Tolerance study

The tests performed in vivo have shown that the product is neither toxic nor irritant at the concentration used. In these tests, we have studied:

- acute toxicity by oral administration on mice,
- ocular irritation on rabbits,
- primary cutaneous irritation on rabbits,
- cutaneous irritation following iterative applications on rabbits,
- sensitivity effect on healthy volunteers,
- photosensitivity on healthy volunteers (phototoxicity and photoallergy).

Formulation

CAPILLISIL HAUTE CONCENTRATION® is a stable solution, titrated at 30 g/l in organic silicon. It may be formulated in all lotions, gels or emulsions without any difficulty, in presence of water and/or alcohol. The mean suggested concentration is between 0.1 and 1%, but CAPILLISIL HAUTE CONCENTRATION® should be incorporated as high as 3% in the formulations aimed at treating alopecia.

Analytical composition

- Silanediol salicylate (and) triethanolamine (and) butylene glycol
- I.N.C.I. name: Silanediol salicylate (and) triethanolamine (and) butylene glycol
- MHW database n°: 21200CZY00064000

Chemical family

CAPILLISIL HAUTE CONCENTRATION® is a High Concentration Silanol, pre-hydrolyzed in a glycolic solution and chemically pure. It is obtained, at high concentration, by mild hydrolysis of the dimethylsilyl salicylate leading to biologically active Silanols, rich in hydroxy functions.

CAPILLISIL HAUTE CONCENTRATION® exhibits all Silanols’ biological properties as well as a specific response due to the presence of the salicylic radical.

Technical characteristics

- Limpid liquid, slightly opalescent with yellow sheens.
- pH (3% in water): about 4.5
- Refractive index: 1.47
- Density at 25°C: about 1.08
- Miscible with water, alcohols and glycols.

Availability

1, 5 and 30 kg drums

HAIR CARE

use of

High Concentration Dimethyl Silanediol Salicylate

Si : 30 g.l^-1

Anti hair loss treatment

Oily hair treatment

Seborrhoea
IMPORTANCE OF CONCENTRATION OF SILICON FOR HAIR TREATMENT

Given the location of the hair root (in the dermis), it was logical to expect the necessity of applications of substantial amounts of silicon in order to finally get enough material in contact with the hair bulb and with the keratinocytes contained in there.

The first tests, actually performed with regular silanols, used at high concentrations (about 30 to 50%) confirmed our expectation.

A subjective study (questionnaire) was conducted after a short term treatment applied twice a day, on a group using a lotion containing 0.05 % of silicon and on other group a lotion at 0.03%.

The results underline that the higher the concentration in silicon, the better the results quoted by the volunteers. These results have been corroborated by a quantitative study (see next page).

### INCORPORATION OF SILICON

Hair and nails are annex outgrowths of the skin. They are both highly keratinized. These elements of the skin are rich in silicon and therefore we experimented the incorporation of silicon when CAPILLISIL HAUTE CONCENTRATION® was applied on nails.

A test was carried out on 15 volunteers on a period of 17 days. The product tested is a hydroalcoholic solution incorporating CAPILLISIL HAUTE CONCENTRATION® at 1%.

The silicon incorporation after applying a hydroalcoholic solution with 1%.

These results have been corroborated by a quantitative study (see next page).

### CLINICAL STUDY

A clinical study was carried out on 22 volunteers displaying an hereditary androgenogenic alopecia. The tested product is a hydroalcoholic lotion containing 25% of ethyl alcohol, 0.70% of ALISTIN® and 1.40% of CAPILLISIL HAUTE CONCENTRATION®.

The ratio of the number of hair in the anagen phase (“growth phase”) over those in the non-anagen phase is measured.

Hair was shared into 3 categories at the beginning and the end of the treatment:

- **Mediocre hair**: (more that 50% of hair in non-anagen phase)
- **Healthy hair**: (between 50 and 75% hair in anagen phase)
- **Very healthy hair**: (more than 75% of hair in anagen phase)

The results evidence that 91% of the treated volunteers hair improved from mediocre hair to healthy and very healthy hair. Part of the results observed are due to using a hydroalcoholic lotion containing 25% of ethyl alcohol which in itself evidenced but in lesser proportions only 50 *10% improvement. The use of hydroalcoholic lotion is indeed of significant interest in the design of a powerful anti-hair loss.

The lotion containing CAPILLISIL HAUTE CONCENTRATION® in association with ALISTIN® helps to stimulate hair growth, slow down hair loss and also improve the appearance and the brightness.

### INCREASE HAIR DENSITY

Hair density is characteristic of the number of hair in a given area. It is evaluated on the same volunteers as above undergoing the same treatment as previously. The rate of improvement (A) in hair density (difference between end and beginning of treatment) is measured and the volunteers are shared into 4 categories:

- **Degradation** : A≤0
- **Slight improvement** : 0≤A<20 %
- **Good improvement** : 20 %≤A<40 %
- **Very good improvement** : A≥40 %

82% of the volunteers treated with CAPILLISIL HAUTE CONCENTRATION® see their capilar density improve. A placebo response due to the presence of ethyl alcohol was measured but revealed only 20% of "good" and "very good" improvements against the 45% observed with the lotion containing CAPILLISIL HAUTE CONCENTRATION®.
**Tolerance study**

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**Performed studies**

- Technical document
- Anti-free radical activity
- In vitro evaluation of the anti-inflammatory activity
- Clinical study on healthy volunteers for the treatment of alopecia

- Tolerances
  - (acute toxicity, primary and iterative cutaneous irritation, alternative methods.
  - Tests of allergenicity, cutaneous sensitivity, phototoxicity and photoallergy on healthy volunteers)
  - Effect on androgenic alopecia of **CAPILLISTIN**, a lotion containing **CAPILLISIL HAUTE CONCENTRATION®** and **ALISTIN®**

**Analytical composition**

<table>
<thead>
<tr>
<th>Silanediol salicylate</th>
<th>246 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutalizing agent</td>
<td>160 g</td>
</tr>
<tr>
<td>Glycolic solvent sq</td>
<td>1000.0 g</td>
</tr>
</tbody>
</table>

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- pH (3% in water): about 4.5
- Refractive index: 1.47
- Density at 25°C: about 1.08
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**Availability**

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**HAIR CARE use of High Concentration Dimethyl Silanediol Salicylate**

- **Si : 30 g.l⁻¹**

**Anti hair loss treatment**

- Oily hair treatment
- Seborrheas