VirusBom

[Lot No.: 20131024]

Acute Oral Toxicity Study

FINAL REPORT

Client: **MONEY MARKETING COMMUNICATION LTD.**

Testing Institution: **SGS Taiwan Ltd.**

Protocol No. : **UB/2013/A1312A-02**

Protocol Date: **2014.01.02**

Note:

1. The content of this report is invalid if it is not presented as the entire report.
2. Any unauthorized alteration, forgery or falsification of the content or appearance of this report is unlawful and offenders may be prosecuted to the fullest extent of the law.
3. The results shown in this test report refer only to the sample(s) tested.
4. This report in the Chinese version of translation UB/2013/A1312A-05

STUDY SCHEDULE

Acute Oral Toxicity Study

VirusBom

Protocol No.:	UB/2013/A1312A-02
Study Initiation date:	2013.12.02
Expected experimental starting date:	2013.12.10
Expected experimental completion date:	2014.12.27
Observation of reaction	2013.12.11~27
Study completion date:	See Study Director's signature date in the report
Study Personnel:	Yu Jung Pan

Testing Institution

Name: SGS TAIWAN LTD.

Address: No. 38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku Dist., New Taipei City 24890, Taiwan (R. O. C.)

Client / Sponsor

Name: MONEY MARKETING COMMUNICATION LTD.

Address: 10F-1, NO. 15, SEC 4, JHONGSIAO E, RD.

SGS

SGS

TEST ARTICLE INFORMATION

INFORMATION FOR ☒ TEST ARTICLE/ ☐ CONTROL ARTICLE

Sponsor Company Name	MONEY MARKETING COMMUNICATION LTD.
Sponsor Address	10F-1, NO. 15, SEC 4, JHONGSIAO E, RD.
Contract study item	☒ Base on the contract ☐ Others _____
Name of Test article/ Control article	Virus Bom
Batch/Lot number	☒ Base on the specific number on the package : 20131024 ☐ Base on the date on the package : _____ ☐ Base on the arrived date ☐ Others : _____
Specification & Amount	50mL/bottle*6 bottles (e.g.10ml / bottle * 6 bottles)
Retention amount (Note 2)	The amount of the same lot is sufficient for ☐ One test ☒ Two test (for retention)
External features	External features: ☒ liquid ☐ powder ☐ tablet ☐ capsule ☐ Other_____ Color : CLEAR
Major components & Purity	Major components: C17H32O4S Purity: 3000 ppm
Solvent and solubility	N/A
Storage condition	☐ Room temperature ☒ 4℃ ☐ Dry ☐ Light sensitive ☐ Others_____
Expiration date(Note 3)	☐ Date: ____/____/____ (YYYY/MM/DD) or ☒ Period : 5 year0 month 0 day
Attachment(Note 4)	☐ Certificate of Analysis ☐ Material Safety Data Sheet ☐ Stability Test Result ☐ Other : _____ ☒ No attachment (Note4)
Sterilization	Has been sterilized ☐ YES ☒ NO (If Yes, please select the following item) Methods ☐ EOsterilization ☐ Gamma sterilization ☐ Steam sterilization ☐ Other_____
Categorization of devices (The column is only for device used)	1. ☐ Contact with intact skin or mucosa (cumulative contact duration) ☐ Short-term (no greater than 4 hr) ☐ Long-term (exceeding 4 hr) Maximum duration is_____hrs 2. ☐ Implanted device
Specific requirement (Note 5)	N/A 本產品非醫療器材

Sponsor Signature/ Date : 張尚敏 / 2013.10.28

Note 1. Above all information is disclosure by the sponsor.
Note 2. If the sponsor doesn't provide the retention of test article/control article, the retention of a reserved test article/control article from each batch of test article /control article is the responsibility of the Sponsor.
Note 3. If the effective period is less than 5 years, the test article/control article will be retained till the expiry date. If the effective period is longer than 5 years, the test article/control article will be retained for 5 years only.
Note 4. Determination and documentation of identity, strength, purity, stability, composition, method of synthesis, fabrication, derivation or other characteristics of the test article/control article are the responsibility of the Sponsor.
Note 5. The test article/control article which has been destroyed or cutting will be discarded after the end of experiment. For retention or return of the kind of test article/control article, please indicate in the "special requirement". The human intake suggests or dose requested by the sponsor also can fill in the "special requirement". Note treatment method after test if the test article need to be retreated
Note 6. The code number of test article is the same as the report number.
Note 7. Note 'N/A' if not applicable. Do not leave blank.

TABLE OF CONTENTS

SGS

STATEMENT OF GLP COMPLIANCE

All study activities performed by SGS Taiwan Ltd, are carried out in compliance with the GLP (Good Laboratory Practices) for Nonclinical Laboratory Studies (Department of Health, Taiwan, 2006), current OECD Principles of Good Laboratory Practice (Organization for Economic Cooperation and Development, Paris, ENV/MC/CHEM (98) 17) and U.S. Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58. The study is conducted in accordance with the protocol and standard operating procedures and monitored in conformity with the protocol. All laboratory data are accurately recorded and verified. SGS Taiwan makes no GLP compliance claim for characterization and verification of the test article identity and properties; this is the responsibility of the sponsor.

