24-Hour Occlusive Human Patch Test

(FINAL REPORT)

Product Name: ZAINT FOLLICLE ACTIVATOR SERUM

DRC (Thailand) Co., Ltd.

24-Hour Occlusive Human Patch Test

(English Version)

24-Hour Occlusive Human Patch Test

Test described in this report has been carried out in accordance with SOPs of the agreed test plan between the administrative facility and the sponsor.

For DRC Thailand Co., Ltd. prepared by:

Khemmanat Maneepong 22/08/2025

Khemmanat Maneepong Date:
Safety Evaluation Manager

Written by:

Thanatchaya Suknivatsiri Sasivimol Sanunaue Wissuta Hemwiset 22/08/2025

Thanatchaya Suknivatsiri Date:
Sasivimol Sanunaue
Wissuta Hemwiset
Safety Evaluation Section

This ensures the report is accurately describes the implementation and confirms the test results.

Approved by:

22/08/2025

Churaphon Manee-In Date:
Quality Assurance Manager

Table of Contents

1 Summary

A 24-hour occlusive human patch test was carried out to confirm the safety of the test material, “ZAINT FOLLICLE ACTIVATOR SERUM” with 3 male and 20 female participants. As a result, the “ZAINT FOLLICLE ACTIVATOR SERUM” received a skin irritation score of 0.0. Therefore, under the conditions of this study, “ZAINT FOLLICLE ACTIVATOR SERUM” can be considered a safe and non-irritating product.

2 Study Purpose

The test materials are intended to observe the skin irritation of adult males and females when apply to the human skin for 24 hours single occlusive.

3 Organization Implementing the Study

3.1 Sponsor

Name : ONLINE REVENUE OY
Address : Konepajankuja 1, 00510, HELSINKI , Finland
TEL : - FAX : -
Person in charge : -

3.2 Administrative Facility

Name : DRC (Thailand) Co., Ltd.
Address : 6 Soi Sukhaphiban 2, Soi 11 Yak 2-3, Prawet, Prawet, Bangkok, 10250
TEL : 063-8079598 FAX : -
Managing Director : Chaiwat Klangvijit

Technician:	Thanatchaya	Suknivatsiri	(Safety Evaluation Section)
	Kulanit	Palee	(Safety Evaluation Section)
	Sasivimol	Sanunaue	(Safety Evaluation Section)
	Wissuta	Hemwiset	(Safety Evaluation Section)
	Supicha	Phiriyanantakorn	(Safety Evaluation Section)
Dermatologist:	Janthorn	Krisadapong	(Dermatologist)
	Natwadee	Nimitkul	(Dermatologist)

3.3 Ethical Review Board

Name：Krisada Laboratories Ethical Review Board

Address: 6 Soi Sukhaphiban 2, Soi 11 Yak 2-3, Prawet, Prawet, Bangkok, 10250

Ethic Approval No: K20250619-499

4 Method

4.1 Test Samples Overview

4.1.1. Test Materials

Below shows the name, DRC sample No., methods of preparation and dosage of the test.

Name: ZAINT FOLLICLE ACTIVATOR SERUM

DRC Sample No.: Sample No.40

Method of Preparation: Prepare by using Eppendorf Micropipette and leave it volatilized.

Dosage: 15 μL

4.1.2. Control Substances (Positive Control)

Below shows the name, DRC sample No. and dosage of the control substances.

Name: 0.1% Benzalkonium Chloride (Beijing Sunpu Biochemical and Technology Co., Ltd.)

DRC Sample No.: Sample No.1

Dosage: 15 μL

4.1.3. Control Substances (Negative Control)

Below shows the name, DRC sample No. and dosage of the control substances.

Name: White Petrolatum (Hansen & Rosenthal KG Co., LTD)

DRC Sample No.: Sample No.8

Dosage: 20 μL

Name: Sterile Water for Irrigation (Otsuka Pharmaceutical Co., Ltd.)

DRC Sample No.: Sample No.9

Dosage: 15 μL

Name: Physiological Saline Solution (Otsuka Pharmaceutical Co., Ltd.)

DRC Sample No.: Sample No.10

Dosage: 15 μL

4.2 Test Method

4.2.1. Test Schedule

After obtaining the informed consent and confirming the inclusion criteria respectively, the technician consulted the back (paravertebral area) of each selected subject. Furthermore, the technician determined and photographed the test site where patch test unit to be applied. Then the subjects were applied with test samples using patch test unit with an appropriate dosage. After 24 hours of application the patch was removed by the subjects themselves. Test area was photographed by the technician after 1 hour (After 24 hours) and 24 hours (After 48 hours) of the patch removal. Further judgments were conducted by the dermatologist. For more clear idea the test schedule is shown below in the Table 1.

