

BIOGRÜNDL, S.L.
POLÍGONO LES FALLULLES, NAVE 34 -SECTOR 2-
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TECHNICAL DATA SHEET

SILICUM GEL **/ A / H / CA11 /**



Trade Name: SILICUM GEL / A / HG / CA11 /

Product Code: SILICAHCA11.

INCI Name: AQUA, SILICA DIMETHYL SILYLATE, POTASSIUM SORBATE.

INCI Status: Conforms.

REACH Status: Low Volume Exemption.

CAS Number: 7732-18-5, 68611-44-9, 24634-61-5/ 590-00-1.

EC Number: 231-791-2, 271-893-4, 246-376-1.

Origin: **SILICA DIMETHYL SILYLATE:** Vegetable origin.

POTASSIUM SORBATE: Synthetic origin.

Processing: GMO Free. / No Ethoxylation. / No Irradiation. / No Sulphonation. / No BSE/TSE. / No CMR. / No SVHC. / No Nanomaterial. / No DEG. / No DEHP. / No Formaldehyde. / No Phthalates. /

Additives: Preservatives: Potassium sorbate. Paraben Free. / Antioxidants: None. / Other additives: None.

Appearance: Clear or slightly opalescent liquid.

Colour: Characteristic (yellowish to deep brown).

Odour: Characteristic.

Specific gravity: 0,990 - 1,050 g/cm³ (20°C approx.).

Direct pH value: 4,5 - 6,5 (20°C approx.).

Soluble/ Miscible: Dispersible in water (20°C approx.). Insoluble in organic solvents and lipids.

Dispersible in surfactants and hydroalcoholic, hydroglyceric and hydroglycolic mixtures.

Ecological Information: Sustainable.

Microbial Count: **Total aerobics:** Max. 300 microorganisms / gram.

Fungi and yeasts: Max. 200 microorganisms / gram.

Pathogens: Total absence in 1 gram.

Suggested Use Levels: 2,0 – 10,0%.

Suggested Applications: Aging, toneless, impure or with acne, rosacea and/or psoriasis skin treatment.

Weak and prone to fall hair or brittle nails products. Burn treatment from sun, inflammation and damaged skin treatment. Treatment of arthritic and arthrosic muscular aches.

Properties: Curative, soothing, healing, anti-cellulite and anti-inflammatory.

Industrial packing: 1Kg., 5Kg., 25Kg., 225Kg.

Storage conditions: It is very important to keep the product in well closed containers, away from direct sunlight at temperatures not over 15°C. In case of not having refrigerators, store the product in the coolest and free from artificial light area.

Bibliography: - Atlas Ilustrado de Plantas Medicinales y Curativas, Ed. Susaeta.

- Dumont's grosse Kräuter Enzyklopädie.

- Fitocosmeticos ALVAREZ CRUZ i BAGUE SERRANO.

- Gran enciclopedia de las plantas medicinales, BERDONCES i SERRA.

- Plantas medicinales, FONT i QUER.

- Proserpio G., Martelli A., Patri GF.; Elementi di Fitocosmeci; Ed. Sepem / Milano 1983.

- Websites.



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OVERVIEW

SILICUM GEL by BIOGRÜNDL, S.L., is an active preparation of silica, based on colloidal silica whose particle size is below 20 microns.

Silica is a trace element necessary for human body, having a lot of properties that can be summarized as follows:

- It contributes to fixation of calcium in bones.
- It is essential for protein synthesis in the skin connective tissue, particularly of collagen.
- It strengthens the body defenses.
- It is necessary for proper growth of hair and nails.
- It accelerates the healing of burns, skin lesions and inflammation.
- It relieves muscle aches, arthritis and arthrosis.
- It treats skin impurities and helps skin tissue disorders such as cellulite, acne, rosacea and psoriasis.

SILICUM GEL by BIOGRÜNDL, S.L., contains silica oxid (Si O_2), finely dispersed in an aqueous medium and partially neutralized with an aliphatic base, to a pH between 6.0 and 8.0, in order to achieve higher siloxane link formation ($\rightarrow \text{Si} - \text{O} - \text{Si} \leftarrow$) and siloxanol ($\rightarrow \text{Si} - \text{OH}$). This increases its effectiveness markedly.

