KIDS-BTG001-ONG

Clinical Study Report

A safety test of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' after 24 hours patch on human skin

Date: July 29, 2020

Requested by : Ongoong Co., Ltd. (Korea)

Performed by: Korea Institute of Dermatological Sciences (Korea)



Contents



Statement for Submission	i
Information of Clinical Trial Institution and Sponsor ····	ii
Certificate for Reliability Assurance	iii
Summary of the Clinical Study	iv
I. Purpose ·····	1
II. Trial Period ·····	1
III. Clinical Trial Institution·····	1
IV. Sponsor·····	1
V. Methods·····	2
VI. Results ······	8
VII. Conclusions	11

Appendices

[Appendix 1] Detailed Data

[Appendix 2] Ingredients of Test Materials

[Appendix 3] Researchers' Profiles in the Institution

[Appendix 4] Major Facilities in the Institution



STATEMENT FOR SUBMISSION



As Ongoong Co., Ltd. requested that Korea Institute of Dermatological Sciences determines a safety test of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' after 24 hours patch on human skin, Korea Institute of Dermatological Sciences conducted this clinical study according to the regulations of designation as the test institution for drugs, quasi-drugs, cosmetics, and medical devices; the guidelines of the management standards for clinical drug evaluations; the guidelines of in vivo clinical and in vitro evaluation studies; the guidelines of the experimental methods for cosmetic display and advertisements; and the guidelines of the validation of functional cosmetics of the Ministry of Food and Drug Safety, Republic of Korea; the laws of the bioethics and safety of the Ministry of Health and Welfare. Republic of Korea; and the standard operation procedure of the Korea Institute of Dermatological Sciences. The results to be reported are as follows.

July 29, 2020

Clinical trial Korea Institute of Dermatological Sciences institution

> In Sook An. Ph.D. Director, Korea Institute of Dermatological Sciences

director Adjunct Professor, Department of Cosmetology,

Graduate School of Konkuk University

Chief Director, Korea Institute of Dermatological Sciences In Sook An, Ph.D. researcher Adjunct Professor, Department of Cosmetology,

Graduate School of Konkuk University

Assistant Assistant chief researcher, Korea Institute of

Chief Dermatological Sciences

Researcher Professor and Dermatology specialist,

Department of Dermatology,

Konkuk University School of Medicine

Research Director, Korea Institute of Researchers

Dermatological Sciences

Kyu Joong Ahn, M.D., Ph.D.

Seung Bin Kwon, Ph.D.

This report is the confidential document and property of the Koea Institute of Dermatological Sciences; its transfer, plagiarization, and disclosure to third partiess prohibited.



Scientific







Title of the clinical study	A safety test of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' after 24 hours patch on human skin
Case control No.	KIDS-BTG001-ONG

	Name	Ongoong Co., Ltd.
Sponsor requesting	Address	480-46, Seobunam-ro, Sinchang-myeon, Asan-si, Chungcheongnam-do, 31544, Republic of Korea
the clinical study Tel. +82 41 429 2233		+82 41 429 2233
	E-mail	aromania14@naver.com
	Name	Korea Institute of Dermatological Sciences
Institution performing the clinical	Address	6th Floor, Tower A, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, 05 836, Republic of Korea
study	Tel.	+82 1566 8668
	E-mail	research@skinresearch.or.kr

Chief	Institution	Korea Institute of Dermatological Sciences	Name	In Sc	ook An, Ph.D.	
researcher	Address	6th Floor, Tower A, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, 05 836, Republic of Korea				
Dermatology specialist Kyu Joong Ahn, M.D., Ph.D. Research Director Seung Bin Kwon, Ph.D. Research Engineer Yujeong Kwon·Seulki Yoon Associate Research Engineer Minji Jo·Sujeong Shin· Dasom Shin·Songhee Ha						
	Duration of Study	June 26, 2020 ~ July	29, 2020	Report date	July 29, 2020	



CERTIFICATE FOR RELIABILITY ASSURANCE



□Title of the clinical studyA safety test of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and

Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' after 24 hours patch
on human skin

☐ Case control No.: KIDS-BTG001-ONG

This study was conducted according to the regulations of designation as the test institution for drugs, quasi-drugs, cosmetics, and medical devices; the guidelines of the management standards for clinical drug evaluations; the guidelines of *in vivo* clinical and *in vitro* evaluation studies; the guidelines of the experimental methods for cosmetic display and advertisements; and the guidelines of the validation of functional cosmetics of the Ministry of Food and Drug Safety, Republic of Korea; the laws of the bioethics and safety of the Ministry of Health and Welfare, Republic of Korea; and the standard operation procedure of the Korea Institute of Dermatological Sciences. All procedures were investigated by the person in charge of reliability assurance.

