REPORT OF TEST

SGS U.S. Testing Company Inc.
75 Passaic Avenue • Fairfield, NJ 07004-3833 • Tel: 973-575-5252 • Fax: 973-244-1823

Report Number: 203697
Date: 10/23/97

Acute Inhalation Toxicity Limit Test
4 Hours
on
JG302 (at a 1:10 Dilution)

Conducted for:

Fire-Freeze Worldwide, Inc.
270 Route 46
Rockaway, NJ 07866

Prepared by:

Joan Breheny, M.S.
Supervisor of Toxicology

10/23/97
Date

SIGNED FOR THE COMPANY BY:

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

10/23/97
Date

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Statement of No Data Confidentiality Claims

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

Sponsor: Fire-Freeze Worldwide, Inc.

Signature: Stephanie E. Gerdes

Date: 10/23/97

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GLP Compliance

This study was conducted in compliance with the United States Environmental Protection Agency's Good Laboratory Practice Standards, as described in 40 CFR Part 160 (revised August 17, 1989) except the characterization of the test substance, which was the responsibility of the study sponsor. This deviation did not affect the outcome of the study

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

10/23/97
Date

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QAU Statement

Test Substance (Sponsor's Code)	JG302 (at a 1:10 Dilution)
Nature of Study:	Acute Inhalation Toxicity Limit Test (4 Hours)
Study Number:	203697
Study Initiation Date:	06/11/97
QAU Review of Protocol:	06/11/97
QAU Review of In-Life Phases:	08/08/97 and 08/21/97
Reported to Study Director:	08/15/97 and 08/21/97
Reported To Management:	08/15/97 and 08/21/97
QAU Review of Raw Data:	10/17/97
QAU Review of Draft Report:	10/17/97
Reported to Study Director:	10/17/97
Reported To Management:	10/20/97
QAU Review of Final Report:	10/23/97
Study Termination Date:	10/23/97

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

Andrea R. Demby
Andrea R. Demby, B.S.
Quality Assurance Coordinator

10/23/97
Date

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Project Summary

When tested as specified, the submitted test substance, JG302 (at a 1:10 Dilution) was not acutely toxic to the test animals following a 4-hour inhalation exposure at a nominal concentration of 35.3 mg/L (actual concentration was 16.9 mg/L). The LC_{50} was estimated to be greater than 35.3 mg/L.

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Test Substance Description: Test substance was submitted and identified by the Sponsor as:

JG302

Project Description: Acute Inhalation (LC_{50}) Toxicity Testing With Rodents

Test Animals:
Strain: Sprague-Dawley rats (males and females)
Source: Ace Animals, Boyertown, PA
Dates Received: 07/15/97

Test Substance Preparation:

JG302, a clear solution and submitted as a liquid in a 5 gallon bucket (no lot # was provided), was diluted at 1:10 with deionized water in this test facility prior to use. The liquid was collected into the Collision Nebulizer immediately prior to the inhalation procedure.

Procedure: Acute Inhalation (4-hour) Toxicity Limit Test

Ten Sprague-Dawley rats (5 males and 5 females), each weighing between 200 and 300 grams, were selected for each dosage. The animals were housed in wire mesh cages with raised floors in a conditioned animal room. The animals were maintained on a commercial rat food diet. Water was available ad libitum. The inhalation test was conducted in an inhalation apparatus manufactured by CH Technologies (USA), Westwood, NJ 07675 and shown in Figure 1. The exposure was nose-only.

The inhalation test was performed using a single 4-hour exposure.

Following the 4-hour exposure period, the animals were then returned to their cages for observation at one hour, after four hours, and once daily thereafter for a period of fourteen days.

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Inhalation Apparatus and Sample Delivery:

Compressed air, passed through a silica gel drying tube, was delivered to a flow meter and then to a collision nebulizer (BGI 6-Jet modified MRE-type) prior to entry into the exposure chamber (Figure 1). The airflow rate into the exposure chamber was 8 liters per minute throughout the 4 hours of exposure. Animals were housed individually in cylindrical holders that opened into the middle of the chamber. The contaminated air exited the chamber and passed through two aqueous scrubbers. The system was verified to have a total of 8 liters per minute at any one time coming out of the ten ports.

