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Study Report # DA24A632 (version 1.0)

Related to quote# DA24A632-2

**EVALUATION OF THE ACUTE CUTANEOUS TOLERANCE OF A COSMETIC PRODUCT
ON ADULT SUBJECTS
SINGLE PATCH TEST**



CME CHEERTSUME HYPER CLEAR SAKURA CLEANSING OIL & FOAM

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Dermscan Asia is certified ISO 9001 : 2015

including 15 pages

TABLE OF CONTENTS

SUMMARY OF THE STUDY REPORT# DA24A632	3
1. EXPERIMENTAL PROTOCOL.....	4
1.1. Subjects	4
1.1.1. Characteristics of included subjects	4
1.1.2. Inclusion criteria	4
1.1.3. Non-inclusion criteria	4
1.2. Study product.....	4
1.3. Methodology.....	5
1.3.1. Instruments, dose, duration	5
1.3.2. Readings	5
1.3.3. Result interpretation	6
1.3.4. Bibliography:.....	6
2. RESULTS-CONCLUSION.....	7
3. ETHICAL CONSIDERATION	8
3.1. CONFIDENTIALITY AND GENERAL DATA PROTECTION REGULATION	8
APPENDIX I	9
APPENDIX II	13

SUMMARY OF THE STUDY REPORT# DA24A632

EVALUATION OF THE ACUTE CUTANEOUS TOLERANCE OF A COSMETIC PRODUCT ON ADULT SUBJECTS: SINGLE PATCH TEST					
Objective	To determine the acute irritating potential of a cosmetic product after single application under patch-test.				
Methodology	Descriptive, Monocentric and single blind study.				
Kinetics		D0	D2	D2 t30min	D3 t24h
	Collection of the subject's informed consent	•			
	Verification of inclusion and non-inclusion criteria	•			
	Patch-test : application	•			
	Patch-test : removal		•		
Clinical scoring			•	•	
Dates	Product reception:	Study start:		Study end:	
	December 13, 2024	January 13, 2025		January 16, 2025	
Product	Reference:	Form:		Storage temperature:	
	CME CHEERTSUME HYPER CLEAR SAKURA CLEANSING OIL & FOAM	Clear colorless viscous liquid with pink petal		Room temperature (Thailand climate)	
Application	Zone:	Patch duration:	Concentration	Patch type:	
	Scapular part of the back	48 hours	Diluted 5% in purified water	Occlusive	
Studied Population	Main inclusion criteria		Average age:	Number of subjects analysed:	
	Age ≥ 18 years old. Phototype I to IV.		45±2 years (24 - 56)	22	
Results	M.C.I.I. value : 0.03				
	Conclusion: Non irritating				
Investigator: Dermatologist	Name and quality:	Date:	Signature:		
	Sujitra SOMBUNTHAM	February 25, 2025			

1. EXPERIMENTAL PROTOCOL

The study was conducted according to the current internal procedures.

1.1. Subjects

1.1.1. Characteristics of included subjects

- 22 subjects with every skin type were included in the study:

Female subjects	18
Male subjects	4
Age (mean±SEM)	24 to 56 years old (45±2)

1.1.2. Inclusion criteria

- subjects having given their informed, written consent,
- no previous experience of intolerance or allergic reactions to this kind of product,
- phototype I to IV.

1.1.3. Non-inclusion criteria

- pregnant or breast-feeding women or women planning to be pregnant during the study,
- cutaneous pathology on the study zone (psoriasis, eczema, vitiligo, pityriasis versicolor, acne, etc...),
- subjects with medical treatments which may interfere with the acute skin tolerance evaluation, according to the investigator,
- exposure to the sun or to UV rays on the back during the previous month,
- subjects with very irritative skin,
- subjects presenting an important hairiness of the back, freckles, beauty spots or a tattoo on the back,
- subjects with a serious or progressive disease,
- excessive use of alcohol or tobacco.

1.2. Study product

The product supplied by the sponsor had the following specifications:

Product reference	Product aspect	Receipt date at Dermscan Asia
CME CHEERTSUME HYPER CLEAR SAKURA CLEANSING OIL & FOAM	Clear colorless viscous liquid with pink petal	December 13, 2024

1.3. Methodology

1.3.1. Instruments, dose, duration

The studied product was applied under the following conditions:

Areas:	Scapular part of the back
Patch tests type:	Finn Chamber® 8mm (50mm ²) – occlusive
Dose*:	25 µl
Application conditions:	Diluted 5% in purified water
Application duration:	48 hours
Control:	Patch without product

*Note: The quantity is determined according to the cupule capacity, indicated by the manufacturer

1.3.2. Readings

The macroscopic skin examinations were carried out under the same conditions, specifically the lighting (standardized light), 30 minutes after removal of the patch tests and 24 hours later. If the subject had a cutaneous reaction >1, he had to return to the centre and readings were done until complete reversibility of the cutaneous reactions.