Study Director: Howard Kao　　2014.01.09

Howard Kao / SGS Taiwan Ltd.　　Date Completed

QUALITY ASSURANCE STATEMENT
UB/2013/A1312A-02
VirusBom

Acute Oral Toxicity Study

This study was audited by Quality Assurance personnel of LEON Biotechnology Company Limited Biocompatibility Testing Laboratory. The QA inspection report includes review of result of a study-based audit and results of audit of raw data and study report. The audit report was issued upon the completion of each testing. LEON Biotechnology Company Limited Biocompatibility Testing Laboratory was audited by Quality Assurance personnel of SGS Life Science Service.

QA:

Melissa Lin / SGS Taiwan Ltd.

2014. 01. 06

Date Completed

ARCHIVING

All the study-related records, protocol and the final report will be kept in archives room of SGS (TAIWAN) LTD and study-related raw data will be kept in archives cabinet of LEON Biotechnology Company Limited Biocompatibility Testing Laboratory for 5 years. Furthermore, retention of the test articles will be in Sample Storage Room of SGS (TAIWAN) LTD for 5 years. All of the records and test articles are handled according to GLP guideline. Agent authorized by the sponsor can apply for the review according to SGS procedure.

Archives Room Address

SGS TAIWAN LTD.: No. 38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku Dist., New Taipei City 24890, Taiwan (R. O. C.)

LEON Biotechnology Company Limited Biocompatibility Testing Laboratory:

4F.-2, No. 288-8, Xinya Rd., Qianzhen Dist., Kaohsiung City 806, Taiwan (R.O.C.)

Archiving List	
Final Report	Final Report Copy Final Report Amendment (if necessary)
Raw Data*	Skin Irritation Study Data Sheet
Records	Application Form Information for test article-control article and other supplementary record
Protocol	Protocol and Protocol Amendment (if necessary)

*kept in archives cabinet of LEON Biotechnology Company Limited Biocompatibility Testing Laborator

PURPOSE

The test is to obtain information on the biologic activity of a chemical. This study is performed to assess the acute oral toxicity of test article in mice. The experiment is performed following OECD #423 and SOP-T13.

EXPERIMENTAL DESIGN

A. Test system:

1. Species/ Strain: ICR Mice
2. Resource: LASCO. Co. Ltd
3. Reason: According to OECD #423
4. Body weights/Age: >20 g/ 5-8 weeks
5. Sex: female, the female mice were nulliparous and not pregnant
6. Numbers: 6
7. Quarantine/ acclimation: Once animals are introduced in-house, they are subjected to quarantine and acclimatize before treatment. Animals are selected based on health status by qualified staff.
8. Identification

   (1)Individual identification: Animals are identified by ear-marking.

   (2)Group identification: Cages are properly labeled for identification including species/ strain, sex, in-housing date, IACUC number, animal I.D. number.
9. Housing condition

   1.Environment temperature: 20-26℃

   (1)Humidity: 30-70%

   2. Cage and animal number: 3 animals/cage

   3 .Fodder/ Supply: Lab Diet; *ad libitum*

   4. Drinking water/ Supply: Tape water; *ad libitum*

B. Reagents

None

Preparation

Apply undiluted test article directly

C. Grouping

First step	Second step
3 animals	3 animals
2000 mg/kg bw.	2000 mg/kg bw.
Test article	Test article

D. Test Method

1 Dose level: Administer the test substance in 2000 mg/kg body weight in first step; administer the test substance in 2000 mg/kg body weight in second step.

2 Administer the test substance in a single dose by a ball tipped stainless steel gavage needle attached to a syringe. Animals should be fasted 3~4 hours prior to dosing. Following the period of fasting, the animals should be weighed and the test substance administered. After the substance has been administered, food may be withheld for a further 1~2 hours. The volume of aqueous solutions should not normally exceed 2 ml/100g of body weight.

3 Select the starting test dose levels from dosage of 2000 mg/kg of body weight, and conduct tests in accordance with Appendix 1.

4 If there is 1 death or none at a dose level of 2000 mg/kg administered to 3 animals during the first 3 days (first step), 2000 mg/kg can be administered to an additional 3 animals (second step). All steps should be observed for a total of 14 days. If there were 2~3 deaths occurs in the first step, 300mg/kg should administered t an additional 3 animals in accordance with appendix 1.

5 Carefully observe the general condition of animals at least once within 30 minutes ~4 hours after dosing, frequently during the following day, and thereafter at least once daily. Keep a

record of all types of symptoms of poisoning noted by gross observation in each animal, as well the time of occurrence, and the time of recovery or death. Weigh the test animals immediately prior to and 1 week after test substance administration. At the end of test (Day 14), surviving animals are weighed and humanely killed. Conduct necropsies of all test animals, and record gross pathological findings.

