N	N
	2361-F	5.2	2.6	2.6	2.7	N	N
	2362-F	5.2	2.6	3.0	3.2	N	N
	2363-F	5.2	2.6	2.8	3.0	N	N,2
	2364-F	5.2	2.6	2.9	3.2	N	N
		Average:	2.6	2.8	3.0		
2.0	2370-M	5.0	2.5	2.8	3.0	N	N
	2372-M	5.2	2.6	2.8	3.0	N	N
	2374-M	5.4	2.7	2.9	3.1	N	N
	2375-M	5.4	2.7	3.0	3.2	N	N
	2376-M	5.0	2.5	2.8	2.9	N,1	N
		Average:	2.6	2.9	3.0		

N = Normal.

1 = Slight blanching and dermal irritation at test site.

2 = A lobular red, brown mottled lesion (4 cm x 3 cm x 2 cm) on the right lateral lobe of the liver

APPENDIX 2

REPORT OF TEST

SUMMARY OF PROCEDURE: Acute Dermal Toxicity Test (LD50)

REFERENCE: USTC Procedure TOX DERMLD50.008 to conform to current Guidelines

PURPOSE: To assess the potential of a test substance to induce toxicity following skin contact

Sponsor:	NuMar Technologies, Inc. 841 Mountain Avenue Springfield, NJ 07081
Sponsor Contact:	Ms. Robyn Williamson
Laboratory:	SGS United States Testing Company, Inc. Biological Services 75 Passaic Avenue Fairfield, New Jersey 07004
Study Director:	Charles C. Tong, Ph.D., D.A.B.T. (201) 575-5252 Ext. 2521
Test Substance (Sample):	Cold Fire
Storage, Handling Conditions:	Ambient temperature
Procedures Proposed:	Acute dermal toxicity Toxicology Procedure DERMLD50.008
Amendments/ Specifications:	Limit Test
Proposed Experimental Start Date:	May 14,1996
Proposed Experimental Termination Date:	May 28,1996
1. DURATION OF STUDY:	14 days
2. EXPOSURE SCHEDULE:	Once, test day 0, 24 hrs
3. OBSERVATION PERIOD:	Daily, up to 14 days

4. ROUTE OF ADMINISTRATION:	Dermal. After exposure, if the skin site is intact, it will be rinsed with deionized water and wiped with a soft gauze pad or other appropriate material. If the site is "broken," it will be rinsed with normal saline only. There will be no "wiping."
5. EXPOSURE GROUPS:	One group exposed to the test substance at 2.0g/Kg body weight
6. CONTROL GROUP:	None
7. ANIMALS PER GROUP:	5 males and 5 females, females shall be nulliparous & non-pregnant
8. SPECIES/STRAIN:	New Zealand strain albino rabbits
9. SEX/AGE/WEIGHT:	Male & female - not less than 2.3 Kg
10. SOURCE:	Sgarlats, Harvey's Lake, PA 18618
11. RANDOMIZATION OF ANIMALS:	Randomly selected from large pool of healthy subjects maintained at USTC
12. MEANS OF IDENTIFICATION:	Ear Tags
13. FOOD & WATER:	Purina Rabbit Chow Brand Feed Purina Mills, St. Louis, MO and municipal filtered water. Analysis at least once a year for specific microorganism, heavy metals (water); for specific heavy metals and pesticides (feed). None of these contaminants are reasonably expected to be present at levels sufficient to interfere with this study.
14. JUSTIFICATION OF TEST SYSTEM:	Rabbits historically have been used in safety evaluation studies and are recommended by appropriate regulatory agencies. No alternatives to animal use are currently available. This protocol will be reviewed by the U.S. Testing IACUC for compliance with regulatory guideline concerning the care and use of animals. If not in compliance, modification will be required.

15. TEST MEASUREMENTS:

PRE-TEST QUARANTINE	- observations only, 7 days
	- body weights & physical examinations, on test day 0
POST EXPOSURE SURVIVAL CHECKS	- at least once daily
CLINICAL OBSERVATIONS	- once daily, 7 days per week
PHYSICAL EXAMINATION	- pretest only
BODY WEIGHTS	- pretest, day 7 and day 14
FOOD CONSUMPTION	- not required
CLINICAL CHEMISTRY	- not required
HEMATOLOGY	- not required
URINALYSIS	- not required
OPHTHALMOLOGY/ DERMATOLOGY	- dermatology if applicable
NECROPSY	- all test animals
HISTOPATHOLOGY	- not required

