Virus Bom

[Lot No.: 20131024]

Skin Irritation Test

FINAL REPORT

Client: **MONEY MARKETING COMMUNICATION LTD.**
Testing Institution: **SGS Taiwan Ltd**
Report No. : **UB/2013/A1312**
Report Date: **2013.12.12**

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 theVirus Bom-3000ppm(s) tested.

STUDY SCHEDULE

Skin Irritation Test:

Virus Bom

Report No.:	UB/2013/A1312
Study Initiation date:	2013.11.11
Experimental starting date:	2013.11.25
Experimental completion date:	2013.11.28
Study completion date:	See Study Director's signature date in the report
Name of 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.)

Subcontract Lab

Name: LEON Biotechnology Company Limited Biocompatibility Testing Laboratory

Address: 4F.-2, No. 288-8, Xinya Rd., Qianzhen Dist., Kaohsiung City 806, 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.

版次：3.1 试验-对照物资资料表 Information for test article-control article
發行日期：2013.06.14

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SGS

STATEMENT OF GLP COMPLIANCE

All study activities performed by SGS Taiwan and LEON Biotechnology Company Limited Biocompatibility Testing Laboratory 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 and LEON Biotechnology Company Limited Biocompatibility Testing Laboratory make 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 / SGS Taiwan Ltd. Date Completed: 2013.12.5

Facility Manager:

Yuanmin Wen / SGS Taiwan Ltd. Date Completed: 2013.12.5

SGS

QUALITY ASSURANCE STATEMENT

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.

2013.12.25

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 theVirus Bom-3000ppms will be in Sample Storage Room of SGS (TAIWAN) LTD for 5 years. All of the records and test article 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
Raw Data*	Skin Irritation Test Data Sheet
Records	Application Form Information for test article-control article and other supplementary record
Protocol	Protocol

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

PURPOSE

The study was performed following OECD #404 and internal document of standard operating procedure SOP-T04, to investigate the response of skin irritation of “Virus Bom” on New Zealand White Rabbits.

EXPERIMENTAL DESIGN

A. Animals

1. Species/Strain	New Zealand White Rabbit(NZW)
2. Resource	Taiwan Livestock Research Institute
3. Body weights (sex)	>2kg/2-12 month (Female)
4. Reason	According to OECD#404
5. Numbers	3
6. Quarantine/acclimation	Animals were subjected to quarantine and acclimated before test. Guinea pigs were selected based on health status. The female guinea pigs were nulliparous and not pregnant

B. Feeding and care

1. Environment	
Temperature	20~26 ℃(30~70%)
2. Cage and animal no.	
Quarantine/acclimation	1 animals /cage
3. Feed	
Name	LabDiet
Brand	LabDiet
Way to supply	*ad libitum*
4. Drinking water	
Sort	Tape water
Way to supply	*ad libitum*

C. Individual and group identification

1. Individual identification	Animals were identified by ear-marking.
2. Group identification	Cages were properly labeled for identification including the Study Title/No., Administration/ Observation Period, Room No., Cage No., Quantity/cage, Species, Strain, Sex, In House Date, In House Age, Animal ID No.

D. Administration of Virus Bom-3000ppm extracts and control solutions

1. Reagent: 0.9% Normal Saline (Tai Yu Pharmaceutical Co., Ltd. Lot No. MH2502)

2. Method, route and frequency of administration

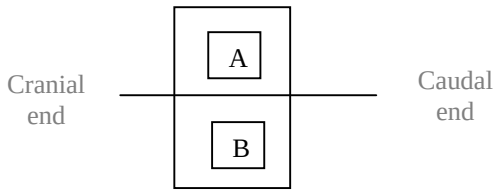
According to request from sponsor, the undilutedVirus Bom-3000ppm was tested directly.

E. Groups

Test group	Control group
3 animals	
Virus Virus Bom-3000ppm	0.9% saline

F. Procedure

1. Prior to the test, furs of NZW rabbit backside from scapula to middle back were clipped before test. Clipped zone were about 3cm x 6cm to exposure skin surface. A maker pen was used to divide clipped zone into two regions (see figure below). Animals with scratches or skin diseases in the clipped zone were rejected from study.



2. Sterile gauzes were saturated with 0.5 mL of Virus Bom-3000ppm and applied on B site (see figure above). In addition, A site was applied with sterile gauze saturated with 0.5 mL of 0.9% saline for control. The application sites were wrapped with elastic and porous bandages. After 4 hours, the elastic and porous bandages and gauzes were all removed, and then the Virus Virus Bom-3000ppm and control solution were washed off with distilled water.

3. Irritant reaction evaluation

The dermal reactions at the treated areas were observed and recorded at the time points of

1h, 24h, 48h and 72h after the gauze removed. The observation items included erythema, oedema, and other toxicity reactions.

4. Determination of dermal reaction

After a single dose treatment, the skin responses at time point of 24h, 48h and 72h were checked and evaluated, according to “Scoring system for skin reaction” described in Table 1

RESULTS

1. Body weight of animals.

Animal No.	Sex	Weight before test (kg)	Weight after test (kg)
RB-130822-03	F	3.2	3.3
RB-130822-04	F	3.3	3.3
RB-130822-08	F	3.2	3.3

2. Grades in clinical observation of individual rabbit were as below.

Applied Regions	Treated article	Animal No.	Items for Grading	Clinical Observation (time point/h)			
				1	24	48	72
Site B	Virus Virus Bom-3000ppm	RB-130822-03	Erythema and eschar formation	0	0	0	0
			Oedema formation	0	0	0	0
		RB-130822-04	Erythema and eschar formation	0	0	0	0
			Oedema formation	0	0	0	0
		RB-130822-08	Erythema and eschar formation	0	0	0	0
			Oedema formation	0	0	0	0
Site A	0.9% normal saline (control solution)	RB-130822-03	Erythema and eschar formation	0	0	0	0
			Oedema formation	0	0	0	0
		RB-130822-04	Erythema and eschar formation	0	0	0	0
			Oedema formation	0	0	0	0
		RB-130822-08	Erythema and eschar formation	0	0	0	0
			Oedema formation	0	0	0	0

The results showed that there was no significant erythema and oedema finding in either the control or test group, and there was no mortality or obvious weight loss.

CONCLUSION

The results showed that there was no significant erythema and oedema finding in either the control or test group, and there was no mortality. Therefore, a single topical application of “Virus Bom-3000ppm” did not cause skin irritation.

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 dermal irritation/corrosion, OECD guideline for the testing of chemicals. #404 (2002) OECD.
4. Biological evaluation of medical devices- Part 2: Animal welfare requirements. ISO 10993-2:2006.
5. Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization, ISO 10993-10:2010.
6. Biological evaluation of medical devices- Part 12: Sample preparation and reference materials. ISO 10993-12:2012.

TABLE

1. Score System of Skin Reaction

Reaction	Primary Irritation Score
Erythema and eschar formation	
· No erythema	0
· Very slight erythema (barely perceptible)	1
· Well-defined erythema	2
· Moderate erythema	3
· Severe erythema (beet redness) to eschar formation preventing grading or erythema	4
Oedema formation	
· No oedema	0
· Very slight oedema (barely perceptible)	1
· Well-defined oedema (edges of area well-defined by definite raising)	2
· Moderate oedema (raised approximately 1 mm)	3
· Severe oedema (raised more than 1 mm and extending beyond exposure area)	4

TEST ARTICLE PHOTO

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