Title of the clinical study	A safety test of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' after 24 hours patch on human skin				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
June 26, 2020	Study plan	Reporting plan	Approved	June 26, 2020	
July 06, 2020 ~ July 10, 2020	Performing clinical trial (Measurement progress)	Reporting implementation	Approved	July 10, 2020	
July 13, 2020 ~ July 20, 2020	Analyzing data, Confirming the information on test material	Inspecting raw data	Approved	July 20, 2020	
July 21, 2020 ~ July 28, 2020	Report work	Inspecting draft report	Approved	July 28, 2020	
July 29, 2020	Report final report	Inspecting final report	Approved	July 29, 2020	

This report was prepared on the basis of the experiment results and accurately reflects the data.

July 29, 2020

Scientific Director In Sook An, Ph.

Reliability Assurance Ka Ram Kim, Ph. D. (s



SUMMARY OF THE CLINICAL STUDY



Title of the clinical study	A safety test of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' after 24 hours patch on human skin	
Clinical trial institution	Korea Institute of Dermatological Sciences 6th Floor, Tower A, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, 05 836, Republic of Korea	
Trial period	June 26, 2020 (study initiation) \sim July 29, 2020 (study termination) For the study initiation, the person in charge of the study signed the clinical study proposal: for the study termination, the person in charge of the study signed the final report.	
Trial period (Measurement period)	July 6, 2020 (First date of visit) ~ July 10, 2020 (End date of visit)	
Subjects	Thirty four subjects of either sex who met the inclusion criteria and were not included in the exclusion criteria were selected for this study.	
Name of the test materials	Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) (Test material #1) Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE) (Test material #2)	
Methods	Thirty four healthy volunteers participated in the patch test using Finn Chamber on skin. Each of Finn Chambers containing a test material were fixed on the upper back of the subjects after cleaning up the test area with 70% ethanol and drying. 20 µL of a test material was dropped into a filter paper disc placed on 8 mm Finn Chamber. The test material was applied after dilution water. The test area was assessed at 30 minutes, 24 hours and 48 hours after a single application during 24 hours patch on the subjects. Skin reactions were scored by a dermatology specialist, following the criterion of International Contact Dermatitis Research Group (ICDRG).	
Results	Requested by Ongoong Co., Ltd., skin reaction was assessed at 30 minutes, 24 hours and 48 hours after a single application during 24 hours patch of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER (SPRAY TYPE)' on human skin. According to the criterion of International Contact Dermatitis Research Group (ICDRG), mean score was calculated after categorizing the degree of skin reaction. No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'Dr.LIBEAUTE HAND SANITIZER (GEL TYPE)' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non irritant. No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non irritant.	





Conclusion

Requested by Ongoong Co., Ltd. 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' can be considered as non irritant according to the results of the safety test.





I. Purpose

This clinical study aims to evaluate the safety of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' after 24 hours patch on human skin.

II. Trial Period

June 26, 2020 through July 29, 2020

III. Clinical Trial Institution

Institution: Korea Institute of Dermatological Sciences

Address: 6th Floor, Tower A, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, 05836, Republic

of Korea

Tel.: +82 1566 8668

Fax: +82 2 6957 8004

E-mail: research@skinresearch.or.kr

Website: www.skinresearch.or.kr

Researchers: Dermatology specialist Kyu Joong Ahn, M.D., Ph.D.

Research Director Seung Bin Kwon, Ph.D.

Research Engineer Yujeong Kwon Seulki Yoon

Associate Research Engineer Minji Jo·Sujeong Shin·Yoonmi Choi

Dasom Shin·Songhee Han·Heemin Kwon

IV. Sponsor

Company: Ongoong Co., Ltd.

