FINAL REPORT(Draft)

Dermal Irritation Study of Water that passed through the Waters Therapy Shower in Rabbits

Study No. : GT11-00001

April 2011

the way to trust KCL 한국건설생활환경시험연구원 Korea Conformity Laboratories

Bioconvergence Technology Dept.

STATEMENT

Study No. : GT11-00001

Study title : Dermal Irritation Study of Water that passed through the Waters Therapy Shower
in Rabbits

This final report was written in Korean and translated into English.

This study was carried out in compliance with the test method of Korea Food & Drug Administration (KFDA) [Notice No. 2009-116, (Revised 24th August, 2009)], OECD Guidelines for the Testing of Chemicals (24 April 2002) TG 404 Acute Dermal Irritation/Corrosion and SOPs of KCL (KCL/SIT/002)

The test article information such as identity, strength, purity, composition or other characterization is the responsibility of the study sponsor.

11 April, 2011

Study director : (sign)

Confirmed by

Management : (sign)

Bioconvergence Technology Dept., Korea Conformity Laboratories

QUALITY ASSURANCE STATEMENT

Study No. : GT10-00079

Title : Acute Dermal Irritation/Corrosion Study of Dodecylbenzenesulphonic acid in Rabbits

This study was subject to audit by the independent Quality Assurance Unit of KCL as indicated below. The findings of each audit were reported to the study director and management as prescribed by Standard Operating Procedures.

The final report audit was designed to confirm that as far as can be reasonably established the methods described and results incorporated in the final report accurately reflect the raw data produced during the study.

Audit phases and dates reported to the responsible personnel were as indicated below and these were based upon the audit records.

Phase Inspected	Date	Reports to Study Director	Reports to Management
Study Plan	2010. 08. 17	2010. 08. 17	2010. 08. 18
Storage of Test substance and vehicle	2010. 08. 24	2010. 08. 24	2010. 08. 26
Animal receipt	2010. 08. 19	2010. 08. 19	2010. 08. 19
Preparation of test substance	2010. 09. 07	2010. 09. 07	2010. 09. 07
Animal care and Administration	2010. 09. 07	2010. 09. 07	2010. 09. 07
Clinical sign	2010. 09. 07	2010. 09. 07	2010. 09. 07
Dermal irritation/corrosion evaluation	2010. 09. 10	2010. 09. 10	2010. 09. 10
Raw data	2010. 10. 14	2010. 10. 14	2010. 10. 14
Final Report	2010. 10. 14	2010. 10. 14	2010. 10. 14

QA director : Won-Kwen Kuk, Ph.D. Date : 2010.10.14
Auditor, Quality Assurance

Study Personnel

Animal experiment	Hyeon-Yeol Ryu	**Date**	28 March 2010
Preparation of test substance	Byung-Gil Choi	**Date**	28 March 2010
Animal care	Sang-Sik Lee	**Date**	28 March 2010
Archives	Mi-Ra Han	**Date**	28 March 2010

1. Sponsor

Name	:	WATERS.Co.,Ltd
A person in charge	:	Sung-Taek Lim
Address	:	Manhatan B/D., 36-2, Youido-dong, Youngdeungpo-ku Seoul, KOREA
Contact	:	+82.2-783-5206(Tel), +82.2-783-3498(Fax)

2. Testing facility

Name	:	Bioconvergence Technology Dept., Korea Conformity Laboratories
Address	:	7-44, Songdo-dong, Yeonsu-gu, Incheon, Korea

3. Study director

Name	:	Hyeon-Yeol Ryu
Address	:	7-44, Songdo-dong, Yeonsu-gu, Incheon, Korea
Phone	:	+82-32-858-0011(Tel), +82-32-858-0020(Fax)

4. Schedule

Study initiation	:	28 January 2011
Animal acquisition	:	08 February 2011
Administraion	:	15 February 2011
Experimental Completion	:	18 February 2011
Final report	:	28 March 2011

5. Archive of data and specimens

1) Duration : 5 years after the completion of the study
2) Data : Study plan, data related test substance, data related animal acquisition, raw data, final report, document of GLP, document of correspondences and specimens
3) Storage facility : The depository(126-06) and specimen depository of Bioconvergence Technology Dept., Korea Conformity Laboratories

Contents

1. SUMMARY

This study was performed to evaluate skin irritation potential of Water that passed through the Waters Therapy Shower in six male New Zealand White Rabbits. The test substance was applied to the dorsal skin of abrasion & intact region at the dosage 0.5 ㎖. After application of test substance on the skin, dermal irritation was measured by the test method of Korea Food & Drug Administration (KFDA) [Notice No. 2009-116, (Revised 24th August, 2009)]
The finding results were as follows :

1) No clinical signs and mortalities related to test substance treatment were observed.
2) No significant body weight changes related to test substance treatment was observed.
3) 24 and 72 hours After removal of occlusive patch, all animals showed no-sign of skin irritation.

On the basis of the above results, the calculated Primary Irritation Index (P.I.I.) of the test substance was 0.1. and Water that passed through the Waters Therapy Shower on dermal application of New Zealand White rabbit was classified as a non irritant.

2. TEST SUBSTANCE AND VEHICLE

1) Test substance [Annex 1]

(1) Chemical Name : Water that passed through the Waters Therapy Shower
(2) CAS No. : No relevant data
(4) Molecular Weight : No relevant data
(5) Lot No. : 20110105
(6) Received date : 18 January 2011
(7) Received quantity : 639.88 g (including container)
(8) Appearance : liquid
(9) Purity : 100%
(10) Storage condition : refrigeration
(11) Stability : Store in sealed for prevention of bacteria infection
(12) Caution and storage method : Do not mixed with base
(13) Supplier : WATERS.Co.,Ltd

2) Preparation of test substance

The test substance was pulverized and weighed 0.1 ㎖. The stability analysis test was not performed because the test substance was prepared on the day of administration.

3) Storage and Treatment

For the duration of the study, test substances were kept in a refrigerator (108-4) in storage room.

