

EL-241126616-02

Clinical Trial Report

BIO BIOPHARMACEUTICAL COMPANY LIMITED

**Evaluation of cutaneous tolerance of
Deepclean Oil Makeup Remover Keyshu
by primary irritant patch test**

December 27, 2024

Ellead Co., Ltd.



Table of contents

Authentication.....	3
Ellead IRB notice of approval	4
Quality assurance certification.....	5
Summary of clinical study.....	6
Study contents.....	7
Method.....	9
Results.....	15
Conclusion.....	17
References	18
Attachment 1. Details of results	19
Attachment 2. Career of research director.....	20
Attachment 3. Career of quality assurance director	25
Attachment 4. Career of researcher	27
Attachment 5. Career of product management staff	29
Attachment 6. Research facilities	30

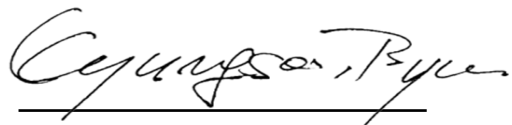
Authentication

This clinical study requested by BIO BIOPHARMACEUTICAL COMPANY LIMITED for the evaluation of cutaneous tolerance of Deepclean Oil Makeup Remover Keyshu by primary irritant patch test have been conducted after the approval based on standard operating procedures of Ellead IRB following Ministry of Food and Drug Safety (MFDS) regulations for approval regarding the functional cosmetics (2021-55)¹, Personal Care Products Council (PCPC) Safety Evaluation Guidelines² and Draize Dermal Irritation Scoring System³ with clinical reading according to the EPA (Environmental Protection Agency) Standard Evaluation Procedure Dermal Classification System⁴ as the standard.

December 27, 2024


Research institution: Ellead Co., Ltd.

Representative director:



Kyung Soo Byun
President

Research director:



Tae Kee Moon, M.D.
Dermatologist

Ellead IRB notice of approval

IRB No.	IRB-241202T001-01
Study No.	EL-241126616-02
Requesting institution	BIO BIOPHARMACEUTICAL COMPANY LIMITED
Research director	Tae Kee Moon
Study title	Evaluation of cutaneous tolerance of M-241126616-02 by primary irritant patch test

The clinical study has been approved by Ellead Institutional Review Board

- ※ Ellead Institutional Review Board acknowledges that the details of the above presented notice of approval are in accord with the records of Ellead Institutional Review Board.
- ※ Ellead Institutional Review Board complies with the relevant laws and regulations such as KGCP, Cosmetics Act, and Bioethics and Safety Act.
- ※ Any IRB members with conflict of interest were excluded from the review process.

December 27, 2024

Ellead Institutional Review Board

Quality assurance certification

Study title: Evaluation of cutaneous tolerance of Deepclean Oil Makeup Remover

Keyshu by primary irritant patch test

Study number: EL-241126616-02

This study was inspected by the quality assurance director, and the report was submitted to the research director in accordance with standard operating procedures, as follows:

<u>Phase</u>	<u>Date</u>
Date of experiment protocol approval	December 06, 2024
Date of approval from IRB review	December 09, 2024
Product test audit	December 10, 2024 – December 13, 2024
Data audit	December 16, 2024
Final report review	December 23, 2024
Approval by research director	December 27, 2024

This study has been conducted in compliance with the standard operating procedures and clinical test method of Ellead Co., Ltd. It has been confirmed that the results reported closely reflect the experimental data.

December 27, 2024

Quality assurance director: _____



Sun Hwa Lee, M.S.

Summary of clinical study

Study title	Evaluation of cutaneous tolerance of Deepclean Oil Makeup Remover Keyshu by primary irritant patch test
Study number	EL-241126616-02
Requesting institution	BIO BIOPHARMACEUTICAL COMPANY LIMITED Lot D10-1, Tan Trieu Craft Village Industrial Cluster, Trieu Khuc Village, Tan Trieu Commune, Thanh Tri District, Hanoi City, Vietnam
Research institution	Ellead Co., Ltd. 7&8 fl., 325, Hwangsaеul-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea
Duration of the study	December 09, 2024 – December 27, 2024
Name of test product (product management number)	Deepclean Oil Makeup Remover Keyshu (M-241126616-02)
Method	24 hours single occlusive patch test 1. Volunteers: minimum 30 males and females of age 20 to 60 years 2. Procedure: 24 hours single application occlusive patch test on the back 3. Evaluation: Observations at 30 minutes, 24 hours and 48 hours after the removal of the test product by reading of skin reactions using a 5-point scale (each erythema, eschar and edema) 4. Test method and results assessment: In accordance with MFDS regulations for approval regarding the functional cosmetics (2021-55), PCPC Safety Evaluation Guidelines and Draize Dermal Irritation Scoring System with clinical reading according to the EPA Dermal Classification System criteria as a standard 5. Assessment of adverse skin reactions by volunteer and dermatologists
Results	1. Volunteers: 34 (final 34 females average age 48.24 ± 8.62 years old) 2. Results: The results demonstrated that Deepclean Oil Makeup Remover Keyshu has the grades of “Negligible”. Also the test product did not cause any special adverse skin reactions during the test period other than those foreseeable or concomitant positive reactions of patch tests.
Date of report issue	December 27, 2024
Research director	Tae Kee Moon, M.D.
Quality assurance director	Sun Hwa Lee, M.S.
Researcher	Ha Young Kim, B.S. / Hye Ji Lee, M.S. / Eun Jung Lee, B.S. / Min Young Jung
Product management staff	Ga Eun Yoo

