Jakarta, May 18th, 2026

No. : QS.26.05.070
As regards : Clinical Testing Report and Certificate of Analysis

To,
PT NAYUE KOSMETIK INDONESIA
Pantai Indah Utara 1 No. 03, RT 4/RW 7, Kamal Muara, Kecamatan Penjaringan,
Jakarta Utara, Daerah Khusus Ibukota Jakarta 14470

Dear, Sir/Madam,
Herewith, we attached the Clinical Testing Report and Certificate of Analysis for product details as follows:

Sample Code	TP.26.02.104*
Sample Name	OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM*
***Batch* No.**	NYHHD25081301A*

This statement was made to be used accordingly. Thank you for your understanding and cooperation during this project.

Best regards,
SKINPROOF

Ditandatangani oleh BULAN TRESNA HERYUDI (LOBUL1926)
Ditandatangani pada 19 Mei 2026 08:50:24

Bulan Tresna Heryudi
Quality System Sr. *Specialist*

*Surat pengantar hanya berlaku untuk produk yang diterima dan diuji oleh Skinproof. /
Covering letter only applicable for product received and tested by Skinproof.

PT. DERMA LAB ASIA
Jl. KS Tubun II C Nomor 30, Slipi, Palmerah
Kota Adm. Jakarta Barat, DKI Jakarta 11410
T 021-3878-2040

SKINPROOF
science creates speed

CERTIFICATE OF ANALYSIS
COA.26.02.151

Customer
Pelanggan
: PT NAYUE KOSMETIK INDONESIA

Product Information
Informasi Produk
:

Product Code	TP.26.02.104*
Product Name	OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM*
***Batch* No.**	NYHHD25081301A*
***Report* No.**	SPF.PDD.R.254, *version* 26.00

Product Description
Deskripsi Produk
: *Semi-solid*
Setengah Padat

Result
Hasil
:

Under these study conditions and Dermotological control,
the product can be considered as:
"Non-Irritant Potential".

Pada pengujian ini, serta di bawah pengendalian Dermatologis,
menunjukkan bahwa produk tersebut:
"Tidak Berpotensi Menimbulkan Iritasi".

*Sertifikat Analisa hanya berlaku untuk produk yang diterima dan diuji oleh Skinproof. /
Certificate of Analysis only applicable for product received and tested by Skinproof.

Approved by,
Disetujui oleh

Ditandatangani oleh BULAN TRESNA HERYUDI (LOBUL1926)
Ditandatangani pada 18 Mei 2026 08:50:41

Bulan Tresna Heryudi
Quality System Sr. *Specialist*
May 18th, 2026

PT. DERMA LAB ASIA
Jl. KS Tubun II C Nomor 30, Slipi, Palmerah
Kota Adm. Jakarta Barat, DKI Jakarta 11410
T 021-3878-2040

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IN VIVO EVALUATION OF THE POTENTIAL IRRITATION IN COSMETICS AND HOUSEHOLD PRODUCT USING SINGLE PATCH TEST METHOD ON HEALTHY INDONESIAN SUBJECTS

RESEARCH SITE	**SKINPROOF** Jl. K.S. Tubun II C No. 30, Slipi, Palmerah, Kota Administrasi Jakarta Barat, DKI Jakarta 11410 T (021) 3878 2040
PRINCIPAL INVESTIGATOR	Indrawati Widjaja, M.D., DV.
RESEARCH COORDINATOR	Evelyn Jeanette Wijaya, PharmB.
TEST PRODUCT	OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM (TP.26.02.104)
BATCH NO.	NYHHD25081301A
SPONSOR	**PT NAYUE KOSMETIK INDONESIA** Pantai Indah Utara 1 No.03, RT 4/RW 7, Kamal Muara, Kecamatan Penjaringan, Jakarta Utara, Daerah Khusus Ibukota Jakarta 14470 T (+62) 888-0892-0559

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RESEARCH SITE		**SKINPROOF** Jl. K.S. Tubun II C No. 30, Slipi, Palmerah, Kota Administrasi Jakarta Barat, DKI Jakarta 11410 T (021) 3878 2040	
STATISTIC ANALYSIS		**SKINPROOF** Jl. K.S. Tubun II C No. 30, Slipi, Palmerah, Kota Administrasi Jakarta Barat, DKI Jakarta 11410 T (021) 3878 2040	
SPONSOR		**PT NAYUE KOSMETIK INDONESIA** Pantai Indah Utara 1 No.03, RT 4/RW 7, Kamal Muara, Kecamatan Penjaringan, Jakarta Utara, Daerah Khusus Ibukota Jakarta 14470 T (+62) 888-0892-0559 **Personnel Monitoring:** Michelle Gracella T (+62) 888-0892-0559 prodev03@nayuecosmetics.com	
PROTOCOL NUMBER		SPF.PDD.P.088, Version 25.00	
STUDY CODE		26.02.02.006C	
STUDY START DATE		April 25th, 2026	
STUDY END DATE		April 29th, 2026	
REPORT NO.		SPF.PDD.R.254	
VERSION	**26.00**	May 18th, 2026	First published

REPORT SYNOPSIS

Study Title

In Vivo Evaluation of The Potential Irritation in Cosmetics and Household Product using Single Patch Test Method on Healthy Indonesian Subjects.

Study Objective

Evaluate the potential for irritation in both cosmetic and household products after application of the test product using patch for 48 hours on the skin of healthy subjects under the supervision of a dermatologist.

Study Outcome

Evaluate the irritation reactions produced by the skin after application of the test product using patch.

Measurement Parameters	Clinical Endpoint
Evaluate the irritation reaction on the skin	Skin reaction to the test product at T+30 minutes, T+24 hours and T+48 hours after patch was removed.

Study Design

An open study for 48 hours, non-randomized in the test area, use of positive and negative control, with Occlusive Patch Test method using Finn Chamber® Aqua 8 mm, in finished product.

Subject Number

58 subjects.

Study Population

Inclusion Criteria:

1. Healthy male and female subjects, aged 19 – 50 years old,
2. Subjects had ITA° value between 0-41,
3. Subjects had sensitive and resistant skin types based on self-assessment,
4. Subjects were willing to use the product in accordance with the instructions provided by the researcher,
5. Subjects were willing to sign the Informed Consent (IC) form,
6. Subjects were willing not to participate in other studies during the course of the patch test period,
7. Subjects were willing to give photo approval for the test area taken during the study, which may be used for the purpose of writing research reports, publishing research journals, evaluating intervention results, educational purposes for the profession, scientific conferences, or scholarly publications,
8. Subjects did not have abnormal skin pigmentation, wounds and so on at the test site which may interfere with the evaluation of the skin reaction that may arise, not allergic to the components of the test product.

Exclusion Criteria:

1. Pregnant and breastfeeding Subject,
2. Subjects who participated in other research that may Interfere with this research,
3. Subjects who had a history of asthma, diabetes or epilepsy,
4. Subjects with a history of certain dermatological diseases or conditions, such as psoriasis or eczema, within the last 6 months, as well as subjects currently experiencing a relapse of these conditions,
5. Subjects who were underwent drug therapy, either orally or by injection, such as steroids, antihistamines, immunosuppressive drugs, and long-term non-steroidal,
6. Subjects who used a type of topical anti-inflammatory drug on the test area in the last 2 weeks,
7. Subjects with a history of immune deficiency or autoimmune diseases,
8. Participated as a subject in another patch test study within the last 6 months.

Test Product

Product Name	:	OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM
Dosage Form	:	Semi-solid
Product Code (**SKINPROOF**)	:	TP.26.02.104
Batch No./Lot No.	:	NYHHD25081301A
Manufacturing/Expired Date	:	NA/NA

Positive Control

Product Name	:	SLS 1%
Dosage Form	:	Liquid
No. Batch/Lot	:	R253175
Manufacturing/Expired Date	:	January 17th, 2026/January 17th, 2027

Negative Control

1. Product Name : Water for Injection
   Dosage Form : Liquid
   No. Batch/Lot : K24016FC
   Manufacturing/Expired Date : October 25th, 2024/ October 25th, 2029

2. Product Name : Blank Chamber
   Dosage Form : NA
   No. Batch/Lot : 1623GEN
   Manufacturing/Expired Date : NA/December 31st, 2026

Study Duration and Kinetics

The duration of the study was carried out for ±5 days.

Treatment

The test product was applied to subject's back area area (lower left back, above the waist) using a patch for 48 hours.

Statistical Analysis

Data evaluation includes descriptive statistical analysis. Descriptive statistical analysis was carried out for all measurement data (scoring/visual assessment of each subject), reported as a single value (Cumulative Irritation Index (CII)) and average value (Mean Cumulative Irritation Index (MCII)). The MCII results of the test product were compared with the positive control and negative control. Evaluation of the reactions produced by the skin was carried out at T+30 minutes, T+24 hours and T+48 hours after the patch was removed.

Result

MCII scoring result on the Test Product (TP.26.02.104), positive control and negative control:

Score		Evaluation											
		Test Product (TP.26.02.104)			Positive Control (SLS 1%)			Negative Control (Water for Injection)			Negative Control (Blank Chamber)		
		30min	24h	48h	30min	24h	48h	30min	24h	48h	30min	24h	48h
0	n	56	56	58	37	19	23	55	58	58	56	58	58
	%	96.552	96.552	100.000	63.793	32.759	39.655	94.828	100.000	100.000	96.552	100.000	100.000
0.5	n	2	2	0	21	39	35	3	0	0	2	0	0
	%	3.448	3.448	0.000	36.207	67.241	60.345	5.172	0.000	0.000	3.448	0.000	0.000
1	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
2	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
3	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
∑ N		**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**
MCII		**0.011 (Non-irritant)**			**0.273 (Slightly irritant)**			**0.009 (Non-irritant)**			**0.006 (Non-irritant)**		

Conclusion

MCII value of **OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM (TP.26.02.104)** is **0.011** (<0.25), which indicate that **the product** had **no irritating potential (non-irritant)**.

QUALITY STATEMENT

I, the undersigned, assure:

STUDY TITLE	In Vivo Evaluation of The Potential Irritation in Cosmetics and Household Product using Single Patch Test Method on Healthy Indonesian Subjects
REPORT NUMBER	SPF.PDD.R.254, Versi 26.00
AUDIT DATE	May 15th, 2026
REPORT DATE	May 18th, 2026

Clinical study with the title mentioned above, has been through audit and verification process, carried out according to the approved protocol and applicable procedure in **SKINPROOF**. The data which is contained in this report already in accordance with the source data.

Name	Job Function	Signature and Date
Bulan Tresna Heryudi	Quality System Sr. Specialist	
		Date: May 15th, 2026

INVESTIGATOR'S SIGNATURE SHEET

I, the undersigned, has reviewed the report and its attachments, ensure the accuracy of data during study and conduct clinical studies in compliance with ethical considerations and applicable regulations, and have conducted research in accordance with **SKINPROOF**'s SOPs and the ethical principles of the Declaration of Helsinki and Good Clinical Practice (GCP).

