Irritancy Study Results

Objective

To determine the role Detachol® may play in local skin reactions in areas of exposure to medical adhesives

Research Team

Joseph Fowler, MD, Principal Investigator

Study took place in December 2010 at Dermatology Specialists Research, Louisville, KY.

Ingredients Tested

The ingredients in Detachol® were tested separately. These ingredients include Petroleum Distillates (also called Odorless Mineral Spirits), Fragrance and Red Dye.

Study Population

Twenty volunteers who met the study criteria were scheduled for an initial visit.

Experiment

Patch Testing

The chamber was held in place by an adhesive tape. For this study, the chambers stayed in place for 24 hours then were removed. They were evaluated for reaction/s at 24, and 96 hours. Participants were patch tested with the study products as described above. Patients were provided with verbal standard instructions regarding the care of the patches.

The second visit took place approximately 24 hours after the initial visit. At this time, the patches were removed, and the skin examined. Investigator Assessments (IA) of each reaction were graded after a 30 minute waiting period according to standard North American Contact Dermatitis Group guidelines: 0=no reaction,; 0.5=doubtful (faint erythema with no induration), 1= mild (erythema, induration, +/- papules), 2=moderate (erythema, induration, papules, vesicles), 3=severe (intense erythema, induration, coalescing vesicles, bullae, spreading) IR=irritant. If a reaction is deemed IR, then the severity will be graded on a 0.5 to 3 basis as above. At the third visit, approximately 96 hours after the first visit, IA was again graded according to above guidelines.

ROAT Testing

At the first visit, an area of about 3 X 3 cm. on normal skin of the forearm was marked. The study product was gently wiped on this area using a cotton tipped applicator in an amount consistent with normal use and allowed to dry. The area was examined at the second visit and graded as with patch testing. Visit 3 was for evaluation only, not reapplication, and concluded the study.

Eloquest HEALTHCARE®

The healthcaring company®

Patch Test/ROAT – Results

Subject Initials	Subject Number	Red Dye (D&C Red No. 17)		Fragrance (Many Flowers)		Odorless Mineral Spirits		Detachol Adhesive Remover	
		24 hours	96 hours	24 hours	96 hours	24 hours	96 hours	24 hours	96 hours
RLN	001	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
DMM	002	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
JJB	003	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
MDO	004	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
DLM	005	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
CAA	006	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
JHL	007	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
CGN	008	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
DLS	009	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
HEM	010	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
JLV	011	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
LJR	012	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
SLO	013	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
HJL	014	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
BSK	015	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
JAH	016	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
GAW	017	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
SSS	018	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
TMV	019	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
SKS	020	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG

Conclusion

The results as compiled for both the patch testing and repeat open application test (ROAT) testing of Detachol® and its 3 ingredients, odorless mineral spirits, red dye and fragrance mix would indicate that this product does not have a tendency to induce either allergic or irritant contact dermatitis.

All sites showed completely negative results for all 20 participants. I consider the ROAT test especially important, since this simulates actual usage conditions.

This testing reaffirms the safety of topical usage of the Detachol® product.

-Joseph F. Fowler Jr. MD