FINAL REPORT - ALIVIUM CBD FORTE

1. GENERAL INFORMATION OF THE STUDY

This Final Report corresponds to the 'Open Test': open application of a cosmetic product on a specific body surface similar to its normal use, left to act for 30 minutes, over 3 consecutive days. The test, performed under controlled conditions and dermatologist supervision (subjects individually examined), allows verification in a population of 10 volunteers of the absence of discomfort reactions and cumulative irritations.

STUDY IDENTIFICATION

TITLE: CLINICAL SAFETY STUDY IN HEALTHY ADULT VOLUNTEERS FOR THE VERIFICATION OF GOOD SKIN COMPATIBILITY OF THE PRODUCT ALIVIUM CBD FORTE
BATCH: L307306A: OPEN TEST
CODE: OT_LBE_23_01

TYPE OF CLINICAL STUDY

Safety test in healthy adult volunteers, with application on the inner right forearm, keeping the left forearm as control area, to verify good skin compatibility and absence of undesirable reactions after repeated applications for 3 consecutive days.

PRODUCT DESCRIPTION

PRODUCT: ALIVIUM CBD FORTE BATCH: L307306A
MANUFACTURER: LABORATORIOS BEEMINE, S.L.

RESPONSIBLE TECHNICAL DIRECTOR

LABORATORIOS BEEMINE, S.L.

COMPANY AND STUDY CENTER

ANMAR CLINICAL SERVICES, S.L., Pamplona (Navarra)

INVESTIGATORS

Principal Investigator: Dr. Inmaculada Domínguez Fernández
Collaborating Investigator: Mª Luisa Giráldez Quiroga

STUDY DURATION

Experimental phase: May 2–4, 2023
Final Report: May 8, 2023

2. OBJECTIVE

To verify the good skin compatibility and safety of the product ALIVIUM CBD FORTE L307306A.

3. SUBJECT SELECTION AND STUDY DEVELOPMENT

Inclusion and exclusion criteria were applied. 10 volunteers participated. Inclusion: Healthy men and women, 18–65 years, sensitive skin, Fitzpatrick I–IV, informed consent.
Exclusion: Acute/chronic disease, skin pathology, medication, pregnancy, breastfeeding, interfering skin marks, allergies.

El estudio se realizó de acuerdo con el siguiente esquema:

	SELECCIÓN	DÍA 1	DÍA 2	DÍA 3
HISTORIA CLÍNICA	+			
CRITERIOS INCLUSIÓN / EXCLUSIÓN	+			
CONSENTIMIENTO INFORMADO	+			
APLICACIÓN DEL PRODUCTO		+	+	+
EVALUACIÓN DERMATOLÓGICA		+	+	+
ACONTECIMIENTOS ADVERSOS		+	+	+

4. PRODUCT DESCRIPTION AND EVALUATION VARIABLES

PRODUCT UNDER STUDY AND ITS APPLICATION

The product under study was applied to the inner right forearm, while the left forearm served as the control area. Applications were repeated for 3 consecutive days at the clinic, applied by the dermatologist.

The investigator evaluated the application area before and after each application to assess possible adverse or irritation reactions caused by the cosmetic product.

The mode of use was as declared by the laboratory: apply on intact skin at a distance of 20 cm for between 2 and 5 seconds, spraying with circular movements.

EVALUATION VARIABLES

The expression of the clinical examination results and questioning is defined for this type of study:

- In case of reactivity: the main signs observable to the naked eye are recorded: erythema, edema, vesicle, blister, papule, crust, dryness, discoloration, macula.

- The intensity of the signs is assessed using a 3-point ordinal scale: mild, moderate, severe.

- The appearance of erythema is specified as diffuse or localized.

- The main discomfort sensations are described: heat, stinging, itching, tightness, and burning. The intensity of these sensations is also assessed on a 3-point ordinal scale: mild, moderate, severe.

5. RESULTS

ID	EDAD	SEXO*	FOTOTIPO	TIPO DE PIEL**	DÍA 1	DÍA 2	DÍA 3
1	49	M	III	N	0	0	0
2	46	M	III	S	0	0	0
3	22	M	II	S	0	0	0
4	48	F	III	S	0	0	0
5	62	F	III	N	0	0	0
6	43	F	III	N	0	0	0
7	52	F	III	S	0	0	0
8	38	F	III	N	0	0	0
9	46	M	III	N	0	0	0
10	64	F	II	S	0	0	0
TOTAL					**0**	**0**	**0**

* SEXO F/FEMENINO M/MASCULINO

** TIPO DE PIEL S/SENSIBLE N/NORMAL

6. CONCLUSIONS

The product did not produce any irritative response in any participant.
The product SPRAY ALIVIUM CBD COOLING EFFECT 6678/3 is considered NON-IRRITANT and shows VERY GOOD skin compatibility and safety.

7. BIBLIOGRAPHY

References translated into English. Insert list here.

1. SCCS (Scientific Committee on Consumer Safety), SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10th revision, 24-25 October 2018, SCCS/1602/18.
2. Sherertz E., Byers V.:" Estimating Diluitions for Patch Testing Skin Care Products: A Practical Method" American Journal of Contact Dermatitis, Vol 8, No 3, 1997.
3. Masakatsu O, Rie H, Tomoyasu O. Physiological characteristics of sensitive skin classified by stinging test. Journal of Japanese Cosmetic Science Society 2000; 24(3):163-167.
4. North American Contact Dermatitis Group Patch-Test Results, 2001-2002 Study Period. Dermatitis: December 2004. Marks, James G. Jr; Belsito, Donald V.; DeLeo, Vincent A.; Fowler, Joseph F. Jr; Fransway, Anthony F.; Maibach, Howard I.; Mathias, Toby C.G.; Nethercott, James R.; Rietschel, Robert L.; Rosenthal, Lawrence E.; Sherertz, Elizabeth F.; Storrs, Frances J.; Taylor, James S.
5. Patel, S.M., E. Patrick, and H.I. Maibach, 1976 "Animal, Human, and In Vitro Test Methods for Predicting Skin Irritation". Dermatotoxicology, Chpt. 33; 5th Ed., F.N. Marzulli; H.I. Maibach; Taylor and Frances.

8. ANNEX 1

PRODUCT NAME: ALIVIUM CBD FORTE L307306A
INCI:

INCI: AQUA(WATER), CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, CETEARYL OLIVATE, CANNABIS SATIVA SEED OIL, CERA ALBA(BEESWAX), MENTHA PIPERITA OIL, MENTHOL, SORBITAN OLIVATE, CANNABIDIOL, ROSA MOSCHATA SEED OIL, MEL(HONEY), CYMBOPOGON CITRATUS LEAF OIL, ARNICA MONTANA FLOWER EXTRACT, EUGENIA CAROYPHYLLUS LEAF OIL, CAMPHOR, TOCOPHEROL, HELIANTHUS ANNUUS(SUNFLOWER) SEED OIL, BENZYL ALCOHOL, GLYCERIN, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, POTASSIUM SORBATE, SODIUM HYDROXIDE, DEHYDROACETIC ACID, EUGENOL, ISO EUGENOL, CITRONELLOL, CITRAL, GERANIOL, LIMONENE, LINALOOL.