The grading of the possible irritation reaction, on each zone that received the studied product and on the control zone, was done according to the following scale:

Score	Quotation	CRITERIA:	
		ERYTHEMA «E»	OEDEMA «O»
0	Absent	no erythema	no oedema
0.5	Very slight	fairly detectable: discreet pinkness of one part of the tested area	palpable, barely visible
1	Slight	discreet pinkness of the complete tested area or rather visible on one part of the tested area	palpable, visible
2	Obvious	clearly distinguishable, dull red erythema covering the whole tested area	obvious oedema (thickness < 1 mm) with or without papule(s) or vesicle(s)
3	Important	deep dark or fiery bright red color covering all the tested area or moderate erythema diffusing outside the tested area	severe oedema (thickness ≥ 1 mm or diffusing outside the tested area) with or without vesicle(s) or blister(s)

A change in skin structure (dryness (D), roughness (R), thickness (T), reflectivity (Re)) that could be linked to the nature of the studied product or one of its components is clinically described and its intensity graded according to the following scale:

- 0.5 = doubtful
- 1 = slight
- 2 = obvious
- 3 = important.

1.3.3. Result interpretation

The analysis and the interpretation were carried out according to the results obtained in the experimental conditions. They are descriptive and completed by the calculation of the cumulative irritation index (C.I.I.) for each subject according to the formula:

$$C.I.I. = \frac{\sum \text{of the grade (erythema + oedema)}}{\text{Number of readings}}$$

This index is then divided by the number of subjects in order to obtain the Mean Cumulative Irritation Index (M.C.I.I.):

$$M.C.I.I. = \frac{\sum C.I.I.}{\text{number of subjects}}$$

The obtained index (maximum 6) allow to arbitrarily classify the studied product according to the following scale:

M.C.I.I.	Class
M.C.I.I. < 0.25	Non irritating (NI)
0.25 ≤ M.C.I.I. < 0.50	Very slightly irritating (VSI)
0.5 ≤ M.C.I.I. < 1	Slightly irritating (SI)
1 ≤ M.C.I.I. < 2	Moderately irritating (MI)
M.C.I.I. ≥ 2	Irritating (I)

Individual values and the product class were taken into account to write a suitable conclusion under the study conditions.

1.3.4. Bibliography:

1. COLIPA "Cosmetic product test guidelines for the assessment of human skin compatibility" 2nd edition – August 1997.
2. Patch-testing with the patient's own products - Peter J. FROSCHE, Johannes GEIER, Wolfgang UTER, An GOOSENS - CONTACT DERMATITIS 4TH EDITION – 2006
3. Comparison of the cumulative irritation potential of Adapalene gel and cream with that of Erythromycin/Tretinoin solution and gel and Erythromycin/Tretinoin gel - Catherine QUEILLE-ROUSSEL, Michel PONCET, Stephane MESAROS, Alan CLUCAS, Michael BAKER and Andrew-Marc SOLOFF - CLINICAL THERAPEUTICS / VOL.23 N°2, 2001

2. RESULTS-CONCLUSION

The individual reading results at each experimental time are presented in the APPENDIX I.

The readings at 30 minutes and 24 hours after patch-tests removal gave of the following M.C.I.I value:

Product reference	Conditions	Patch duration	M.C.I.I.	Conclusion
CME CHEERTSUME HYPER CLEAR SAKURA CLEANSING OIL & FOAM	- Concentration : Diluted 5% in purified water - Patch tests type: Occlusive	48 hours	0.03	Non irritating

3. ETHICAL CONSIDERATION

The study had to be risks were determined to be minimal for the safety of the test subjects.

So, according to the procedure of the investigating centre, the protocol, the information sheet and informed consent and the information concerning the investigational product (particularly referring to its safety) had to be submitted to the opinion of an Institutional Ethics Committee.

The Institutional Ethics Committee gave the approval on expedited approval certificate no. EXP#3031

The study began after the approval of the Institutional Ethics Committee.

3.1. CONFIDENTIALITY AND GENERAL DATA PROTECTION REGULATION

In this study, Dermscan Asia processes personal data of subjects on behalf of the Sponsor, in accordance with the rules on the protection of personal data and in particular, Thailand's Personal Data Protection Act B.E. 2562 (2019) ("PDPA") comes into full force on 1 June 2022, on the protection of natural persons regarding the processing of personal data.