Study contents

1. Objective

The purpose of this clinical study was the evaluation of skin irritation potential of Deepclean Oil Makeup Remover Keyshu after a single application under occlusive patch on human skin.

2. Duration of study

December 09, 2024 – December 27, 2024

(Test period: December 10, 2024 – December 13, 2024)

3. Research institution

Ellead Co., Ltd.

Address : 7&8 fl., 325, Hwangsaeul-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea

E-mail : hykim77@ellead.co.kr Homepage : www.ellead.com

Tel : +82-31-709-9070 Fax : +82-31-703-9071

4. Requesting institution

BIO BIOPHARMACEUTICAL COMPANY LIMITED

Address : Lot D10-1, Tan Trieu Craft Village Industrial Cluster, Trieu Khuc Village, Tan Trieu Commune, Thanh Tri District, Hanoi City, Vietnam

5. Information of test product

1) List of test product

No.	Name (product management number)	Formulation	Conc.
1	Deepclean Oil Makeup Remover Keyshu (M-241126616-02)	Liquid	1% in DW

2) Test products handling

Upon arrival at Ellead Co., Ltd., test products were assigned with the individual code number. The recipient, the date of receipt, the assigned code number and requesting institution were then recorded in test product management log. The standard products will be retained for a period of 3 years at the product storage facility.

3) Safety and specification

The requesting institution shall take full responsibility for the safety of test substance and for any abnormal response that might happen during the test period.

Method

1. Volunteers

1) Inclusion criteria

- 20 to 60 years old male and female.
- Those who fully understand the objective and contents of the study and voluntarily decided to participate.
- Those who understand the possible adverse reactions and sign the informed consent form.
- Those who do not have acute or chronic diseases including skin diseases which can affect the study (severe infections or eczematous skin diseases including atopic dermatitis).
- Those who are physically available for observations throughout the entire study.
- Those who are able to visit the laboratory according to set schedules and follow the study instructions.

2) Exclusion criteria

- Those who have experienced allergic reactions to cosmetics and tape or have sensitive and hyper-sensitive skin.
- Those who are pregnant, breast feeding or planning pregnancy.
- Those who have prominent nutrition disorder.
- Those who are drug addict or alcoholic.
- Those who have moles, acne, tattoo, scars, red spots, telangiectasis, burns, etc. on the test site.
- Those who have participated in the same clinical evaluation within 3 months.

- Those who have been using steroid or retinoid for treatment of skin disease more than 1 month or are taking medicines which can affect the skin (e.g. anti-histamines, immunosuppressants).
- Those who are participating in the same clinical study/studies conducted by Ellead or other clinical institution on the same body/bodies.
- Those who have otherwise been judged by the research director to be unsuitable for enrollment in this clinical trial.

3) Volunteer restrictions

- Avoid cleansing of the test site until the patch is removed.
- Avoid sauna or any action that could affect the test site (physiotherapy, cupping, pain relieving patch, electric heating pad, etc.).
- Avoid use of cosmetics (body wash, soap, lotion, etc.) on the test site.
- Avoid exposure to the sun.
- Avoid excessive smoking or drinking.

4) Volunteer withdrawal criteria

- Those who fail to comply with the study instructions/restrictions or schedules.
- Those who experience serious adverse reactions or request to withdraw due to adverse reactions.
- Those who cannot continue with the study due to an occurrence of skin disease
- The test results are affected by excessive drinking or smoking, etc.
- Those who request to withdraw from the study or cannot be followed up due to personal circumstances.
- Those who have taken medicines which can affect the test results during test period.

- Research director judges that continued participation is inappropriate or is not in the volunteer's best interest.

5) Volunteer selection

The final 34 volunteers who met inclusion criteria and does not meet exclusion was assessed for cutaneous tolerance of the test product by primary irritant patch test.