USE AND DOSAGE

Its use is indicated, particularly, for aging, toneless, impure or with acne, rosacea and/or psoriasis skin treatment. Also, in products for weak hair and prone to fall, as well as, in brittle nails. SILICUM GEL by BIOGRÜNDL, S.L., gives very good results in the treatment of burns from fire or sun, in inflammation and in all types of skin lesions. Added to cremigel or massage emulsions it helps to treat arthritic and arthrosic muscular aches.

If turbidity is observed, it is advisable to previously dissolve the product in a portion of the water provided to manufacture the final product and filter after 12-24 hours.

The recommended concentrations of use are between 2% and 10%. For very special effects the dosage can raise up to 15%.



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PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Opaque semi-gelatinous liquid.

Colour: Characteristic (slightly yellowish to brown).

Odour: Characteristic.

Direct pH value: 4,5 - 6,5 (20°C approx.).

Specific gravity: 0,990 - 1,050 g/cm³ (20°C approx.).

Solubility in water: Dispersible (at 20°C approx.).

Solubility in other solvents: Insoluble in organic solvents and lipids. Dispersible in surfactants, hydroalcoholic, hydroglyceric and hydroglycolic mixtures.

Heavy metals: No more than 5 mg/Kg.

Sulfated ash: No more than 0,01%.

Chlorides: No more than 0,007%.

Sulfates: No more than 0,002%.

Other information: None.

Total aerobics: Max. 300 microorganisms / gram.

Fungi and yeasts: Max. 200 microorganisms / gram.

Pathogens: Total absence in 1 gram.

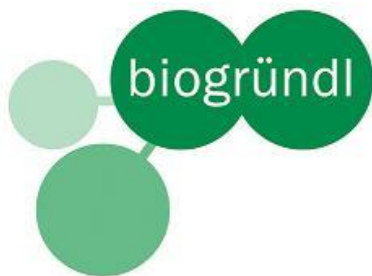
DERMATOLOGY INNOCUOUSNESS

It was performed by the patch test (Patch test) on 10 volunteers. To this purpose, 15% SILICUM GEL by BIOGRÜNDL, S.L., was added to an O/W emulsion; 0,5g. of this emulsion was poured over the patch and attached on the forearm. It is thus maintained for 24, 48 and 72 hours, after which, the given reaction was evaluated, according to the following table of values:

1. No erythema.
2. Slight erythema.
3. Well defined erythema.
4. Severe erythema.

The result was absence of erythema on the 10 volunteers.

On the recommended concentrations, the product is skin innocuous.



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STORAGE CONDITIONS

It is very important to keep the product in well closed containers, away from direct sunlight at temperatures not over 15°C. In case of not having refrigerators, store the product in the coolest and free from artificial light area.

INCI DENOMINATION

AQUA, SILICA DIMETHYL SILYLATE, POTASSIUM SORBATE.

EFFECTIVENESS TESTS

Assay: Double blind spot trial and subsequent cosmetic evaluation.

Assayed parameters: Anti-inflammatory action.

N (volunteers): 30 (15 ♀ and 15 ♂).

Age (volunteers): 30 - 60 years old.

Left side part to be treated:

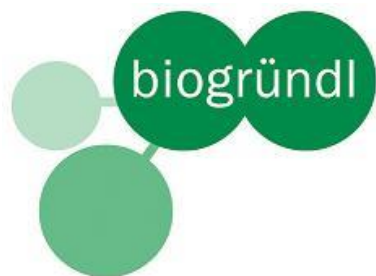
Placebo, 30 volunteers, suitable cosmetic base.

Right side part to be treated:

SILICUM GEL 2%, 15 volunteers, suitable cosmetic base.

Right side part to be treated:

SILICUM GEL 5%, 15 volunteers, suitable cosmetic base.