16. STATISTICAL METHODS : (IF APPLICABLE)

17. RECORD MAINTENANCE: Equipment maintenance\calibration records, test\control article records, environmental records, specimen, raw data, QA\QC reports, communication and final reports will be archived in secured file at USTC

18. REGULATORY COMPLIANCE: This study will be conducted in accordance with the Good Laboratory Practice Regulations as set forth in 21 CFR Part 58, Dec. 22, 1978 (effective June 20, 1979) and any applicable amendments, 40 CFR Part 160, Subpart F (EPA-FIFRA-GLP) and 40 CFR Part 792, Subpart F (EPA TSCA-GLP) as applicable

SGS®

Upon approval of this protocol, the sponsor assumes the responsibility of performing, documenting and maintaining documentation that test, control and reference substance are properly characterized in accordance with the guidelines set forth in the following: 40 CFR 160, Subpart F - Test, Control and Reference Substances (EPA-FIFRA); or 40 CFR 792 - Subpart F - Test, Control and Reference Substances (EPA-TSCA); or 21 CFR 58, Subpart F - Test and Control Articles (FDA-GLP), as applicable to this study.

All data generated in support of this study shall be archived at USTC for a period of five years from the date of the final report of test. Upon completion of this time period, the original data (or where applicable, certified photocopies of the original data) shall be inventoried and transferred to the sponsor who shall then assume responsibility for archiving the data in accordance with appropriate GLP guidelines. Concurrently, the inventory of the study and a notice that the files have been transferred to the custody of the sponsor shall be sent to the FDA or EPA, as applicable.

Submitted by:

5/13/96

Charles C. Tong, Ph.D., D.A.B.T.
Director of Toxicology

Reviewed by:
(reserved)

5/13/96

Tina Nuccitelli
Quality Assurance Auditor

Approved by:
(Sponsor)

5/13/96

Guy T. Falzarano
Executive Vice President
NUMAR TECH, INC.

United States Testing Company, Inc.
Biological Services

1415 Park Avenue
Hoboken, New Jersey 07030
Tel: 201-792-2400
Fax: 201-656-0636

REPORT OF TEST

Safety Testing
on
Cold Fire 30: Fire Suppressing Agent

Conducted for:

North American Environmental
Oil & Chemical Cleaning Supply Co.
270A Route 46
Rockaway, New Jersey 07866

April 13, 1993

TEST REPORT NO. 065318-2

SIGNED FOR THE COMPANY

BY

Prepared by:

Joan Breheny, B.S.
Supervisor, Toxicology

Charles C. Tong, Ph.D., D.A.B.T.
Director of Toxicology

SGS Member of the SGS Group (Société Générale de Surveillance)

THIS REPORT APPLIES ONLY TO THE STANDARDS OR PROCEDURES IDENTIFIED AND TO THE SAMPLE(S) TESTED. THE TEST RESULTS ARE NOT NECESSARILY INDICATIVE OR REPRESENTATIVE OF THE QUALITIES OF THE LOT FROM WHICH THE SAMPLE WAS TAKEN OR OF APPARENTLY IDENTICAL OR SIMILAR PRODUCTS. NOTHING CONTAINED IN THIS REPORT SHALL MEAN THAT UNITED STATES TESTING COMPANY, INC., CONDUCTS ANY QUALITY CONTROL PROGRAM FOR THE CLIENT TO WHOM THIS TEST REPORT IS ISSUED, UNLESS SPECIFICALLY SPECIFIED. OUR REPORTS AND LETTERS ARE FOR THE EXCLUSIVE USE OF THE CLIENT TO WHOM THEY ARE ADDRESSED, AND THEY AND THE NAME OF THE UNITED STATES TESTING COMPANY, INC. OR ITS SEALS OR INSIGNIA, ARE NOT TO BE USED UNDER ANY CIRCUMSTANCES IN ADVERTISING TO THE GENERAL PUBLIC AND MAY NOT BE USED IN ANY OTHER MANNER WITHOUT OUR PRIOR WRITTEN APPROVAL. SAMPLES NOT DESTROYED IN TESTING ARE RETAINED A MAXIMUM OF THIRTY DAYS.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

Study Compliance Statement for United States Testing Company, Inc. final report entitled Safety Testing on Cold Fire 30: Fire Suppressing Agent for North American Environmental Oil & Chemical Clenaing Supply Co., 270A Route 46, Rockaway, NJ 07866.

In accordance with United States Testing Company, Inc.'s intent that all toxicity tests conducted by our facility follow Good Laboratory Practices, United States Testing Company, Inc.'s Study Director for the above test herein confirms that to the best of our knowledge the study was conducted in accordance with the U.S. EPA Good Laboratory Practice Regulations 40 CFR, Pt. 160 or 40 CFR, Pt. 792.

