



**RESEARCH**

**Bio Sculpture is the first and to date the only nail company to do Clinical Research on their product.**

Bio Sculpture has done thorough research on the effect that the product range has on clients and technicians. Not withstanding the good and positive results from the toxicology and clinical trail reports, technicians and clients should refrain from using the product if they experience any form of discomfort on their fingers or if any adverse reaction occurs. Bio Sculpture takes no responsibility for Allergies or Contact Dermatitis that may occur.

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**CLINICAL RESEARCH REPORT**

Bio Sculpture Gel  
2004 Safety Survey

**PURPOSE**

**THEY SAY IT'S MORE EFFECTIVE TO SHOW THAN TO TELL**

Bio Sculpture has done a scientific research study to assess the efficacy and tolerability of UV Light cured gel (Bio Sculpture) - 02 August 2004

Bio Sculpture Gel is to our knowledge the first UV cured nail gel that has undergone and passed this stringent test.

Bio Sculpture Gel  
2004 Safety Survey

**METHOD**

**Tested to the Highest Standards**

Clinical Research report to assess the tolerability and efficiency of Bio Sculpture UV light-cured nail gel was conducted on first-time and long-term users.

Twenty-five (25) sites participated in the trial and more than 500 volunteers were entered into the study. Previous users as well as first time users were included to ensure that the data gathered over the 6 month evaluation period comprised of not only volunteers that have been exposed to the product over a long period, but also those with no previous exposure. Informative writing confirms that adverse effect like nail fungus infection can be expected after a treatment period of 6 months, therefore the evaluation period was determined accordingly. Data for the evaluation and statistical analysis were collected by means of questionnaires and physical examinations at 2 monthly intervals on three visits. Participants were evaluated for adverse events of fungus infections or (paronychia) and contact dermatitis.

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## FINDINGS

### ***Five- Star Safety Rating - Tested to the Highest Standards***

The research result showed that one hundred percent (100%) of first-time users, and ninety nine percent (99%) of long-term users, reported no paronychia or contact dermatitis. Consequently, the conclusion is drawn that Bio Sculpture® UV light-cured nail gel is both highly effective and tolerable for use as cosmetic nail gel.

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## ARTICLE

### Article that appeared in the **Dec/Jan 2005 Pharmaceutical & Cosmetic Review**

UV-Light curable gel for nails

Bio Sculpture UV-light curable nail gel provides an almost instantaneous binding and curing of the nail gel-coat due to cross-linking of polymers induced by ultraviolet light. Once cured, it leaves the nail hard, yet flexible, with a natural glossy finish.

The product is odorless and fume-free and is thought to be the first color nail gel on the market. This innovative product from Clocolan, South Africa, is exported to some 20 countries.

One of the cosmetics industry's goals is labeling products as "hypoallergenic". Although the term may have considerable market value in promoting products to consumers, there is, according to the FDA, no such thing as a "non-allergenic" cosmetic (see [www.cfsan.fda.gov](http://www.cfsan.fda.gov)). However, Bio Sculpture International's nail gel has been tested on 500 volunteers over a six month period by a pharmaceutical research organization and the research shows that neither first-time users, nor 99% of long-term users experience contact dermatitis. This is because Bio Sculpture nail gel is applied without the use of primers and bonders which minimizes allergic reactions.

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## **TOXICOLOGY REPORT**

By SA Drug & Toxicology Information Trust

No animal studies were involved in the development or the toxicological evaluation of the Bio Sculpture Products.

Summary Quote: "We are of the opinion that this product, when applied under normal or reasonable foreseeable conditions of use, poses virtually no risk for systemic toxicity, although it does pose a limited risk for local skin reaction in sensitive users, which can be minimized by the correct usage. In general the toxicology profile of the ingredients of the product compares very favorable with that of some of the other nail cosmetic products on the market.