Client: Lee Seung Jae

Address: 480-46, Seobunam-ro, Sinchang-myeon, Asan-si, Chungcheongnam-do, 31544,

Republic of Korea

Tel.: +82 41 429 2233 Fax: +82 41 544 8015

E-mail: aromania14@naver.com





V. Methods

1. Subjects

Male and female volunteers over the age of twenty were selected on the basis of predetermined inclusion and exclusion criteria. The volunteers satisfied all 1) the inclusion criteria and were not in conflict with any of 2) the exclusion criteria. The person in charge of the examination or the examiner who was delegated by the person in charge informed the subjects of all of the matters related to the tests, and the subjects gave their written informed consent voluntarily before participation in the study.

1) Inclusion criteria

- (1)Person who voluntarily signed the informed consent form after understanding the matters explained by the researcher or the person delegated by the researcher
- (2) Healthy volunteers over the age of twenty without acute or chronic physical diseases, including any skin diseases
- (3) Person available for follow-up during the testing period

2) Exclusion criteria

A person with any of the following factors was excluded from the study

- (1) Woman who was pregnant, breast feeding or potentially pregnant
- (2) Person who had been treated with any external application containing steroids for a skin disease treatment more than 1 month
- (3) Person who had participated in the same test within the last 4 weeks
- (4) Person with sensitive or hypersensitive skin
- (5) Person with skin abnormality on the test area, including moles, acne, erythema, and dilated capillaries
- (6) Person taking any oral contraceptive, antihistamine or-antiammatory
- (7) Person presenting severe irritation or allergy to patch
- (8) Person considered to be unsuitable for the test





3) Withdrawal standards

Participants were withdrawn for the following reasons and the following criteria were reported on the final report.

- (1) An adverse event, such as itching or erythema at the test area
- (2) Hindrance of the evaluation due to a medical treatment, application of another product, excessive UV exposure, or excessive drinking or smoking during the trial period
- (3) Inability to participate in a follow-up appointment during the trial period due to personal reasons
- (4) Person who flouted the directions without specific reason

2. Test area

On the upper back

3. Test materials application

The responsibility to examine and secure the physicochemical properties and safety of the test materials used in this test is on the sponsor, and the Korea Institute of Dermatological Sciences (KIDS) does not perform any additional analytical procedure to determine the physicochemical properties of the test materials. KIDS keep the test materials for 180 days from the date of publication and discard it if there is no request from sponsor. The test materials are stored at room temperature (1~30°C) avoiding high temperatures and direct sunlight.

1) Test materials information

- (1) Name of test materials
 - 1 Test material #1: Dr.LIBEAUTE HAND SANITIZER(GEL TYPE)
 - ② Test material #2: Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)
- (2) Management number of test materials
 - 1) Test material #1: M-KIDS-BTGP01-ONG
 - 2 Test material #2: M-KIDS-BTGP02-ONG





- (3) Test Sponsor: Ongoong Co., Ltd.
- (4) Product type
 - 1 Test material #1 : Colorless transparent gel type
 - 2 Test material #2: Colorless transparent liquid type
- (5) Ingredients: See Appendix 2
- 2) Usage and quantity of test materials
 - (1)A researcher cleaned up the upper back of all subjects with 70% ethanol and dried them.
 - (2) Each of Finn Chambers containing a test material were fixed on the upper back of the subjects. 20 μL of a test material was dropped into a filter paper disc placed on 8 mm Finn Chamber. The test material was applied after dilution with sterile distilled water.
 - (3) The patches were left in 24 hours.





4. Evaluation

1) Test location

All clinical studies were conducted in the controlled temperature and humidity room (temperature: $22\pm2\%$, humidity: $50\pm5\%$).

2) Measurements

(1) A safety test after 24 hours patch on human skin

To evaluate the safety of the test materials by the patch test on human skin, 34 subjects participated in this clinical study. A researcher cleaned up the test area on the upper back of the subjects with 70% ethanol and dried them. Each of Finn Chambers containing a test material were fixed on the upper back of the subjects. 20 µL of a test material was dropped into a filter paper disc placed on 8 mm Finn Chamber. The test material was applied after dilution with sterile distilled water. After removing the patches, the test area was marked with a marking pen (Skin marker pen, DeRoyal, Inc., USA).