Charles C. Tong, Ph.D., D.A.B.T. — Date 4/13/93
Study Director
United States Testing Company, Inc.

Based on the signatures of the Study Director and the Quality Assurance Unit, it is our belief that this study was, to the best of our knowledge, conducted in accordance with U.S. EPA Good Laboratory Practice Regulations.

Sponsor — Date

Applicant/Submitter — Date

Client: North American Environmental Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

QA REPORT

Sponsor:	North American Environmental Oil & Chemical Cleaning Supply Co.
Sponsor Code:	Cold Fire 30: Fire Suppressing Agent
Study:	Eye Irritation Test, Dermal Irritation Test, Acute Oral Toxicity Test
Report:	065318-2
Study Initiation Date:	2/18/93
Study Termination Date:	4/13/93

The purity and stability of the test substance was not determined. To the best of our knowledge, the remaining part of the study was conducted in compliance with the Good Laboratory Practice of US EPA 40 CFR, Pt. 792 or 40 CFR, Pt. 160.

The studies are conducted at USTC/Biological Services in a setting which involved frequent repetition of similar or identical procedures. At or about the time the studies were conducted, inspections were made by the QA Auditor of the critical procedures relevant to this study type.

The findings of these inspections were reported promptly to the Study Director and management.

To the best of our knowledge and belief, the final report accurately reflects the conduct of the study, data obtained and the conclusion that can be shown, within the limits of the procedures used.

Dates of Audits:

Eye Irritation:	3/4/93, 3/11/93
Dermal Irritation:	3/4/93, 3/11/93
Acute Oral Toxicity:	2/18/93, 2/25/93, 3/4/93, 3/11/93, 4/13/93

Dates of Reports to Management:

Eye Irritation:	3/4/93, 3/11/93
Dermal Irritation:	3/4/93, 3/11/93
Acute Oral Toxicity:	2/18/93, 2/25/93, 3/4/93, 3/11/93, 4/13/93

James Siniscalchi
Quality Assurance Auditor

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Project Summary

When tested as specified, Cold Fire 30: Fire Suppressing Agent was not considered to be a dermal irritant. The sample was shown to cause eye irritation in all six test animals with complete recovery observed in all six test animals by day 7. Cold Fire 30, was not acutely toxic to laboratory animals following oral administration at 5.0 g/kg.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Subject: Sample submitted and identified by Client as:

Cold Fire 30: Fire Suppressing Agent

Project: Primary Skin Irritation Test (EPA)

Introduction:

The purpose of such safety tests is to assess and evaluate the potential of a test article to induce irritation or corrosion to the skin following intimate contact with the substance. Information derived from such tests indicates the existence of possible health hazards associated with contact exposure of skin to the test article.

The test was conducted in accordance with the procedures as outlined in:

Environmental Protection Agency (EPA)
Health Effects Test Guidelines, EPA 560/6-82-001
and Pesticide Assessment Guidelines, EPA 540/9-82-025,
Office of Pesticides and Toxic Substances

Animals and Husbandry

The albino rabbit is the preferred species for these tests and the New Zealand strain is most often used in this laboratory. Animals are cared for following standard practices.

Upon delivery, the young adult animals (2.3-3.5 kg) are housed singly in stainless steel pens with raised flooring suspended over drip pans lined with absorbent paper bedding. Food and water are available ad libitum. Food rations are dispensed daily while water is supplied by an automatic watering system. Animals are housed in a conditioned room kept at 65-75°F and 40-60% relative humidity. Lighting is controlled using a 12:12 hour light-dark photoperiod.

It is the policy of this laboratory to use the minimum number of animals necessary to evaluate a test article without compromising the intent of the safety test performed. While various regulatory agencies require different numbers of animals to be used in skin irritation/corrosion tests to evaluate test samples, the Study Director may choose to use less than the recommended number of test animals, particularly if the chemical insult is severe.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Procedure: Primary Skin Irritation Test

Preparation of Test Animals

Six albino rabbits are selected for the test procedure. At up to 24 hours before the test, the fur is clipped from the dermal area of the trunk of the animals using electric clippers with a fine (#40) surgery prep blade. Care should be taken to avoid abrading the skin when shaving the animals.

