

SILVADUR™ Treated Articles Dermatological Studies

May 11, 2020

SILVADUR™ Treated Articles Are Neither Irritating or Sensitizing to Humans

A battery of third-party clinical studies was performed on fabric treated with SILVADUR™. These studies were used to evaluate the potential for SILVADUR™ to cause skin irritation or skin sensitization in humans. **These evaluations found no evidence that SILVADUR when applied to fabrics at up to 10 times higher than recommended levels either irritates or causes sensitization in humans.**

21-Day Cumulative Irritation Patch Tests of SILVADUR on Cotton and Polyester Fabrics:

Using 10 times the recommended dosage and use levels, SILVADUR's use in treated articles has proven neither to irritate or cause sensitizations in humans.

These studies evaluated the potential for SILVADUR treated cotton and polyester fabrics to irritate human skin following multiple exposures. The procedures for the two studies were identical in all respects.

- In each case, cotton and polyester fabric squares, moistened with water and treated with SILVADUR at a concentration of 200 ppm silver active and applied directly to the skin of 30 individuals involved in the cotton study and 32 individuals participating in the polyester study.
- Positive controls were also applied.
- Twenty-four hours later, the patches were removed and the sites evaluated for skin irritation.
- These procedures were repeated 15 times over a three-week period. The cotton and polyester squares were applied Monday through and left on over the weekend.

Conclusion

Under the conditions of these studies over 21 days, there was no evidence of skin irritation among the participants of the cotton and polyester tests at any observation period.

Human Repeat Insult Patch Tests (HRIPT) of SILVADUR on Cotton and Polyester Fabrics:

These studies evaluated the potential of SILVADUR treated cotton and polyester fabrics to produce skin sensitization, such as contact allergy, on humans following multiple exposures.

The procedures for the two, six-week studies were identical in all respects.

In each case, cotton and polyester fabric squares, moistened with water and treated with SILVADUR at a concentration of 200 ppm silver active, were applied directly to the skin of the 106 individuals who completed the cotton study and the 102 participants who completed the polyester study.

Each study was divided into three phases:

- An Induction Phase consisted of nine applications of the test material every Monday, Wednesday and Friday over a three-week period. The patches were removed approximately 24 hours after each application. At 48-hour intervals, the skin sites were evaluated and identical fresh patches were applied to the same sites.
- A Rest Phase of 10 to 15 days.
- A Challenge Phase during week six of the study. During this phase, identical patches were applied to sites previously unexposed to the test material. The patches were removed after 24 hours and the sites graded after additional 24-hour and 48-hour periods.

Conclusion

Under the conditions of this study, there was no evidence of skin sensitization among the 106 participants in the cotton study and the 102 participants in the polyester study during any observation period.

SILVADUR™ Is Approved by the International OEKO-TEX® Association

These studies evaluated the potential of SILVADUR treated cotton and polyester fabrics to produce skin sensitization, such as contact allergy. The International OEKO-TEX Association assessed and approved SILVADUR as harmless to human health if it is used correctly, according to its operating instructions and product safety standards.

It is also registered with the U.S. Environmental Protection Agency (EPA) and its active ingredient is notified and supported under the EU Biocidal Products Regulation (BPR). SILVADUR components meet REACH requirements in the European Union.



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