A key element of the PDPA are the rights protecting data subjects, such as Section 19 which grants data subjects the right to withdraw consent at any time, Section 32 the right to object to collection, use or disclosure of personal data and Section 73 the right to file a complaint in case of violation, among others.

For this purpose, Dermscan Asia limits the collection and use of personal data to that which is needed for analysis and control purposes, by ensuring their security and integrity and by guaranteeing their confidentiality.

Dermscan Asia makes sure beforehand and throughout the duration of the data-processing:

of the compliance with the obligations of the applicable data protection law,

to inform subjects of their personal data-processing after obtaining their consent,

to implement and maintain appropriate technical and organizational measures.

An identification code is attributed to each subject for the purpose to keep his/her identity confidential. This code consists of the first two letters/first letter of the subject's name and the first letter of his/her first name.

The concerned subject must be informed of the identity and the contact details of the Controller and, where applicable, of the controller's representative. However, considering the objective of the study, to avoid any bias in the investigational product evaluation, the identity of the Sponsor is not revealed to the subject participating.

APPENDIX I

SUBJECTS CHARACTERISTICS

TABLES OF THE READINGS

FORMULA

SUBJECTS CHARACTERISTICS

Subject#	Last name	First name	Age	Sex	Phototype	Inclusion date	End date
1	WA	S	24	F	IV	January 13, 2025	January 16, 2025
2	PE	P	41	M	IV	January 13, 2025	January 16, 2025
3	SA	P	46	F	IV	January 13, 2025	January 16, 2025
4	PH	P	47	M	IV	January 13, 2025	January 16, 2025
5	PH	S	54	F	III	January 13, 2025	January 16, 2025
6	CH	S	48	F	IV	January 13, 2025	January 16, 2025
7	TA	P	56	F	IV	January 13, 2025	January 16, 2025
8	PA	R	45	F	IV	January 13, 2025	January 16, 2025
9	BU	J	32	F	IV	January 13, 2025	January 16, 2025
10	CH	C	56	F	IV	January 13, 2025	January 16, 2025
11	KO	W	46	F	III	January 13, 2025	January 16, 2025
12	PA	N	44	M	IV	January 13, 2025	January 16, 2025
13	SO	K	44	F	III	January 13, 2025	January 16, 2025
14	CH	A	51	F	IV	January 13, 2025	January 16, 2025
15	PH	P	36	F	IV	January 13, 2025	January 16, 2025
16	KR	C	56	F	IV	January 13, 2025	January 16, 2025
17	SI	N	49	F	IV	January 13, 2025	January 16, 2025
18	NG	A	32	F	IV	January 13, 2025	January 16, 2025
19	SI	N	53	F	IV	January 13, 2025	January 16, 2025
20	PU	R	36	F	IV	January 13, 2025	January 16, 2025
21	SA	J	40	F	IV	January 13, 2025	January 16, 2025
22	SU	C	47	M	IV	January 13, 2025	January 16, 2025
Mean			45	F	18	I	0
Minimum			24	M	4	II	0
Maximum			56			III	3
SEM			2			IV	19
95% CI			4				

F = Female

M = Male

0=: values not included in the analysis

TABLE OF READINGS

Subject	Reading in 30 minutes after patch removal					Reading in 24 hours after patch removal					C.I.I.
	Control		Product		Change in skin structure	Control		Product		Change in skin structure	
	E	O	E	O		E	O	E	O		
1	0	0	0	0	no change	0	0	0	0	no change	0.00
2	0	0	0	0	no change	0	0	0	0	no change	0.00
3	0	0	0	0	no change	0	0	0	0	no change	0.00
4	0	0	0	0	no change	0	0	0	0	no change	0.00
5	0	0	0.5	0	no change	0	0	0	0	no change	0.25
6	0	0	0	0	no change	0	0	0	0	no change	0.00
7	0	0	0	0	no change	0	0	0	0	no change	0.00
8	0	0	0	0	no change	0	0	0	0	no change	0.00
9	0	0	0	0	no change	0	0	0	0	no change	0.00
10	0	0	0	0	no change	0	0	0	0	no change	0.00
11	0	0	0	0	no change	0	0	0	0	no change	0.00
12	0	0	0	0	no change	0	0	0	0	no change	0.00
13	0	0	0.5	0	no change	0	0	0.5	0	no change	0.50
14	0	0	0	0	no change	0	0	0	0	no change	0.00
15	0	0	0	0	no change	0	0	0	0	no change	0.00
16	0	0	0	0	no change	0	0	0	0	no change	0.00
17	0	0	0	0	no change	0	0	0	0	no change	0.00
18	0	0	0	0	no change	0	0	0	0	no change	0.00
19	0	0	0	0	no change	0	0	0	0	no change	0.00
20	0	0	0	0	no change	0	0	0	0	no change	0.00
21	0	0	0	0	no change	0	0	0	0	no change	0.00
22	0	0	0	0	no change	0	0	0	0	no change	0.00
M.C.I.I.											0.03