Name	Job Function	Signature and Date
dr. Indrawati Widjaja, MD., DV.	Principal Investigator	 Tanggal: May 16th, 2026
Evelyn Jeanette WIjaya, PharmB.	Coordinator	 Tanggal: May 15th, 2026
Agnes Susianti, PharmD.	Research Assistant	 Tanggal: May 16th, 2026
Anita Dara Dewa Tantri	Research Assistant	 Tanggal: May 18th, 2026

ABBREVIATION

ACD	Allergy Contact Dermatitis
AE	Adverse Event
BPOM	*Badan Pengawas Obat dan Makanan*
CII	Cumulative Irritation Index
CRF	Case Report Form
GCP	Good Clinical Practice
CD	Contact Dermatitis
CCDA	Cosmetics Contact Dermatitis Allergy
FDA	Food and Drug Administration
ICD	Irritation Contact Dermatitis
IC	Informed Consent
ICH-GCP	International Conference on Harmonization – Good Clinical Practice
MCII	Mean Cumulative Irritation Index
SAE	Serious Adverse Event
SCCS	Scientific Committee on Consumer Safety

I. INTRODUCTION

1.1. Background

The increasing purchasing power of the people and the widespread use of cosmetics have caused the incidence of Allergic Contact Dermatitis to increase. Cases of Cosmetic Allergic Contact Dermatitis are relatively significant, it is estimated that approximately 10% of all cases of Contact Dermatitis. Based on a report from NACDG (North American Contact Dermatitis Group) it was found that 713 (5.4%) of 13,216 Contact Dermatitis patients reacted positively to the tested cosmetic ingredients, in 421 patients (59%) of which occurred on the face and around the eyes and 563 patients (79%) are women.[2]

Skin care products, hair, cosmetics, nails, perfumes, make-up, sunscreen, shaving supplies and deodorants are the most common causes of allergic reactions.[2] Allergic reactions to cosmetics can be caused by the ingredients contained in them, such as preservatives, vehicles/emulsifiers, fragrances and dyes. However, serious adverse effects caused by cosmetics are rare when compared with their widespread use.[3]

The Cases of Cosmetic Allergic Contact Dermatitis follows the iceberg phenomenon, because almost all Cases of Cosmetic Allergic Contact Dermatitis sufferers do not go to the doctor but stop their use and replace the cosmetics that have been used. This happens because the allergic reactions that appear are usually mild, while severe reactions are quite rare. Itching, prickling (feeling like prickling) and dry skin are often complained by people who use cosmetics. This is certainly a problem for people who experience a dilemma between using cosmetics to maintain their appearance, while on the other hand there is a fear of possible allergic reactions.[1,2]

In response to this, many cosmetic manufacturers include claims on their product packaging to convince consumers, such as a stating that the product does not cause irritation. The inclusion of claims on a cosmetic product becomes important in a cosmetic product development process, this is to protect consumers from using the wrong product. The need to prove the efficacy of cosmetic products is not only for the sake of marketing activities but is needed to legally prove that the cosmetic products used are safe and the claims stated on the packaging or product information have been proven by an accurate and reliable method. In the registration process, to be able to provide information on claims on a cosmetic product, supporting data is needed related to the product claims.[4] Testing for anti-irritation claims on a product can be carried out using the patch test method. [21]

1.2. Allergic Contact Dermatitis

Contact dermatitis is a general term for an acute or chronic inflammatory reaction to a substance that comes into contact with the skin. There are 2 types of contact dermatitis, namely Irritant Contact Dermatitis (ICD) which is caused by chemical irritation and Allergic Contact Dermatitis (ACD) caused by antigens (allergens) which causes a type IV hypersensitivity reaction (cell-mediated or delayed type).[5,9]

Table 1. Difference between Allergic Contact Dermatitis and Irritant Contact Dermatitis[6,7]

	Allergic Contact Dermatitis	Irritation Contact Dermatitis
Onset	Sudden, 1 – 2 days in sensitized individuals.	Sudden, several hours to 5 (five) days after exposure.
Sign	Predominantly acute and subacute signs. Well-defined, erythema, edema, vesicles and watery.	Predominantly acute and chronic signs. Initially dry and fissured, it eventually becomes erythema, lichenified and excoriated by chemical trauma.

	Allergic Contact Dermatitis	Irritation Contact Dermatitis
Symptom	Pruritic.	Heat and pain (sometimes pruritic).
Mechanism	Immunological reactions, The first exposure is induction and the following exposure is a challenge.	Non-immunological reactions, Single exposure to chemicals.
Patch test	Gives positive results after 24 – 48 hours and the reaction given is getting bigger and permanent.	Gives positive results in minutes and the reaction does not get bigger and fades.

Because Irritation Contact Dermatitis is toxic, the inflammatory reaction is only limited to the area of exposure, the boundaries are firm and never spread. While Allergic Contact Dermatitis is an immune reaction that tends to involve the surrounding skin (spreading phenomenon) and can even spread beyond the affected area. In Allergic Contact Dermatitis there can be a complete spread.[5]

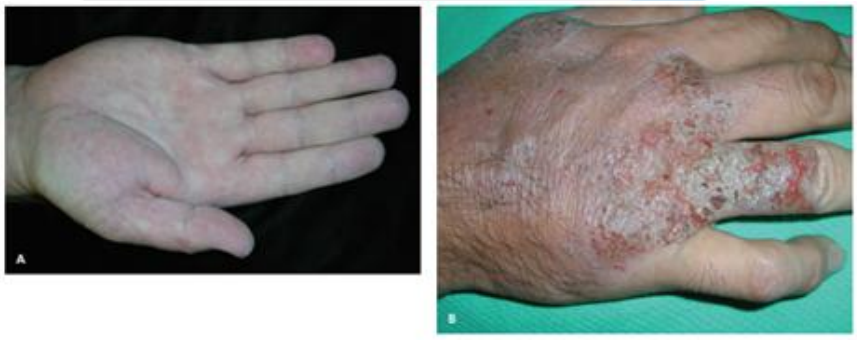


Figure 1. Contact dermatitis on hands. (A) irritation Contact Dermatitis (B) Allergic Contact Dermatitis[6]

Symptoms commonly felt by sufferers are itching or pruritus which is generally constant and often intense (very itchy). Allergic Contact Dermatitis is usually characterized by the presence of eczematous lesions in the form of erythema, edema, vesicles and the formation of papulo vesicles, this picture shows activity at the cellular level. Vesicles arise due to the occurrence of spongiosis and if they rupture will release fluid which causes the lesion to become wet. At first the lesions are confined to the site of contact with the allergen, so their pattern and distribution can often indicate the cause, for example: those who have been exposed to their scalp may become suspicious because of the shampoo or hair dye they use. Those affected by the face can be suspicious because of the creams, soaps, powders and various other types of cosmetics they use. In severe cases, dermatitis that spreads throughout the body is called eczematization. Characteristics of Allergic Contact Dermatitis are inflammation that slowly spreads, the boundaries of inflammation are not clear (diffuse), and pain and heat are not as intense as in Irritant Contact Dermatitis. Chronic dermatitis presents as dry, lichenified, scaly skin and fissures. The chronic phase is very difficult to distinguish from Irritant Contact Dermatitis, both clinically and histopathologically, because both have erythema, thickening, desquamation, fissures and itching.[5-6]

1.3. Patch Test

Patch testing is the method of choice for demonstrating an allergic contact dermatitis and assessing the clinical relevance of the patch test results to the exposure history obtained through a careful history. The patch test aims to produce “in miniature” an eczematous reaction, by applying an exogenous agent in occlusion to the skin of a patient with suspected allergies. Improvements in indications and contraindications, standardization and interpretation of patch test procedures have been carried out by the International

Contact Dermatitis Research Group (ICDRG), to obtain similar results for all educational centers. However, the standardization of patch test units to date still varies.[10,11]

Jadassohn was the first researcher to describe allergic contact dermatitis in 1895, so Jadassohn developed a patch test to identify chemicals for allergic patients. Patch test is used to determine hypersensitivity to a material in contact with the skin. According to the American Academy of Allergy, Asthma and Immunology, this patch test is the golden standard for the identifying contact dermatitis, especially for chronic and recurrent patients. Place to do the patch test is usually on the back, it can also be on the outside of the upper arm. The test material is placed on a piece of cloth or paper, attached to intact skin, covered with an impermeable material, then glued with plaster. After 48 hours the patch was removed, then the skin reaction was read after 48 hours of the patch being removed. For certain new ingredients react after one week.

Positive results can range from erythema with urticaria to vesicles or bullae. It is important to distinguish, whether the reaction is due to contact allergy or due to irritation, with respect to the concentration of the test substance being too high. If due to irritation, the reaction will decrease after 48 hours (decrescendo type reaction), while contact allergic reactions increase (crescendo type reaction). The patch test requirement is that the dermatitis is calm or has healed so that there is no angry back, use of topical corticosteroids must be stopped for at least 1 week, the patch test is carried out with standard materials or suspected materials. An angry back reaction is a false positive reaction, which is a regional phenomenon caused by several strong positive reactions, with the other edge of the patch test being reactive. This phenomenon was described by Bruno Bloch in the 20th century, then re-examined by Mitchell in 1975. Usually occurs in patients with hypersensitive skin, who are suffering from active dermatitis, so it is necessary to retest these patients with less allergen compounds, to rule out non-specific false-positive reactions. Meanwhile, false negative reactions can also occur if the concentration of the test compound is too low, the patch test material does not adhere well or is loose and can also occur due to insufficient time to stop using corticosteroid drug products, both topically and systemically.[10,12,13 ,14,15]

Some of the internationally recognized patch test units include Finn Chambers and IQ Chambers. Finn Chambers units have been widely used worldwide since 1975, while IQ Chambers were introduced in 1997. Outboard assembly materials can affect the results of patch tests performed. Finn Chambers are made of spherical aluminum attached to acrylate-based adhesive tape (Scanpor) and Finn Chambers are also available which are coated with polypropylene. One of the Finn Chambers sizes is on the inside of the chamber with a diameter of 8 mm and an outer diameter of 11 mm. The method of application of Finn Chambers is to apply the patch from the bottom while pressing to help in expelling the air. After the patch is attached, apply a little pressure to the patch using the palm of the hand so that the test material contained in the chamber can actually come into contact with the test area. The advantages of this method include a strong occlusion state, better fixation because the chamber size is relatively small compared to adhesives, few chemicals so that the reaction occurs is small and can be tested in large quantities.[15,16]

Figure 2. Finn Chambers® various sizes with or without filter paper[16]

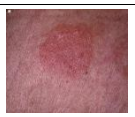
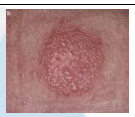
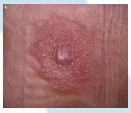
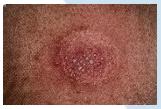
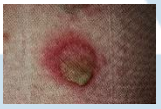
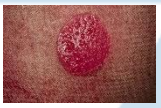
Another type of chamber is IQ Chambers, which consists of 3 types of chambers, namely IQ Chambers, IQ Ultra and IQ Ultimate Chamber. This type of chamber does not contain aluminum so it is safe for the environment and can be recycled. The size of the chamber itself is relatively small, so it does not use a large test area on the subject's back. Each patch contains 2 rows of 5 chambers, so that in 1 patch there are 10 chambers. The size of the patch itself is 118 x 52 mm, with the volume of the test compound that can be accommodated is 32 µL with a chamber area of 64 mm^2. The edges of each chamber have an adhesive layer, so as to optimize adhesion to the skin and to avoid leakage of the test product. The difference between the IQ Ultimate Chamber and the other 2 types of chambers is that the IQ Ultimate Chamber is water resistant, transparent and has a more elastic adhesive (tape) because it is made of a polyurethane layer.[16]

Figure 3. IQ Chamber, IQ Ultra and IQ Ultimate chamber[16]

Based on research conducted by Fitriani et al. (2014), it shows that Finn Chambers and IQ Chambers have the same capability in detecting sensitizers causing Allgergic Contact Dermatitis at RSUPMH Palembang. While Finn Chambers still relies on an additional adhesive in its application, whereas IQ Chambers no longer require additional adhesive, the usage of Finn Chambers resulting in a more economical and efficient of the usage.[17]

The patch test that was carried out in this study used The European Baseline Series of Contact Allergens. Reading of the patch test results was carried out in accordance with the International Contact Dermatitis Research Group (ICDRG), namely[6]:

Table 2. Reading of Patch Test Results based on ICDRG criteria [6]

Criteria	ICDRG* Scoring	Image
No reaction (no visible or felt change)	-	
Doubtful reactions (faint erythema)	?+	
Weak positive reactions (erythema, infiltration and there possibly papules)	+	
Strong positive reactions (erythema, infiltration, papules and vesicles)	++	
Extreme positive reactions (intense erythema and infiltration, with coalescing vesicles)	+++	
Irritant reactions (various forms such as erythema, pustular, blistering or bullous reactions, and necrosis)	IR	 Pustular follicular
		 Pustular diffuse
		 Nekrosis

*International Contact Dermatitis Research Group

1.4. Single Patch Test

In risk assessments or safety evaluations, such as the potential irritation of a product or compound, it is necessary to test the compound directly on humans. One of the methods that can be used is Single Patch Test method. Single Patch Test is a test carried out to assess the sensitivity of the skin after induction using a test substance that is applied to the skin for 48 hours. In this test, the test product at a certain concentration to be used is placed into a chamber on the patch, and then the patch containing the test product is applied to the test area (usually on the back or inner arm area) for a pre-determined time. In this study, the patch attachment time used was 48 hours, after which the patch was removed and the response from the skin evaluated at T+30 minutes, T+24 hours, and T+48 hours after the patch was removed.[10]

1.5. Cosmetic and Household Product

Cosmetic are defined as any material or preparation intended to be placed in contact with various external parts of the human body (epidermis, hair, system, nails, lips and external genitals) or in the teeth and mucous membranes of the oral cavity. Household cleaning product are an important source of skin exposure to irritants and allergent. Irritant contact dermatitis due to cleaning agents is mostly caused by chemical agent

used in the cleaning agent. The example of the ingredients is an anionic surfactant such as sodium lauryl sulfate (SLS). Some of the chemical agents are known to cause skin rashes, allergies, eye irritation and respiratory irritation in adults and children. Cosmetics and household products are products that are used for a long time in the community. One type of test on humans that is widely used for evaluating cosmetics and household products is Single Patch Test. The following is the classification of cosmetic and household products:[26,27]

Table 3. Cosmetic and Household Product Classification

Classification	Product Category	
Cosmetic	Leave-on	Toners
		Lotions and Cream
		Foundations
		Sunscreen Creams
		Lip Products
		Body Lotions and Creams
		Face Powders, Eye Shadows
		Eye Liners, Mascaras
	Tissue-off	Make-up Remover
		Packs and Massage Creams
	Wash-off	Facial Cleansers
		Soap and Bath
		Shampoos, Rinses and Water Treatments
Household	All-purpose cleaner liquid/spray/wipes, bleach, hand-dishwashing detergent, kitchen cleaner liquid/spray, bathroom cleaner liquid/spray, toilet cleaner, glass cleaner, carpet cleaner, fungicide spray.	