2. Confidentiality of the information

- 1) Volunteers' identities are guaranteed by the confidentiality regulation. However, for medical, academic, research, or marketing purposes they can be released preserving the volunteers' anonymity.
- 2) Volunteers must keep information confidential until the end of the test.
- 3) Each volunteer must fill in the informed consent honestly. Their personal information will be kept secure. The signed consent forms are available for inspection on the premises of Ellead Co., Ltd.

3. Evaluation

The volunteers visited the research institution for total of 3 times on patch application day (day 1), patch removal day (day 2), 24 hours (day 3) and 48 hours (day 4) after the removal of the patch test strips and the test site was assessed by the researcher for skin irritation.

1) Application of test product

On the first visit, the volunteers were briefed carefully and precisely on the study objectives, experimental methods and foreseeable potential risks. Those who voluntarily decided to participate in the study signed informed consent forms by filling out case report forms. After completion of the forms, patch test was performed on the back of the volunteers.

The test product was applied to 34 volunteers between shoulder blades and waist lines on the back using Van der Bend chambers (Van der Bend, Brielle, the Netherlands) in case of occlusive patch application. The wash-off product was diluted to 1% in distilled water.

For 24 hours occlusive patch application, the site was first wiped with cotton wool soaked in distilled water, and approximately 35 µL of Deepclean Oil Makeup Remover Keyshu was placed on Van der Bend chambers.

2) Patch removal and observation of test site

The patch was removed and the test site was wiped with distilled water and dried to mark the site with a marking pen. The test site was observed after 30 minutes, 24 hours and 48 hours.

3) Evaluation of test sites

Visual grading for skin irritation was conducted at 30 minutes, 24 hours and 48 hours after the removal of patch. The skin reactions were scored according to the Draize Dermal Irritation Scoring System as shown in Table 1. The results were analyzed by calculating the Mean Irritation Index (M.I.I.) according to the formula. The calculated indirect Mean Irritation Index (M.I.I.) was classified according to EPA (Environmental Protection Agency) Standard Evaluation Procedure Dermal Classification System, as shown in Table 2.

4. Assessment of adverse skin reactions by researcher and volunteers

The test area was closely observed and examined for adverse skin reactions. If any adverse skin reactions other than the foreseeable or concomitant positive reactions of patch tests were observed, further assessment was carried out in accordance with Ellead adverse reactions regulation.

5. Archiving

All original products, raw data, technician's notebooks, correspondence files, copies of final reports and remaining specimens are maintained on the premises of Ellead Co., Ltd.

Table 1. Clinical evaluation criteria of Draize Dermal Irritation Scoring System

Erythema and Eschar Formation	Value	Edema Formation	Value
No erythema	0	No edema	0
Very slight erythema (barely perceptible)	1	Very slight edema (barely perceptible)	1
Well-defined erythema	2	Slight edema (edges of area well-defined by definite raising)	2
Moderate-to-severe erythema	3	Moderate edema (raised approximately 1 mm)	3
Severe erythema (beet redness) to slight, eschar formation (injuries in depth)	4	Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4

※ The formula of Mean Irritation Index (M.I.I.)

$$\text{Mean Irritation Index} = \frac{\text{Sum of 2 irritation scores of each volunteer}}{\text{Number of volunteer} \times 3}$$

Table 2. Analysis of results according to EPA Dermal Classification System

Grade	M.I.I.
Negligible	$0.00 \leq \text{M.I.I.} < 0.50$
Slight	$0.50 \leq \text{M.I.I.} < 2.00$
Moderate	$2.00 \leq \text{M.I.I.} < 5.00$
Strong	$5.00 \leq \text{M.I.I.} \leq 8.00$

Results

1. Volunteers

The final 34 volunteers completed this study, and the information and age grouping of the volunteers are shown below (Table 3, 4 / Figure 1).

Table 3. The information of volunteers

Number of volunteers enrolled	34
Number of volunteers completing the study	34
Average of age (Stdev.)	48.24 (8.62)
Sex	Female (34)

Table 4. Age distribution of volunteers

Age	20s	30s	40s	50s	60s	Total
n (%)	2 (5.88)	2(5.88)	12 (35.29)	17 (50.00)	1 (2.94)	34 (100.00)