Sample Administration

Doses of 0.5ml of liquid or 0.5g of solid sample are applied to the test sites. Solids, in the form of powders, should be moistened sufficiently with water to form a paste to ensure good contact with the skin. Samples are placed on test skin sites of approximately one square inch and contained under an adhesive dressing (Coverlet 2x2 inch) to hold the sample in place. The trunks of the animals are then wrapped with an elastic bandage and tape to prevent the animals from removing or ingesting the sample. Animals are not restrained during or after the 4 hour exposure period.

Clinical Observation and Scoring

At the end of the exposure period, the adhesive patches are removed and the skins are cleansed of the test sample using water or 70% isopropyl alcohol.

The test skin sites are evaluated at the appropriate exposure observation times in part of the basis of the following weighed rating scale:

Erythema and Eschar Formation	Weighed Value
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Maximum erythema score	4

Edema Formation	Weighed Value
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (area raised approximately 1mm)	3
Severe edema Severe edema (raised more than 1mm and extending beyond area of exposure	4
Maximum edema score	4
Total Maximum score for primary irritation	8

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Evaluation of Test Results:

The dermal irritation scores should be evaluated in conjunction with the nature and reversibility of the responses observed. Individual scores do not represent an absolute standard for the irritant properties of a material but should be viewed as reference values which are only meaningful when supported by a description of the observations.

Results:

302

Sample ID: Cold Fire 30: Fire Suppressing Agent

Test Dates: 1/20 - 1/23/93

Post Exposure Observation Period (hrs)	Non-abraded Skin Irritation Index	Individual Animal Test Values 1	2	3	4	5	6	Avg
1	Erythema-Eschar	0	0	0	0	0	0	0
	Edema	0	0	0	0	0	0	0
24	Erythema-Eschar	0	0	0	0	0	0	0
	Edema	0	0	0	0	0	0	0
48	Erythema-Eschar	0	0	0	0	0	0	0
	Edema	0	0	0	0	0	0	0
72	Erythema-Eschar	0	0	0	0	0	0	0
	Edema	0	0	0	0	0	0	0

Observations:

No dermal reaction was observed in any test animal throughout the 72 hour observation period.

Conclusion:

When tested as specified, the submitted sample was not considered to be a primary skin irritant.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Project: Eye Irritation Test (EPA)

Introduction:

The purpose of such safety tests is to assess and evaluate the potential of a test article to induce irritation or corrosion to the eye. Information derived from such tests indicates the existence of possible hazards associated from the exposure of the eye and associated mucous membranes to the test substance.

The test was conducted in accordance with the procedures as outlined in:

> Environmental Protection Agency (EPA) Health Effects Test Guidelines EPA 560/6-82-001 and Pesticide Assessment Guidelines, EPA 540/9-82-025, of the Office of Pesticides and Toxic Substances.

Animals and Husbandry

The albino rabbit is the preferred species for these tests and the New Zealand strain is most often used in this laboratory. Animals are cared for following standard practices.

Upon delivery, the young adult animals (2.3-3.5kg) are housed singly in stainless steel pens with raised flooring suspended over drip pans lined with absorbent paper bedding. Food and water are available ad libitum. Food rations are dispensed daily while water is supplied by an automatic watering system. Animals are housed in a conditioned room kept at 65-75°F and 40-60° relative humidity. Lighting in controlled using a 12:12 hour light-dark photoperiod.

It is the policy of this laboratory to use the minimum number of animals necessary to evaluate a test article without compromising the intent of the safety test performed. While various regulatory agencies require different numbers of animals to be used in skin irritation/corrosion tests to evaluate test samples, the Study Director may choose to use less than the recommended number of test animals, particularly if the chemical insult observed is severe.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Procedure: Eye Irritation Test

Six albino rabbits without existing eye defects or irritations are selected for the test. The test sample (0.1ml for liquids or extracts; 0.1g for powdered materials) is placed in the conjunctival sac of one eye of each animal after gently pulling the lower lid away from the eyeball. The lids are then gently held together for one second to minimize loss of the sample. One eye of each animal is so treated while the untreated eye serves as a control. The animals are returned to their cages for the 24 hour exposure period before the remaining test substance is flushed from the test eyes.

The eyes of the animals are examined at the end of the first hour of the 24 hour exposure period (no flushing) and at 24, 48 and 72 hours. The test eye is compared to the control eye and rated in accordance with the following four scales for eye irritation effects.

Cornea

No ulceration or opacity 0
Scattered or diffuse areas of opacity but
detail of iris clearly visible . . . . . (1)*
Easily discernible translucent areas, details
of iris slightly obscured. 2
Nacreous areas, no details of iris visible
size of pupil barely discernible 3
Complete corneal opacity, iris not discernible 4

Iris

Normal 0
Markedly deepened folds, congestion, swelling,
moderate circumcorneal injection, iris still
reacting to light. . . . . (1)*
No reaction to light, hemorrhage, gross
destruction. 2

*Bracketed figures indicate lowest grades considered positive effects.