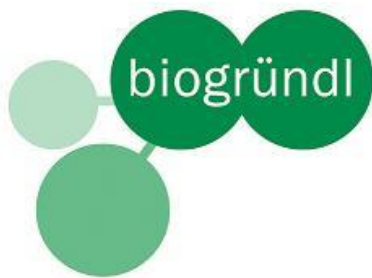


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Assayed parameter:

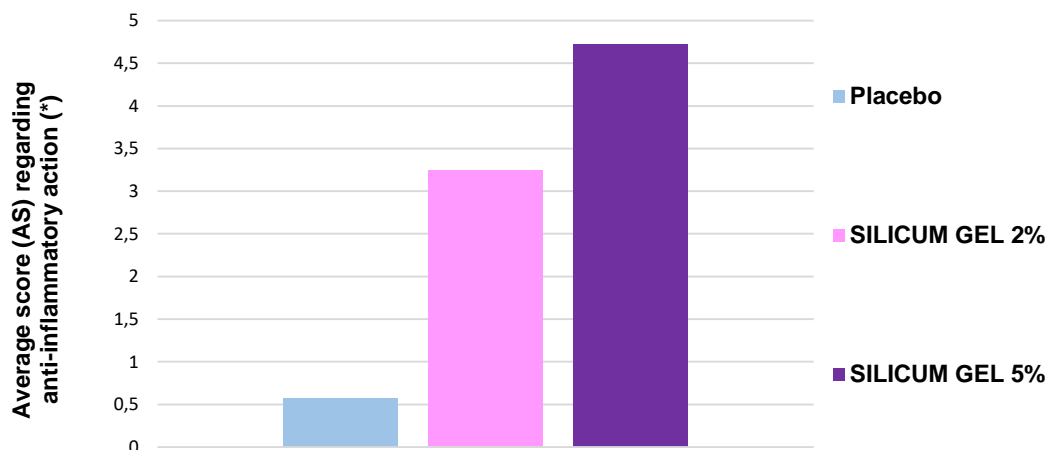
	Assay	N (volunteers)	Age (volunteers)	Placebo	SILICUM GEL 2%	SILICUM GEL 5%	Assay performed (Days)	Results measured (Days)
Anti-inflammatory action	Double blind spot trial and subsequent cosmetic evaluation.	N = 30 15 ♀ 15 ♂	30 - 60	Left side part	Right side part 15 volunteers.	Right side part. 15 volunteers.	D = 30	D' = 1



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SKIN CONDITION EVALUATION AFTER 30 DAYS



(*) Anti-inflammatory action was determined by direct measurement and observation of inflammation reduction from volunteers.

Total number of days in which the assay was performed (treatment was applied):
D = 30 days (every day during the effectiveness test).

Total number of days in which the results were measured:
D' = 1 day (effectiveness test last day).

Average score:

Worst result: Zero limit value is assigned.

Best result: Five limit value is assigned.

Score is assigned to obtained results between the two limit values.

Average computation for each obtained results group is done:

Placebo, 2% SILICUM GEL by BIOGRÜNDL, S.L., 5% SILICUM GEL by BIOGRÜNDL, S.L..

Results meaning:

AS rank between 0 – 1: No significant changes.

AS rank between 1 – 2: Slight improvement regarding placebo.

AS rank between 2 – 3: Appreciable improvement regarding placebo.

AS rank between 3 – 4: Great improvement regarding placebo.

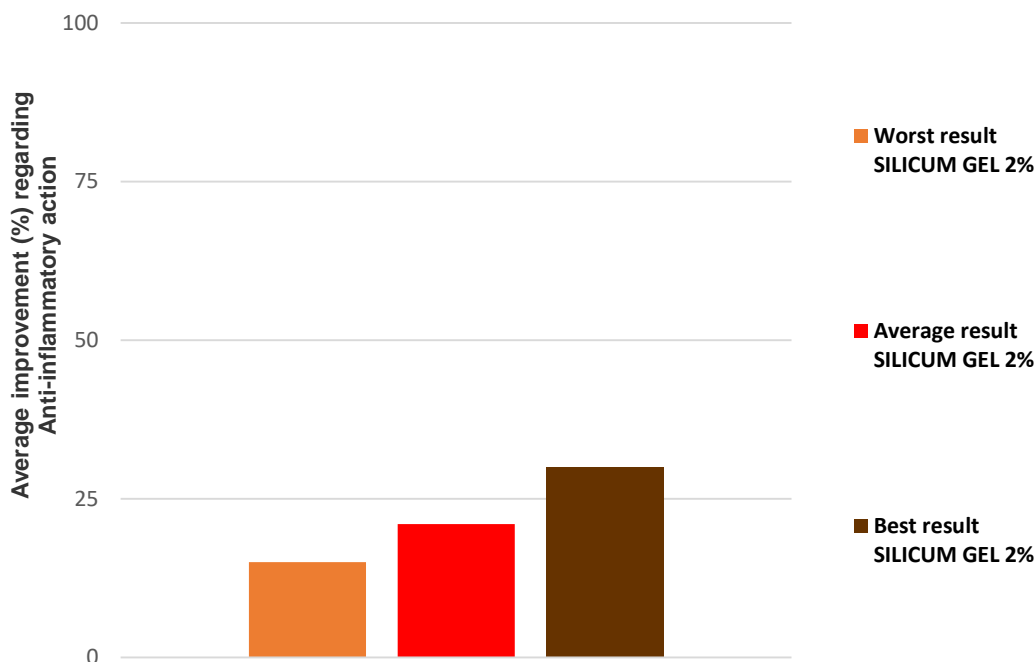
AS rank between 4 – 5: Excellent cosmetic result.



