An evaluation of healthcare products on children 0 to 36 months of age with normal skin

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Purpose/Rational

The barrier property of skin can be compromised by a variety of agents/activities, such as adhesive trauma, irritation caused by urine and/or fecal incontinence, digestive juices, and shear/friction: all of which can lead to a wound. Film forming skin protectants have been used routinely to minimize damage to adult skin[1-5], yet the effect on pediatric skin is not well studied. The purpose of this study[6] (single-center, randomized, evaluator blinded) was to evaluate a new (non-stinging) formulation and two marketed adhesive removers on children with normal skin. These products have been used on adults only and have not been previously tested in children. The primary objective was to assess safety through visual evaluations and assessment of subjective questionnaires, diary comments and adverse events during a 4-week period of use under the conditions specified in the study protocol.

Methodology

This was a single-center, randomized, evaluator blinded study. Thirty children, age 0 to 36 months, completed the study. All subjects were assigned all three test articles and an untreated site (control). The test articles were applied to the skin (forearm and buttock) daily for the 4 week study period. A trained evaluator conducted clinical evaluations of irritation (dryness and erythema) at Baseline, Week 2 and Week 4. Subjective questionnaires were also administered at Baseline, Week 2 and Week 4. Subjects were visually evaluated for irritation (dryness and erythema) by a trained grader at each time point. Each forearm and buttock was evaluated separately. The following grading scale was used for all evaluations:

Dryness/Erythema	
0 =	No visible signs of dryness/No visible signs of erythema
0.5 =	Barely distinguishable dryness/Barely distinguishable erythema
1 =	Slight dryness/Slight erythema
2 =	Moderate dryness/Moderate erythema
3 =	Severe dryness/Severe erythema

The subject's parent or legal guardian applied the test articles to the designated test Sites and then completed a subjective questionnaire, which included questions related to the condition of the subject's skin and product opinion. Subject's parent or legal guardian was given the test articles to take home and were instructed by the study staff on the test article instructions, diary and study restrictions.

Week 2 Visit: Each subject was visually evaluated for irritation by a trained grader. If a grade of 3 was observed, the subject was withdrawn from the study and an Adverse Event was recorded. The subject's parent or legal guardian completed a subjective questionnaire and diaries were reviewed. Adverse events were assessed and concomitant medications were reviewed.

Week 4 Visit: Each subject was visually evaluated for irritation by a trained grader. If a grade of 3 was observed, the subject was withdrawn from the study and an Adverse Event was recorded. The subject's parent or legal guardian completed a subjective questionnaire. Diaries and test articles were collected.

Results

There were five adverse events reported during the course of the study. The adverse events were all mild in severity and included rashes (to buttocks and crease of forearm), stinging, redness and small bumps on the buttocks. The data indicated no scores above '0' for the no-sting formulation, though one adhesive remover had scores of 1, 0.5 and 0.5; the other 1.0 and 0.5. A total of 5 adverse events were recorded, though these scores indicated slight/barely noticeable erythema/irritation.

Conclusion

As no adverse events nor scores above '0' were noted for the no-sting formulation, it was concluded that the no-sting formulation is safe for use on this population.

Acknowledgement/Disclosure
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Products evaluated:
NO-STING SKIN-PREP® (skin protectant), Smith & Nephew, Inc.
UNI-SOLVE® (adhesive remover), Smith & Nephew, Inc.
REMOVE® (adhesive remover), Smith & Nephew, Inc.

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