The BGI 6-Jet modified MRE-type collision nebulizer was calibrated with the test substance for the production of respirable size aerosol. The aerosol generated was evaluated using an 8 stage Anderson 2000 particle fractionating sampler with a stage 3 cut-off value of 3.3-4.7 microns and a stage 7 cut-off value of 0.43-0.65 microns. Particles collected in stage 3 and below were considered respirable. When calibrated with the test substance, 65.0% the aerosol generated was respirable with a mean median aerodynamic diameter of 2.2 microns and a geometric standard deviation of 2.5.

Gravimetric measurement of the test substance in the nebulizer at specific time points of the run was used to monitor the test substance being delivered into the system. This information was presented in Table 1. To monitor the minimum actual concentration of the test substance at the breathing zone, one of the two remaining and unused ports were opened periodically for a period of 5 to 10 minutes and a piece of cotton was used to trap the aerosol coming out of the port. The increase in weight of the cotton was then used to calculate the actual aerosol concentration. This would be the minimum actual concentration of the test substance in mg/L at the breathing zone. The concentration of the test substance at the breathing zone was presented in Tables 1 and 2. A summary of the various test conditions was presented in Table 3.

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Procedure: Acute Inhalation (4-hour) Toxicity Limit Test

Test Substance Identification: JG302, a clear solution and submitted as liquid in a 5 gallon bucket (no lot # was provided). The submitted test substance was diluted 1:10 v/v with deionized water in this test facility just prior to use.

Test Dates: 08/08/97 - 08/22/97

Results:

Summary of Dose: (From Tables 1 & 2)

Time	Delivered (nominal)	Actual
1st Hour	34.4 mg/L	9.4 mg/L
2nd Hour	34.4 mg/L	16.4 mg/L
3rd Hour	36.3 mg/L	24.1 mg/L
4th Hour	36.0 mg/L	17.7 mg/L
Average	35.3 mg/L	16.9 mg/L

Summary of Animal Data: (From Individual Animal Body Weight Data)

No. Of Animals	Initial Weight (g)	Nominal Dosage (mg/L)	Exposure Mortality	14 -Day Mortality Ratio	Final Weight (g)
5F	241.7	35.3	0/5	0/5	266.7
5M	290.9	35.3	0/5	0/5	381.7

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Table 1
Nominal Sample Concentration

Gravimetric:

Test Substance Identification: JG302 (at a 1:10 Dilution)

Time	Initial Test Substance Weight (g)	Final Test Substance Weight (g)	Amount Delivered (g)	Nominal Conc. (mg/L) [2a]
0- 60 min.	287.7	271.2	16.5	34.4
60-120 min.	271.2	254.2	16.5	34.4
120-180 min.	254.7	237.3	17.4	36.3
180-240 min.	237.3	220.0	17.3	36.0
Average of Run (240 min.):	35.3			

[2a] Based on a flow rate of a total of 8 liters per minute per 10 ports.

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Table 2
Actual Sample Concentration

Time Into Runs	Initial Weight of Cotton(g)	Final Weight of Cotton(g)	Weight of Test Substance Collected (g)	Actual Concentration (mg/L)[4]
0 - 10 min.	3.0057	3.0806	0.0749	10.3
40-50 min.	3.3091	3.3714	0.0623	8.6
Average (For 1st Hour) 9.4				
60 - 70 min.	3.2133	3.2981	0.0848	11.7
100 - 110 min.	3.6919	3.8457	0.1538	21.1
Average (For 2nd Hour) 16.4				
120 - 130 min.	3.5081	3.7205	0.2124	29.2
160 - 170 min.	3.0306	3.1688	0.1382	19.0
Average (For 3rd Hour) 24.1				
180 - 190 min.	3.2060	3.3578	0.1518	20.9
210 - 220 min.	3.5001	3.6057	0.1056	14.5
Average (For 4th Hour) 17.7				

[4]Based on an average flow rate of 8 liters per 11 ports (0.727 liters per port) per minute and adjusted for collection time of 10 minutes.