The measurements for skin reaction were undertaken by a dermatology specialist in 30 minutes, 24 hours and 48 hours after removing the patches, according to International Contact Dermatitis Research Group (ICDRG) criterion in table 1. Mean score was calculated with the formula for the degree of the average skin reaction. Then, the irritant degree of the test material was finally assessed according to the grading scale for the results of patch test on skin in table 2.

Table 1. Criterion of International Contact Dermatitis Research Group

Notation	Score	Description	
_	0	Negative	
±	0.5	Doubtful or slight reaction and erythema	
+	1	Erythema + Induration	
++	2	Erythema + Induration + Vesicle	
+++	3	Erythema + Induration + Bullae	

- *Criterion of skin reaction
- Negative (-): No skin changes
- Doubtful or slight reaction and erythema (±): Faint, non-palpable erythema
- Erythema + hduration (+): Weak positive reaction.

Palpable erythema - moderate edema or infiltrate, papules not present or scarce, vesicles not present

- Erythema + hduration+ Vesicle (++): Strong positive reaction.

 Strong infiltrate, numerous papules, vesicles present
- Erythema + hduration+ Bullae (+++): Extreme positive reaction.

 Coalescing vesicles bullae or ulceration





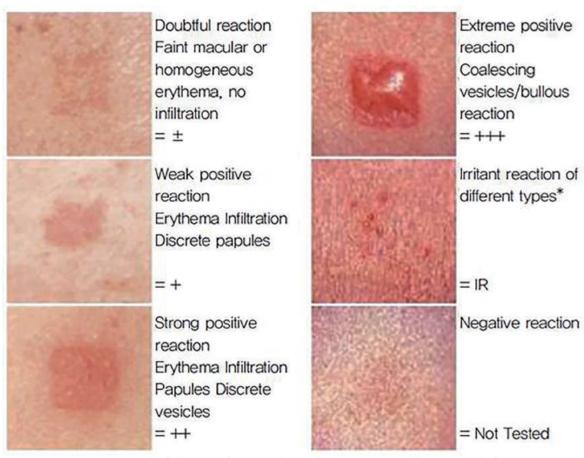


Figure 1. Criterion of International Contact Dermatitis Research Group

* The formula for the degree of the average skin reaction

Mean score =
$$\frac{(A+B+C) \times 100}{3 \text{ (maximum score)} \times \text{No.of total subjects} \times \text{No.of evaluation}}$$
$$A = \sum_{i=1}^{n} \text{Score } i \qquad B = \sum_{i=1}^{n} \text{Score } j \qquad C = \sum_{k=1}^{n} \text{Score } k$$

i = Number of total subjects with skin reaction in 30 minutes after removing patches

j = Number of total subjects with skin reaction in 24 hours after removing patches

k = Number of total subjects with skin reaction in 48 hours after removing patches

As the score indicating results of patch test in 30 minutes, 24hours and 48 hours after removing patches in accordance with ICDRG criterion, it is applied to both of erythema and edema.





Table 2. Grading scale for the results of patch test on skin

Grade	Mean score
Non irritant (1)	0.00~0.75
Very slightly irritant (2)	0.76~1.50
Slightly irritant (3)	1.51~2.50
Moderately irritant (4)	2.51~4.00
Strong irritant (5)	4.01~

(2) Survey

Seven multiple choice questions were asked to subjects for survey of skin condition characteristics.

5. Adverse events

Adverse events, including erythema, edema, scaling, itching, stinging, burning, tightness, prickling, and other abnormalities, were visually examined and described on the case report form at every visit. The records included the degree of symptoms and whether these were mild, moderate, or severe. Each subject's attendance was also recorded. Whether the participant was excluded from the study due to withdrawal was also noted. If a subject was unable to continue in the study, she signed an abandonment consent form.

6. Statistical analysis

SPSS 17.0 for Windows was used for statistical analysis. For the analysis of the survey, averages, standard deviations, frequencies, and percentages were calculated.





VI. Results

1. General characteristics of the subjects

The general characteristics of the participants are shown in Table 3.

Table 3. General characteristics of the subjects

Subjects registered	34
Subjects completed	34
Gender	Male and Female
Average age (years)	47.44
Standard deviation (SD)	9.58

The age distribution of the subjects is shown in Figure 2 (see Appendix 1 for details).