Product = "CME CHEERTSUME HYPER CLEAR SAKURA CLEANSING OIL & FOAM"

E = Erythema

O = Oedema

()*: values not included in data analysis

FORMULA

PARTIE VIII – FORMULE / FORMULA						
Formule quantitative à fournir avant le début de(s) l'évaluation(s) - MERCİ DE NOUS COMPLETER LE TABLEAU SUIVANT						
En précisant bien chaque information demandée (Noms chimiques + INCI + n° CAS + fonctions prévues des ingrédients) et en donnant le pourcentage exacte de chaque ingrédient pour un rapport total à 100% (ne pas noter de QSP)						
Quantitative formula to supply before the beginning of the evaluation(s) - THANKS TO FİLL THE FOLLOVING TABLE						
Please specify each requested information (Chemical names + INCI + CAS# + functions of each ingredient reported to 100%)						
Type de produit / Type of product						
Reference						
Merci de ne saisir qu'un ingrédient par ligne / Please enter only one ingredient by line						
NUMERO CAS	NOM INCI	CONCENTRATION	FONCTION	NOM CHIMIQUE	n° EINECS/ELINCS (Et. No.)	NOM COMMERCIAL
CAS NUMBER	INCI NAME	CONCENTRATION	FUNCTION	CHEMICAL NAME	EINECS/ELINCS (Et. No.)	TRADE NAME
0007732-18-5	Aqua (Water)	50.00-80.00	Solvent			
0000056-81-5	Glycerin	5.00-20.00	HUMECTANT			
0068954-87-0	Potassium Laureth Phosphate	1.00-10.00	SURFACTANT - CLEANSING			
0068201-46-7	PEG-7 Glyceryl Cocoate	1.00-10.00	SURFACTANT - CLEANSING			
0000107-88-0	Burlyene Glycol	1.00-10.00	HUMECTANT			
0000504-63-2	Propyleneol	1.00-10.00	HUMECTANT			
0025133-98-6	Acrylates Copolymer	1.00-10.00	FİLM FORMING			
0013197-76-7	Lauryl Hydroxysulfaine	1.00-10.00	SURFACTANT - CLEANSING			
0000077-93-0	Triethyl Citrate	1.00-10.00	Solvent			
0000387-74-9	Sodium Cocoyl Glycinate	1.00-10.00	SURFACTANT - CLEANSING			
0039322-79-6	Potassium Lauryl Phosphate	1.00-10.00	SURFACTANT - CLEANSING			
0009005-64-5	PEG-80 Sorbitan Laurate	1.00-10.00	SURFACTANT - CLEANSING			
N/A--	Coconut-Glucoside	1.00-10.00	SURFACTANT - CLEANSING			
0061789-85-0	PEG-40 Hydrogenated Castor Oil	1.00-10.00	SURFACTANT - EMULSIFYING			
0009005-64-5	Polysorbate 20	0.10-1.00	SURFACTANT - EMULSIFYING			
0025265-71-8	Dipropylene Glycol	0.10-1.00	HUMECTANT			
0000122-99-6	Phenoxyethanol	0.10-1.00	PRESERVATIVE			
0007647-14-5	Sodium Chloride	0.10-1.00	VISCOSITY CONTROLLING			
0001310-73-2	Sodium Hydroxide	0.10-1.00	BUFFERING			
0000104-28-0	Chlorophesin	0.10-1.00	PRESERVATIVE			
0005132-04-3	Sodium Citrate	0.10-1.00	BUFFERING			
0000077-92-9.0009	Citric Acid	0.01-1.00	BUFFERING			
0000139-33-3	Disodium EDTA	0.01-1.00	CHELATING			
0026590-05-6	Polyquaternium-7	0.01-1.00	FİLM FORMING			
0010043-52-4	Calcium Chloride	0.01-1.00	VISCOSITY CONTROLLING			
0000057-55-6	Propylene Glycol	0.001-0.10	HUMECTANT			
0009087-61-0	Aluminum Starch Octenylsuccinate	0.001-0.10	VISCOSITY CONTROLLING			
0061789-91-1	Simmondsia Chinensis (Jojoba) Seed Oil	0.001-0.10	SKIN CONDITIONING - EMOLLIENT			
0008007-43-0	Sorbitan Sesquiolate	0.001-0.10	SURFACTANT - EMULSIFYING			
0009005-67-8	Polysorbate 60	0.001-0.10	SURFACTANT - EMULSIFYING			
0125304-04-3	Benzotriazolyl Dodecyl p-Cresol	0.001-0.10	UV ABSORBER			
0009000-07-1	Carrageenan	0.001-0.10	VISCOSITY CONTROLLING			
0007695-91-2	Tocopheryl Acetate	0.001-0.10	SKIN CONDITIONING			
0009002-18-0	Agar	0.001-0.10	VISCOSITY CONTROLLING			
0000320-32-1	Sodium Benzate	0.001-0.10	PRESERVATIVE			
0009005-36-3	Algin	0.001-0.10	VISCOSITY CONTROLLING			
0013463-67-7	CI 77891 (Titanium Dioxide)	0.001-0.10	COLORANT			
0000098-92-0	Niacinamide	0.0001-0.001	SMOOTHING			
N/A--	Maris Aqua (Sea Water)	0.0001-0.001	HUMECTANT			
0010191-41-0	Tocopherol	0.0001-0.001	SKIN CONDITIONING			
0220410-74-2	Tris (Tetramethylhydroxypiperidino) Citrate	0.0001-0.001	UV ABSORBER			
0002379-74-0	CI 73360 (Red 30)	0.00001-0.00001	COLORANT			
N/A--	Pinus Yedensis Leaf Extract	0.00001-0.00001	SKIN CONDITIONING			
1176234-54-0	Tarminalia Ferdinandiana Fruit Extract	0.00001-0.00001	ANTIOXIDANT			
1174331-57-7	Micrococcus Australasica Fruit Extract	0.00001-0.00001	SKIN CONDITIONING			
0009005-25-8	Zea Mays (Corn) Starch	0.000001-0.00001	SKIN PROTECTING			
0125109-81-1	Hydrolyzed Corn Starch Octenylsuccinate	0.000001-0.0010	FİLM FORMING			
0008029-43-4	Hydrolyzed Corn Starch	0.000001-0.0010	FİLM FORMING			
0125109-81-1	Hydrolyzed Corn Starch Octenylsuccinate	0.000001-0.0010	FİLM FORMING			
0008029-43-4	Hydrolyzed Corn Starch	0.000001-0.0010	FİLM FORMING			
0194043-92-0	Butyrospermum Parkii (Shea) Butter	0.000001-0.0010	SKIN CONDITIONING			
0068140-01-2	Cocamidopropyl Dimethylamine	0.000001-0.0001	SURFACTANT - EMULSIFYING			
0000085-27-8	Phenylethyl Resorcinol	0.000001-0.0001	ANTIOXIDANT			
0000050-21-5	Lactic Acid	0.000001-0.0001	BUFFERING			
0623172-56-5	Palmitoyl Tripeptide-5	0.0000001-0.00001	SKIN CONDITIONING - MISCELLANEOUS			
0007601-86-9	Hydroxy Silyla	0.0000001-0.00001	VISCOSITY CONTROLLING			