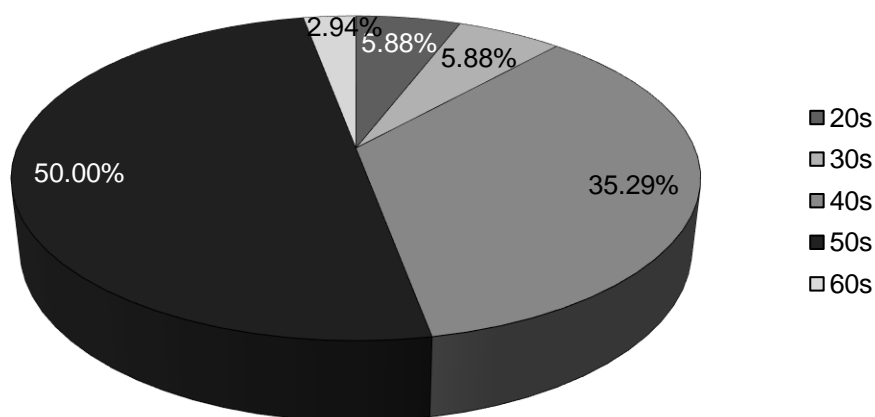


Figure 1. Age groupings of the volunteers

2. Results

No.	Name of test product	Number of volunteers who showed reaction		Irritation Scoring Value												M.I.I.
				After 30 mins				After 24 hrs				After 48 hrs				
				1	2	3	4	1	2	3	4	1	2	3	4	
#1	Deepclean Oil Makeup Re mover Keyshu	Erythema	1	1	-	-	-	-	-	-	-	-	-	-	0.01	
		Edema	0	-	-	-	-	-	-	-	-	-	-	-		

Deepclean Oil Makeup Remover Keyshu was graded as “Negligible” with the M.I.I. score of 0.01 according to the analysis system in Table 2.

The test results of each volunteer are shown in Table 5. (Attachment 1).

3. Assessment of adverse skin reactions

The results of assessment of adverse skin reactions on the final 34 volunteers showed that the test product did not cause any special adverse skin reactions during the test period other than those foreseeable or concomitant positive reactions of patch tests.

Conclusion

Ellead Co., Ltd. conducted the evaluation of cutaneous tolerance of Deepclean Oil Makeup Remover Keyshu requested by BIO BIOPHARMACEUTICAL COMPANY LIMITED by primary irritant patch test with final 34 volunteers.

The results demonstrated that Deepclean Oil Makeup Remover Keyshu has the grades of “Negligible”.

Also the test product did not cause any special adverse skin reactions during the test period other than those foreseeable or concomitant positive reactions of patch tests.

This study was inspected in accordance with the standard operating procedures of Ellead Co., Ltd. To assure compliance with the study protocol, the quality assurance unit completed an audit of the study results and final report.

References

1. Ministry of Food and Drug Safety (MFDS) regulations for approval regarding the functional cosmetics (2021-55)
2. PCPC Safety Evaluation Guidelines. 2014, 23-24
3. Draize, J.H., Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, The Association of Food and Drug Officials of the United States, Austin, TX, 1959, p.49
4. U.S. Environmental Protection Agency, Federal Insecticide, Fungicide, Rodenticide Act, Pesticide Assessment Guidelines, Hazard Evaluation Division, Standard Evaluation Procedure, Guidance for Evaluation of Dermal Irritation Testing, 1984, 1.

Attachment 1. Details of results

- The result was summarized and analyzed in Table 5.

Table 5. Summary and individual results of cutaneous tolerance evaluation

Test product #1		Deepclean Oil Makeup Remover Keyshu					
Actual test period		December 10, 2024 – December 13, 2024					
Volunteers		Final 34		Age		23 – 60 (48.24 ± 8.62 as average)	
Reaction No.		After 30 minutes		After 24 hours		After 48 hours	
		Erythema	Edema	Erythema	Edema	Erythema	Edema
1		-	-	-	-	-	-
2		-	-	-	-	-	-
3		-	-	-	-	-	-
4		-	-	-	-	-	-
5		-	-	-	-	-	-
6		-	-	-	-	-	-
7		-	-	-	-	-	-
8		-	-	-	-	-	-
9		-	-	-	-	-	-
10		-	-	-	-	-	-
11		-	-	-	-	-	-
12		-	-	-	-	-	-
13		-	-	-	-	-	-
14		-	-	-	-	-	-
15		1	-	-	-	-	-
16		-	-	-	-	-	-
17		-	-	-	-	-	-
18		-	-	-	-	-	-
19		-	-	-	-	-	-
20		-	-	-	-	-	-
21		-	-	-	-	-	-
22		-	-	-	-	-	-
23		-	-	-	-	-	-
24		-	-	-	-	-	-
25		-	-	-	-	-	-
26		-	-	-	-	-	-
27		-	-	-	-	-	-
28		-	-	-	-	-	-
29		-	-	-	-	-	-
30		-	-	-	-	-	-
31		-	-	-	-	-	-
32		-	-	-	-	-	-
33		-	-	-	-	-	-
34		-	-	-	-	-	-
Intensity of the reaction	1	1	0	0	0	0	0
	2	0	0	0	0	0	0
	3	0	0	0	0	0	0
	4	0	0	0	0	0	0
M.I.I. score		0.01					
Grade		Negligible					