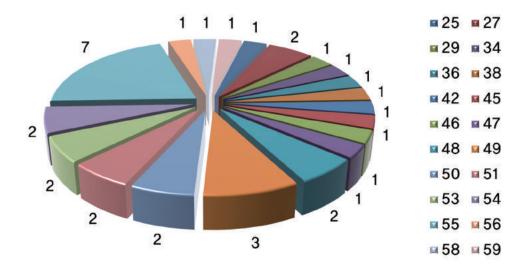


Figure 2. Age distribution of subjects.





2. Evaluation of the safety of the test materials by the patch test on human skin

The evaluation results of safety using patch test on human skin are shown in Table 4. No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE)' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non irritant. No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non irritant. The evaluation details are shown in Appendix 1.

Table 4. Results of patch test on skin

No. of test	Material name	No. of positive	Score of skin reaction			Mean score of skin
materials	Material Harrie	case	after 30 min.	after 24 hrs.	after 48 hrs.	
#1	Dr.LIBEAUTE HAND SANITIZER(GEL TYPE)	0	0.0	0.0	0.0	0.00
#2 5	Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)	0	0.0	0.0	0.0	0.00





3. Survey for skin condition characteristics of the subjects

Survey results of the skin condition characteristics are shown in Table 5.

Table 5. Skin condition characteristics

(N=34)

able 5. Skill condition characteristics			(11-34)
Question		Frequency	Percentage (%)
	Oily	1	2.9
Chin tuno	Dry	16	47.1
Skin type	Neutral	12	35.3
	Complex	5	14.7
Traublad akin	Yes	0	0.0
Troubled skin	No	34	100.0
Lleve any skin trauble	Yes	0	0.0
Have any skin trouble	No	34	100.0
Event of any side effect by cosmetics	Yes	0	0.0
within the last one year	No	34	100.0
Allergie to motel (pickel)	Yes	0	0.0
Allergic to metal (nickel)	No	34	100.0
Experience of any infantile	Yes	0	0.0
eczema or atopic dermatitis	No	34	100.0
Allerais to suplicht (shotoconsitive)	Yes	0	0.0
Allergic to sunlight (photosensitive)	Dry Neutral Complex Yes No	34	100.0
Total		34	100.0





VII. Conclusions

As requested by Ongoong Co., Ltd., Korea Institute of Dermatological Sciences conducted a clinical study of thirty four subjects for a safety test of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' after 24 hours patch on human skin. According to the criterion of International Contact Dermatitis Research Group (ICDRG), mean score was calculated after categorizing the degree of skin reaction.

No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE)' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non irritant. No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non irritant.

As requested by Ongoong Co., Ltd., 'Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) and Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE)' can be considered as non irritant according to the results of the safety test.