Client: North American Environmental 065318-2
Oil & Chemical Cleaning Supply Co. 4/13/93

Procedure: Eye Irritation Test (continued)

Conjunctivae

Vessels normal 0
Some vessels definitely injected 1
Diffuse, crimson red, individual vessels not easily discernible . . . . . (2)*
Diffuse beefy red. 3

Chemosis

No swelling. 0
Any swelling above normal. 1
Obvious swelling with partial eversion of lids . . . . . (2)*
Swelling with lids about half closed 3
Swelling with lids more than half closed 4

Discharge

No discharge. 0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals. 1
Discharge with moistening of the lids and hairs just adjacent to lids. 2
Discharge with moistening of the lids and hairs, and considerable area around the eye. 3

*Bracketed figures indicate lowest grades considered positive effects.

The rating was further aided by comparison with the Illustrated Guide for Grading Eye Irritation by Hazardous Substances, obtained from the U.S. Consumer Product Safety Commission.

According to the EPA Test Guidelines, eye irritation score should be evaluated in conjunction with the nature and reversibility, or otherwise, of the responses observed. Individual scores do not represent an absolute standard for the irritant properties of a material, but should be viewed as reference values which are only meaningful when supported by a full description and evaluation of the observations.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Sample ID: Cold fire 30: Fire Suppressing Agent

Sample Preparation: None. The test sample was administered neat.

Test Dates: 3/2/93 - 3/9/93

Results:

Animal Rating After 1 Hour	1	2	3	4	5	6
Cornea	0	0	0	0	0	0
Iris	0	0	0	0	0	0
Conjunctivae	1	1	1	1	1	1
Chemosis	2	2	3	2	2	3
Discharge	0	0	0	0	0	0

Animal Rating After 24 Hours	1	2	3	4	5	6
Cornea	1	1	0	1	1	1
Iris	1	0	1	1	0	0
Conjunctivae	2	2	2	2	2	2
Chemosis	2	2	2	2	2	2
Discharge	1	0	0	0	0	0

Animal Rating After 48 Hours	1	2	3	4	5	6
Cornea	1	1	1	1	1	1
Iris	1	0	0	0	0	0
Conjunctivae	2	2	3	1	1	2
Chemosis	1	1	2	0	2	1
Discharge	0	0	0	0	1	0

Animal Rating After 72 Hours	1	2	3	4	5	6
Cornea	1	1	1	1	1	0
Iris	0	0	0	0	0	0
Conjunctivae	2	2	2	0	1	1
Chemosis	1	1	1	0	1	0
Discharge	0	0	0	0	0	0

Animal Rating After 7 Days	1	2	3	4	5	6
Cornea	0	0	0	0	0	0
Iris	0	0	0	0	0	0
Conjunctivae	0	0	0	0	0	0
Chemosis	0	0	0	0	0	0
Discharge	0	0	0	0	0	0

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Observation:

Twenty-four hours after dosing, five of the six test animals display corneal irritation with scattered or diffuse areas of opacity with details of the iris clearly visible. By 48 hours, all six test animals displayed this irritation. The corneal irritation completely disappeared by day 7.

Twenty-four hours after dosing, three of the six test animals showed iris irritation with markedly deepened folds, congestion, with iris still reacting to light. The iris irritation completely disappeared in all three test animals by 72 hours.

One hour after dosing, all six test animals showed conjunctivae irritation with some vessels definitely injected. By 24 hours the irritation became more severe in all six test animals. Complete recovery was observed in all six test animals by day 7.

One hour after dosing, all six test animals displayed chemosis. The swelling ranged from obvious swelling with partial eversion of lids to swelling with lids about half closed. Complete recovery was observed in all six test animals by day 7.

Above normal discharge was observed in one test animal at 24 hours and a second test animal by 48 hours. Complete recovery was observed by 72 hours.

Conclusion:

When tested as specified, the submitted test sample was observed to cause eye irritation in all six test animals with complete recovery observed by day 7.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Project: Acute Oral Toxicity Test (continued)

Testing Regime:

The Client requested characterization of the acute oral toxicity of the submitted sample. These data were established through the use of acute oral toxicity upper limit tests.