Attachment 2. Career of research director

Tae Kee Moon

1. Academic career

- 1982.03 – 1989.02 B.M. in College of Medicine, Yonsei University
1995.03 – 1997.06 M.S. in College of Medicine, Graduate School of Yonsei University
1998.03 – 2003.02 Ph.D. in Medical Science, College of Medicine, Graduate School of Yonsei University

2. Career

- 1989.03 Licensed Doctor (License No. ; 38101)
1992.04 – 1993.02 Intern, Sinchon Severance Hospital affiliated to College of Medicine, Yonsei University
1993.03 – 1997.02 Residency, Department of Dermatology, College of Medicine, Yonsei University
1997.03 – 1998.02 Instructor, Department of Dermatology, College of Medicine, Yonsei University
1997 Clinical Fellowship, Dermatopathology Laboratory, Kawasaki Medical University
1997.03 Qualified Dermatology Specialist (Qualification No. ; 903)
1998.03 – 1999.12 Professor, Department of Dermatology, College of Medicine, Kwandong University
2000.01 – present Director, Yonsei Monet Dermatologic Clinic Adjunct Assistant Professor
Department of Dermatology, College of Medicine, Yonsei University Adjunct Associated Professor
Department of Dermatology, College of Medicine, Ajou University Adjunct Associated Professor
Department of Dermatology, College of Medicine, Pochon Cha University
2001.02 – present Research Director, Ellead Co., Ltd.

3. Academic activity

The Regular Member of Korean Dermatological Association

The Regular Member of the Korean Society for investigative Dermatology

The Regular Member of Korean Dermatopathology Association

The Regular Member of International Society for Dermatologic Surgery

4. Research experience

1) Published articles

- (1) Tae Kee Moon, Beom Joo Lee, Seung Hun Lee, Seong Koo Ahn, Won Soo Lee. Leukemic Macrocheilia Associated with Chronic Lymphocytic Leukemia. Kor J Dermatol 1994; 32(6): 114-118.
- (2) Tae Kee Moon, Juho Yoon, Kwang Hoon Lee. Two Cases of Pigmentary Demarcation Lines Associated with Pregnancy. Kor J Dermatol 1994; 32(5): 903-906.
- (3) Tae Kee Moon, Sung Nam Chang, Soo Chan Kim. Skin Rash in a Patient with Infectious Mononucleosis after the Intake of Ampicillin. Kor J Dermatol 1994; 32(6): 1095-1098.
- (4) Juho Yoon, Tae Kee Moon, Kwang Hoon Lee, Soo Chan Kim. Fetal vascular involvement in SLE following epidermolysis bullosa acquisita. Acta Derm Venereol 1995; 75: 143-146.
- (5) Tae Kee Moon, Hee Sung Kim, Min Geol Lee. Frey's Syndrome in a Child without Definite Causes. Kor J Dermatol 1995; 33(4): 733-737.
- (6) Tae Kee Moon, Sung Bin Yim, Seung Kyung Hann, Sung Whan Cho, Yoon Kee Park. The Effect of Small Doses of Oral Corticosteroids in Vitiligo Patients. Kor J Dermatol 1995; 33(5): 880-885.
- (7) Myung Soo Cha, Tae Kee Moon, Ewn So Lee, Won Hyoung Kang, Sunghack Lee. Spindle cell lipoma of the palm. Kor J Dermatol 1996; 34(5): 847-850.
- (8) Han Seung Lee, Tae Kee Moon, Kwang Hoon Lee, Dongsik Bang. Variations of serum-soluble E-selectin and soluble ICAM1 in patients with Behcet's disease. Kor J Dermatol 1996; 34(5): 847-850.