1.6. Side Effects of Using the Products

Although it is very rare to report undesirable events from the use of this cosmetic product, the following side effects may occur:

a. Irritation (objective or Subjective irritation)[20]

Irritation is subjectively defined as chemical composition that can cause sensory discomfort such as burning, stinging, itching or other uncomfortable feelings without any clinical appearance that can look like inflammation. Irritation is objectively defined as a non-immunologic inflammatory reaction usually characterized by mild erythema (redness), dry skin causing scaling and desquamation of the skin. The content of surfactants, emulsifiers and chemical substances that are acidic can cause an irritating effect.

b. Allergic reactions (contact allergy/urticaria)[20]

In cosmetic use, allergic reactions and urticaria can be characterized by mild irritation reactions and localized (usually in the non-immunological type) to dermatitis. Subsequent reactions from allergies and urticaria may cause systemic effects (asthma, otolaryngeal or ENT organs, gastrointestinal symptoms).

1.7. Evalution of Potential Irritation of Products

The FD&C Law does not demand the FDA for safety data from a cosmetic product before it is marketed. However, the manufacturer or distributor remains fully responsible for obtaining the data and information needed to substantiate the safety claims of their own products before being marketed. The Federal Register suggests having available toxicological test data on each component of the cosmetic product. However, it is still necessary to carry out toxicological testing with a complete formulation to ensure the safety of a finished cosmetic product. One of them is by conducting in vitro and in vivo tests on toxicological data on product components and impurities contained in cosmetic products, to see potential irritation (skin and eyes). Thus, the safety of a cosmetic product must be evaluated by analyzing the relevant physicochemical and toxicological properties of each ingredient in relation to the exposure that is expected to result from using the finished product from that cosmetic.[22]

According to the Scientific Committee on Consumer Safety (SCCS), the safety of a cosmetic product is based on the safety of each component of the product. Specifically for the evaluation of cosmetic ingredients related to skin sensitization, SCCS recommends evaluating the safety of a component of a cosmetic product using a patch test on humans because it can provide stronger evidence, then the data is evaluated together with data from previous animal testing results. For cosmetic products, it is more focused in evaluating local toxicity such as possible irritation to the skin and eyes, as well as skin sensitization.[23]

This clinical trial was conducted for in vivo evaluation to see the potential for irritation of cosmetic products from **PT NAYUE KOSMETIK INDONESIA**, on healthy Indonesian subjects. This test was conducted in accordance with the ethical principles stated in the Declaration of Helsinki (75th WMA General Assembly, Helsinki, Finlandia, October, 2024) dan International Conference on Harmonization – Good Clinical Practice (ICH-GCP).

II. STUDY OBJECTIVE

Evaluate the potential for irritation in both cosmetic and household products after application of the test product using patch for 48 hours on the skin of healthy subjects under the supervision of a dermatologist.

III. STUDY OUTCOME

Evaluate the irritation reactions produced by the skin after application of the test product using patch.

Table 4. Measurement Parameters and Clinical Endpoints

Measurement Parameters	Clinical Endpoint
Evaluate the irritation reaction on the skin.	Skin reaction to the test product at T+30 minutes, T+24 hours, and T+48 hours after patch was removed.

IV. STUDY DESIGN

An open study for 48 hours, non-randomized in the test area, use of positive and negative control, with Occlusive Patch Test method using Finn Chamber® Aqua 8 mm, in finished product.

Figure 4. Finn Chambers® Aqua 8 mm* Various Sizes with or without Filter Paper

4.1. Randomization

In this study, a non-randomized design was employed.

4.2. Blinding

In this study, blinding procedures were not applied (open-label or unblinded study).

V. SELECTION AND DISCONTINUATION OF CLINICAL TRIAL SUBJECTS

5.1. Number of Subjects

The subjects used were 60 people. Previous research shows that the erythema score to be observed from cosmetic products is 0.06 points from the baseline, with a standard deviation of 0.15.

$$N = \frac{\sigma^2 \left(z_{1-\beta} + z_{1-\alpha/2}\right)^2}{(\mu_0 - \mu_1)^2} = \frac{0{,}15^2 (0.84 + 1.96)^2}{(0 - 0.06)^2}$$

$$N = \frac{0.0225\ (7.84)}{0.0036} = 49$$

Based on these data, the number of subjects was taken as 50 people, and by estimating a drop-out rate of 10%, so that the number of subjects needed was 60 people. Based on guidelines from the FDA (Food and Drug Administration), the number of subjects that can be included in the irritation test study is 30 – 200 subjects.[24]

5.2. Inclusion Criteria

a. Healthy male and female subjects, aged 19 – 50 years old,
b. Subjects had ITA° value between 0-41,
c. Subjects had sensitive and resistant skin types based on self-assessment,
d. Subjects were willing to use the product in accordance with the instructions provided by the researcher,
e. Subjects were willing to sign the Informed Consent (IC) form,
f. Subjects were willing not to participate in other studies during the course of the patch test period,
g. Subjects were willing to give photo approval for the test area taken during the study, which may be used for the purpose of writing research reports, publishing research journals, evaluating intervention results, educational purposes for the profession, scientific conferences, or scholarly publications,
h. Subjects had no abnormal skin pigmentation, wounds and so on at the test site which may interfere with the evaluation of the skin reaction that may arise, not allergic to the components of the test product.

5.3. Exclusion Criteria

a. Pregnant and breastfeeding subject,

b. Subjects who participated in other research that may Interfere with this research,
c. Subjects who had a history of asthma, diabetes or epilepsy,
d. Subjects with a history of certain dermatological diseases or conditions, such as psoriasis or eczema, within the last 6 months, as well as subjects currently experiencing a relapse of these conditions,
e. Subjects who underwent drug therapy, either orally or by injection, such as steroids, antihistamines, immunosuppressive drugs, and long-term non-steroidal,
f. Subjects who used a type of topical anti-inflammatory drug on the test area in the last 2 weeks,
g. Subjects with a history of immune deficiency or autoimmune diseases,
h. Participated as a subject in another patch test study within the last 6 months.

5.4. Subject Instruction

During the testing period, subjects were required to:

a. Refrain from using cosmetics or medications on the test area throughout the study,
b. Avoid sun exposure beyond regular daily activities, UV therapy, or tanning,
c. Not use any medications, either orally or by injection, such as steroids, non-steroidal drugs, antihistamines, or immunosuppressants, and not use any medication without prior notification to the investigator,
d. Not apply any topical anti-inflammatory products to the test area,
e. Avoid engaging in activities that may cause excessive sweating,
f. Not remove the patch applied to the test area.

5.5. Subjects Recruitment, Informed Consent (IC) and Subjects Screening

Recruitment and selection procedures were outlined to ensure that subjects receive all information about the purpose of testing and the consequences of their participation. This recruitment procedure includes:

a. Recruitment was carried out by providing explanations to prospective subjects regarding the purpose of the test, treatment/action to be taken, as well as potential risks or inconvenience and compensation. Researchers give sufficient time to prospective subjects to ask all things related to the study,
b. Subjects who were willing to take part in the study filled out an Informed Consent (IC) form and signed it as confirmation that they were willing to voluntarily participate in the study and follow all applicable procedures as described,
c. Subjects were selected after a screening process was carried out based on a questionnaire filled out before testing. The pre-inclusion and exclusion questionnaire provides a medical history and possible allergies, as well as some administrative information,
d. Documentation of medicinal products used in the last 3 months.

5.6. Subject Enrollment

All subjects who met the inclusion and exclusion criteria in the screening process were included in this study. Subjects were asked to come **SKINPROOF**'s site and given a sequence number based on the order of attendance on the attendance list form upon arrival.

5.7. Discontinuation of Clinical Trial Subjects

Subjects might withdraw at any time during the clinical trial. The subjects' documents up until the subject withdraws were kept and the subjects signed the withdrawal form, if possible. The investigator might remove a Subject from the clinical trial (drop-out) for the following reasons:

a. The perceived side effects of testing would interfere with clinical trial results,
b. Subjects' non-compliance with clinical trial procedures, such as not complying with test protocol and visit schedules,
c. Other reasons that according to the researcher's assessment may affect the security and integrity of the data.

If the number of subjects who completed the study was less than 50 people, the researcher would re-do the screening process so that the minimum number of subjects was met.

VI. TEST PRODUCT

All test products were provided by Sponsor in sufficient quantities during testing. The Sponsor was responsible for the production process of the test product and packaging, product identification, purity, safety and other characteristics of each product to be tested prior to the start of testing. Sponsor provided a safety assessment certificate for each test product prior to testing. The procedure for coding the test products was carried out by the research coordinator by labeling all test products as follows:

Table 5. Test Product Information

No.	Product Name	Description
Test Products		
1.	OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM	
	Dosage form	Liquid
	Product Code (**SKINPROOF**)	TP.26.02.104
	Batch No./Lot No.	NYHHD25081301A
	Manufacturing/Expired date	NA/NA
	Ingredients	Aqua, Glycerin, Niacinamide, Dimethicone, Cyclopentasiloxane, Silica, Methylpropanediol, Panthenol, C12-15 Alkyl Benzoate, Titanium Dioxide, Butyl Methoxydibenzoylmethane, PEG-100 Stearate, Glyceryl Stearate, Phenoxyethanol, Polysorbate 80, Cetearyl Alcohol, Fragrance, Methylene Bis-Benzotriazolyl Tetramethylbutylphenol, Ammonium Acryloyldimethyltaurate/VP Copolymer, Potassium Cetyl Phosphate, Menthol, Sorbitan Oleate, Xanthan Gum, Chlorphenesin, BHT, Tocopheryl Acetate, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Triethoxycaprylylsilane, Ethylhexylglycerin, Decyl Glucoside, Butylene Glycol, Isohexadecane, Disodium EDTA, Sodium Hyaluronate, Tranexamic Acid, Silk Extract, Propylene Glycol, Butyrospermum parkii (Shea) Butter, Glutathione, Panax ginseng Root Extract, Thymus serpyllum Extract, Alpha-Glucan Oligosaccharide, Pentylene Glycol, Camellia sinensis Ectract, Polymnia sonchifolia Root Juice, 3-O-Ethyl Ascorbic Acid, Caprylic/Capric Triglyceride, Maltodextrin, Chlorella vulgaris Extract, Phospholipids, Potassium Sorbate, Sodium Benzoate, Lactobacillus, Astaxanthin.
Positive Control		
1.	SLS 1%	
Negative Control		
1.	Solvent (Water for Injection)	

No.	Product Name	Description
2.	Blank Chamber	

6.1. Test Product Storage

All test products were stored in **SKINPROOF** facilities with controlled access and temperature in accordance with the product storage requirements stated on the test product labels or in accordance with the recommendations of the Sponsor.

6.2. Test Product Management, Post Trial Access and Sample Returment

Recording of the test products was carried out in accordance with the applicable test product management procedures at **SKINPROOF**. The remaining test product was managed according to procedure number POS/SPF-U - Manajemen Produk Uji.