[Appendix 1] Detailed Data

[Appendix 2] Ingredients of Test Materials

[Appendix 3] Researchers' Profiles in the Institution

[Appendix 4] Major Facilities in the Institution





[Appendix 1] Detailed Data

1. Basic information about the subjects

1 2007-BTG001-001 55 Female 2 2007-BTG001-002 55 Female 3 2007-BTG001-003 56 Female 4 2007-BTG001-004 49 Female 5 2007-BTG001-005 46 Female 6 2007-BTG001-006 58 Female 7 2007-BTG001-007 55 Female 8 2007-BTG001-008 59 Female 9 2007-BTG001-009 38 Female 10 2007-BTG001-010 48 Female 11 2007-BTG001-011 48 Female 12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 19 2007-BTG001-020 53	Subject No.	Subject identification code	Age	Gender
3 2007-BTG001-003 56 Female 4 2007-BTG001-004 49 Female 5 2007-BTG001-005 46 Female 6 2007-BTG001-006 58 Female 7 2007-BTG001-007 55 Female 8 2007-BTG001-008 59 Female 9 2007-BTG001-009 38 Female 10 2007-BTG001-010 48 Female 11 2007-BTG001-011 48 Female 12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-015 50 Female 17 2007-BTG001-016 54 Female 18 2007-BTG001-017 50 Female 19 2007-BTG001-018 45 Female 20 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-020 53 Female 22 2007-BTG001-020 53 Female 23 2007-BTG001-021 29 Male 24 2007-BTG001-022 25 Male 25 2007-BTG001-023 49 Female 26 2007-BTG001-024 55 Female 26 2007-BTG001-025 55 Female 27 2007-BTG001-026 54 Female 28 2007-BTG001-027 27 Female 29 2007-BTG001-028 55 Female	1	2007-BTG001-001	55	Female
4 2007-BTG001-004 49 Female 5 2007-BTG001-005 46 Female 6 2007-BTG001-006 58 Female 7 2007-BTG001-007 55 Female 8 2007-BTG001-009 38 Female 9 2007-BTG001-010 48 Female 10 2007-BTG001-011 48 Female 12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-020 53 Female 21 2007-BTG001-022 25 </td <td>2</td> <td>2007-BTG001-002</td> <td>55</td> <td>Female</td>	2	2007-BTG001-002	55	Female
5 2007-BTG001-005 46 Female 6 2007-BTG001-006 58 Female 7 2007-BTG001-007 55 Female 8 2007-BTG001-008 59 Female 9 2007-BTG001-010 48 Female 10 2007-BTG001-010 48 Female 11 2007-BTG001-011 48 Female 12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 19 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-020 53 Female 22 2007-BTG001-023 49<	3	2007-BTG001-003	56	Female
6 2007-BTG001-006 58 Female 7 2007-BTG001-007 55 Female 8 2007-BTG001-008 59 Female 9 2007-BTG001-010 48 Female 10 2007-BTG001-011 48 Female 11 2007-BTG001-012 51 Female 12 2007-BTG001-013 36 Female 13 2007-BTG001-014 34 Female 14 2007-BTG001-015 50 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 19 2007-BTG001-018 45 Female 20 2007-BTG001-019 55 Female 21 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 </td <td>4</td> <td>2007-BTG001-004</td> <td>49</td> <td>Female</td>	4	2007-BTG001-004	49	Female
7 2007-BTG001-007 55 Female 8 2007-BTG001-008 59 Female 9 2007-BTG001-010 48 Female 10 2007-BTG001-011 48 Female 11 2007-BTG001-012 51 Female 12 2007-BTG001-013 36 Female 13 2007-BTG001-014 34 Female 14 2007-BTG001-015 50 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 <td>5</td> <td>2007-BTG001-005</td> <td>46</td> <td>Female</td>	5	2007-BTG001-005	46	Female
8 2007-BTG001-008 59 Female 9 2007-BTG001-009 38 Female 10 2007-BTG001-010 48 Female 11 2007-BTG001-011 48 Female 12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-026 54 </td <td>6</td> <td>2007-BTG001-006</td> <td>58</td> <td>Female</td>	6	2007-BTG001-006	58	Female
9 2007-BTG001-009 38 Female 10 2007-BTG001-010 48 Female 11 2007-BTG001-011 48 Female 12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-015 50 Female 17 2007-BTG001-016 54 Female 18 2007-BTG001-017 50 Female 19 2007-BTG001-018 45 Female 20 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-021 29 Male 23 2007-BTG001-022 25 Male 24 2007-BTG001-023 49 Female 25 2007-BTG001-024 55 Female 26 2007-BTG001-025 55 Female 27 2007-BTG001-026 54 Female 28 2007-BTG001-027 27 Female 29 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male	7	2007-BTG001-007	55	Female
10 2007-BTG001-010 48 Female 11 2007-BTG001-011 48 Female 12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-021 29 Male 23 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 </td <td>8</td> <td>2007-BTG001-008</td> <td>59</td> <td>Female</td>	8	2007-BTG001-008	59	Female
11 2007-BTG001-011 48 Female 12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-021 29 Male 23 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 207-BTG001-028 55 <td>9</td> <td>2007-BTG001-009</td> <td>38</td> <td>Female</td>	9	2007-BTG001-009	38	Female
12 2007-BTG001-012 51 Female 13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female <td>10</td> <td>2007-BTG001-010</td> <td>48</td> <td>Female</td>	10	2007-BTG001-010	48	Female
13 2007-BTG001-013 36 Female 14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-024 55 Female 26 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female <td>11</td> <td>2007-BTG001-011</td> <td>48</td> <td>Female</td>	11	2007-BTG001-011	48	Female
14 2007-BTG001-014 34 Female 15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	12	2007-BTG001-012	51	Female
15 2007-BTG001-015 50 Female 16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	13	2007-BTG001-013	36	Female
16 2007-BTG001-016 54 Female 17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	14	2007-BTG001-014	34	Female
17 2007-BTG001-017 50 Female 18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	15	2007-BTG001-015	50	Female
18 2007-BTG001-018 45 Female 19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	16	2007-BTG001-016	54	Female
19 2007-BTG001-019 55 Female 20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	17	2007-BTG001-017	50	Female
20 2007-BTG001-020 53 Female 21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	18	2007-BTG001-018	45	Female
21 2007-BTG001-021 29 Male 22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	19	2007-BTG001-019	55	Female
22 2007-BTG001-022 25 Male 23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	20	2007-BTG001-020	53	Female
23 2007-BTG001-023 49 Female 24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	21	2007-BTG001-021	29	Male
24 2007-BTG001-024 55 Female 25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	22	2007-BTG001-022	25	Male
25 2007-BTG001-025 55 Female 26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	23	2007-BTG001-023	49	Female
26 2007-BTG001-026 54 Female 27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	24	2007-BTG001-024	55	Female
27 2007-BTG001-027 27 Female 28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	25	2007-BTG001-025	55	Female
28 2007-BTG001-028 55 Female 29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	26	2007-BTG001-026	54	Female
29 2007-BTG001-029 49 Male 30 2007-BTG001-030 53 Female	27	2007-BTG001-027	27	Female
30 2007-BTG001-030 53 Female	28	2007-BTG001-028	55	Female
	29	2007-BTG001-029	49	Male
31 2007-RTG001-031 47 Female	30	2007-BTG001-030	53	Female
2007 B10001 001 47 1 emale	31	2007-BTG001-031	47	Female
32 2007-BTG001-032 42 Female	32	2007-BTG001-032	42	Female
33 2007-BTG001-033 27 Female	33	2007-BTG001-033	27	Female
34 2007-BTG001-034 51 Female	34	2007-BTG001-034	51	Female
Average 47.44 Male: 3	Average		47.44	
Standard deviation (SD) 9.58 Female : 31	Standar	d deviation (SD)	9.58	Female: 31