- (9) Tae Kee Moon, Seung Kyung Hann, Yoon Kee Park, Han Seung Lee. Differences in Expression of HLA Antigens among Subtypes of Vitiligo. Korean J Dermatol 1998; 36(6): 981-989.
- (10) Sang Ju Lee, Tae Kee Moon, Seung Kyung Hann. Two cases of cutaneous larva migrans. Annals of Dermatology 1998; 10: 61-63.
- (11) Mira Yoon, Seung Kyung Hann, Tae Kee Moon, Min Geol Lee. Acantholytic dyskeratotic epidermal nevus induced by ultraviolet B radiation. JAAD 1998; 39: 301-4.
- (12) Yun Seong Jeon, Tae Kee Moon, Min Geol Lee, Kyung Il Im. Loiasis. Yonsei Med J 1998; 39: 184-188.
- (13) Jung Hoan Yoo, Woo Taek Chun, Eun Young Oh, Tae Kee Moon, Soo Min Kim, Seung Kyung Hann, Woo Taek Chun. The Relationship between Coping Mechanisms and Psychological Symptoms in Vitiligo Patients. Korean J Dermatol 1998; 36(6): 990-996.
- (14) Ho Jung Lee, Tae Kee Moon, Min Geol Lee, Jung Bock Lee. Histopathologic Finding and Modulation of Expression of The Cell Surface Molecules in The Primary Syphilitic Lesions of a Rabbit Infected with Treponema pallidum. Korean J Dermatol 1999; 37(8): 1038-1046.
- (15) Kyung Jin Moon, So Un Kim, Ju Hee Moon, Su Jin Kim, A Young Kim, Tae Kee Moon, Nam Soo Kim. Study on the Sun Protection Factor (SPF) Test Method for Sun Product Water Resistance. Society of Cosmetic Scientists of Korea 2008; 34(1): 63-66.
- (16) Suh Hee Choi, Hyun Ju Kim, Bum Chun Lee, Tae Kee Moon, Nam Soo Kim. Clinical Evaluation of Residual Effectiveness of Antibacterial Agents. Society of Cosmetic Scientists of Korea 2013; 39(2): 133-140.
- (17) Sun Hwa Lee, Jung Im Lee, Yoo-Ri Kim, Bum Chun Lee, Min Ji Kang, Kwang Seong Choi, Tae Kee Moon. Use of Oil Red O Staining Method in Non-Comedogenic Test for Cosmetics. Society of Cosmetic Scientists of Korea 2013; 39(3): 215-224.

- (18) Mi Seon Woo, Kyung Jin Moon, Ho Young Jung, Sae Rom Park, Tae Kee Moon, Nam Soo Kim, Bum Chun Lee. Comparison of skin elasticity test results from the Ballistometer® and Cutometer®. *Skin Res Technol* 2014; 20: 422-428.
- (19) Eun Jeong Song, Jung A Lee, Jung Jun Park, Hyun Ju Kim, Nam Soo Kim, Kyung Soo Byun, Gwang Seong Choi, Tae Kee Moon. A study on seasonal variation of skin parameters in Korean males. *International Journal of Cosmetic Science* 2014, 1-6, doi:10.1111/ics.12174.
- (20) Hye Kyong Park, Nam Soo Kim, Tae Kee Moon, Bora Kim, Ho Young Jung, A Comparison Study between Image Analysis and Conventional Methods in the Evaluation of Asian Skin Color, *Society of Cosmetic Scientists of Korea* 2015;41(2):97-103.
- (21) Sae Rom Park, Hyun Ju Kim, Hye Kyong Park, Ju Yeon Kim, Nam Soo Kim, Kyung Soo Byun, Tae Kee Moon, Ji Won Byun, Jong Hyuk Moon, Gwang Seong Choi. Classification by causes of dark circles and appropriate evaluation method of dark circles. *Skin Res Technol* 2016; 22(3): 276-283.
- (22) Sung Hae Bae, Jung Jun Park, Eun Jeung Song, Jung Ah Lee, Kyung Soo Byun, Nam Soo Kim, Tae Kee Moon. The comparison of the melanin content and UV exposure affecting aging process: seven countries in Asia. *J Cosmet Dermatol*, 2016; 15(4):335-342.
- (23) Jung Ah Lee, Eun Jeung Song, Jung Jun Park, Hyun Ju Kim, Sin Hae Kim, Nam Soo Kim, Tae Kee Moon. The Comparison of Skin Physical Parameters in Asian Women. *Journal of the Society of Cosmetic Scientists of Korean* 2017; 43(4); 297-307.
- (24) Sun Hwa Lee, Jung Ah Lee, Sun Mi Park, Younghee Kim, Yoon Jung Jang, Bora Kim, Nam Soo Kim, Tae Kee Moon. Digitization of Adjectives that Describe Facial Complexion to Evaluate Various Expressions of Skin Tone in Korean. *Journal of the Society of Cosmetic Scientists of Korean* 2017; 43(4); 349-355.
- (25) Sung-Il Yun, Sang-Kyu Lee, Eun-Ah Goh, Oh Seung Kwon, Woorim Choi, Jangseon Kim, Mi Sun Lee, Soon Ja Choi, Seung Sik Lim, Tae Kee Moon,

Sin Hae Kim, Keeyeol Kyong, Gaewon Nam, Han-Oh Park. Weekly treatment with SAMiRNA targeting the androgen receptor ameliorates androgenetic alopecia. Scientific Reports 2022; 12(1); 1-15

- (26) Sun Hwa Lee, Hye Kyong Park, Hye Ji Lee, Ah Reum Jo, Eun-Ju Lee, Se-Hee Hwang, Hee-Chul Chung, Jin-Hee Lee, Do-Un Kim, Jongsung Lee, Tae Kee Moon. Oral Supplementation with Low-molecular-weight Collagen Peptide Improves Hydration, Facial Lifting, Dermal Density, Skin Desquamation and Nails: A Randomized, Double-blind, Placebo-controlled, and Maintenance of Effect Study J.FNR,2022, Vol.10,No.8,546-559.