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Table 3:
Summary of Test Conditions

Test Substance Test Conditions:	Dry Air Carrier; Collision Nebulizer
Chamber Dynamics:	8 LPM flow rate
Flow Rate Control:	>20 LPM from compressor . 8 LPM - compressor air (with Nebulizer on line)
Exposure:	Head only Temperature - ambient - 75.0 - 77.0F Relative Humidity - 56 - 82%
Monitoring:	Gravimetric Temperature and Humidity - Psychrometer

Observations:

Animals did not appear to be lethargic during the 4-hour exposure period. Normal breathing was observed in all animals immediately post-exposure. The test animals appeared normal throughout the 14-Day observation period.

Gross Pathology:

No abnormalities were observed in the test animals at 14-Day post-exposure.

Discussion:

In the study, JG302 (at a 1:10 Dilution) was delivered at a nominal concentration of 35.3 mg/L (actual concentration was 16.9 mg/L) for four hours (Tables 1 & 2).

Conclusion:

When tested as specified, JG302 (at a 1:10 Dilution) was not toxic to the test animals following a 4-hour exposure at a nominal concentration of 35.3 mg/L (actual concentration was 16.9 mg/L with 71.4% of the aerosol being respirable). The LC_{50} was estimated to be greater than 35.3 mg/L (actual concentration was 16.9 mg/L).

SUMMARY OF PROCEDURE:	Acute Inhalation Toxicity Testing with Rodent (LC_{50})
REFERENCE:	SGS USTC Procedure TOX/INHALC$_{50}$.009 to conform to current Guidelines.
PURPOSE:	To access and evaluate the lethal toxicity of a single inhalation dose of an extract/liquid in rodents.
Sponsor:	Fire-Freeze Worldwide, Inc. 270 Route 46 Rockaway, NJ 07866 Tel: 201-627-0722
Sponsor Contact:	Ms. Stephanie E. Giessler
Laboratory:	SGS U.S. 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):	JG302 (at dilution to be specified & appended)
Storage, Handling Conditions:	Ambient temperature
Procedures Proposed:	Acute Inhalation Toxicity Testing with Rodents LC_{50} Toxicology Procedure INHALCO$_{50}$.009.
Amendments/Specifications:	A Limit Test will be conducted.
Proposed Experimental Start Date:	June 27, 1997
Proposed Experimental Termination Date:	July 11, 1997
1. DURATION OF STUDY:	14 Days
2. EXPOSURE SCHEDULE:	Once, Test Day 0
3. OBSERVATION PERIOD:	14 Days
4. ROUTE OF ADMINISTRATION:	Inhalation

5.	EXPOSURE GROUPS:	One test group receiving a fixed concentration/volume of the test substance.
6.	CONTROL GROUP:	None.
7.	NUMBER PER GROUP:	5 males and 5 females
8.	SPECIES/STRAIN:	Sprague-Dawley Rats
9.	SEX/AGE/WEIGHT:	Male and female - 200-300 grams (young adult)
10.	SOURCE:	Ace Animals, Boyertown, PA 19512
11.	RANDOMIZATION OF ANIMALS:	There is no randomization method used. Test animals are randomly selected from a large pool of healthy subjects maintained at SGS USTC.
12.	MEANS OF IDENTIFICATION:	Ear Tags
13.	FOOD, WATER AND ENVIRONMENT:	Laboratory Rodent Diet 5001, PMI Feeds, Inc. St. Louis, MO and municipal filtered water. Analysis at least once a year for specific microorganisms, 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. Animal rooms will be kept approximately at 64-79°C and 35-75% Relative Humidity, to the maximum extent possible.
14.	JUSTIFICATION OF TEST SYSTEM:	Rats 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 SGS U.S. Testing IACUC for compliance with regulatory guidelines concerning the care and use of animals. If not in compliance, modifications will be required.

15. TEST MEASUREMENTS:

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

16. STATISTICAL METHODS:
(IF APPLICABLE) - temperature, relative humidity, particle size and distribution and concentration of test substance at breathing zone 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 SGS USTC.

18. REGULATORY COMPLIANCE:

This study will be conducted in accordance with 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.

Upon approval of this protocol, the sponsor assumes the responsibility of performing, documenting and maintaining documentation that test, control and reference substances 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 SGS 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:

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

6/11/97
Date

Reviewed by:
(reserved)

Andrea R. Demby

Andrea R. Demby, B.S.
Quality Assurance Coordinator

6/11/97
Date

Approved by:
(Sponsor)

Date

SGS U.S. Testing Company Inc.

