Safety assessment of octylmethoxycinnamate, butylmethoxydibenzoylmethane, and octyltriazone sunscreens by human repeated insult patch tests to compare the Shelanski and maximization tests

Jun Choi, Won-Young Chey, Al-Young Lee
Department of Dermatology, Eulji Hospital Eulji Medical College

Background: Human repeated insult patch tests (HRIPTs) are a final method for safety assessment of chemical ingredients. In the representative HRIPTs, the Shelanski and modified Draize require 200 participants, but the maximization and modified maximization tests require only 25.

Objective: To evaluate the safety of three sunscreen ingredients using the Shelanski and maximization methods.

Methods: Octylmethoxycinnamate, butylmethoxydibenzoylmethane, and octyltriazone (BASF) were prepared for the induction, as 25% ointment in white petrolatum base. After a 2-3 week resting phase, patch and photopatch tests were conducted, but pretreatment with SLS was only performed in the maximization test. The results were analyzed using the Chi-Square test.

Results: During the induction phase, there were only two (4%) weak positive reactions observed with the Shelanski method, whereas all 25 displayed strong or extremely positive reactions with the maximization method. Butylmethoxydibenzoylmethane displayed the most frequent elicitation reactions; the patch and photopatch tests displayed weak positive reactions in four (2%) and six (3%), and in one (4%) and two (8%), with the Shelanski and maximization tests, respectively. Taking into account two of the six reactors displayed positive reactions to petrolatum with the Shelanski test, the actual number of positive patch test reactions would be four (2%). The difference in results of the two methods was not statistically significant.

Conclusion: Although it is not easy to conduct HRIPT on 200 subjects, and the results from the two tests were not significantly different, the reactions from the maximization tests were too severe to be recommended in humans.