Procedure: Acute Oral Toxicity Test

White laboratory rats (male and female) each weighing between 200 and 300 grams were selected for each dosage. The animals were housed in stainless steel wire mesh cages with raised floors in a conditioned animal room. Animals were maintained on a commercial rat food diet and water was available ad libitum. Eighteen hours prior to dosing, all food was removed to fast the animals before initiating the test. On the day of the test, animals were identified and body weights recorded. The dosage to be administered was calculated based on the animal's body weight.

For test articles that are liquids or could be administered as solutions, suspensions or extracts, appropriate doses were administered to animals using a feeding needle and syringe. For certain solid-form test articles, doses were administered by incorporating the material into a feed mix that was fed to laboratory animals over a 24 hour period. The method of sample administration used for the submitted test articles is outlined in the Sample Preparation section of this report.

Animals were closely observed for gross toxicological effects immediately after administration of the sample and then daily for a 14-day observation period. Test animals' body weights, a sensitive indicator of toxic insult, were recorded during the observation period. Necropsies of dead, moribund or surviving animals were performed if indicated during the progression of the study.

Test Animals

Strain: Sprague-Dawley rats (male, female)
Source: Ace Animals, Boyertown, PA
Date(s) Received: 1/19/93

Upon arrival, animals were housed in the observation battery rack and ear-tagged with a 4 digit animal identification number. Animals were observed for at least one week for signs of illness or disease prior to initiating tests.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Procedure: Acute Oral Toxicity Test (continued)

Sample Preparation:

The test article was administered as a neat liquid; density = 1.0 g/ml.

Results: Definitive Testing, Acute Oral Toxicity Upper Limit Test

Ten Sprague-Dawley rats (5 male, 5 female) were administered an oral dose of the test article 5 g/kg.

Test Dates:

Sample	Animals	Dose (g/kg)	14-Day Mortality % Total	Average Body Weight (g) Initial	Final
Cold Fire: 302	F	5.0	0	210	261
	M	5.0	0	267	374

Observations:

One female test animal showed slight diarrhea/discharge on day 7 of the study. The remaining test animals appeared normal throughout the 14 day observation period.

Gross Pathology:

No abnormalities were noted at necropsy on day 14 of the study.

Conclusion:

When tested as specified, the test article was not acutely toxic to laboratory animals following oral administration at 5.0 g/kg.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

APPENDIX

Individual Animal Body Weight Data
Rats

Sample	Dose (g/kg)	Animals/ Sex	Dose Vol(ml)	Body Weight (kg) Day 0	Day 7	Day 14
Cold Fire: 30	5.0	5 F	1.0	204	236	242
			1.1	218	249	280
			1.1	226	252	272
			1.0	200	231	248
			1.0	203	243	263
		5 M	1.4	272	348	386
			1.3	262	335	363
			1.4	270	345	385
			1.3	254	325	351
			1.4	275	358	386

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

APPENDIX

Individual Animal Body Weight Data
Rats

Sample	Dose (g/kg)	Animals/ Sex	Dose Vol(ml)	Body Weight (kg) Day 0	Day 7	Day 14
Cold Fire: 30	5.0	5 F	1.0	204	236	242
			1.1	218	249	280
			1.1	226	252	272
			1.0	200	231	248
			1.0	203	243	263
		5 M	1.4	272	348	386
			1.3	262	335	363
			1.4	270	345	385
			1.3	254	325	351
			1.4	275	358	386

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

Archive Information:

All original data, communication and final report will be archived in separate secure files at U.S. Testing Co., Inc.

United States Testing Company, Inc.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

ADDENDUM 1

United States Testing Company, Inc.

Client: North American Environmental
Oil & Chemical Cleaning Supply Co.