APPENDIX II

AUTHENTICATION PAGE

**QUALITY ASSURANCE
CERTIFICATE OF CONFORMITY**

AUTHENTICATION PAGE

I am aware that the study number DA24A632

has been conducted according to the STUDY PROTOCOL

Dr. Sujittra SOMBUNTHAM
Dermatologist

Date

February 25, 2025

Signature

Laddawan HENGSAE
Technician

Date

February 25, 2025

Signature

Any modifications are the sole responsibility of the author of the modification, whether he/she is acting for the Sponsor or independently.

The on-line publishing, on the Internet, of this study protocol/report with the names and signatures is strictly prohibited.

**QUALITY ASSURANCE
CERTIFICATE OF CONFORMITY**

QUALITY ASSURANCE

The described study has been conducted in the spirit of the Good Clinical Practice defined by the ICH Topic E6 "Note for Guidance and good clinical practice" (CPMP/ICH/135/95), the Helsinki Declaration (1964, WMA) and its successive updates.

The study has been conducted according to Standard Operating Procedures and to the study protocol defined with the sponsor. All the case report form and data were checked.

Controls on data veracity and conformity with the protocol have been performed and confirmed by persons participating in the study (APPENDIX II).

Certificate of conformity

I am aware that the study DA24A632 has been conducted according to the "**Quality Assurance**" described before.

There was no event which may have affected the quality or integrity of the data.

Atippaporn BOONVANICH
Quality Assurance Manager

Date February 25, 2025

Signature