3. MATERIALS AND METHODS

(1) Species and strain

Specific Pathogen Free (SPF) New Zealand White (NZW) rabbits. **[Annex 2]**

(2) Supplier

SamtaKo BIO KOREA Co., Ltd.
(Address; 77-1 Seorang-dong, Osan-si, Gyeonggi-do, Korea)

(3) Species selection Justification

The NZW rabbits used in this study are widely used in general ocular irritation experiments for toxicity testing. In addition, sufficient raw data associated with this species has been accumulated and is available for interpretation and evaluation of study results.

(4) Date of the acquisition : 08 February 2011

(5) Number of received animals : 7 males

(6) Age and body weights on arrival : 2186.18 ~ 2342.32 g, 10 weeks

(7) Quarantine and acclimation **[Annex 3]**

On arrival, animals were examined based on the certificate provided by the supplier. The period of acclimation was 7 days.

(Only healthy animals were used for the tests after observing general symptoms in the acclimated period.)

(8) Age and body weight at Administration : 2569.04 ~ 2775.61 g, 11 weeks

(9) Number of animals administered test substance : 6 male rabbits

(10) Identification of animals

Each animal is identified for this study by a unique number marked indelibly on the inner surface of the ear and written on the cage label. Information about animals and study was also posted on the door of the animals room.

(11) Grouping

After selection animals having 2.0 to 3.0 kg weigh, animals with no corneal injury were used in this study using the eye examination (Slit Lamp, ECONOM SET, GERMANY), within 24 hours, before administration.

(12) Disposal of remaining animals

All remaining animals were euthanized by CO_2 on experimental completion day.

2) Animal Care Facility [**Annex 4**]

(1) Room No. : Animal care room for rabbits No. 1

(2) Range of temperature and humidity during test work

Temperature of 20.4 ~ 21.6 ℃, Relative humidity of 43.5 ~ 48.5 %

(3) Ventilation frequency : 10 ~ 15 air changes/hr.

(4) Lighting cycle : 12 hrs lighting duration (lighting on at 8 a.m. ~ lighting off at 8 p.m.)

(5) Lighting intensity : 286 Lux.

(6) Ambient noise level : 57.2 dB

(7) Ammonia concentration : less than 5 ppm

(8) Housing

All animals were individually housed in stainless steel cages (380W×500D×330H mm) during the test period.

(9) Feed

① Type : Laboratory rabbit diet

② Producer : Agribrands Purina Korea Inc.

(Address: 8th Floor Hanlimwon Building, 7-1, Gu Mi-Dong, Bun Dang-Gu, Sung Nam-Shi, Kyong Gi-Do, Korea)

③ Supply method : *ad libitum*

④ Analysis

The data analyzed by the feed supplier was used.

No significant factors to affect the experimental results were found. **[Annex 5]**

(10) Water

① Type : Incheon, Korea municipal tap water purified by reverse osmosis filtering system.

② Supplying method : *ad libitum*

③ Analysis

Performed by national certificated inspection organization.

No significant factors to affect the experimental results were found. **[Annex 6]**

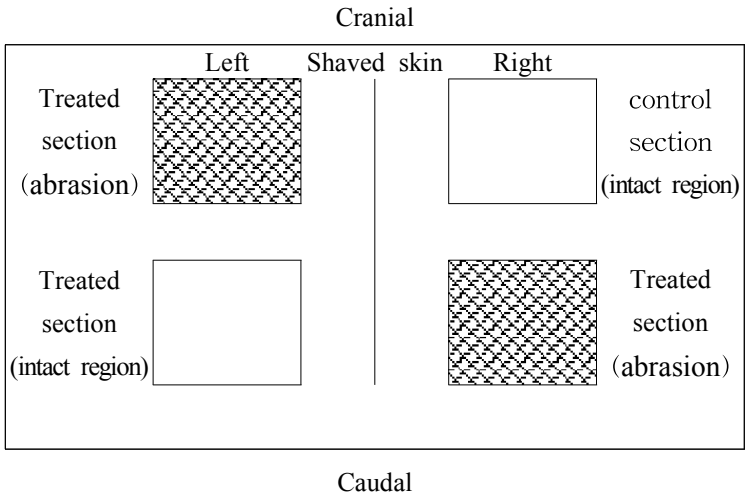
3) Methods

(1) Application method

① Preparation of animal and test site

Six animals were used in this study. Shaved area of animal was divided into left and right sections. 2.5×2.5 cm each. areas were marked in each section. The left sections were used for application of test substance, and the right sections were used for control (saline only).

Diagram 1. Arrangement of skin application site



② Application method and volume

The volume of test substance administered in this study (0.5㎖) was determined in accordance with OECD Guidelines for the Testing of Chemicals (24 April 2002) TG 404 Acute Dermal Irritation/Corrosion and the test method of Korea Food & Drug Administration (KFDA) [Notice No. 2009-116, (Revised 24th August, 2009)].

Approximately 24 hours before the test, the dorsal back side of animals were clipped free of fur. 0.5 ㎖ of test substance was applied onto left treated section. And, 0.5 ㎖ of physiological saline (03G0P61, DAIHAN Pharm Co. Ltd) was applied for the control in the same way as the test substance. The entire trunk of the animals was wrapped with non-irritant adhesive tape (Tegaderm™ 1626W, 3M Health Care) for occulsive patch.

③ Frequency of administration & period of administration

The test substance was applied once at dermal and allowed to remain for 24 hours. After 24 hours application, the treated sections of animals were carried out for removal of patch and washed gently with the physiological saline (03G0P61, DAIHAN Pharm Co. Ltd) to remove the residual of test substance.

(2) Observations

① Clinical signs

All animals were observed daily for clinical signs and survival during 72 hours after application of test substance.

② Body weight

Individual body weight was measured before test substance application, and at 24, 48, 72 hours intervals after application.

③ Observation of application site

The test sites were evaluated for erythema, eschar, edema, etc. at 24 and 72 hours after removal of test substance.