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SILICUM GEL 2%



Results:

Worst result SILICUM GEL 2%: 15%.
Average result SILICUM GEL 2%: 21%.
Best result SILICUM GEL 2%: 30%.

Results meaning:

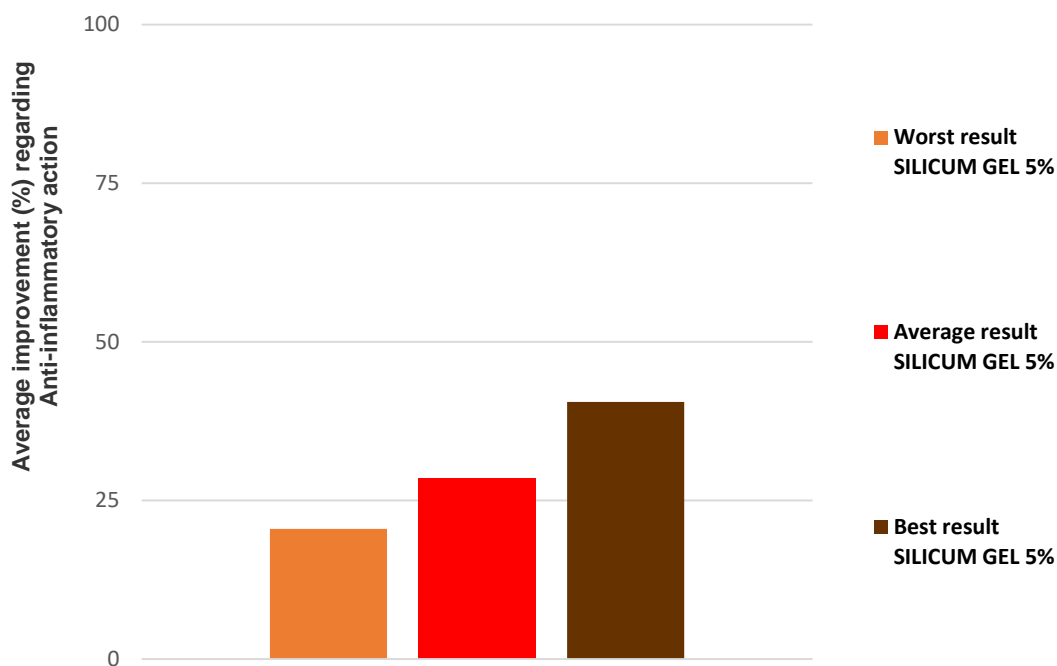
AI rank between < 20%: No significant changes.
AI rank between 21 – 40%: Slight improvement regarding placebo.
AI rank between 41 – 60%: Appreciable improvement regarding placebo.
AI rank between 61 – 80%: Great improvement regarding placebo.
AI rank between > 81%: Excellent cosmetic result.



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SILICUM GEL 5%



Results:

Worst result SILICUM GEL 5%: 20,5%.
Average result SILICUM GEL 5%: 28,5%.
Best result SILICUM GEL 5%: 40,5%.

Results meaning:

AI rank between < 20%: No significant changes.
AI rank between 21 – 40%: Slight improvement regarding placebo.
AI rank between 41 – 60%: Appreciable improvement regarding placebo.
AI rank between 61 – 80%: Great improvement regarding placebo.
AI rank between > 81%: Excellent cosmetic result.