Table 6. Test Product Management

Number of Test Products Received	3 pcs, received on March 17th, 2026.
Number of Test Products Used	a. 1 pc used as Retained Sample, b. 1 pc used for the study.
Number of Test Products Remaining	1 pc managed according to the applicable procedures.

6.3. Concomitant Medication

Additional therapy might be administered to the subject to address side effects arising from the use of the test product as long as in the judgment of the investigator it would not affect the interpretation of the study results. The recording of adjunctive therapy during study was documented in the Case Report Form.

VII. METHODOLOGY

7.1. Instrument and Dosage

The test product was applied in clean test area, prior to patch application the area was cleaned by water.

Table 7. Instrument and Dosage

Test Area	Back area (lower left back, above the waist)
Patch Type	Finn Chamber® 8 mm aqua (50 mm^2) – Occlusive
Product Category	Leave on
Amount	20 mg.
Application frequency	The patch was attached for 48 hours and observed at T+30 minutes, T+24 hours, and T+48 hours after the patch was removed.
Positive Control	SLS 1 %
Negative Control	1. Solvent (Water for Injection), 2. Blank Chamber,

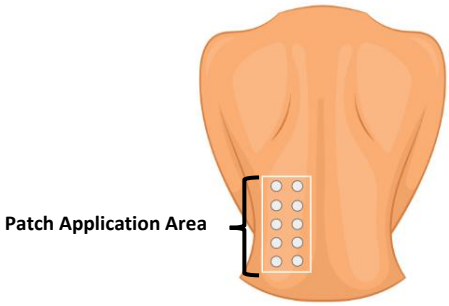
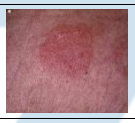
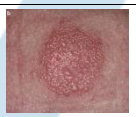
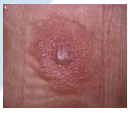
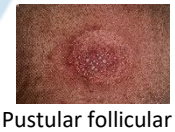
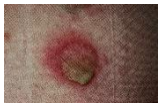
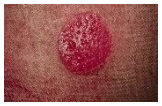


Figure 5. Patch Application Area

7.2. Clinical Assessment

After applying the patch to the back area for 48 hours, the patch was removed and the reaction on the back was assessed at T+30 minutes to eliminate the pressure effect of the patch attachment. The assessment of skin irritation and sensitization reactions was carried out based on the scoring criteria below:

Table 8. Irritation Potential Assessment Criteria

Criteria	ICDRG* Scoring	Numberic Scoring	Image
No reaction (no visible or felt change)	-	0	
Doubtful reactions (faint erythema)	?+	0.5	
Weak positive reactions (erythema, infiltration and there possibly papules)	+	1	
Strong positive reactions (erythema, infiltration, papules and vesicles)	++	2	
Extreme positive reactions (intense erythema and infiltration, with coalescing vesicles)	+++	3	
Irritant reactions (various forms such as erythema, pustular, blistering or bullous reactions, and necrosis)	IR	-	 Pustular follicular
Irritant reactions (various forms such as erythema, pustular, blistering or bullous reactions, and necrosis)	IR	-	 Pustular diffuse
			 Nekrosis

*International Contact Dermatitis Research Group

7.3. Schedule for Implementation of Study and Evaluation Procedures

All measurements and evaluations were carried out in the **SKINPROOF** facility after a 20 minutes acclimatization period in a controlled temperature and humidity environment (temperature 18 – 24°C, relative humidity 40 – 70%). Each data collection at the follow-up visit was carried out at the same time (± 1 hour) as when the baseline data was collected. Deviations in subject follow-up data collection that were permitted were no more than 15% from the predetermined schedule. The schedule for implementing testing procedures can be seen in Table 9.

The duration of study was carried out for 5 days. The test product that was added to the patch was applied to the back area (lower left back, above the waist). The test product was attached for 48 hours. On the third to fifth day, the subject returned to **SKINPROOF** to evaluate the skin reaction to the test product that had been applied.

Table 9. Subject Visit Schedule

Day- / Procedure	Screening D-7	D1	D2	D3	D4	D5
	Visit-1	Visit-2*		Visit-3	Visit-4	Visit-5
Informed Consent and Screening	X					
Patch (product) Application		X				
Patch Removal				X		
Evaluation/Scoring				X	X	X
Side Effect Recording				X	X	X

Note :
*patch application for 48 hours
Visit-3 : Evaluation 30 minutes after patch removal
Visit-4 : Evaluation 24 hours after patch removal
Visit-5 : Evaluation 48 hours after patch removal

1. **Screening Procedure**
   a. Subjects came to **SKINPROOF** according to the scheduled time,
   b. Researchers obtained the subjects' willingness to participate by signing the Informed Consent (IC) form,
   c. Researchers carried out a screening process (inclusion and exclusion criteria). The entire screening process was recorded in the Case Report Form (CRF),
   d. All subjects who met the inclusion and exclusion criteria were included in the study (subject enrollment),
   e. All types of medication used by the subject were documented in the last 3 months.

2. **Study Procedure and Skin Reaction Evalution**
   a. Subjects came to **SKINPROOF** according to the scheduled time,
   b. The patch was attached to the back area (lower back, above the waist). Then the subjects were allowed to go home,

c. After patch application for 48 hours, the subject came back to **SKINPROOF**. The patch was removed from the test area, and the reaction was evaluated after T+30 minutes, T+24 hours and T+48 hours. The reaction caused by the skin was photographed.

7.4. Administration of Test Products

The number of products applied to the subject in a single patch application was 4 namely: 20 mg of the test product, 20 µL of positive control (SLS 1%), 20 µL of negative control (water for injection), and a blank chamber. The subject was informed that the use of the test product will be carried out in the **SKINPROOF** laboratory and the subject was also informed about the things that need to be known and paid attention to (according to the method of use and treatment at the time of application of the test product).

7.5. Test Parameter

Observation of reactions arising in the test area and its evaluation were carried out by researchers with the following tools and principles:

- Tools : Skin Marker Pen

Measurement Principle

- Instructions : Researchers evaluated and scored the reactions that arised in the test area. Scoring was carried out by dermatologist.
- Measurement Area : Measurement was conducted on the entire test area at each assessment time point (Day 3, Day 4, and Day 5).
- Measurement : The results of the scoring carried out by the researcher were documented, shown as an average. Then the raw data was analyzed using Microsoft Excel.

7.6. Evaluate Potential Skin Irritation

Based on the visual scoring that has been carried out on T+30 minutes, T+24 hours and T+48 hours observations, the Cumulative Irritation Index (CII) is calculated for each subject, with the formula:

$$\text{CII} = \frac{\text{Sum of clinical score } (\text{T} + 30\text{min}, \text{T} + 24\text{h}, \text{and T} + 48\text{h})}{\text{Frequency of scoring}}$$

Next the CII values of each subject were averaged to count the Mean Cumulative Irritation Index (MCII) value of each subject. The MCII value was used to determine the potential irritation that the test product may cause. The MCII was calculated using the formula below:

$$\text{MCII} = \frac{\Sigma\text{CII}}{\text{Number of Subjects}}$$

After the MCII value of each subject was calculated. The irritation potential of the test product can be determined using the category below:

Table 10. Irritancy Category[29,30]

MCII value	Product Classification
<0.25	Non-irritant
≥0.25 Until <1.00	Slightly irritant
≥1.00 Until <2.00	Moderately irritant
≥2.00 Until <3.00	Very irritant
≥3.00 Until <4.00	Extremely severely irritant

VIII. DATA EVALUATION

Data evaluation includes descriptive statistical analysis. Descriptive statistical analysis was carried out for all measurement data (scoring/visual assessment of each subject), reported as a single value (Cumulative Irritation Index (CII)) and average value (Mean Cumulative Irritation Index (MCII)). The MCII results of the test product were compared with the positive control and negative control. Evaluation of the reactions produced by the skin was carried out at T+30 minutes, T+24 hours and T+48 hours after the patch was removed.

IX. SAFETY ASSESSMENT

9.1. Definition

a. Adverse Event (AE)

Any untoward medical occurrence in a subject to whom a product has been administered, including occurrences which are not necessarily caused by or related to that product. Event can be in the form of abnormal laboratory results, untoward symptoms or disease that occur due to product usage.

b. Serious Adverse Event (SAE)

A serious adverse event is any untoward medical occurrence that:

a. Results in death,
b. Is life-threatening,
c. Requires inpatient hospitalization or prolongation of existing hospitalization,
d. Results in persistent or significant disability/incapacity,
e. Consists of a congenital anomaly or birth defect.

9.2. Assessment of Causality

Both the investigator and the Sponsor-investigator make a causality assessment of adverse events of the products during the study period, based on the criteria listed:

Table 11. Causality Assessment of Test Products

Casuality Term	Information
Certain	a. Event or laboratory test abnormality, with plausible time relationship to product usage, b. Cannot be explained by disease or other product, c. Response to withdrawal, the event stops if there is discontinuation of the test product and will reappear when the test product is used again, d. Related to the mechanism of test product.
Probable/Likely	a. Event or laboratory test abnormality with reasonable time relationship to product usage, b. Unlikely to attributed to disease or other product, c. Response to withdrawal clinically reasonable.
Possible	a. Event or laboratory test abnormality, with reasonable time relationship to product usage, b. Could also be explained by disease or other product,

Casuality Term	Information
	c. Information on product withdrawal may be lacking or unclear.
Unlikely	a. Event or laboratory test abnormality, with a time to product usage that makes a relationship improbable (but not impossible), b. Disease or other product provide plausible explanations.
Conditional/ Unclassified	a. Event or laboratory test abnormality, b. More data for proper assessment needed, or additional data under examination.
Unassessable/ Unclassificable	a. Report ruggestiong an adverse reaction, b. Cannot be judged because information is insufficient or contradictory, c. Data cannot be supplemented or verified.

*Conditional and unassessable causal relationship can be ruled out and be include to not related causality term,

*Improvement after dechallenge only taken into consideration, if applicable to reaction.

9.3. Reporting of Adverse Events (AE) and Serious Adverse Events (SAE) and Other Safety Related Events

All adverse events (AE) including all serious adverse events (SAE) were collected, fully investigated and documented in the adverse event form and attached in Case Report Form (CRF) during the entire study period, i.e. from subjects' informed consent until the last protocol-specific procedure, including a safety follow-up period. Documentation includes dates of event, treatment, resolution, assessment of seriousness and causal relationship to device and/or study procedure.

Serious Adverse Events (SAEs) must be reported to the Sponsor as soon as possible, no later than within 24 hours, and to the Ethics Committee no later than within 3 calendar days from the time the SAE is first identified. If the SAE is ongoing, follow-up reports must be submitted until the SAE case is considered resolved. Reporting shall be conducted both verbally and in writing. Sponsor personnel who may be contacted for reporting Adverse Events (AEs) and Serious Adverse Events (SAEs) are as follows:

Michelle Gracella
PT NAYUE KOSMETIK INDONESIA
Pantai Indah Utara 1 No. 03, RT 4/RW 7, Kamal Muara, Kecamatan Penjaringan, Jakarta Utara, Daerah Khusus Ibukota Jakarta 14470

Email : prodev03@nayuecosmetics.com

X. DATA ACCESS, SOURCE DOCUMENTS AND CASE REPORT FORM (CRF)

Source Documents are documents in the form of original notes about observations, observations result and supporting documents needed during clinical trials. Source Documents are filled in and stored in accordance with applicable procedures. The Case Report Form (CRF) was made using a printed version for clinical trial subjects and filled in by personnel who have been given training in filling out the Case Report Form (CRF). Original Case Report Form (CRF) documents along with Source Documents are used as attachments and stored in **SKINPROOF** in accordance with document retention procedures.

10.1. Monitoring

The Sponsor could carry out monitoring activities during clinical testing. All Source Documents related to clinical trials can be viewed and accessed by Sponsor for monitoring activities.

10.2. Audit and Inspection

Clinical trial documents can be viewed and accessed by regulatory authorities for audit and inspection purposes.

10.3. Confidentiality and Data Protection

Access to clinical trial source data is only permitted by the Sponsor and regulatory authorities for monitoring activities, audits and inspection. All data is stored in **SKINPROOF** storage facilities in accordance with established procedures and can only be accessed by designated personnel.