2. Evaluation results of safety using patch test

(1) Safety assessment of the test material #1

34 subjects		Male: 3 / Female: 31		Test material #1 : Dr.LIBEAUTE HAND SANITIZER(GEL TYPE)			
No.	Subject identification code	Age	Gender	after 30 min.	after 24 hrs.	after 48 hrs	
1	2007-BTG001-001	55	Female	_	_	_	
2	2007-BTG001-002	55	Female	_	_	_	
3	2007-BTG001-003	56	Female	_	_	_	
4	2007-BTG001-004	49	Female	_	_	_	
5	2007-BTG001-005	46	Female	_	_	_	
6	2007-BTG001-006	58	Female	_	_	_	
7	2007-BTG001-007	55	Female	_	_	_	
8	2007-BTG001-008	59	Female	_	_	_	
9	2007-BTG001-009	38	Female	_	_	_	
10	2007-BTG001-010	48	Female	_	_	_	
11	2007-BTG001-011	48	Female	_	_	_	
12	2007-BTG001-012	51	Female	_	_	_	
13	2007-BTG001-013	36	Female	_	_	_	
14	2007-BTG001-014	34	Female	_	_	_	
15	2007-BTG001-015	50	Female	_	_	_	
16	2007-BTG001-016	54	Female	_	_	_	
17	2007-BTG001-017	50	Female	_	_	_	
18	2007-BTG001-018	45	Female	_	_	_	
19	2007-BTG001-019	55	Female	_	_	_	
20	2007-BTG001-020	53	Female	_	_	_	
21	2007-BTG001-021	29	Male	_	_	_	
22	2007-BTG001-022	25	Male	_	_	_	
23	2007-BTG001-023	49	Female	_	_	_	
24	2007-BTG001-024	55	Female	_	_	_	
25	2007-BTG001-025	55	Female	_	_	_	
26	2007-BTG001-026	54	Female	_	_	_	
27	2007-BTG001-027	27	Female	_	_	_	
28	2007-BTG001-028	55	Female	_	_	_	
29	2007-BTG001-029	49	Male	_	_	_	
30	2007-BTG001-030	53	Female	_	_	_	
31	2007-BTG001-031	47	Female	_	_	-	
32	2007-BTG001-032	42	Female	_	_	-	
33	2007-BTG001-033	27	Female	_	_	_	
34	2007-BTG001-034	51	Female	_	_	_	
			±	0.0	0.0	0.0	
Grading of skin reaction			+	0.0	0.0	0.0	
Grading of skin reactio		71.1	++	0.0	0.0	0.0	
			+++	0.0	0.0	0.0	
	Mean score			0.00			
	Decision			Non i	rritant		