④ Evaluation of dermal irritation/corrosion

The skin responses were scored according to 'Grading of skin reaction', OECD Guidelines for the Testing of Chemical No. 404 'Acute Dermal Irritation/Corrosion' , the test method of Korea Food & Drug Administration (KFDA) [Notice No. 2009-116, (Revised 24th August, 2009)] and SOPs of KCL.

The average scores were checked with the scores of erythema and eschar formation, edema obtained at 24 and 72 hours observations followed by 「Grading of skin reaction and Evaluation of skin reaction」. The primary irritation index (P.I.I.) was calculated from the sum of average score of each animals divided by 4.

※ Grading of skin reaction

Erythema and eschar formation		Edema formation	
Response	Grade	Response	Grade
No erythema	0	No edema	0
Very slight erythema (barely perceptible)	1	Very slight edema (barely perceptible)	1
Well-defined erythema	2	Well-defined edema (edges of area well-defined by definite raising)	2
Moderate erythema	3	Moderate edema (raised apporximately 1 millimetre)	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4	Severe edema (raised more than 1millimetre and extending beyond exposure area)	4
Total possible score	4	Total possible score	4

※ Evaluation of skin reaction

Primary Irritation Index(P.I.I)	Classification
0.0 ~ 0.5	Non irritant
0.6 ~ 2.0	Mild irritant
2.1 ~ 5.0	Moderate irritant
5.1 ~ 8.0	Severe irritant

4. RESULTS

1) Mortalities and clinical signs (Table 1)

No significant clinical signs and mortalities was observed during this study.

2) Body weight changes (Table 2)

After treatment with the test substance, a slight decrease in body weight were observed in all animals caused by stress. However, it was temporary and soon recovered. there was no any other weight change for the experimental periods.

3) Observation of application site (Table 3)

① Erythema and eschar formation

On skin reaction of the test substance abrasion sites showed very slight erythema in two animals at 24 hours, and there was no reaction at 72 hours. The test substance intact site showed no skin reaction at 24 and 72 hours observation.

However, control abrasion sites showed very slight erythema in three animals and well-defined erythema in one animal. In control intact site showed very slight erythema in one animal at 24 hours. Control abrasion sites showed very slight erythema in one animals at 72 hours

② Edema

All test and control sites showed no significant signs of skin edema at 24 and 72 hours after treatment

4) Evaluation of dermal irritation and corrosion (Table 3)

The average score of evaluation of dermal irritation by the test substance was 0.3 at 24 and 72 hours. The calculated Primary Irritation Index(P.I.I.) of the test substance was 0.3 .

Therefore, Water that passed through the Waters Therapy Shower was evaluated as a non irritant substance.

5. DISCUSSION AND CONCLUSION

This study was performed to evaluate skin irritation potential of Water that passed through the Waters Therapy Shower in six male New Zealand White Rabbits. The test substance was applied to the skin of NZW rabbits at the dosage 0.5ml for 24 hours. Parameters (mortalities, clinical signs, body weight changes) were measured and the response of each skin irritation was observed at 24 and 72 hours after application. The findings were as follows :

No clinical sign and mortality was observed relating to test substance treatment.

There was temporarily decreasing body weight in the next day of application. But body weight during study period increased normally. No treatment-related mean body weight changes were observed.

On skin reaction of the test substance abrasion sites showed very slight erythema in two animals at 24 hours, and there was no reaction at 72 hours. The test substance intact site showed no skin reaction at 24 and 72 hours observation.

The calculated Primary Irritation Index(P.I.I.) of the test substance were 0.1 at 24 and 72 hours.

On the basis of the above results, Water that passed through the Waters Therapy Shower on dermal application of New Zealand White rabbit was classified as a non irritant.

6. REFERENCES

1) Korea Food & Drug Administration (KFDA) Notice No. 2009-116 'Standard of toxicity test in pharmaceutical, etc. products',(Revised 24th Nov. 2009)

2) OECD Guidelines for the Testing of Chemicals No. 404 'Acute Dermal Irritation/Corrosion' (Adopted 24th Apr. 2002)

3) Draize JH, Woodard G and Calvery HO. (1944) : Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. J Pharmacol Exp Ther, 82:377-390.

4) Draize, J.H. (1959) : Dermal toxicity. Assoc. Food and Drug Officials, U.S. Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics. pp. 46 ~ 59, Texas State Dept. of Health, Austin, Texas.

7. Tables

Table 1. Mortality and clinical signs

MORTALITY AND CLINICAL SIGNS			
STUDY : GT11-00001			SEX : MALE
	No. of animals	Mortality (%)	Clinical signs
	6	0	No clinical signs

Table 2. Body weight changes

BODY WEIGHTS (g)					
STUDY : GT11-00001					SEX : MALE
		Days after treatment			
	Animal No.	0-day	1-day	2-day	3-day
	01-1	2569.04	2483.28	2514.48	2553.30
	01-2	2660.65	2629.47	2610.91	2647.89
	01-3	2720.23	2593.07	2729.16	2685.37
	01-4	2775.61	2661.38	2800.33	2755.57
	01-6	2669.15	2696.81	2417.67	2686.68
	01-7	2584.75	2459.03	2521.51	2498.64
	Mean	2663.24	2587.17	2599.01	2637.91
	S.D.	78.68	96.50	143.98	95.00
	N	6	6	6	6

Table 3. Primary Irritation Index

PRIMARY IRRITATION INDEX

STUDY : GT11-00001 SEX : MALE

Test

Response	Erythema and Eschar formation				Edema			
Animal ID/ Application site	Intact Skin		Abraded Skin		Intact Skin		Abraded Skin	
Time (hrs)	24	72	24	72	24	72	24	72
01-1	0	0	0	0	0	0	0	0
01-2	0	0	1	0	0	0	0	0
01-3	0	0	1	0	0	0	0	0
01-4	0	0	0	0	0	0	0	0
01-6	0	0	0	0	0	0	0	0
01-7	0	0	0	0	0	0	0	0
Total	0	0	2	0	0	0	0	0
Mean	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0
Sum	0.3							
P.I.I	0.1							