XI. QUALITY ASSURANCE AND CONTROL

Quality control and assurance was carried out in accordance with the procedures applicable at **SKINPROOF**. The Principal Investigator was responsible for ensuring that all personnel involved in clinical trials have received the necessary training and are carrying out quality assurance procedures.

XII. ETHICAL PRINCIPLE

Before the clinical trial starts, all protocols and the amandements including the Informed Consent (IC) has been approved by the ethical review body, namely the Ethics Commission of the Faculty of Medicine, University of Indonesia. The Investigator ensured that this study was conducted in accordance with the principles of the Declaration of Helsinki (75th WMA General Assembly, Helsinki, Finlandia, October, 2024) dan International Conference on Harmonization – Good Clinical Practice (ICH-GCP).

Table 12. Ethical Approval Information

No. Ethical Approval	KET-1674/UN2.F1/ETIK/PPM.00.02/2025
Date of Ethical Approval	December 05th, 2025
Issued by	Health Research Ethics Committee, Faculty of Medicine, University of Indonesia
Additional Information	Ethical approval was first issued (Effective from December 05th, 2025, until December 05th, 2026)

XIII. DOCUMENT HANDLING AND ARCHIVING

All study documents are stored as essential documents for clinical trials at the document storage facility at **SKINPROOF** in accordance with applicable procedures. Retention of essential documents is for a minimum of 2 years from the date of approval of the test product by the regulatory body or a minimum of 5 years from the end of the clinical trial or in accordance with the agreement with the Sponsor. Destruction of essential clinical trial documents after the shelf life has expired is carried out using the Minutes of Document Destruction and will be reported to the Sponsor.

XIV. FINANCE AND INSURANCE

The Sponsor was responsible for funding study-related cost. Financing and Insurance statements were addressed in a separate agreement between **SKINPROOF** and Sponsor.

XV. PUBLICATION POLICY

Any form of publication and dissemination of information related to the clinical trial results may only be carried out upon obtaining prior written approval from both parties, namely the Sponsor and **SKINPROOF**.

Sponsor is not permitted to do any of the following without prior written consent from **SKINPROOF**:

1. Exhibit, display, show, or disclose any deliverables publicly in any manner,
2. Use **SKINPROOF**'s name, trademark, logo, or slogans in any form.

XVI. RESULT AND DISCUSSION

16.1. Subject Disposition

A total of 60 potential subjects were invited to take part in the study, undergo the screening process, and sign the informed consent form. The total number of subjects included in the per-protocol evaluation was 57 subjects, disposition can be seen in the following chart:

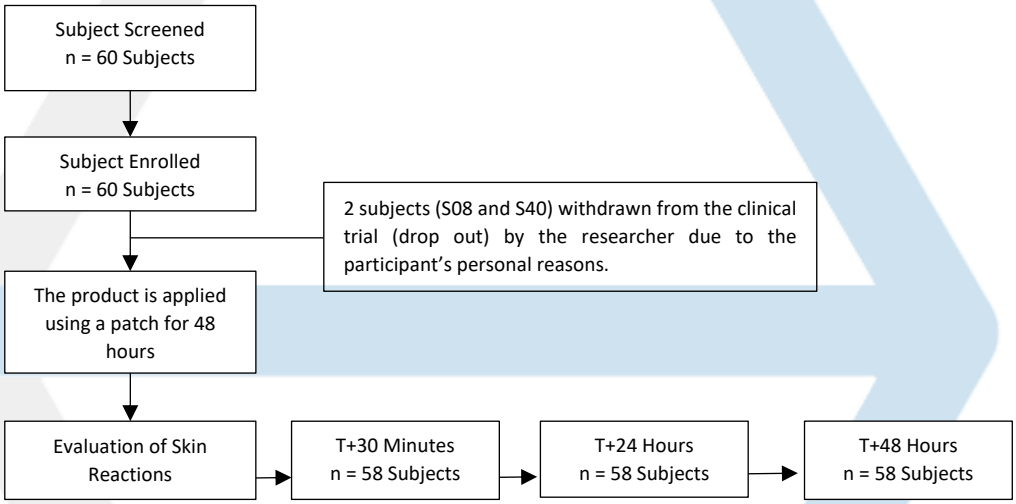


Figure 6. Subject Disposition

16.2. Subject Demographics

The subjects consisted of 60 individuals, both male and female, aged between 20-49 years, with sensitive (50.00%) and resistant (50.00%) skin types. The demographic data of the subjects can be found in Appendix B.

16.3. Protocol Deviation

16.3.1. Deviation of Visit Time

There was no deviation in visit time from the study protocol has been observed during the test.

16.3.2. Deviation of the Number of Subjects

There was no deviation in number of subjects from the study protocol that was observed during the test.

16.4. Irritation Potential

During the study, researchers observed the reaction of the test product, positive control and negative control after the patch was removed at T+30 minutes, T+24 hours and T+48 hours. During the observation period, subjects were in the testing room at room temperature 18 – 24°C and relative humidity 40 – 70%.

Table 13. Skin Irritation Scoring in Test Products

Score		Evaluation											
		Test Product (TP.26.02.104)			Positive Control (SLS 1%)			Negative Control (Water for Injection)			Negative Control (Blank Chamber)		
		30min	24 h	48 h	30min	24 h	48 h	30min	24 h	48 h	30min	24 h	48 h
0	n	56	56	58	37	19	23	55	58	58	56	58	58
	%	96.552	96.552	100.000	63.793	32.759	39.655	94.828	100.000	100.000	96.552	100.000	100.000
0.5	n	2	2	0	21	39	35	3	0	0	2	0	0
	%	3.448	3.448	0.000	36.207	67.241	60.345	5.172	0.000	0.000	3.448	0.000	0.000
1	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
2	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
3	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
∑ N		**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**	**58**
MCII		**0.011 (Non-irritant)**			**0.273 (Slightly irritant)**			**0.009 (Non-irritant)**			**0.006 (Non-irritant)**		

In this test, observations were made on the test product, positive control, and negative control. The **positive control (SLS 1%)** demonstrated **mild irritating potential (slightly irritant),** with an MCII value of **0.273** (≥0.25 until <1.00). The MCII value of the test product was is **0.011** (<0.25), indicating that the **OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM (TP.26.02.104)** exhibited **no irritating potential (non-irritant)**. Detailed data can be found in Appendix C.

XVII. CONCLUSION

MCII value of **OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM (TP.26.02.104)** is **0.011** (<0.25), which indicate that **the product** had **no irritating potential (non-irritant)**.

XVIII. LITERATURE

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XIX. APPENDIX

APPENDIX A

UNIVERSITAS INDONESIA
FAKULTAS KEDOKTERAN

Gedung Fakultas Kedokteran U
Jl. Salemba Raya No.6, Jakarta 1043
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Nomor : KET- 1674 /UN2.F1/ETIK/PPM.00.02/2025

KETERANGAN LOLOS KAJI ETIK
ETHICAL APPROVAL

Komite Etik Penelitian Kesehatan Fakultas Kedokteran Universitas Indonesia – RSUPN Dr. Cipto Mangunkusumo dalam upaya melindungi hak asasi dan kesejahteraan subjek penelitian kedokteran, telah mengkaji dengan teliti protokol penelitian yang berjudul:

The Ethics Committee of the Faculty of Medicine, University of Indonesia – Cipto Mangunkusumo Hospital with regards of the Protection of human rights and welfare in medical research, has carefully reviewed the research entitled:

"Evaluasi *In Vivo* Potensi Iritasi pada Produk Kosmetik dan Produk Rumah Tangga Melalui *Singe Patch Test* pada Partisipan Indonesia Sehat (No. Protokol: SPF.PDD.P.088, Versi: 25.00, Tanggal Rilis: 27 Oktober 2025)."

Protocol Number	: **25-10-1641**
Peneliti Utama *Principal Investigator*	: **dr. Indrawati Widjaja, Sp.DVE.**
Nama Institusi *Name of the Institution*	: **Skinproof**
Lokasi Penelitian *Site*	: **Skinproof/ Jl. K.S. Tubun II C No. 30, Desa/Kelurahan Slipi, Kecamatan Palmerah, Kota Administrasi Jakarta Barat, DKI Jakarta 11410**
Tanggal Persetujuan *Date of Approval*	: **05 DEC 2025** ***(valid for one year beginning from the date of approval)***
Dokumen Disetujui *Document Approved*	: **Proposal Penelitian, Version 25.00 tanggal 27 Oktober 2025** **Lembar Penjelasan kepada Calon Subjek, Version 25.00 tanggal 27 Oktober 2025**

dan telah menyetujui protokol berikut dokumen terlampir.
and approves the above mentioned protocol including the attached document.

Ditetapkan di : Jakarta
Signed in

Ketua
Chair

Prof. Dr. dr. Andri Maruli Tua Lubis, Sp.OT(K)

** Peneliti berkewajiban
1. Menjaga kerahasiaan identitas subjek penelitian.
2. Memberitahukan status penelitian apabila:
   a. Setelah masa berlakunya keterangan lolos kaji etik, penelitian masih belum selesai, dalam hal ini *ethical approval* harus diperpanjang. Harap pengajuan perpanjangan etik dilakukan 30 hari sebelum masa aktif lolos kaji etik habis.
   b. Penelitian berhenti ditengah jalan.
3. Melaporkan kejadian serius yang tidak diinginkan (*serious adverse events*).
4. Peneliti tidak boleh melakukan tindakan apapun pada subjek sebelum protokol penelitian mendapat lolos kaji etik dan sebelum memperoleh *informed consent* dari subjek penelitian.
5. Menyampaikan laporan akhir, bila penelitian sudah selesai.
6. Cantumkan nomor protokol ID pada setiap komunikasi dengan KEPK FKUI-RSCM.

APPENDIX B

APPENDIX B. DEMOGRAPHY DATA

1. Subject's Data

No.	Subject No.	Initial	Gender (M/F)	Age (Year)	ITA° values	Skin Type
1	S01	DOS	M	32	1	Resistant
2	S02	LLF	M	44	29	Sensitive
3	S03	HLD	F	36	13	Sensitive
4	S04	FIJ	M	29	13	Sensitive
5	S05	APL	M	40	1	Sensitive
6	S06	RDW	F	35	24	Resistant
7	S07	MYS	M	49	25	Resistant
8	S08	MBA	F	37	9	Sensitive
9	S09	SJN	F	39	13	Resistant
10	S10	TFD	F	33	15	Sensitive
11	S11	EEI	F	47	28	Sensitive
12	S12	NJG	F	31	5	Sensitive
13	S13	TYA	F	36	12	Sensitive
14	S14	YPA	M	27	11	Resistant
15	S15	AJR	M	33	20	Resistant
16	S16	HTR	F	29	6	Resistant
17	S17	HFA	F	33	11	Resistant
18	S18	RRH	M	45	11	Sensitive
19	S19	IWR	F	32	17	Sensitive
20	S20	HUS	F	46	14	Sensitive
21	S21	DML	F	40	17	Resistant
22	S22	IAG	F	37	23	Resistant
23	S23	FCH	F	34	19	Sensitive
24	S24	AIE	F	33	8	Resistant
25	S25	MGA	F	34	11	Resistant
26	S26	WRP	F	41	27	Resistant
27	S27	DKP	M	30	9	Sensitive
28	S28	EEM	F	41	9	Sensitive
29	S29	EDN	M	35	4	Sensitive
30	S30	MKE	F	48	35	Resistant
31	S31	MAQ	F	35	9	Sensitive
32	S32	AER	F	38	23	Sensitive
33	S33	YPU	F	38	28	Sensitive
34	S34	TPU	F	30	21	Resistant
35	S35	YII	F	47	14	Resistant
36	S36	RFY	F	40	29	Sensitive
37	S37	SBU	F	46	19	Resistant
38	S38	OOK	F	30	24	Sensitive
39	S39	VVR	F	34	10	Resistant

