A Comparative Dermal Irritancy Evaluation of Hand Sanitizers: Are Non-Alcohol Products Actually the Real Skin Irritants?

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Introduction

Hand sanitizer is frequently used in educational settings. Due to concerns about potential irritancy of alcohol-based hand sanitizers (ABHS) and the need for school districts to consider non-alcohol sanitizers. There are numerous hand sanitizer products available, including: gel (62% ethanol, purell® instant hand sanitizer), alcohol-free foam (Betco Winning Hands Alcohol Free Foaming Hand Sanitizer), foaming hand sanitizer (X3 Clean Foaming Hand Sanitizer), and aerosol hand sanitizer (Aero Instant Foaming Hand Sanitizer).

There are anecdotal reports of ABHS causing skin dryness and irritation, and multiple non-alcohol hand sanitizers are known to cause skin irritation and other side effects. Therefore, a direct comparison of the irritancy potential of ABHS and non-alcohol-based hand sanitizer products is necessary.

Materials and Methods

Study Design:
The 21-day cumulative irritation test was conducted according to the method of Phillips et al., with modifications. A total of 12 test articles were applied to the backs of study participants for 24 hours, removed, and 20 minutes after patch removal was evaluated for erythema and edema using the 0-4 scale (0 = no reaction to 4 = severe reaction). Each test article was applied to the back of two adult patients, and the total irritation score was calculated using the method of Phillips et al.

Test Method:
The 21-day cumulative irritation test was conducted according to the method of Phillips et al., with modifications. A total of 12 test articles were applied to the backs of study participants for 24 hours, removed, and 20 minutes after patch removal was evaluated for erythema and edema using the 0-4 scale (0 = no reaction to 4 = severe reaction). Each test article was applied to the back of two adult patients, and the total irritation score was calculated using the method of Phillips et al.

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Results

The results of the study are shown in the table below. The data shows that alcohol-based hand sanitizers can be toxic and cause irritation, while non-alcohol-based hand sanitizers are less irritating than ABHS. While it is known that both alcohol and QACs have the potential for mild-moderate cumulative irritation, all scores are reflective of test conditions and may not represent product performance during “real-world” usage.

Conclusions

The irritancy potential of non-alcohol hand sanitizers is formulation dependent and not on the active ingredient alone, as products with identical active ingredients were statistically different in this test.

• Claims that non-alcohol IHS are less irritating than alcohol-based IHS should be interpreted with caution.

• School nurses should advise their school district to carefully evaluate hand hygiene products for objective skin performance data to ensure that the IHS is mild enough for frequent use.

• Ethanol is considered safe and effective by the FDA for use in hand antiseptics, and the proven safety of ethanol makes it a standard ingredient for use in hand hygiene products.

References

4. RCTS. Inc. The SCAN method (General Clinical Evaluation of Irritancy). The SCAN method is an industry standard for assessing the cumulative irritancy potential of new products. SCAN is a 3-point system that includes: a “Mild” irritant, a “Moderate” irritant, and a “Mild-Moderate” irritant. The SCAN method is used to evaluate the irritancy potential of new products and is recommended by the FDA for dermal patches used for topical products.

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Summary

• All non-alcohol IHS products tested were significantly more irritating than the ABHS gel and foam.

• The only products to achieve a mild rating were the ABHS gel and foam. In addition, the ABHS were the only products tested that were rated as mild by baby oil.

• BAK products appear to be more irritating than BAC products, which is consistent with previous findings.

• Natural products (thymol) have the potential to be irritating, and it should not be assumed that “natural” means “non-irritating.”

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