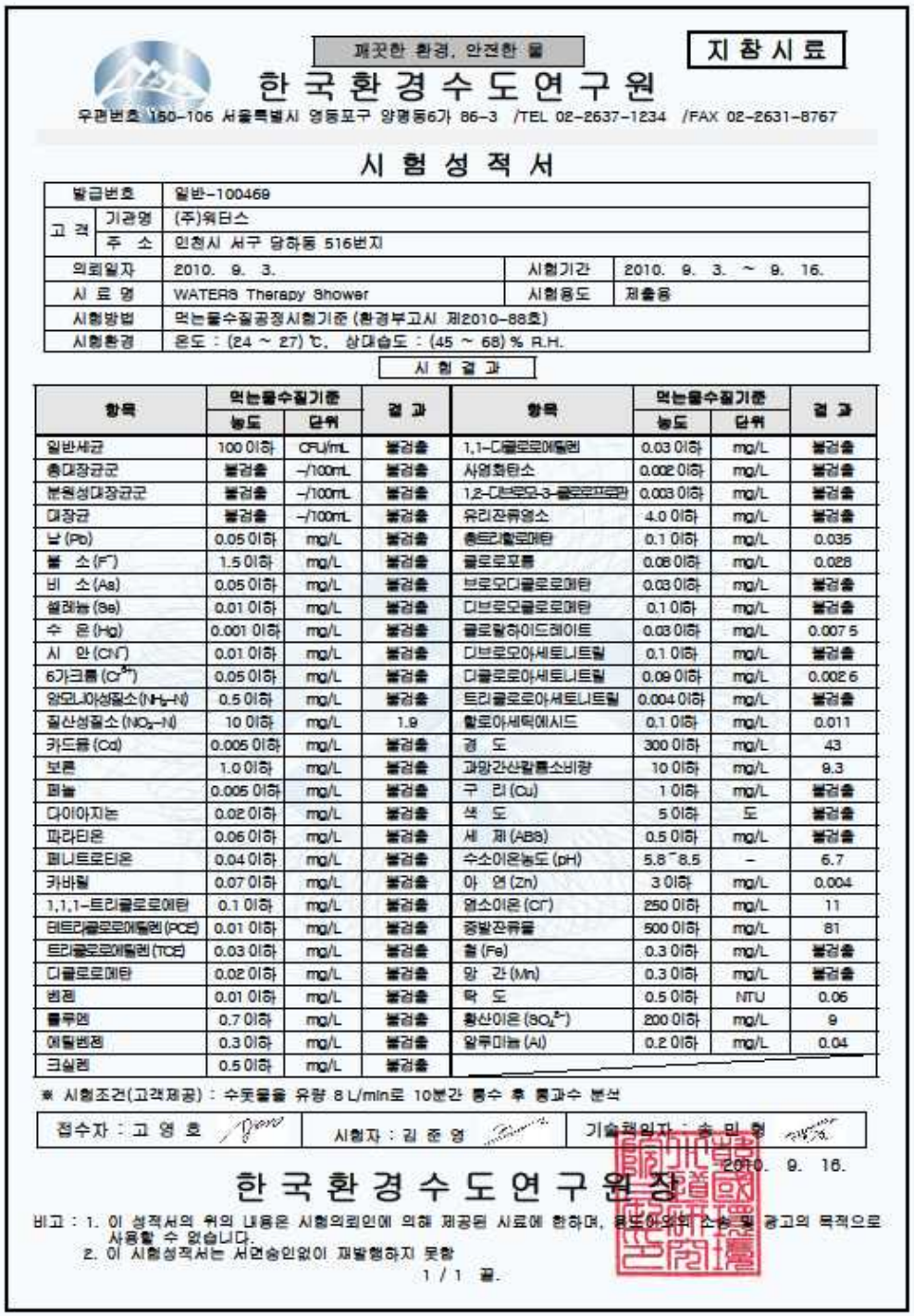
Control

Response	Erythema and Eschar formation				Edema			
Animal ID/ Application site	Intact Skin		Abraded Skin		Intact Skin		Abraded Skin	
Time (hrs)	24	72	24	72	24	72	24	72
01-1	0	0	2	1	0	0	0	0
01-2	0	0	1	0	0	0	0	0
01-3	0	0	1	0	0	0	0	0
01-4	0	0	0	0	0	0	0	0
01-6	1	0	1	0	0	0	0	0
01-7	0	0	0	0	0	0	0	0
Total	1	0	5	1	0	0	0	0
Mean	0.2	0.0	0.8	0.2	0.0	0.0	0.0	0.0
Sum	1.2							
P.I.I	0.3							

* P.I.I = Sum/4

9. Annex

Annex 1. Test substance chemical data sheet



깨끗한 환경, 안전한 물

지 참 시 료

한 국 환 경 수 도 연 구 원

우편번호 150-106 서울특별시 영등포구 양평동6가 86-3 /TEL 02-2637-1234 /FAX 02-2631-8767

시 험 성 적 서

발급번호		일반-100469		
고 객	기관명	(주)워터스		
	주 소	인천시 서구 당하동 516번지		
의뢰일자		2010. 9. 3.	시험기간	2010. 9. 3. ~ 9. 16.
시 료 명		WATER8 Therapy Shower	시험용도	제출용
시험방법		먹는물수질공정시험기준 (환경부고시 제2010-88호)		
시험환경		온도 : (24 ~ 27) ℃, 상대습도 : (45 ~ 68) % R.H.		