No.	Subject No.	Initial	Gender (M/F)	Age (Year)	ITA° values	Skin Type
40	S40	RUJ	F	38	37	Sensitive
41	S41	UYY	M	43	40	Sensitive
42	S42	ISJ	M	36	48	Sensitive
43	S43	FFY	F	46	46	Resistant
44	S44	VNR	F	33	45	Resistant
45	S45	IFN	F	28	43	Resistant
46	S46	HRS	M	38	21	Sensitive
47	S47	MHT	F	49	30	Sensitive
48	S48	LNT	F	47	46	Sensitive
49	S49	FOR	M	39	39	Sensitive
50	S50	SMI	F	20	45	Sensitive
51	S51	IUK	M	29	32	Sensitive
52	S52	WWE	F	31	20	Sensitive
53	S53	BSY	M	26	29	Resistant
54	S54	KSK	F	42	43	Sensitive
55	S55	ELN	F	31	28	Sensitive
56	S56	YPP	M	24	36	Resistant
57	S57	DFI	M	27	22	Resistant
58	S58	YNG	F	28	47	Sensitive
59	S59	RGG	F	23	40	Resistant
60	S60	EWI	M	23	39	Sensitive

2. Subject's Characteristic

Variable	Category	n	Percentage (%)
Gender (M/F)	Male (M)	19	31.670
	Female (F)	41	68.330
Age (Year)	Min.	20	
	Max.	49	
	Mean	37	
	Median	37	
	SD	7.090	
ITA° values	> 28° to 41°	7	11.670
	> 10° to 28°	34	56.670
	> -30° to 10°	19	31.670
Skin Type*	Resistant	25	41.670
	Sensitive	35	58.330

*According to Baumann's Skintype Questionnaire

APPENDIX C

APPENDIX C. POTENTIAL IRRITATION SCORING RESULT

Subject No.	Product		Scoring			CII
			30 min	24 h	48 h	
S01	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S02	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S03	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S04	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S05	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S06	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S07	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0	0	0.167
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S09	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S10	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S11	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000

Subject No.	Product		Scoring			CII
			30 min	24 h	48 h	
S12	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S13	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S14	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S15	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S16	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S17	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S18	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0	0.167
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S19	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S20	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S21	Patch 1	TP.26.02.136	0.5	0	0	0.167
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0.5	0	0	0.167
S22	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333

Subject No.	Product		Scoring			CII
			30 min	24 h	48 h	
S22	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S23	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S24	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S25	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S26	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S27	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S28	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S29	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S30	Patch 1	TP.26.02.136	0	0.5	0	0.167
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S31	Patch 1	TP.26.02.136	0.5	0.5	0	0.333
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0.5	0	0	0.167
	Patch 4	Blank Chamber	0	0	0	0.000
S32	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000

Subject No.	Product		Scoring			CII
			30 min	24 h	48 h	
S33	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S34	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0	0.167
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S35	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S36	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S37	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S38	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S39	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S41	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S42	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0	0	0.167
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S43	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S44	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500

Subject No.	Product		Scoring			CII
			30 min	24 h	48 h	
S44	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S45	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S46	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S47	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S48	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0.5	0	0	0.167
	Patch 4	Blank Chamber	0	0	0	0.000
S49	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S50	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S51	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0.5	0	0	0.167
	Patch 4	Blank Chamber	0.5	0	0	0.167
S52	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S53	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S54	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000

Subject No.	Product		Scoring			CII
			30 min	24 h	48 h	
S55	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S56	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S57	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0	0	0.000
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S58	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S59	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0.5	0.5	0.5	0.500
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000
S60	Patch 1	TP.26.02.136	0	0	0	0.000
	Patch 2	SLS 1%	0	0.5	0.5	0.333
	Patch 3	Water for Injection	0	0	0	0.000
	Patch 4	Blank Chamber	0	0	0	0.000

Products	CII	MCII
TP.26.02.136	0.667	0.011
SLS 1%	15.833	0.273
Water for Injection	0.500	0.009
Blank Chamber	0.333	0.006

MCII Value Test Product:

$$\text{MCII} = \frac{\Sigma \text{CII}}{\text{Number of subject}} = \frac{0.667}{58} = 0.011$$

MCII Value Positive Control (SLS 1%):

$$\text{MCII} = \frac{\Sigma \text{CII}}{\text{Number of subject}} = \frac{15.833}{58} = 0.273$$

MCII Value Negative Control (Water for Injection):

$$\text{MCII} = \frac{\Sigma \text{CII}}{\text{Number of subject}} = \frac{0.500}{58} = 0.009$$

MCII Value Negative Control (Blank Chamber):

$$\text{MCII} = \frac{\Sigma \text{CII}}{\text{Number of subject}} = \frac{0.333}{58} = 0.006$$

Conclusion:
MCII value of **NPURE Cica Sport Sunscreen (TP.26.02.136)** is **0.003** (<0.25), which indicate that **the product** had **no irritating potential (non-irritant)**.

APPENDIX D

APPENDIX D. SCORING TABLE SINGLE PATCH TEST

Product Name	OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM
Product Code (SKINPROOF)	TP.26.02.104
Batch No./Lot No.	NYHHD25081301A
Sponsor	PT Nayue Biotech Indonesia

Subject No.	Scoring			CII per subject
	30 min	24 h	48 h	
S01	0	0	0	0.000
S02	0	0	0	0.000
S03	0	0	0	0.000
S04	0	0	0	0.000
S05	0	0	0	0.000
S06	0	0	0	0.000
S07	0	0	0	0.000
S09	0	0	0	0.000
S10	0	0	0	0.000
S11	0	0	0	0.000
S12	0	0	0	0.000
S13	0	0	0	0.000
S14	0	0	0	0.000
S15	0	0	0	0.000
S16	0	0	0	0.000
S17	0	0	0	0.000
S18	0	0	0	0.000
S19	0	0	0	0.000
S20	0	0	0	0.000
S21	0.5	0	0	0.167
S22	0	0	0	0.000
S23	0	0	0	0.000
S24	0	0	0	0.000
S25	0	0	0	0.000
S26	0	0	0	0.000
S27	0	0	0	0.000
S28	0	0	0	0.000
S29	0	0	0	0.000
S30	0	0.5	0	0.167
S31	0.5	0.5	0	0.333
S32	0	0	0	0.000
S33	0	0	0	0.000
S34	0	0	0	0.000
S35	0	0	0	0.000

Subject No.	Scoring			CII per subject
	30 min	24 h	48 h	
S36	0	0	0	0.000
S37	0	0	0	0.000
S38	0	0	0	0.000
S39	0	0	0	0.000
S41	0	0	0	0.000
S42	0	0	0	0.000
S43	0	0	0	0.000
S44	0	0	0	0.000
S45	0	0	0	0.000
S46	0	0	0	0.000
S47	0	0	0	0.000
S48	0	0	0	0.000
S49	0	0	0	0.000
S50	0	0	0	0.000
S51	0	0	0	0.000
S52	0	0	0	0.000
S53	0	0	0	0.000
S54	0	0	0	0.000
S55	0	0	0	0.000
S56	0	0	0	0.000
S57	0	0	0	0.000
S58	0	0	0	0.000
S59	0	0	0	0.000
S60	0	0	0	0.000
Total	**1.000**	**1.000**	**0.000**	**0.667**
n	**58**	**58**	**58**	
MCII				**0.011**

Conclusion:
MCII value of **OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM (TP.26.02.104)** is **0.011** (<0.25), which indicate that **the product** had **no irritating potential (non-irritant)**.

Prepared by,	**Approved by,**
EJW	
Evelyn Jeanette Wijaya S.Farm.	dr. Indrawati Widjaja, MD., DV.
Product Delivery Coordinator	Principal Investigator
Date: May 15th , 2026	Date: May 16th, 2026

Product Name	Positive Control (SLS 1%)
Amount	20 µL

Subject No.	Scoring			CII per subject
	30 min	24 h	48 h	
S01	0.5	0.5	0.5	0.500
S02	0.5	0.5	0.5	0.500
S03	0	0	0	0.000
S04	0	0	0	0.000
S05	0	0.5	0.5	0.333
S06	0	0.5	0.5	0.333
S07	0.5	0	0	0.167
S09	0.5	0.5	0.5	0.500
S10	0.5	0.5	0.5	0.500
S11	0.5	0.5	0.5	0.500
S12	0	0.5	0.5	0.333
S13	0.5	0.5	0.5	0.500
S14	0	0	0	0.000
S15	0.5	0.5	0.5	0.500
S16	0.5	0.5	0.5	0.500
S17	0	0	0	0.000
S18	0	0.5	0	0.167
S19	0.5	0.5	0	0.333
S20	0.5	0.5	0	0.333
S21	0.5	0.5	0.5	0.500
S22	0	0.5	0.5	0.333
S23	0	0.5	0.5	0.333
S24	0	0.5	0.5	0.333
S25	0.5	0.5	0.5	0.500
S26	0	0.5	0.5	0.333
S27	0	0.5	0.5	0.333
S28	0	0.5	0.5	0.333
S29	0	0.5	0.5	0.333
S30	0	0	0	0.000
S31	0.5	0.5	0.5	0.500
S32	0	0	0	0.000
S33	0.5	0.5	0.5	0.500
S34	0	0.5	0	0.167
S35	0	0.5	0.5	0.333

Subject No.	Scoring			CII per subject
	30 min	24 h	48 h	
S36	0	0.5	0.5	0.333
S37	0	0	0	0.000
S38	0	0	0	0.000
S39	0	0	0	0.000
S41	0	0	0	0.000
S42	0.5	0	0	0.167
S43	0	0	0	0.000
S44	0.5	0.5	0.5	0.500
S45	0	0.5	0.5	0.333
S46	0	0	0	0.000
S47	0	0	0	0.000
S48	0.5	0.5	0.5	0.500
S49	0	0.5	0.5	0.333
S50	0.5	0.5	0.5	0.500
S51	0.5	0.5	0.5	0.500
S52	0	0	0	0.000
S53	0	0.5	0.5	0.333
S54	0	0	0	0.000
S55	0	0.5	0.5	0.333
S56	0	0	0	0.000
S57	0	0	0	0.000
S58	0	0.5	0.5	0.333
S59	0.5	0.5	0.5	0.500
S60	0	0.5	0.5	0.333
Total	**10.500**	**19.500**	**17.500**	**15.833**
n	**58**	**58**	**58**	
MCII				**0.273**

Conclusion:
MCII value of **Positive Control (SLS 1%)** is **0.273** (≥0.25 until <1.00), which indicate that **Positive Control (SLS 1%)** had **mild irritating potential (slightly irritant)**.

Prepared by,	Approved by,
	
Evelyn Jeanette Wijaya S.Farm.	dr. Indrawati Widjaja, MD., DV.
Product Delivery Coordinator	Principal Investigator
Date: May 15th , 2026	Date: May 16th , 2026

Product Name	Negative Control (Water for Injection)
Amount	20 µL

Subject No.	Scoring			CII per subject
	30 min	24 h	48 h	
S01	0	0	0	0.000
S02	0	0	0	0.000
S03	0	0	0	0.000
S04	0	0	0	0.000
S05	0	0	0	0.000
S06	0	0	0	0.000
S07	0	0	0	0.000
S09	0	0	0	0.000
S10	0	0	0	0.000
S11	0	0	0	0.000
S12	0	0	0	0.000
S13	0	0	0	0.000
S14	0	0	0	0.000
S15	0	0	0	0.000
S16	0	0	0	0.000
S17	0	0	0	0.000
S18	0	0	0	0.000
S19	0	0	0	0.000
S20	0	0	0	0.000
S21	0	0	0	0.000
S22	0	0	0	0.000
S23	0	0	0	0.000
S24	0	0	0	0.000
S25	0	0	0	0.000
S26	0	0	0	0.000
S27	0	0	0	0.000
S28	0	0	0	0.000
S29	0	0	0	0.000
S30	0	0	0	0.000
S31	0.5	0	0	0.167
S32	0	0	0	0.000
S33	0	0	0	0.000
S34	0	0	0	0.000
S35	0	0	0	0.000

Subject No.	Scoring			CII per subject
	30 min	24 h	48 h	
S36	0	0	0	0.000
S37	0	0	0	0.000
S38	0	0	0	0.000
S39	0	0	0	0.000
S41	0	0	0	0.000
S42	0	0	0	0.000
S43	0	0	0	0.000
S44	0	0	0	0.000
S45	0	0	0	0.000
S46	0	0	0	0.000
S47	0	0	0	0.000
S48	0.5	0	0	0.167
S49	0	0	0	0.000
S50	0	0	0	0.000
S51	0.5	0	0	0.167
S52	0	0	0	0.000
S53	0	0	0	0.000
S54	0	0	0	0.000
S55	0	0	0	0.000
S56	0	0	0	0.000
S57	0	0	0	0.000
S58	0	0	0	0.000
S59	0	0	0	0.000
S60	0	0	0	0.000
Total	**1.500**	**0.000**	**0.000**	**0.500**
n	**58**	**58**	**58**	
MCII				**0.009**

Conclusion:
MCII value of **Negative Control (Water for Injection)** is **0.009** (<0.25), which indicate that the **Negative Control (Water for Injection)** had **no irritating potential (non-irritant)**.