Result

1. Incidence of Clinical Observation in mice during the observation period

Group	First step	Second step
Sex	Female	Female
Clinical signs	0/3	0/3
Death	0/3	0/3

n/n：No. of mice with clinical signs/No. of mice per group

2. The body weight of each animal

Group	Dose (mg/kg)	Sex	Animal No.	Body weight (g)		
				Day 1	Day 7	Day 14
First step	2000	Female	131114-60	28.3	30.6	30.0
			131114-61	27.3	27.3	27.5
			131114-62	27.4	25.9	28.2
Second step	2000	Female	131114-57	28.8	28.6	29.2
			131114-58	28.9	32.3	33.4
			131114-59	26.2	26.3	27.0

Clinical observation of the test animals was carried out once a day for a period of 14 days. The test animals were observed for mobility, mortality and other clinical signs. In first step, no adverse effects were observed on all the test animals during the dosing and observation period. No animal died during the dosing and observation period. In second step, no adverse effects were observed on all the test animals during the dosing and observation period. No animal died during the dosing and observation period. No obvious body weight loss was observed in all test animals during the observation period. Each animal was sacrificed at the end of the 14-day observation period, and full gross necropsy was performed. No gross pathological findings were observed at the time of necropsy.

CONCLUSION

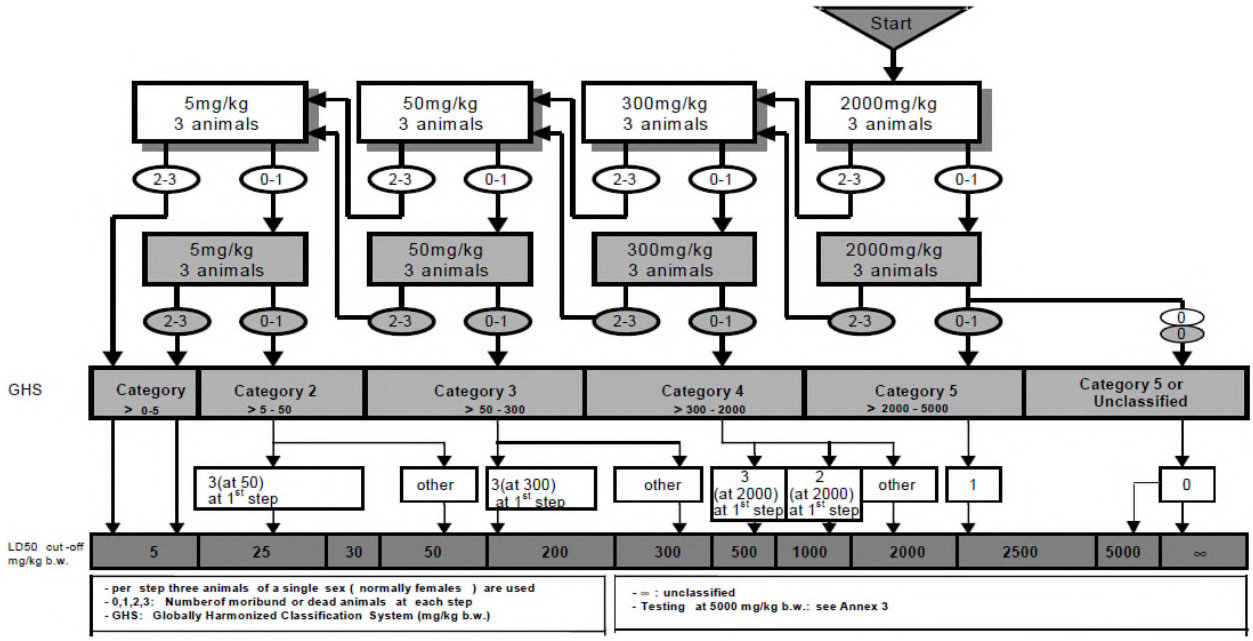
Therefore, the LD50 of “VirusBom” was estimated to be greater than 2000 mg/kg in the mice, belong GHS Category 5 ranges.

REFERENCES

1. Good Laboratory Practice for Nonclinical Laboratory Studies. Title 21 of the U.S. Code of Federal Regulations, Part 58. United States Food and Drug Administration.
2. Current OECD Principles of Good Laboratory Practice (Organization for Economic Cooperation and Development, Paris, ENV/MC/CHEM (98) 17).
3. Acute oral toxicity/ Acute toxic class method, OECD guideline for the testing of chemicals. #423 (2001) OECD.
4. Biological evaluation of medical devices- Part 12: Sample preparation and reference materials. ISO 10993-12:2012
5. Biological evaluation of medical devices-Part 2: Animal welfare requirements. ISO 10993-2:2006.

APPENDIX

1. Test procedure with a starting dose of 2000 mg/kg body weight (OECD#423)



TEST ARTICLES PHOTO

UB/2013/A1312

UB/2013/A1312