065318-2
4/13/93

ADDENDUM 2

F/D-found dead | Ab-abnormal | 2. unkempt | 5. eyes | 8. alert study director

14 DAY OBSERVATION RECORD

Technician: Joan Breheny

Date/Day	Ear Tag No / Tail Marking		FEMALES CAGE NO. D14 1/19						MALES CAGE NO. D35 1/19						
			0223	0225	0224	0226	0221	Female Average	0148	0140	0142	0145	0141	Male Average	Combind Average
			1	2	3	4	5		1	2	3	4	5		
	Body Weight, Day-0		204	218	226	200	203	210	272	262	270	254	275	267	238
	Dose (g) 5g/kg	am/pm	1.0	1.1	1.1	1.0	1.0		1.4	1.3	1.4	1.3	1.4		
2/9/93	— hrs. after dosing	0	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		
2·10·93	KC	1	N	N	N	N	N		N	N	N	N	N		
2·11·93	KC	2	N	N	N	N	N		N	N	N	N	N		
2·12·93	KC	3	N	N	N	N	N		N	N	N	N	N		
—			—	—	—	—	—		—	—	—	—	—		
2·13·93	KC	4	N	N	N	N	N		N	N	N	N	N		
2/14/93		5	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		
2/15/93		6	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		
2·16·93	KC	7	N	Ab[3]	N	N	N		N	N	N	N	N		
—	Body Weight, Day-7		236	249	252	231	243	242	348	335	345	325	358	342	292
2·17·93	KC	8	N	N	N	N	N		N	N	N	N	N		
2·18·93	KC	9	N	N	N	N	N		N	N	N	N	N		
2·19·93	KC	10	N	N	N	N	N		N	N	N	N	N		
2·20·93	M.M	11	N	N	N	N	N		N	N	N	N	N		
2·21·93	MM	12	N	N	N	N	N		N	N	N	N	N		
2·22·93	KC	13	N	N	N	N	N		N	N	N	N	N		
2·23·93	KC	14	N	N	N	N	N		N	N	N	N	N		
—	Body Weight, Day-14		242	280	272	248	263	261	386	363	385	351	386	374	318

Cold Fri. 30. Fur dappearing
Agent

GROSS NECROPSY FINDINGS

Examination Initials/Date	All N	Ab (Incidence)	Comments	Examined?	All N	Ab (incidence)	Comments	Examined?
Coat			1♀ No gross changes observed.				10♂ No gross changes observed.	
Eyes								
Nares/Oral Cavity								
Esophagus/Trachea			2♀ No gross changes observed.				20♂ No gross changes observed.	
Lungs								
Liver			3♀ No gross changes observed.				30♂ No gross changes observed.	
Kidneys								
Spleen			4♀ No gross changes observed.				40♂ No gross changes observed.	
Stomach								
Intestine			5♀ No gross changes observed.				50♂ No gross changes observed.	
Urogenital								
Other			KC 2·23·93				KC 2·23·93	

USTC/BSD ACUTE TOXICITY DATA SHEET 5-86

3/10/93 2/25/93 3/4/93 3/11/93 4/2/93

F/D - found dead A/I - abnormal 2. unkempt 5. eyes 8. alert study director

14 DAY OBSERVATION RECORD

USTC/BSD ACUTE TOXICITY DATA SHEET 5-86

Technician: Joann Breheny

Date/Day	Ear Tag No / Tail Marking		FEMALES CAGE NO. D14 1/19						MALES CAGE NO. D35 1/19						
			0223	0225	0224	0226	0221		0148	0140	0142	0145	0141		
			1	2	3	4	5	Female Average	1	2	3	4	5	Male Average	Combind Average
	Body Weight, Day-0		204	218	226	200	203	210	272	262	270	254	275	267	238
	Dose (g) 1.5g/kg	am/pm	1.0	1.1	1.1	1.0	1.0		1.4	1.3	1.4	1.3	1.4		
2/9/93	hrs. after dosing	0	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		
2.10.93	KC	1	N	N	N	N	N		N	N	N	N	N		
2.11.93	KC	2	N	N	N	N	N		N	N	N	N	N		
2.12.93	KC	3	N	N	N	N	N		N	N	N	N	N		
—			—	—	—	—	—		—	—	—	—	—		
2.13.93	KC	4	N	N	N	N	N		N	N	N	N	N		
2/14/93		5	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		
2/15/93		6	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		
2.16.93	KC	7	N	Ab[3]	N	N	N		N	N	N	N	N		
—	Body Weight, Day-7		236	249	252	231	243	242	348	335	345	325	358	342	292
2.17.93	KC	8	N	N	N	N	N		N	N	N	N	N		
2.18.93	KC	9	N	N	N	N	N		N	N	N	N	N		
2.19.93	KC	10	N	N	N	N	N		N	N	N	N	N		
2.20.93	M.M	11	N	N	N	N	N		N	N	N	N	N		
2.21.93	MM	12	N	N	N	N	N		N	N	N	N	N		
2.22.93	KC	13	N	N	N	N	N		N	N	N	N	N		
2.23.93	KC	14	N	N	N	N	N		N	N	N	N	N		
—	Body Weight, Day-14		242	280	272	248	263	261	386	363	385	351	386	374	318