Prepared by,	**Approved by,**
EJW	
Evelyn Jeanette Wijaya S.Farm.	dr. Indrawati Widjaja, MD., DV.
Product Delivery Coordinator	Principal Investigator
Date: May 15th, 2026	Date: May 16th, 2026

Product Name	Negative Control (Blank Chamber)
Amount	NA

Subject No.	Scoring			CII per subject
	30 min	24 h	48 h	
S01	0	0	0	0.000
S02	0	0	0	0.000
S03	0	0	0	0.000
S04	0	0	0	0.000
S05	0	0	0	0.000
S06	0	0	0	0.000
S07	0	0	0	0.000
S09	0	0	0	0.000
S10	0	0	0	0.000
S11	0	0	0	0.000
S12	0	0	0	0.000
S13	0	0	0	0.000
S14	0	0	0	0.000
S15	0	0	0	0.000
S16	0	0	0	0.000
S17	0	0	0	0.000
S18	0	0	0	0.000
S19	0	0	0	0.000
S20	0	0	0	0.000
S21	0.5	0	0	0.167
S22	0	0	0	0.000
S23	0	0	0	0.000
S24	0	0	0	0.000
S25	0	0	0	0.000
S26	0	0	0	0.000
S27	0	0	0	0.000
S28	0	0	0	0.000
S29	0	0	0	0.000
S30	0	0	0	0.000
S31	0	0	0	0.000
S32	0	0	0	0.000
S33	0	0	0	0.000
S34	0	0	0	0.000
S35	0	0	0	0.000

Subject No.	Scoring			CII per subject
	30 min	24 h	48 h	
S36	0	0	0	0.000
S37	0	0	0	0.000
S38	0	0	0	0.000
S39	0	0	0	0.000
S41	0	0	0	0.000
S42	0	0	0	0.000
S43	0	0	0	0.000
S44	0	0	0	0.000
S45	0	0	0	0.000
S46	0	0	0	0.000
S47	0	0	0	0.000
S48	0	0	0	0.000
S49	0	0	0	0.000
S50	0	0	0	0.000
S51	0.5	0	0	0.167
S52	0	0	0	0.000
S53	0	0	0	0.000
S54	0	0	0	0.000
S55	0	0	0	0.000
S56	0	0	0	0.000
S57	0	0	0	0.000
S58	0	0	0	0.000
S59	0	0	0	0.000
S60	0	0	0	0.000
Total	**1.000**	**0.000**	**0.000**	**0.333**
n	**58**	**58**	**58**	
MCII				**0.006**

Conclusion:
MCII value of **Negative Control (Blank Chamber)** is **0.006** (<0.25), which indicate that the **Negative Control (Blank Chamber)** had **no irritating potential (non-irritant)**.

Prepared by,	Approved by,
	
Evelyn Jeanette Wijaya S.Farm.	dr. Indrawati Widjaja, MD., DV.
Product Delivery Coordinator	Principal Investigator
Date: May 15th, 2026	Date: May 16th, 2026

APPENDIX E

APPENDIX E. ADVERSE EVENT

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AE	Serious Adverse Event
1 = Mild 2 = Moderate 3 = Severe 4 = Life-Threatening	0 = Not related 1 = Unlikely related 2 = Possibly related 3 = Probably related 4 = Definitely related	0 = None 1 = Dose modification 2 = Medical intervention 3 = Hospitalization 4 = Intervention discontinued 5 = Other	0 = Resolved 1 = Recovered with minor sequelae 2 = Recovered with major sequelae 3 = Ongoing/Continuing treatment 4 = Condition worsening Death 5 = Unknown	1 = Yes 2 = No (if yes, complete SAE form)

No.	Subject No.	Date		Severity	Relationship	Action Taken	Outcome	SAE?
		Start	End					
NA								

APPENDIX F

SKINPROOF
science creates speed

INFORMASI PRODUK
PRODUCT INFORMATION

CONTROLLED COPY

DIISI OLEH SKINPROOF / *TO BE FILLED BY SKINPROOF*		
NO. *QUOTATION*	**KODE SAMPEL / *SAMPLE CODE***	**KODE STUDI / *STUDY CODE***
DLA-808396	TP.26.02.104	26.02.02.006C

DIISI OLEH PELANGGAN / *TO BE FILLED BY CUSTOMER* (*Coret salah satu bila diperlukan / *Cross out whichever is not applicable*)

JENIS PENGUJIAN ***TESTING CATEGORY***	☐ *Efficacy test*		☐ *Sensory test / Consumer research*	
	☐ *Safety test*	☐ *Non-acnegenic, non-comedogenic* (NANC)	☑ *Patch test* (*Single* /HRIPT*)	
	☐ *Sunscreen test*	☐ *In-vivo* (SPF/UVAPF*)	Target nilai SPF : _____ **SPFi**	
			Target UVAPF : **PA** _____	
		☐ *In -vitro* (SPF/UVAPF*)		
NAMA PRODUK ***PRODUCT NAME***	OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM			
NO. *BATCH* / NO. LOT / NO. FORMULA	NYHHD25081301A	**TGL. PRODUKSI** ***MANUFACTURING DATE***		**TGL. KEDALUWARSA** ***EXPIRED DATE***
KOMPOSISI ***INGREDIENTS***	AQUA, GLYCERIN, NIACINAMIDE, DIMETHICONE, CYCLOPENTASILOXANE, SILICA, METHYLPROPANEDIOL, PANTHENOL, C12-15 ALKYL BENZOATE, TITANIUM DIOXIDE, BUTYL METHOXYDIBENZOYLMETHANE, PEG-100 STEARATE, GLYCERYL STEARATE, PHENOXYETHANOL, POLYSORBATE 80, CETEARYL ALCOHOL, FRAGRANCE, METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, POTASSIUM CETYL PHOSPHATE, MENTHOL, SORBITAN OLEATE, XANTHAN GUM, CHLORPHENESIN, BHT, TOCOPHERYL ACETATE, SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, TRIETHOXYCAPRYLYLSILANE,ETHYLHEXYLGLYCERIN, DECYL GLUCOSIDE, BUTYLENE GLYCOL, ISOHEXADECANE, DISODIUM EDTA, SODIUM HYALURONATE, TRANEXAMIC ACID, SILK EXTRACT, PROPYLENE GLYCOL, BUTYROSPERMUM PARKII (SHEA) BUTTER, GLUTATHIONE, PANAX GINSENG ROOT EXTRACT, THYMUS SERPYLLUM EXTRACT, ALPHA-GLUCAN OLIGOSACCHARIDE, PENTYLENE GLYCOL, CAMELLIA SINENSIS ECTRACT, POLYMNIA SONCHIFOLIA ROOT JUICE, 3-o-ETHYL ASCORBIC ACID, CAPRYLIC/CAPRIC TRIGLYCERIDE, MALTODEXTRIN, CHLORELLA VULGARIS EXTRACT, PHOSPHOLIPIDS, POTASSIUM SORBATE, SODIUM BENZOATE, LACTOBACILLUS, ASTAXANTHIN			
JENIS PRODUK ***PRODUCT CATEGORY***	☑ Produk jadi kosmetik *Cosmetic finished product*	☐ Bahan baku kosmetik *Cosmetic raw materials*	☐ Lainnya, jelaskan! / *Others, please specify* !	
BENTUK SEDIAAN ***PRODUCT DOSAGE FORM***	☐ Padat (Tablet, kapslet, kapsul, serbuk*) *Solid (Tablets, caplets, capsule,powder*)*	☑ Setengah padat (Gel, krim, losion, balsem, salep, suspensi, emulsi*) *Semi-solid (Gel, cream, lotion, balm, ointment, suspension, emulsion*)*		
	☐ Cairan (Sirup, serum, toner, *essence**) *Liquid (Syrup, serum, toner, essence*)*	☐ Lainnya, jelaskan! / *Others, please specify* !		
PEMERIAN ***SPECIFICATIONS***	☐ Warna / *Color* :	☐ Aroma :		
MANUFAKTUR ***MANUFACTURER***	PT NAYUE BIOTECH INDONESIA			
KONDISI PENYIMPANAN ***STORAGE CONDITION***	DISIMPAN DI SUHU RUANG			
CARA PAKAI ***APPLICATION METHOD***	APLIKASIKAN KE SELURUH BADAN SECARA MERATA	Apakah perlu dilakukan pembilasan setelah pemakaian? / *Is rinsing required after use?*	☐ Ya / *Yes* ☑ Tidak / *No*	

RINCIAN PELANGGAN ***CUSTOMER'S INFORMATION***	**NAMA PERUSAHAAN** ***COMPANY NAME***	PT NAYUE KOSMETIK INDONESIA		
	ALAMAT PERUSAHAAN ***COMPANY ADRESS***	Pantai Indah Utara 1 No.03, RT.4/RW.7, Kamal Muara, Kecamatan Penjaringan, Jkt Utara, Daerah Khusus Ibukota Jakarta 14470		
	NAMA LENGKAP PENANGGUNGJAWAB ***PIC FULL NAME***	**Michelle Gracella**	**JABATAN** ***POSISITION***	**Sales Representative**
	E-*MAIL*	prodev03@nayuecosmetics.com	**TELEPON/*PHONE***	(+62)88808920559
	TANDA TANGAN & TANGGAL ***SIGN AND DATE***	 26-Feb-26	Apakah Anda bersedia jika produk dipublikasikan di media sosial Skinproof? / *Are you willing for the product to be published in Skinproof social media?*	
			☐ Ya / *Yes*	☑ Tidak / *No*

SKINPROOF
science creates speed

INFORMASI PRODUK
PRODUCT INFORMATION

CONTROLLED COPY

DIISI OLEH SKINPROOF / *TO BE FILLED BY SKINPROOF*			
DAFTAR PEMERIKSAAN KELENGKAPAN PRODUK UJI ***TEST PRODUCT COMPLETENESS CHECKLIST***			
NO.	**SYARAT / *REQUIREMENTS***	**STATUS**	
1	Kemasan primer tertutup rapat dilengkapi dengan segel produk (dapat berupa parafilm, hologram, atau segel dalam bentuk lainnya). *The primary packaging tightly closed and sealed (with parafilm, hologram, or any other type seal).*	☑ Ya / *Yes*	☐ Tidak / *No*
2	Kemasan primer dalam keadaan baik, tidak pecah, tidak kotor dan tidak bocor. *The primary packaging shall be in good condition, free from damage, contamination, and leakage.*	☑ Ya / *Yes*	☐ Tidak / *No*
3	Pemerian produk (bentuk sediaan, warna, aroma) sesuai dengan deskripsi pada halaman 1. *The product description (dosage form, color, aroma) complies with the description provided on page 1.*	☑ Ya / *Yes*	☐ Tidak / *No*
4	Produk dalam kondisi homogen (tidak terpisah dalam dua fase). *The product is homogeneous, with no phase separation.*	☑ Ya / *Yes*	☐ Tidak / *No*
5	Terdapat label informasi pada kemasan terluar produk untuk setiap pengujian yang mencantumkan nama produk, tanggal produksi, nomor *batch* / lot / formula, dan nama pelanggan. *The outer product packaging for each test must include an information label indicating the product name, production date, batch/lot/formula number, and the customer name.*	☑ Ya / *Yes*	☐ Tidak / *No*
6	Dokumen persetujuan seperti *quotation approval, purchasing order* (PO) atau surat perintah kerja (SPK) telah diterima dengan lengkap dan sesuai dengan rincian produk yang tercantum pada halaman 1. *Supporting documents such as quotation approval, purchase order (PO), or work order (WO) have been fully received and are consistent with the product details listed on page 1.*	☑ Ya / *Yes*	☐ Tidak / *No*
7	Lembar informasi produk telah diisi dengan lengkap. *Information page have been completely filled.*	☑ Ya / *Yes*	☐ Tidak / *No*
8	Surat pernyataan keamanan telah terlampir dengan lengkap dan sesuai dengan rincian produk yang tercantum pada halaman 1. *The Product Safety Declaration has been fully submitted and is consistent with the product details listed on page 1.*	☑ Ya / *Yes*	☐ Tidak / *No*