Table 1 Test Schedule

1st day	Obtaining the informed consent ↓ Test subject selection ↓ Observation and photography of the application area ↓ Application of the test samples ↓
2nd day	Removal the patch test unit 24 hours after applying ↓ The first observation, photography and judgment, 1 hour after removal ↓
3rd day	The second observation, photography and judgment, 24 hours after removal

4.2.2. Test Period

Study start date	2025/07/08
Study end date	2025/07/10

4.2.3. Subjects

4.2.3.1. Number of Subjects

23 Thai adults

4.2.3.2. Selection of Subjects

Individuals who met all the following inclusion criteria and none of the exclusion criteria were chosen as subjects.

1) Inclusion Criteria

(1) Healthy adults between the ages of 20-59 years

(2) Individuals who have received explanations regarding the purpose and content of this study and have provided written informed content prior to participating in the study

2) Exclusion Criteria

(1) Persons who have skin diseases such as atopic dermatitis, eczema etc.
(2) Persons who have skin abnormalities of the application site that effect the evaluation of the study
(3) Persons with history of drug allergy
(4) Persons of constitution prone to allergies such as rash and hives
(5) Persons who receive or the treatment is determined to be required state for the prevention of such diseases (Hormone replacement therapy, drug therapy, exercise therapy, diet etc.) in a medical institution
(6) Persons who have serious diseases with glycol metabolism, lipid metabolism, liver function, renal function, heart function, circulatory organs, respiratory organs, endocrine system, nervous system or past illnesses of mental disorder
(7) Persons with a history of alcohol or drug dependence
(8) Persons who are Pregnant at the time of obtaining the informed consent, who wish to become pregnant or those lactating during the test period
(9) Persons who were receiving medication within 2 weeks before the start of the study which may affect the assessment
(10) Persons who participated in a patch test within 4 months before the start of the test
(11) Persons who presently participating on all tests which involves human subjects (cosmetics, food, pharmaceuticals, quasi-drugs, medical equipment etc.) at the start of the test or plan to participate in other human studies during the test period
(12) Furthermore, those who judged and decided by the technician to be unsuitable for the study participation

4.2.3.3. Restrictions and Prohibitions

(1) Bathing (including shower) is prohibited form the 1st day of patch test unit application until the completion of the inspection of the 2nd day.
(2) Bathing (including shower) is allowed at the end of the 2nd day inspection until the completion of the 3rd day inspection. Be careful not to rub the test site thoroughly.
(3) Being subjected to cosmetic surgeries and special skin care (such as: Este) and exercises which produce excessive sweating is prohibited.
(4) During the test period avoid the strong stimulus, pressure and friction to the test site. Do not use new and tight lingerie; wear those made with soft materials. In addition, since the ink marking may reach to the clothes, use lingerie with dark colors or those which doesn't matter even if the color reaches.

(5) Maintaining regular lifestyle such as: meals, exercising, drinking, smoking, sleeping duration is allowed during the test period.
(6) Be refrain from vigorous exercises (such as: running, swimming, climbing etc.) apart from daily light exercises. Avoid less sleep and excessive alcohol consumption, weight loss diet and gluttony (banquet, all-you-can-eat buffet etc.)
(7) Do not use pharmaceuticals unless unavoidable. Report to the manager if using any pharmaceuticals.

4.2.4. Method of Application and Removal

Test samples were applied occlusive on the upper back of each subject (paravertebral area) using the Finn Chambers on Scanpor tape (SmartPractice Dermatology | Allergy in Phoenix, Arizona, United States of America) as the patch test unit. The patch test unit was removed after 24 hours of the application. If test samples are adhered to subjects' skin and which may disrupt the judgment, the technician wiped the skin with cotton soaked with liquid paraffin (Hansen & Rosenthal KG, Hamburg, United States of America), and then wiped slightly with a dry tissue.

4.2.5. Discontinuation Criteria of the Test

The manager would decide to discontinue the participation of the subject or the entire test in corresponding to the following.