Cold Flu 30, Flu suppressing Agent

Quality 1.0

GROSS NECROPSY FINDINGS

Examination Initials/Date	All N	Ab (Incidence)	Comments	Examined?	All N	Ab (incidence)	Comments	Examined?
Coat			1♀ No gross changes observed.				10♂ No gross changes observed.	
Eyes								
Nares/Oral Cavity			2♀ No gross changes observed.				20♂ No gross changes observed.	
Esophagus/Trachea								
Lungs			3♀ No gross changes observed.				30♂ No gross changes observed.	
Liver								
Kidneys			4♀ No gross changes observed.				40♂ No gross changes observed.	
Spleen								
Stomach			5♀ No gross changes observed.				50♂ No gross changes observed.	
Intestine								
Urogenital			KC 2.23.93				KC 2.23.93	
Other								

03 4/16/93

3/10/93 2/27/93 3/4/93 3/11/93

0/c 4/12/93

U.S.T.C. / B.S.D. PRIMARY SKIN IRRITATION DATA SHEET

092-

Project NO.: 065318-2 Client: N. American Environ.

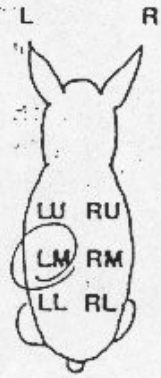
Sample I.D.: Cold Fire 30: Fire Suppressing Agent

Received: 2.5.93

Procedure: PSI - EPA Test Dates: 3.2 - 3.5.93

Animal Source: CAMM Received: 1.26, 2.23.93

Test site:



☒ 0.5 ml of the test sample was placed onto (twelve) 2" square adhesive dressings. Two c the dressings were then applied to the left middle dorsal of each rabbit

☐ The test sample was cut and placed onto (twelve) 2" square adhesive dressings. The dressings were moistened with tap water and two of the dressings were then applied to the _____ _____ dorsal of each rabbit.

☐ Water was added to the test sample until a paste was formed. 0.5 grams of the paste wa placed onto (twelve) 2" square adhesive dressings. Two of the dressings were then applie to the _____ _____ dorsal of each rabbit.

ANIMAL RATING AFTER 45 HOURS/DAYS

Ear Tag No.	623	635	636	637	638	639	Avg
Erythema & Eschar							
~~Abraded~~ Unabraded	0	0	0	0	0	0	
Edema							
Date: 3.2.93 ~~Abraded~~ Unabraded	0	0	0	0	0	0	

Initials: KC

ANIMAL RATING AFTER 24 HOURS/DAYS

Erythema & Eschar							
~~Abraded~~ Unabraded	0	0	0	0	0	0	
Edema							
Date: 3.3.93 ~~Abraded~~ Unabraded	0	0	0	0	0	0	

Initials: KC

Total = _____

Primary Irritation Score (Total ÷ 4) = 0

Comments:

Recorded By: Kristen Cole Date: 3.2.93

Verified By: _____ Date: _____ Page No. 52

Revised 3/4/93
3/11/94

U.S.T.C. / B.S.D. PRIMARY SKIN IRRITATION DATA SHEET 092-

Project NO.: 065318-2 Client: N. American Environ.
Sample I.D.: Cold Fire -30 : Fire Suppressing Agent
Received: 2.5.93
Procedure: PSI - EPA Test Dates: 3.2 - 3.5.93
Animal Source: CAMM Received: 1.26, 2.23.93

Test site:

☐ 0.5 ml of the test sample was placed onto (twelve) 2" square adhesive dressings. Two of the dressings were then applied to the _____ _____ dorsal of each rabb

☐ The test sample was cut and placed onto (twelve) 2" square adhesive dressings. Th dressings were moistened with tap water and two of the dressings were then applied to th _____ _____ dorsal of each rabbit.

☐ Water was added to the test sample until a paste was formed. 0.5 grams of the paste wa placed onto (twelve) 2" square adhesive dressings. Two of the dressings were then applie to the _____ _____ dorsal of each rabbit.

ANIMAL RATING AFTER 48 HOURS/DAYS

Ear Tag No.	623	635	636	637	638	639	Av
Erythema & Eschar							
~~Abraded~~ Unabraded	0	0	0	0	0	0	
Edema							
Date: 3.4.93 ~~Abraded~~	0	0	0	0	0	0	
Initials: KC Unabraded							

ANIMAL RATING AFTER 72 HOURS/DAYS

Erythema & Eschar						
~~Abraded~~ Unabraded	0	0	0	0	0	0
Edema						
Date: 3.5.93 ~~Abraded~~	0	0	0	0	0	0
Initials: KC Unabraded						

Total = _____
Primary Irritation Score (Total + 4) = _____

Comments:

DB 4/2/93

Recorded By: Kristen Cole Date: 3.2.93
Verified By: _____ Date: _____ Page No. 65

3/4/93
3/2/93