CATATAN LAIN / *OTHER NOTES*

KESIMPULAN / *CONCLUSION*				**DILAKUKAN OLEH / *DONE BY***
☑ **DITERIMA / *ACCEPTED***		☐ **DITOLAK / *REJECTED***		
JUMLAH ***QUANTITY***	3 Produk	**JUMLAH** ***QUANTITY***		Nama / *Name* : Shinta Marcela Tanggal / *Date* : 17 Maret 2026

SURAT PERNYATAAN KEAMAANAN

Yang bertanda tangan di bawah ini:

Nama /Jabatan : Michelle Gracella / Sales Representative
Perusahaan : PT Nayue Kosmetik Indonesia
Telp. : 088808920559
E-mail : prodev03@nayuecosmetics.com

Dengan ini menyatakan bahwa produk kosmetik yang disebutkan di bawah ini :

Nama Produk	**OINA - 4 IN 1 MULTI BENEFIT BODY LOTION SERUM**
Kode produk/ Batch /Lot No	**NYHHD25081301A**
Bentuk sediaan	**Setengah Padat (*Semi-solid*)**
Komposisi produk	AQUA, GLYCERIN, NIACINAMIDE, DIMETHICONE, CYCLOPENTASILOXANE, SILICA, METHYLPROPANEDIOL, PANTHENOL, C12-15 ALKYL BENZOATE, TITANIUM DIOXIDE, BUTYL METHOXYDIBENZOYLMETHANE, PEG-100 STEARATE, GLYCERYL STEARATE, PHENOXYETHANOL, POLYSORBATE 80, CETEARYL ALCOHOL, FRAGRANCE, METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, POTASSIUM CETYL PHOSPHATE, MENTHOL, SORBITAN OLEATE, XANTHAN GUM, CHLORPHENESIN, BHT, TOCOPHERYL ACETATE, SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, TRIETHOXYCAPRYLYLSILANE,ETHYLHEXYLGLYCERIN, DECYL GLUCOSIDE, BUTYLENE GLYCOL, ISOHEXADECANE, DISODIUM EDTA, SODIUM HYALURONATE, TRANEXAMIC ACID, SILK EXTRACT, PROPYLENE GLYCOL, BUTYROSPERMUM PARKII (SHEA) BUTTER, GLUTATHIONE, PANAX GINSENG ROOT EXTRACT, THYMUS SERPYLLUM EXTRACT, ALPHA-GLUCAN OLIGOSACCHARIDE, PENTYLENE GLYCOL, CAMELLIA SINENSIS ECTRACT, POLYMNIA SONCHIFOLIA ROOT JUICE, 3-o-ETHYL ASCORBIC ACID, CAPRYLIC/CAPRIC TRIGLYCERIDE, MALTODEXTRIN, CHLORELLA VULGARIS EXTRACT, PHOSPHOLIPIDS, POTASSIUM SORBATE, SODIUM BENZOATE, LACTOBACILLUS, ASTAXANTHIN

1. Mengandung bahan-bahan yang telah memenuhi persyaratan ASEAN COSMETIC DIRECTIVE dan Peraturan bahan baku dan sedian jadi kosmetik yang berlaku untuk produk kosmetik di Indonesia. Seluruh material dalam formula produk di atas sudah dilakukan proses evaluasi keamanan/ *safety assessment* bedasarkan review literatur dan telah memenuhi persyaratan, konsentrasi yang digunakan adalah konsentrasi yang aman digunakan secara topikal untuk kulit manusia sehingga diharapkan tidak menimbulkan reaksi yang merugikan kulit.

2. Produk disiapkan dan diproduksi sesuai dengan **Cara Pembuatan Kosmetik yang Baik/ Cara Pembuatan Obat yang Baik (*silakan pilih sesuai dengan sertifikat yang dimiliki*)** dengan yang menjamin kualitas fisiko-kimia dan mikrobiologi sesuai dengan spesifikasi yang telah ditetapkan oleh produsen untuk produk jadi.

Demikian pernyataan ini dibuat untuk dipergunakan sebagai lampiran data produk yang akan selanjutnya dilakukan pengujian keamanan secara in vivo menggunakan sukarelawan di SKINPROOF

Jakarta, 26 Februari 2026

Michelle Gracella
Penanggung jawab

APPENDIX G

1. KETERANGAN DIRI

Nama Lengkap	dr. Indrawati Widjaja, MD., DV.
Tempat Lahir	Bandung
Jenis Kelamin	Perempuan
Alamat Rumah	Jl. Raya Kelapa Nias LC 12/10, Kelapa Gading, Jakarta 14240, Indonesia
No. Telepon	021-45853536
No. HP	0817764065
E-mail	indrawati2004@yahoo.com

2. PENDIDIKAN DI DALAM DAN DI LUAR NEGERI

No.	Nama Pendidikan	Jurusan	Tahun Ijazah	Tempat
1.	*Dermatovenereologist*	Fakultas Kedokteran	2003	Universitas Indonesia
2.	*General Practitioner*	Fakultas Kedokteran	1991	Universitas Indonesia

3. PENGALAMAN KERJA

No.	Nama Perusahaan	Tahun	Keterangan
1.	PT Kalbe Farma	1991 – 1992	*Scientific Excecutive*
2.	PT Dexa Medica	1992 – 1994	*Product Manager*
3.	Primary Health Center	1994 – 1997	*General Physician*
4.	Erha Skin Specialist Clinic Kelapa Gading & Kemanggisan	2003 – Sekarang	*Dermatologist*
5.	Mitra Keluarga Hospital Kelapa Gading	2003 – Sekarang	*Dermatologist*

4. *CONGRESSES*

No.	Kegiatan	Tempat	Tahun
1.	PROFHILO 2.0: *Advanced Technique for Periorbital & Upper Face Bio-Remodelling*	Jakarta, Indonesia	Februari, 2025
2.	*Aesthetic* & *Anti-Aging Medicine World Congress Southeast Asia*	Bangkok, Thailand	November, 2025
3.	IMCAS ASIA	Bangkok, Thailand	Juni, 2024
4.	PIT XIX PERDOSKI	Jakarta, Indonesia	Agustus, 2023
5.	25th *World Congress of Dermatology*	Singapore	Juli, 2023
6.	PIT XVIII PERDOSKI	Semarang, Indonesia	September, 2022
7.	*International Congress of Aesthetic Dermatology* (ICAD)	Bangkok, Thailand	November, 2022
8.	19th *Aesthetic* & *Anti-aging Medicine World Congress, Monaco*	Monaco	September, 2021
9.	29th *European Academy of Dermatology and Venerology Virtual Congress*	*Online*	Oktober, 2020
10.	12th *5CC World Congress: Virtual*	*Online*	Agustus, 2020

No	Kegiatan	Tempat	Tahun
11.	28th *European Academy of Dermatology and Venerology Congress*	Madrid, Spanyol	Oktober, 2019
12.	22nd *Regional Conference of Dermatology*	Singapore	April, 2016
13.	*Asia-International Master Course of Anti-Aging*	Bali, Indonesia	Juli, 2015
14.	23rd *European Academy of Dermatology and Venereology Congress*	Amsterdam, Netherlands	Oktober, 2014
15.	*National Cosmetic Dermatology Symposium*	Jakarta, Indonesia	Februari, 2014

5. PUBLIKASI (JURNAL INTERNASIONAL, JURNAL NASIONAL, BUKU HKI, SEMINAR, dll.)

No.	Judul	Peran	Tahun	Keterangan
1.	*Low Energy of Non-Ablative Fractional Resurfacing Laser in Indonesian Skin*	*Co-Author*	Mei, 2015	Published in JAAD, May 2015, Vol. 72, Issue 5, Suppl. 1, p.AB269
2.	Terapi Skar Akne dengan Teknik *Skin Needling*	NA	Juli, 2008	Poster Publication at Konas XII Perdoski, Palembang
3.	Pengaruh Pemberian *Lotion* Pelembab Kombinasi Asam Laktat 5% dan Natrium Karboksilat Pirolidon 2,5% Terhadap Nilai pH Kulit Pasien Dermatitis Atopik Bayi dan Anak	*Author*	2003	Tesis S2

6. PERAN SERTA DALAM *TRAINING*/SEMINAR/*WORKSHOP*

No.	Kegiatan	Tahun
1.	*Welcoming the Biostimulator Era*: *Enhancing patient's rejuvenation needs using* CaHa *and* PDLLA *injectables* (*as a Speaker*)	April, 2025
2.	*Good Clinical Practice Course, The Indonesian Association for the Study of Medicinals* (IASMED)	Juni, 2023
3.	*International Anti-Aging Conference 6.0*, Jakarta, Indonesia (*as a Speaker*)	Juli, 2022
4.	*Combination Treatment of Non-Invasive and Minimally Invasive Procedures for Facial Aesthetic*	November, 2022
5.	2nd *International Scientific Meeting of Cosmetic Dermatology* (*as a Speaker*)	September, 2021
6.	*Laser & Aesthetic Skin Therapy, Harvard Medical School* (*online*)	Oktober ,2020
7.	*New Trend and Regulation Cosmetic Product Claim*, Jakarta, Indonesia	Juli, 2018
8.	*Good Clinical Practice Course*, CRSU FKUI, Jakarta, Indonesia	Februari, 2018
9.	*Flap and Wound Closure Workshop, Hands-On Procineskin*	Desember, 2016
10.	*Galderma Filler Anatomy Masterclass and Hands-On Workshop*, Seoul, Korea	April, 2015
11.	*Klein Tumescent Liposuction Course*, California, USA	Mei, 2014

7. ORGANISASI

No.	Kegiatan
1.	Anggota IDI (Ikatan Dokter Indonesia)
2.	Anggota PERDOSKI (Perhimpunan Dokter Spesialis Kulit dan Kelamin)
3.	Anggota *International American Academy of Dermatology*

8. AKTIVITAS SAAT INI

No.	Kegiatan	Tahun
1.	*Minor Surgeries, Aesthetic Treatments with Modalities of Peeling/Laser/Toxin/ Filler/Skin Needling, Laser Lipolysis, Liposuction and Fat Transfer*	2012 - Sekarang

Jakarta, 02 Juni 2025

dr. Indrawati Widjaja, MD., DV.

1. KETERANGAN DIRI

Nama Lengkap	Evelyn Jeanette Wijaya, S. Farm.
Tanggal Lahir/Umur	27 Juni 2000/ 25 Tahun
Tempat Lahir	Jakarta
Jenis Kelamin	Perempuan
Alamat Rumah	Jl. Pademangan 3, Gang 20 No. 259, Kec. Pademangan, Jakarta Utara
No. Telepon	NA
No. HP	081355071736
E-mail	evelyn.wijaya@skinproof.co.id

2. PENDIDIKAN DI DALAM DAN DI LUAR NEGERI

No.	Nama Pendidikan	Jurusan	Tahun Ijazah	Tempat
1.	S1 Farmasi	Fakultas Farmasi	2022	Indonesia International Institute for Life-sciences (i3L)

3. PENGALAMAN KERJA

No.	Nama Perusahaan	Tahun	Keterangan
1.	PT Equilab International	2022 – 2023	*Clinical Research Associate (CRA)*
2.	PT Derma Lab Asia (SKINPROOF)	2024- Sekarang	*Product Delivery Coordinator (Product Testing)*

4. PENELITIAN

No.	Judul	Peran	Tahun	Keterangan
1.	Evaluation of Antimicrobial Properties of Sport Roll-On Deodorant via Clinical Trials on Indonesian Males Subject With the Age Ranging from 26-40 years old	2021	2021	Thesis
2.	Evaluation of Wound Healing and Anti-microbial Properties of Bacterial Cellulose Containing B.subtilis	2019	2019	Penelitian

5. PERAN SERTA DALAM *TRAINING*/SEMINAR/*WORKSHOP*

No.	Kegiatan	Tahun
1.	Data Integrity, PT Equilab International, Jakarta, Indonesia.	2022
2.	Good Clinical Practice and Clinical Trial Mentoring Training, PT Equilab International, Jakarta, Indonesia.	2023

Jakarta, 16 April 2025

Evelyn Jeanette Wijaya, S. Farm.