(1) When the subject withdraws consent after commencing the test
(2) When it becomes clear after the start of the test that the required examinations would not be possible due to the subject's inconvenience
(3) When subject found ineligible after commencing the test.
(4) When serious adverse event occurs, and it becomes difficult for the subject to continue the test
(5) When an adverse event occurs (including exacerbation of a concurrent disease) and it is determined that the subject should discontinue the test

4.2.6. Evaluation Method

4.2.6.1. Evaluation Method and Judging Criteria

About 1 hour after the patch test unit removal, confirms that temporary erythema cause by removal has regressed, then the dermatologist observes the test site and perform a skin reactive judgment by criteria[1)] shown in Table 2 (After 24 hours). Furthermore, 24 hours after the removal, dermatologist again observes the test site and performs skin reactive judgment (After 48 hours).

Table 2 Patch Test Judging Criteria

Judging Criteria (Japan)	Skin Reactions	Irritation Score
-	No reaction	0.0
±	Slight erythema	0.5
+	Definite erythema	1.0
++	Erythema + edema, papule	2.0
+++	Erythema + edema・papule + vesicles	3.0
++++	Oedema	4.0

4.2.6.2. Procedure of Follow-up Survey

To the subject was determined over "±" at the end of the test (After 48 hours), it was decided to follow-up for the skin conditions of the application site after the completion of the test.

4.3 Data Handling and Equation of the Skin Irritation Score

The dermatologist judged the control substances for the handling of the determination result of the subject who became positive and the subject who canceled the test was also identified and excluded from the analysis.

Considering determination results of each test sample scored according to the irritation scores[2)] in the Table 2, following equation is used to calculate the skin irritation score based on the criteria on Table 3.

$$\text{Skin Irritation Score} = \frac{\text{Total After 24 hours or After 48 hours (whichever has highest skin irritation score)}}{\text{Number of subjects}} \times 100$$

Table 3 Classification of Cosmetics by Skin Irritation Score[2)]

Skin Irritation Score	Classification (1995)
Less than 5.0	Safe item
5.0-15.0	Acceptable item
15.1-30.0	Item requiring improvement
More than 30.0	Dangerous item

4.4 Ethical Matters

4.4.1. Compliance with the Declaration of Helsinki and Ethical Guidelines

The study involving human subjects was carried out with the consideration of human rights according to the Declaration of Helsinki (World Medical Association) as well as to the ethical

guidelines of medical system research (Ministry of Education Culture Sports Science and Technology, Ministry of Health Labor and Welfare)

4.4.2. Explanation to the Subjects and Consent receiving

The manager passed a description document to the subject, who sufficiently describe the purpose, content etc. of the study, and confirmed that the subjects had fully understood the contents, and then the manager obtained the written agreement of each subject's voluntary participation in the study.

4.4.3. Protection of Personal Information

The personal information of the subject used only for the purpose of carrying out this study. The subjects' name, age, sex, test data, survey responses were taken as an anonymous process in order to protect and preserve personal information and secrecy of the subject. Furthermore, test data and subjects' identification numbers were archived at the testing facility for the proper management.

5 Results

5.1 Subjects and Skin Irritation Score

The subjects were 3 males and 20 females in the age between 20-59 (34.8 mean ages). The skin irritation score of each test sample is shown in Table 4 and Table 5. Subjects' age, sex, individual test results and scoring details are provided in the Appendix A.

Table 4 Skin Reactions and Skin Irritation Scores of Test Materials (Sample No. 40)

Test Materials	**Sample No. 40**	
Judgment Time / Duration / **Skin Reactions**	**After 24hours**	**After 48hours**
-	23	23
±	-	-
+	-	-
++	-	-
+++	-	-
++++	-	-
Skin Irritation Score	0.0	

Table 5 Skin Reactions and Skin Irritation Scores of Control Substances

Test Materials	Sample No.8		Sample No.9		Sample No.10	
Judgment Time / Duration / Skin Reactions	After 24hours	After 48hours	After 24hours	After 48hours	After 24hours	After 48hours
-	23	23	23	23	23	23
±	-	-	-	-	-	-
+	-	-	-	-	-	-
++	-	-	-	-	-	-
+++	-	-	-	-	-	-
++++	-	-	-	-	-	-
Skin Irritation Score	0.0		0.0		0.0	

5.2 Follow-up Survey

Follow-up survey was not applicable.

6 Conclusion

The “ZAINT FOLLICLE ACTIVATOR SERUM” was found to be safe and can be considered a non-irritating product under the conditions of this study.

7 Archive of Test Document

The original test report was submitted to the sponsor and a duplicate copy was archived in the administrative facility. In addition, the retention period in administrative facility will be for 5 years from the end of the test.