Sponsor: Fire-Freeze Worldwide, Inc

Report Number: 203697
Date: 10/23/97

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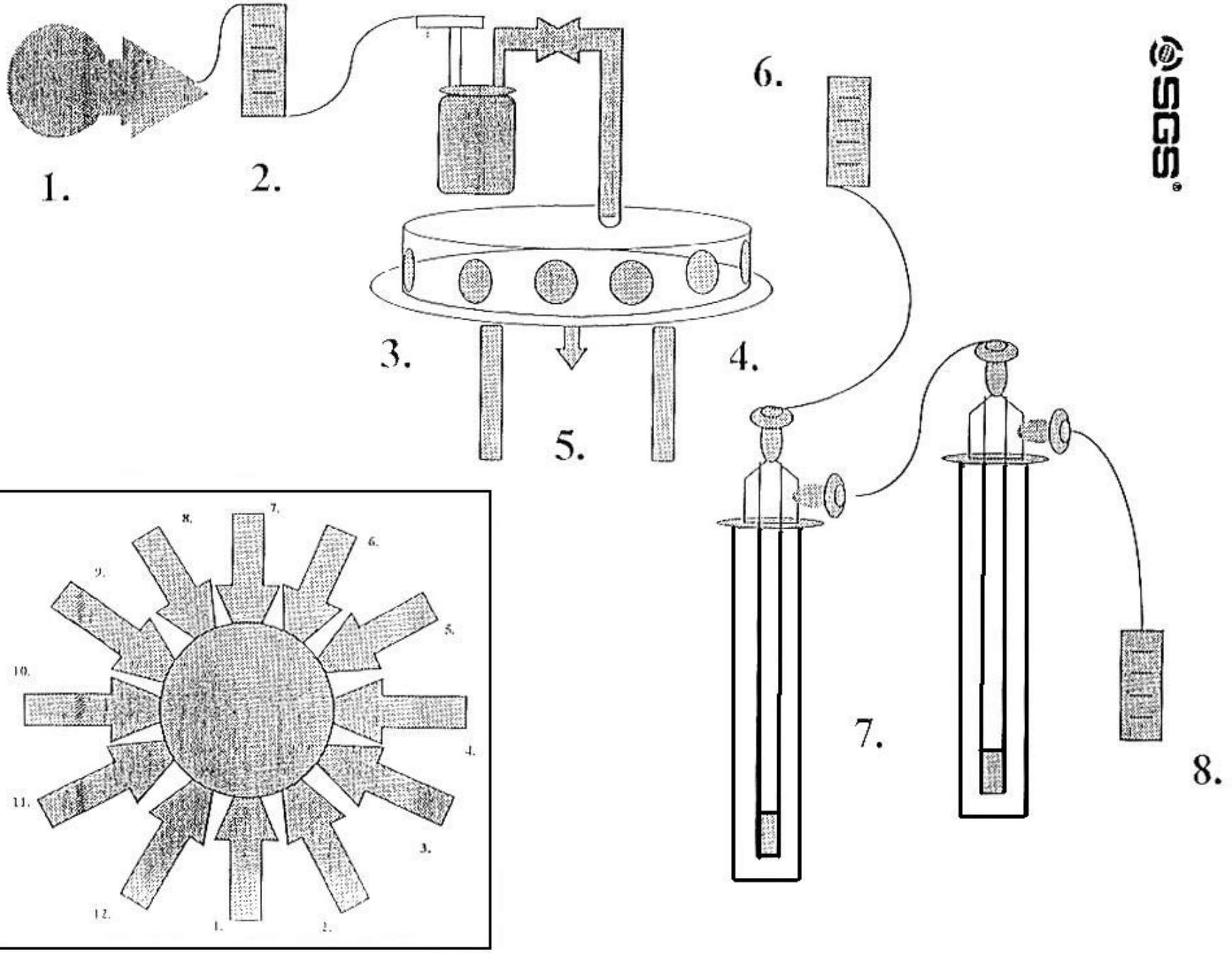
Addendum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