Attachment 3. Career of quality assurance director

Sun Hwa Lee

1. Academic career

- 2002.03– 2006.02 B. S. in Department of chemistry, College of natural science, Inha University
- 2006.03 – 2009.02 M. S. in Molecular genomic medicine College of medicine, Seoul National University

2. Career

- 2009.01 – present Senior Researcher, Ellead Co., Ltd.
- 2016.04 – 2017.02 Quality Assurance Manager of GLP, Ellead Co., Ltd.
- 2017.03 – 2018.08 Quality Assurance Director of GLP, Ellead Co., Ltd.
- 2019.03 – present Quality Assurance Director, Ellead Co., Ltd.

3. Research experience

1) Published articles

- (1) Sun Hwa Lee et al. Role of Transglutaminase 2 in Melanogenesis (2009).
- (2) Jang GY, Jeon JH, Cho SY, Shin DM, Kim CW, Jeong EM, Bae HC, Kim TW, Lee SH, Choi Y, Lee DS, Park SC, Kim IG. Transglutaminase 2 suppresses apoptosis by modulating caspase 3 and NF-kappaB activity in hypoxic tumor cells. *Oncogene* 2010; 29(3): 356-367.
- (3) Sun Hwa Lee, Jung Im Lee, Yoo-Ri Kim, Bum Chun Lee, Min Ji Kang, Kwang Seong Choi, Tae Kee Moon. Use of Oil Red O Staining Method in Non-Comedogenic Test for Cosmetics. *Society of Cosmetic Scientists of Korea* 2013; 39(3): 215-224.
- (4) Jung Ah Lee, Ju Yeon Kim, Sun Hwa Lee, Bora Kim, Nam Soo Kim, and Tae Kee Moon. Use of Redness Assessment in Melasma Lesions in Skin Whitening Evaluation *Journal of the Society of Cosmetic Scientists of Korea* 2016; 42(4); 337-342.
- (5) Sun Hwa Lee, Jung Ah Lee, Sun Mi Park, Younghee Kim, YoonJung Jang,

Bora Kim, Nam Soo Kim and Tae Kee Moon. Digitization of Adjectives that Describe Facial Complexion to Evaluate Various Expressions of Skin Tone in Korean, J.Soc.Cosmet. Sci. Korea 2017; Vol. 43; No. 4.

(6) Hye-ji Lee, YoonJung Jang, Bora Kim, Tae Kee Moon, Nam Soo Kim and Sun Hwa Lee. The Differentiation Criteria between Greasiness and Shininess on The Face Using Mechanical Evaluation and Image, J.Soc.Cosmet. Sci. Korea 2018; Vol. 44; No.3.

(7) Sun Hwa Lee, Hye Kyong Park, Hye Ji Lee, Ah Reum Jo, Eun-Ju Lee, Se-Hee Hwang, Hee-Chul Chung, Jin-Hee Lee, Do-Un Kim, Jongsung Lee, Tae Kee Moon. Oral Supplementation with Low-molecular-weight Collagen Peptide Improves Hydration, Facial Lifting, Dermal Density, Skin Desquamation and Nails: A Randomized, Double-blind, Placebo-controlled, and Maintenance of Effect Study J.FNR,2022, Vol.10,No.8,546-559.

Attachment 4. Career of researcher

Ha Young Kim

1. Academic career

2006.03 – 2010.02 B.S. in department of Life Sciences, College of Natural Sciences, Suwon University

2. Career

2011.07 – present Senior Researcher, Ellead Co., Ltd.

Hye Ji Lee

1. Academic career

2008.03 – 2012.02 B.S. in Department of Biomedical Laboratory Science, College of Medical Science, Konyang University

2012.03 – 2014.02 M.S. in Biotechnology, College of Natural Science, Konkuk University

2. Career

2012.08 Licensed Medical technologists (License No. ; 46961)

2015.03 – present Senior Researcher, Ellead Co., Ltd.

3. Research experience

1) Published articles

(1) Hye-Ji Lee, Kyung-Chul Shin, Gi-Woong Lee, Deok-Kun Oh. Production of aglycone protopanaxatriol from ginseng root extract using *Dictyoglomus turgidum* β -glycosidase that specifically hydrolyzes the xylose at the C-6 position and the glucose in protopanaxatriol-type ginsenosides *Applied Microbiology and Biotechnology* 2014; 98(8): 3659-3667.