8 Reference

1) Japanese Dermatological Association contact dermatitis clinical practice guidelines committee, (2009), contact dermatitis clinical practice guidelines, The Japanese Journal of Dermatology, 119 (9): 1757-1793.
2) Tetsuro Sugai, (1995), Safety Evaluation of Cosmetics Products, cosmetic science, 19: 49-56.

Appendix A

WHITE PETROLATUM

Subject No.	Age	Sex	After 24 hours	After 48 hours
1	46	F	-	-
2	45	M	-	-
3	56	F	-	-
4	27	F	-	-
5	28	F	-	-
6	37	F	-	-
7	21	F	-	-
8	21	F	-	-
9	24	F	-	-
10	41	F	-	-
11	50	M	-	-
12	26	F	-	-
13	28	F	-	-
14	22	F	-	-
15	32	F	-	-
16	21	F	-	-
17	46	F	-	-
18	29	M	-	-
19	49	F	-	-
20	41	F	-	-
21	50	F	-	-
22	32	F	-	-
23	28	F	-	-

		After 24 hours	After 48 hours
0	-	23	23
0.5	±	-	-
1	+	-	-
2	++	-	-
3	+++	-	-
4	++++	-	-
	Skin Irritation Score	0.0	
	Number of Subjects	23	

Minimum Age	Max Age	Average Age	Male	Female
21	56	34.8	3	20

STERILE WATER FOR IRRIGATION

Subject No.	Age	Sex	After 24 hours	After 48 hours
1	46	F	-	-
2	45	M	-	-
3	56	F	-	-
4	27	F	-	-
5	28	F	-	-
6	37	F	-	-
7	21	F	-	-
8	21	F	-	-
9	24	F	-	-
10	41	F	-	-
11	50	M	-	-
12	26	F	-	-
13	28	F	-	-
14	22	F	-	-
15	32	F	-	-
16	21	F	-	-
17	46	F	-	-
18	29	M	-	-
19	49	F	-	-
20	41	F	-	-
21	50	F	-	-
22	32	F	-	-
23	28	F	-	-

		After 24 hours	After 48 hours
0	-	23	23
0.5	±	-	-
1	+	-	-
2	++	-	-
3	+++	-	-
4	++++	-	-
	Skin Irritation Score	0.0	
	Number of Subjects	23	

Minimum Age	Max Age	Average Age	Male	Female
21	56	34.8	3	20

PHYSIOLOGICAL SALINE SOLUTION

Subject No.	Age	Sex	After 24 hours	After 48 hours
1	46	F	-	-
2	45	M	-	-
3	56	F	-	-
4	27	F	-	-
5	28	F	-	-
6	37	F	-	-
7	21	F	-	-
8	21	F	-	-
9	24	F	-	-
10	41	F	-	-
11	50	M	-	-
12	26	F	-	-
13	28	F	-	-
14	22	F	-	-
15	32	F	-	-
16	21	F	-	-
17	46	F	-	-
18	29	M	-	-
19	49	F	-	-
20	41	F	-	-
21	50	F	-	-
22	32	F	-	-
23	28	F	-	-

		After 24 hours	After 48 hours
0	-	23	23
0.5	±	-	-
1	+	-	-
2	++	-	-
3	+++	-	-
4	++++	-	-
	Skin Irritation Score	0.0	
	Number of Subjects	23	

Minimum Age	Max Age	Average Age	Male	Female
21	56	34.8	3	20

ZAINT FOLLICLE ACTIVATOR SERUM

Subject No.	Age	Sex	After 24 hours	After 48 hours
1	46	F	-	-
2	45	M	-	-
3	56	F	-	-
4	27	F	-	-
5	28	F	-	-
6	37	F	-	-
7	21	F	-	-
8	21	F	-	-
9	24	F	-	-
10	41	F	-	-
11	50	M	-	-
12	26	F	-	-
13	28	F	-	-
14	22	F	-	-
15	32	F	-	-
16	21	F	-	-
17	46	F	-	-
18	29	M	-	-
19	49	F	-	-
20	41	F	-	-
21	50	F	-	-
22	32	F	-	-
23	28	F	-	-

		After 24 hours	After 48 hours
0	-	23	23
0.5	±	-	-
1	+	-	-
2	++	-	-
3	+++	-	-
4	++++	-	-
	Skin Irritation Score	0.0	
	Number of Subjects	23	

Minimum Age	Max Age	Average Age	Male	Female
21	56	34.8	3	20