시 험 결 과

항목	먹는물수질기준 농도	먹는물수질기준 단위	결 과	항목	먹는물수질기준 농도	먹는물수질기준 단위	결 과
일반세균	100 이하	CFU/mL	불검출	1,1-디클로로에틸렌	0.03 이하	mg/L	불검출
총대장균군	불검출	-/100mL	불검출	사염화탄소	0.002 이하	mg/L	불검출
분원성대장균군	불검출	-/100mL	불검출	1,2-디브로모-3-클로로프로판	0.003 이하	mg/L	불검출
대장균	불검출	-/100mL	불검출	유리잔류염소	4.0 이하	mg/L	불검출
납 (Pb)	0.05 이하	mg/L	불검출	총트리할로메탄	0.1 이하	mg/L	0.035
불 소 (F^-)	1.5 이하	mg/L	불검출	클로로포름	0.08 이하	mg/L	0.028
비 소 (As)	0.05 이하	mg/L	불검출	브로모디클로로메탄	0.03 이하	mg/L	불검출
셀레늄 (Se)	0.01 이하	mg/L	불검출	디브로모클로로메탄	0.1 이하	mg/L	불검출
수 은 (Hg)	0.001 이하	mg/L	불검출	클로랄하이드레이트	0.03 이하	mg/L	0.007 5
시 안 (CN^-)	0.01 이하	mg/L	불검출	디브로모아세토니트릴	0.1 이하	mg/L	불검출
6가크롬 (Cr^{6+})	0.05 이하	mg/L	불검출	디클로로아세토니트릴	0.09 이하	mg/L	0.002 6
암모니아성질소 (NH_4-N)	0.5 이하	mg/L	불검출	트리클로로아세토니트릴	0.004 이하	mg/L	불검출
질산성질소 (NO_3-N)	10 이하	mg/L	1.9	할로아세틱에시드	0.1 이하	mg/L	0.011
카드뮴 (Cd)	0.005 이하	mg/L	불검출	경 도	300 이하	mg/L	43
보론	1.0 이하	mg/L	불검출	과망간산칼륨소비량	10 이하	mg/L	9.3
페놀	0.005 이하	mg/L	불검출	구 리 (Cu)	1 이하	mg/L	불검출
다이아지논	0.02 이하	mg/L	불검출	색 도	5 이하	도	불검출
파라티온	0.06 이하	mg/L	불검출	세 제 (ABS)	0.5 이하	mg/L	불검출
페니트로티온	0.04 이하	mg/L	불검출	수소이온농도 (pH)	5.8 ~ 8.5	-	6.7
카바릴	0.07 이하	mg/L	불검출	아 연 (Zn)	3 이하	mg/L	0.004
1,1,1-트리클로로에탄	0.1 이하	mg/L	불검출	염소이온 (Cl^-)	250 이하	mg/L	11
테트라클로로에틸렌 (PCE)	0.01 이하	mg/L	불검출	증발잔류물	500 이하	mg/L	81
트리클로로에틸렌 (TCE)	0.03 이하	mg/L	불검출	철 (Fe)	0.3 이하	mg/L	불검출
디클로로메탄	0.02 이하	mg/L	불검출	망 간 (Mn)	0.3 이하	mg/L	불검출
벤젠	0.01 이하	mg/L	불검출	탁 도	0.5 이하	NTU	0.06
톨루엔	0.7 이하	mg/L	불검출	황산이온 (SO_4^{2-})	200 이하	mg/L	9
에틸벤젠	0.3 이하	mg/L	불검출	알루미늄 (Al)	0.2 이하	mg/L	0.04
크실렌	0.5 이하	mg/L	불검출				

※ 시험조건(고객제공) : 수돗물을 유량 8 L/min로 10분간 통수 후 통과수 분석

접수자 : 고 영 호 | 시험자 : 김 준 영 | 기술책임자 : 송 민 형

2010. 9. 16.

한 국 환 경 수 도 연 구 원 장

비고 : 1. 이 성적서의 위의 내용은 시험의뢰인에 의해 제공된 시료에 한하며, 본 성적서는 소송 및 광고의 목적으로 사용할 수 없습니다.
2. 이 시험성적서는 서면승인없이 재발행하지 못함

1 / 1 끝.

FPC05-2B(9) Korea Environment & Water Works Institute A4(210×297)

Annex 2. Certification of strain

SAMTAKO

CERTIFICATE OF STRAIN

Place of birth	Samtako Bio Korea	IBRS # 102
Purchaser	한국건설생활환경시험연구원	
Delivery date	2011-02-08	
Monitoring result	As attached sheet	
Details		
Production Facility	Outbred Rabbit (SPF)	
Temperature & Humidity	16 -22°C / 30~70%	
New Zealand White Rabbit (NZW)		
ILAR Code	Sam:NZW	
Sex	Male	
Age (Weight)	10 Weeks (2.0kg)	
Date of birth	2010.11.30 - 2010.12.02	
Number of animals	17 Heads	
Model Description	The industry standard SPF New Zealand White to meet your specific study objectives. Samtako's NZW Rabbits are produced in autonomous production units. They exhibit high productivity, constant growth rates, and docile dispositions.	
Origin & History	Samtako's New Zealand White Rabbits were received breeder stock from Commercial Breeder in 2001. The stock is maintained using a non - B×S mating system.	
Color	White	

We hereby certify the strain of the animals and their background as follows.

원본대조필

JaeYoung Choi, D.V.M

SAMTAKO BIO KOREA

Annex 3. Animal health monitering report

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EVALUATION

Rabbit (6):Sam IBRS 102

ACCESSION NUMBER

98859

SPONSOR

Samtako Bio Korea

STUDIES CONDUCTED

HEAS-110-RAB: Core Health Assessment - Rabbit
MICRO-020: Presence of dermatophytes
MICRO-022: Conjunctiva
SERO-201-230: Core Panel - Rabbit

Steven M. Stiefel, DVM
Sr. Scientist Pathology

Cynthia A. Smith
Office Administrator

12/21/2010
Date

원본대조필

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SUMMARY PAGE

Client:	Samtako Bio Korea	Accession No.	98859
Species:	Rabbit (6)	Date Received:	12/02/2010
Group Designation:	Sam IBRS 102	Date Completed:	12/21/2010

Services Performed: HEAS-110-RAB - Core Health Assessment - Rabbit
MICRO-020 - Presence of dermatophytes
MICRO-022 - Mycoplasma by Conjunctiva Swab
SERO-201-230 - Core Panel - Rabbit

INTRODUCTION

There were 6 adolescent, albino, female rabbits submitted for a Core Diagnostic Screen. Serum samples were drawn from these rabbits at the time of necropsy for a Core Rabbit Serologic Profile.