(2) Safety assessment of the test material #2

34 subjects		Male: 3 / Female: 31		Test material #2 : Dr.LIBEAUTE HAND SANITIZER(STRAY TYPE)				
No.	Subject identification code	Age	Gender	after 30 min.	after 24 hrs.	after 48 hrs.		
1	2007-BTG001-001	55	Female	_	_	_		
2	2007-BTG001-002	55	Female	_	_	_		
3	2007-BTG001-003	56	Female	_	_	_		
4	2007-BTG001-004	49	Female	_	_	_		
5	2007-BTG001-005	46	Female	_	_	_		
6	2007-BTG001-006	58	Female	_	_	_		
7	2007-BTG001-007	55	Female	_	_	_		
8	2007-BTG001-008	59	Female	_	_	_		
9	2007-BTG001-009	38	Female	_	_	_		
10	2007-BTG001-010	48	Female	_	_	_		
11	2007-BTG001-011	48	Female	_	_	_		
12	2007-BTG001-012	51	Female	_	_	_		
13	2007-BTG001-013	36	Female	_	_	_		
14	2007-BTG001-014	34	Female	_	_	_		
15	2007-BTG001-015	50	Female	_	_	_		
16	2007-BTG001-016	54	Female	_	_	_		
17	2007-BTG001-017	50	Female	_	_	_		
18	2007-BTG001-018	45	Female	_	_	_		
19	2007-BTG001-019	55	Female	_	_	_		
20	2007-BTG001-020	53	Female	_	_	_		
21	2007-BTG001-021	29	Male	_	_	_		
22	2007-BTG001-022	25	Male	_	_	_		
23	2007-BTG001-023	49	Female	_	_	_		
24	2007-BTG001-024	55	Female	_	_	_		
25	2007-BTG001-025	55	Female	_	_	_		
26	2007-BTG001-026	54	Female	_	_	_		
27	2007-BTG001-027	27	Female	_	_	_		
28	2007-BTG001-028	55	Female	_	_	_		
29	2007-BTG001-029	49	Male	_	_	_		
30	2007-BTG001-030	53	Female	_	_	_		
31	2007-BTG001-031	47	Female	_	-	_		
32	2007-BTG001-032	42	Female	_		_		
33	2007-BTG001-033	27	Female		_	_		
34	2007-BTG001-034	51	Female	_	-	_		
			±	0.0	0.0	0.0		
Grading of skin reaction			+	0.0	0.0	0.0		
	Grading of Skill reduction	11	++	0.0	0.0	0.0		
			+++	0.0	0.0	0.0		
	Mean score		0.00					
	Decision			Non irritant				





[Appendix 2] Ingredients of Test Materials

Dr.LIBEAUTE HAND SANITIZER(GEL TYPE) (Test material #1)

Alcohol, Water, Glycerine, Carbomer, Triethanolamine, Tocopheryl acetate, Pinus Koraiensis Seed Extract, Camellia Sinensis Seed Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Mentha Piperita (Peppermint) Oil, Aloe Barbadensis Leaf Extract, Butylene Glycol, 1,2-Hexanediol, Denatonium Benzoate

Dr.LIBEAUTE HAND SANITIZER(SPRAY TYPE) (est material #2)

Alcohol, Water, Glycerine, Citrus Limon (Lemon) Fruit Oil, Eucalyptus Globulus Leaf Oil, Pinus Koraiensis Seed Extract, Camellia Sinensis Seed Extract, Aloe Barbadensis Leaf Extract, Butylene Glycol, 1,2-Hexanediol, Tocopheryl acetate, Denatonium Benzoate