(2) Kyung-Chul Shin, Hye-Ji Lee, Deok-Kun Oh Substrate specificity of β -glucosidase from *Gordonia terrae* for ginsenosides and its application in the production of ginsenosides Rg3, Rg2, and Rh1 from ginseng root extract *Journal of Bioscience and Bioengineering* 2015; 119(5): 497–504.

(3) Hye-Ji Lee, YoonJung Jang, Bora Kim, Tae Kee Moon, Nam Soo Kim and Sun Hwa Lee. The Differentiation Criteria between Greasiness and Shininess on The Face Using Mechanical Evaluation and Image, J.Soc.Cosmet. Sci. Korea 2018; Vol. 44; No.3.

(4) Sun Hwa Lee, Hye Kyong Park, Hye Ji Lee, Ah Reum Jo, Eun-Ju Lee, Se-Hee Hwang, Hee-Chul Chung, Jin-Hee Lee, Do-Un Kim, Jongsung Lee, Tae Kee Moon. Oral Supplementation with Low-molecular-weight Collagen Peptide Improves Hydration, Facial Lifting, Dermal Density, Skin Desquamation and Nails: A Randomized, Double-blind, Placebo-controlled, and Maintenance of Effect Study J.FNR,2022, Vol.10,No.8,546-559.

Eun Jung Lee

1. Academic career

2019.02 – 2023.02 B.S. in Medicinal Biosciences, Konkuk University

2. Career

2023.03– present Researcher, Ellead Co., Ltd.

Min Young Jung

2. Career

2024.01 – present Research assistant, Ellead Co., Ltd.

Attachment 5. Career of product management staff

Ga Eun Yoo

1. Academic career

2021.03 – 2023.02 Suwon Science College, Beauty Coordination

2. Career

2022.09 – present Employee, Ellead Co., Ltd.

Attachment 6. Research facilities

[Clinical Test Facilities]

Skin hydration measuring device: Epidermis, Dermis
Skin hydration imaging device
Transepidermal water loss (TEWL) measuring device
Skin sebum measuring device
Skin color measuring device
Skin elasticity measuring device: face, body, local region (e.g. eyelid, lip etc.)
Microcirculation measuring device
Skin pH meter
Skin ultrasonographic imaging device: Dermis, Subcutaneous fat layer
Skin wrinkle, roughness, texture measuring device
2D skin imaging device
3D skin imaging device: face, body
Skin desquamation measuring device
Skin surface imaging device, Skin surface imaging device with magnification
Skin translucency measuring device
Skin gloss measuring device
Facial topography imaging system
High resolution facial imaging system
High resolution wrinkle imaging system: crow's feet, neck, nasolabial region, glabella, forehead
Image analysis program
Skin temperature measuring device
Solar UV simulator: Multiport simulator, Pre-irradiation Solar Simulator
UV detector: UVA, UVB
Hair tensile strength & frictional force measuring device
Hair gloss imaging system
High resolution hair imaging system: crown, hair line, eyebrow
High resolution hair microscope & analysis program
Cellulite photography device, Body fat analyzer, hematomanometer,
Temperature and humidity meter, Anti-adsorption device of fine dust,
Halitosis measuring device, Dental whitening measuring device, Fume hood,
Specialized clean bench for anti-microbial test (with sink)
Microplate reader, Digital Scale, CO₂ incubator, pH meter, Autoclave, Drying Oven
Water bath, Pass box, Thermo-hygrostat and diffuser controller, Thermo-hygrometer
Digital shaker, Clean bench, Raman confocal microspectroscopy

Quality Assurance Room, IRB Room, Safety Lab, Skincare Lab, Anti-Wrinkle Lab, Whitening Lab, SPF / PA Lab, Waterproof System Room, Clinic Lab, Functional Food Lab, Microbial Lab, Fine dust Lab, Hair Lab, Microcirculation Lab, Hair loss Lab, Children's laboratory, Sensory evaluation Lab, Studios, Cleansing Room, Shower bath, Buffer Room, Climate Condition Control Room, Archives, Sample storage room, Waste room

[*In vitro* Test Facilities]

Ultra-Fast high-performance liquid chromatography

Franz diffusion cell system

ELISA reader

UV-VIS Spectrophotometer

Microtome

Drying Oven

Water bath

CO₂ incubator

Incubator for microbe

Shaking incubator

Clean bench

Microscope

Centrifuge

Deep freezer

Liquid nitrogen tank

Mupid-One electrophoresis system

SDS-PAGE electrophoresis system

UV irradiation system

pH meter

Autoclave

Desiccator

Analytical Lab, *In vitro* Lab, Microbial Lab, Cell Culture Lab, Tissue Culture Lab,
Microscope Room, Darkroom, Archives, Sample preprocessing room