RESULTS AND INTERPRETATION

The results of the Core Diagnostic Screen are summarized in Table 1. Results of the evaluation of serum for the presence of viral antibodies are presented in Table 2. A complete description of all tests is provided in Table 3.

No rabbit pathogens in the viral, mycoplasmal, helminth, protozoan or arthropod groups were isolated or otherwise detected.
It is brought to the reader's attention that the serum of 1/6 rabbits was (+) for antibodies to *Cilia Associated Respiratory Bacillus* (CARB) by ELISA testing. Retesting that sample by IFA gave (-) results. This profile was interpreted as representing a false (+) CARB ELISA result for that sample. The colony should be regarded as free of all other primary rabbit pathogens in the test profile.

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TABLE I
DIAGNOSTIC SCREEN RESULTS

Client: Samtako Bio Korea
Species: Rabbit (6)
Group Designation: Sam IBRS 102
Accession No. 98859
Date Received: 12/02/2010
Date Completed: 12/21/2010

1) Physical Examination: A group of adolescent, albino, female rabbits with a mean body weight = 2.15 kg were presented for diagnosis. The animals arrived in a filtered shipping carton and were clinically normal in terms of posture and activity. No discharges from the nares, conjuctiva or anus were noted. Euthanasia was conducted in a sterile polycarbonite plastic chamber prior to blood sample collection.

2) Necropsy dissection:	NGL NGL NGL NGL NGL NGL
3) Fecal Flotation for Helminth Ova and Coccidia:	Negative Negative Negative Negative Negative Negative
4) Fecal culture:	No Salmonella, Klebsiella or Citrobacter No Salmonella, Klebsiella or Citrobacter No Salmonella, Klebsiella or Citrobacter No Salmonella, Klebsiella or Citrobacter No Salmonella, Klebsiella or Citrobacter No Salmonella, Klebsiella or Citrobacter
5) Direct cecum:	No Helminths No Helminths No Helminths No Helminths No Helminths No Helminths
6) Pathogenic Bacteria:	None None None None None None
7) Middle ear exam:	No exudates No exudates No exudates No exudates No exudates No exudates

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TABLE 1
DIAGNOSTIC SCREEN RESULTS

Client: Samtako Bio Korea
Species: Rabbit (6)
Group Designation: Sam IBRS 102
Accession No. 98859
Date Received: 12/02/2010
Date Completed: 12/21/2010

8) Pelage	No arthropods
	No arthropods
	No arthropods
	No arthropods
	No arthropods
	No arthropods
9) Presence of dermatophytes	Negative
	Negative
	Negative
	Negative
	Negative
	Negative
10) Conjunctiva Sample	Negative
	Negative
	Negative
	Negative
	Negative
	Negative

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TABLE 2
SEROLOGY RESULTS

Client: Samtako Bio Korea
Species: Rabbit (6)
Group Designation: Sam IBRS 102

Accession No. 98859
Date Received: 12/02/2010
Date Completed: 12/21/2010

NOTE: Values and/or findings will be identified with a '*' and footnoted with the Customer ID.

Target Organism	Test Method	Results	Findings
CAR Bacillus (CARB)	ELISA	1/6	*
CAR Bacillus (CARB)	IFA	0/1	
Encephalitozoon cuniculi (ECUN)	ELISA	0/6	
Pasteurella multocida (PMUL)	IFA	0/6	
Treponema cuniculi (TREP)	RPR	0/6	

Tests marked with an asterisk (*):
CARB-E - '+'

It is brought to the reader's attention that the serum of 1/6 rabbits was (+) for antibodies to *Cilia Associated Respiratory Bacillus* (CARB) by ELISA testing. Retesting that sample by IFA gave (-) results. This profile was interpreted as representing a false (+) CARB ELISA result for that sample.

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TABLE 3
TEST PANEL DESCRIPTIONS

CORE HEALTH ASSESSMENT: The full range of clinical examinations, gross necropsy, microbiologic isolations and histopathology to isolate or otherwise detect the presence of the following microorganisms:

(a) Arthropod ectoparasites

Psoroptes cuniculi (ear mite),
Cheyletiella parasitovorax,
Listrophorus gibbus

(b) Helminth endoparasites
Passalurus ambiguus
Taenia pisiformis

(c) Protozoans

Eimeria stiedae (hepatic coccidiosis),
Eimeria perforans, Eimeria irresidum,
and others (intestinal coccidiosis),
Encephalitozoon cuniculi

(d) Bacteria

Pasteurella multocida,
Pasteurella pneumotropica,
Treponema cuniculi,
Clostridium piliformis

(e) Viruses

Oral papilloma (wart) virus

Core Rabbit Serologic Profile: A battery of viral agents whose presence is detected by various tests for antibodies in serum. The presence of the virus in the colony may be inferred by (+) antibody findings.

Rabbit Panel (SERO-201-230)	Virus Name
CARB	CAR Bacillus
ECUN	Encephalitozoon cuniculi
PMUL	Pasteurella multocida
TREP	Treponema cuniculi

Annex 4. Environment Certification for animal care room

동물사육실 환경증명서

시험번호	GT11-00001
시험제목	토끼를 이용한 WATERS THERAPY SHOWER 통과수의 1차 피부자극시험
동물실험실	토끼사육실
동물사육기간	2011년 02월 07일 ~ 2011년 02월 18일

환경조건

구 분	SOP 관리 범위	실측치	비고
온 도	22±3 ℃	21.0±0.5 ℃	
습 도	50±20 %RH	45.9±2.6 %RH	
조 도	150~300 Lux	286 Lux	
소 음	60 dB 이하	56.0dB	
암모니아	15 ppm 이하	5 ppm 이하	

상기 시험의 시험기간 동안 위의 설정치를 2시간 이상 벗어나는 환경의 변화가 없었음을 증명합니다.

