

Kolorsource™ Pigments Proven Safe, Hypoallergenic

Final Report Clinical Trials-Kolorsource pigments hypoallergenic, dermatologist tested

Pigment clinical testing for potential allergic reactions first in history of permanent makeup

10 February 2005: Honolulu, Hawaii

Introduction

Allergic contact dermatitis, also known as sensitization or delayed hyper-sensitivity is a cell-mediated immunological phenomenon involving antigen recognition in the epidermis and subsequent sensitization of T-lymphocytes. In the Gell and coombs system, it is classified as Type IV, analogous to tuberculin sensitivity.

In an unprecedented step in the history of permanent makeup or traditional tattooing, Linda H. Dixon MD subjected all pigments and ingredients in Kolorsource brand pigments to clinical trials by an outside scientific testing facility in order to determine any possible skin sensitization potential of the products. Seventeen (17) talc-free pigments of both synthetic organic and inorganic origin were in the test product. Not all pigments tested are contained in Kolorsource Brand pigments but were included for testing purposes. Historically, tattoo pigments have been known to be tested by experimenting on unsuspecting persons by manufacturers with little understanding that pigments can cause a severe, even disfiguring allergic reaction. Cosmetic pigments that contain talc can cause granuloma formation after cosmetic tattoos as well, according to Charles S. Zwerling, MD, Chairman of the Board of the American Academy of Micropigmentation.

Subject Selection

Criteria for Inclusion

- Subjects over the age of eighteen years
- Male or female subjects of any skin type or race wherein skin pigmentation does not interfere with taking readings of skin reactions.
- Subjects who are cooperative and have given written informed consent after having been advised of the risks and

nature of the study.

- Subjects must be in good health, free of any significant active skin pathology.

Criteria for Exclusion

- History of known sensitivity to cosmetics in general and in particular to the types of products being tested
- Pregnancy or attempting same during study period
- Lactation.
- Use of medications within thirty (30) days of induction, e.g. corticosteroids, antihistamines which may tend to attenuate responses.

Test results support the claim that Kolorsource pigments and ingredients are hypoallergenic.

Informed Consent

All subjects execute an Informed Consent. Said Consent contains information regarding the purpose of the study and possible risks of participation.

Additionally, subjects are given a list of materials being tested. Said list is a general description of the product types; it contains no information with respect to brand names, manufacturers or distributors.

Testing Procedure

The product consisting of 17 pigments in dispersal was applied five (5) times during a two month period to each of 105 participants enrolled in the study. **No reactions to the test product was reported during any phase of the testing period.**

Conclusion

Under the conditions of this test, no evidence of increased likelihood of sensitization to the test product was present, and no alert level was issued.

These results support the claim that Kolorsource pigments and ingredients are hypoallergenic.

Linda H. Dixon MD
Research and Development



"Tests results of Kolorsource Pigments support a claim of hypoallergenic and dermatologist tested, the first such testing done in the history of permanent makeup", according to Dr. Dixon.

Dr. Charles Zwerling, MD, ophthalmologist and author of the book MICROPIGMENTATION: STATE OF THE ART, states *"Kolorsource has created a gold standard by which all pigments will be measured in the future".*

"This (test) goes a long way to assure the public and professionals that hypoallergenic pigments can be and should be used in micropigmentation and cosmetic tattooing." continues Dixon.

Note: The American Academy of Micropigmentation does not endorse any product but welcomes scientific studies or product testing intended to ensure the safety and protection of the public, the profession and professionals.

News

Clinical testing of pigments used in permanent makeup makes history and offers enhanced safety for public and professionals against allergic reactions. Both organic and inorganic pigments were included in test as well as the dispersal agents. Pigments tested from Kolorsource™.

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