시설관리 책임자 백 동 석 (인)

2011년 03 월 10일

Annex 5. Laboratory animal diet certification

Cargill Agri Purina Korea Inc.
Analysis Service of Central Laboratory
627 Jangdang-dong, Pyongtaek-si
Kyonggi-do, 459-020 Seoul, Korea
Tel (031)669-9060 Fax (031)667-3642

ANALYSIS RESULT

LAB NO. 170089 ENTERED August 23, 2010 REPORTED September 28, 2010

38302-AF	RABBIT BIR-C
PRODUCTION	8/11/10 KSN Plant
LOT NO.	KSN100811SPB

ASSAY	ANALYSIS	UNIT
NUTRIENTS		
MOISTURE(OVEN)	12.11	%
PROTEIN(PROTEIN ANALYZER)	15.09	%
FAT(ETHER EXT)	2.93	%
FIBER(ANKOM)	13.74	%
ASH(FURNACE)	9.89	%
CALCIUM(AAS)	1.42	%
PHOSPHORUS(COLORMETRIC)	0.62	%
HEAVY METALS		
As(ICP)	Not detected	ppm
Cd(ICP)	0.37	ppm
Hg(MERCURY ANALYZER)	Not detected	ppb
Pb(ICP)	0.25	ppm
Se(ICP)	0.22	ppm
AFLATOXIN(ELISA)		
B1, B2, G1, G2	0.68	ppb
CHLORINATED HYDROCARBON		
DDT(GC)	Not detected	ppm
ORGANOPHOSPHATES		
MALATHION(GC)	Not detected	ppm
Microbial Tests		
Salmonella	Not detected	mm
Total Bacteria	310000	cfu/g
E. Coli	Not detected	-
PHYSICAL PROPERTIES		
PELLET SIZE(DxL)	5.66 * 10.78	mm
PELLET COLOR	Green	-
HARDNESS	8.36	kg/cm^2

THE LETTER CODE LOCATED BELOW EACH ASSAY IS A METHOD REFERENCE CODE.
FOR ADDITIONAL INFORMATION CONTACT MR. LEE, NAM JIN, CENTRAL LABORATORY MANAGER. (031-669-9060)

PREPARED BY Koo, Jae Yeon CONFIRMED BY Lee, Nam Jin

The Term "Less Than" is used to signify the lower limit of quantitation of the procedure under the conditions employed. The use of the term "Less Than" does not imply that traces of analyte were present. Samples submitted to Central Laboratory Services for routine analysis will be retained for a minimum of thirty(30) days after the report of analysis is issued. Extended storage requirements must be brought to the attention of Central Laboratory services prior to or at the time of sample submission.

Annex 6. Certification of water analysis

the way to trust KCL

시 험 성 적 서

접 수 번 호 : DW10-00802
신 청 인 : 한국건설생활환경시험연구원(인천)
주 소 : 인천 연수구 송도동 7-44
시 료 명 : 바이오융합본부 동물실

접 수 일 자 : 2010.09.07
시험완료일 : 2010.10.06
용 도 : 거래처 제출

시험결과

첨 부 시 험 분 석 결 과 표 와 같 음.

비고 1. 이 성적서는 신청인이 제시한 시료 및 시료명으로 시험한 결과로서 전체제품에 대한 품질을 보증하지는 않습니다.
2. 이 성적서는 우리 연구원의 사전 서면동의 없이 홍보, 선전, 광고 및 소송용으로 사용될 수 없으며, 용도 이외의 사용을 금합니다.

시험원 : 원성민 기술책임자(부) : 김준호

2010년 10월 6일

한국건설생활환경시험연구원

본원 : 153-803 서울 금천구 가산동 459-28 (02)2102-2500
결과문의 : 환경분석팀 02-2102-2596

총 3 페이지 중 1 페이지

the way to trust KCL

시 험 성 적 서

접 수 번 호 : DW10-00802

시 험 항 목	단 위	수질기준	정량한계	시 험 결 과
일반세균	CFU/mL	100 이하	0	0
총대장균군	-/(100mL)	불검출	-	불검출
대장균	-/(100mL)	불검출	-	불검출
납	mg/L	0.05 이하	0.04	불검출
비 소	mg/L	0.05 이하	0.005	불검출
세레늄	mg/L	0.01 이하	0.005	불검출
카드뮴	mg/L	0.01 이하	0.002	불검출
보 론	mg/L	0.3 이하	0.01	불검출
동	mg/L	1.0 이하	0.008	불검출
아 연	mg/L	1.0 이하	0.002	0.002
철	mg/L	0.3 이하	0.05	불검출
망 간	mg/L	0.3 이하	0.005	불검출
알루미늄	mg/L	0.2 이하	0.02	불검출
수 은	mg/L	0.001 이하	0.001	불검출
불 소	mg/L	1.5 이하	0.15	불검출
질산성질소	mg/L	10 이하	0.1	0.5
염소이온	mg/L	250 이하	0.4	2
황산이온	mg/L	200 이하	2	불검출
다이아지논	mg/L	0.02 이하	0.0005	불검출
파라티온	mg/L	0.06 이하	0.0005	불검출
페니트로티온	mg/L	0.04 이하	0.0005	불검출
디클로로메탄	mg/L	0.02 이하	0.003	불검출
1,1,1-트리클로로에탄	mg/L	0.1 이하	0.003	불검출
벤 젠	mg/L	0.01 이하	0.002	불검출
톨루엔	mg/L	0.7 이하	0.002	불검출
에틸벤젠	mg/L	0.3 이하	0.002	불검출
크실렌	mg/L	0.5 이하	0.002	불검출
1,1-디클로로에틸렌	mg/L	0.03 이하	0.002	불검출
사염화탄소	mg/L	0.002 이하	0.002	불검출
테트라클로로에틸렌	mg/L	0.01 이하	0.002	불검출
트리클로로에틸렌	mg/L	0.03 이하	0.002	불검출
1,2-디브로모-3-클로로프로판	mg/L	0.003 이하	0.001	불검출
카바릴	mg/L	0.07 이하	0.0005	불검출
6가크롬	mg/L	0.05 이하	0.02	불검출
암모니아성 질소	mg/L	0.5 이하	0.01	불검출
페 놀	mg/L	0.005 이하	0.005	불검출
세 제	mg/L	0.5 이하	0.1	불검출

the way to trust KCL

시 험 성 적 서

접 수 번 호 : DW10-00802

시 험 항 목	단 위	수질기준	정량한계	시 험 결 과
시 안	mg/L	0.01 이하	0.01	불검출
수소이온농도	-	5.8~8.5	-	7.0
탁 도	NTU	1 이하	0.02	0.16
색 도	도	5 이하	1	불검출
맛	-	무미	-	없 음
냄 새	-	무취	-	없 음
경 도	mg/L	300 이하	1	불검출
과망간산칼륨 소비량	mg/L	10 이하	0.3	0.3
증발잔류물	mg/L	500 이하	2	27
판 정		적 합		
시 험 방 법		먹는 물 수질공정시험기준(환경부고시 제2010-88호)		

- 이 하 여 백 -

총 3 페이지 중 3 페이지

Annex 7. GLP certificate

지정번호(Certification No.) 제 18 호

비임상시험관리기관 지정서
GLP Certificate

시 험 기 관 : 한국생활환경시험연구원 안전성평가본부
Test Facility(ies) Name : Bio-safety Evaluation Headquarters, Korea Environment & Merchandise Testing Institute
소 재 지 : 인천광역시 연수구 송도동 7-44
Address : 7-44, Songdo-dong, Yeonsu-gu, Incheon, Republic of korea
대 표 자 : 박갑록 (주민등록번호 : 460706-1675917)
President : Kap-Rok Park (Personal No. : 460706-1675917)
운 영 책 임 자 : 유일재 (주민등록번호 : 551225-1670916)
Test Facility Management : Il-Je Yu (Personal No. : 551225-1670916)

시 험 의 범 위 : 단회투여독성시험(설치류/비설치류)
유전독성시험(복귀돌연변이시험, 체외염색체이상시험, 체내 소핵시험)
국소독성시험(피부자극시험, 안점막자극시험)
Test Scope : Single Dose Toxicity Test (Rodent/Non-Rodent)
Genetic toxicity (Reverse Mutation Test, Chromosome Aberration Test, Micronucleus Test)
Local toxicity (Skin Irritation Test, Eye Irritation Test)

비임상시험관리기준 제4조에 의하여 비임상시험기관으로 지정하였음을 증명함.

It is hereby certified that the test facility(ies) was(were) inspected by the national compliance monitoring authority regarding compliance with the Principles of Good Laboratory Practice.

issue date 2006 년(yr) 11 월(month) 6 일(date)

식 품 의 약 품 안 전 청

Commissioner, Korea Food and Drug Administration

비임상시험기관지정변경사항	
년 월 일	내 용
2007. 07. 05	대표자 변경 변경 전 : 박강훈 2007. 7. 05 변경 후 : 강창로 (주민등록번호 : 620118-1406914) Chang-Ro, Kim
2008. 08. 06	시험항목 추가 (4) 급성독성 독성시험 (설치류 (흡입)) 반복투여 독성시험 (설치류 (경구 투입)) 변이원성시험 (피부감작성) 2008.8.06
2009. 05. 19	운영책임자 변경 변경 전 : 유일씨 변경 후 : 송경석 (Kyung-Seuk Song) 2009.5.19
2010. 08. 05	상호 변경 : 한국생활환경시험연구원 안전성평가본부 → 한국건설생활환경시험연구원 바이오융합본부 (Bioconvergence technology division, Korea Conformity Laboratories) 2010.8.05
2010. 08. 05	대표자 변경 : 김창로 (Chang-ro kim) -> 오태식 (Taeshik oh) 2010.8.05

Annex 8. Quality assurance statement-Original

신 뢰 성 보 증 확 인 서

시험번호 : GT10-00079

시 험 명 : 토끼를 이용한 Dodecylbenzenesulphonic acid의 급성 피부자극성 및 부식성 시험

이 보고서에 기술된 시험을 독립적으로 아래와 같이 시험과정 단계별로 점검하였으며 각 점검결과를 표준작업지침서에 따라 시험책임자와 운영책임자에게 통보 및 보고하였다.

본 시험은 국립환경과학원 고시 제2009-57호 (2009년 11월 24일) '화학물질유해성시험연구기관의 지정 등에 관한 규정' 및 OECD Guidelines for the Testing of Chemical No. 404 'Acute Dermal Irritation/Corrosion' (Adopted 24th April 2002)에 따라 수행되었으며, 보고서의 방법 및 결과의 기술이 시험의 실시과정에서 발생한 시험기초자료를 바탕으로 정확히 반영되었음을 확인하였다.

점 검 내 용	실 시 일	시험책임자에게 통보일	운영책임자에게 보고일
시험계획서 점검	2010. 08. 17	2010. 08. 17	2010. 08. 18
동물입수	2010. 08. 24	2010. 08. 24	2010. 08. 26
시험물질 및 대조물질	2010. 08. 19	2010. 08. 19	2010. 08. 19
시험물질조제	2010. 09. 07	2010. 09. 07	2010. 09. 07
동물사육 및 투여	2010. 09. 07	2010. 09. 07	2010. 09. 07
증상관찰 및 측정	2010. 09. 07	2010. 09. 07	2010. 09. 07
국소독성반응관찰	2010. 09. 10	2010. 09. 10	2010. 09. 10
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