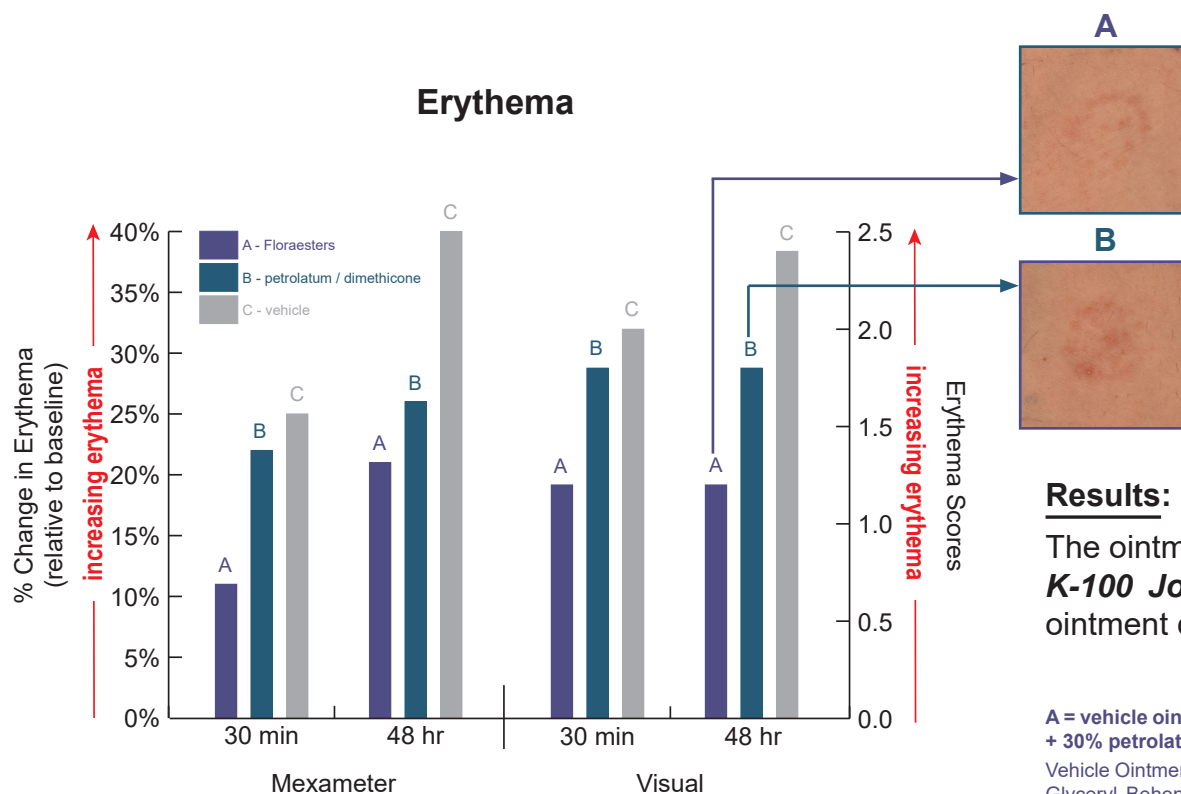




## Floraesters in a Barrier Ointment / Balm Reduced Sensitivity to Nickel



### Objective:

To evaluate Floraesters 20, 30, and 60, and Floraesters K-100 Jojoba in an ointment to reduce nickel sensitivity.

### Method:

Subjects sensitive to nickel were tested with ointments containing Floraesters or a combination of petrolatum and dimethicone (known skin protectants) prior to patching the skin with nickel sulfate. Erythema measurements were made 30 minutes and 48 hours after patch removal both visually and via Mexameter.

### Results:

The ointment containing **Floraesters 20, 30, and 60, and Floraesters K-100 Jojoba reduced erythema by up to 49%** compared to the ointment containing petrolatum and dimethicone.

A = vehicle ointment + 26% Floraesters 20, 30, and 60 + 5% Floraesters K-100 Jojoba / B = vehicle ointment + 30% petrolatum + 1% dimethicone / C = vehicle ointment

Vehicle Ointment (%wt/wt): Macadamia Integrifolia Seed Oil (q.s.), Glycerin (15.0%), Ethyl Macadamiate (14.0%), Glyceryl Behenate/Isostearate/Eicosandioate (5.5%), Helianthus Annuus (Sunflower) Seed Oil (4.0%), Jojoba Oil/Macadamia Seed Oil Esters (and) Squalene (and) Phytosteryl Macadamiate (and) Phytosterols (and) Tocopherol (4.0%), Trihydroxystearin (2.8%), Polyglyceryl-10 Behenate/Eicosadiolate (1.2%), Polyglyceryl-2 Dipolyhydroxystearate (1.0%), Phenoxyethanol (0.6%), and Lactic Acid (q.s.).

## Floratech Ingredient: Floraesters 20, 30, 60, and Floraesters K-100 Jojoba

The clinical study of Floratech® test formulation (CTL\_17-072) was conducted on a panel of 5 male and female subjects, ranging from 25 to 60 years of age (mean age = 44), who demonstrated a sensitivity to nickel. The duration of the study was 6 days (including a 1 day washout) with one application of the ointments, followed by a 48 hour patch with nickel [nickel (II) sulfate heptahydrate] using a Finn Chamber under occlusion. The Mexameter MX 300 is a product of Courage+Khazaka (Köln, Germany). Investigator evaluations of visual erythema were made on a scale of 0 - 3 (0 = none, 1 = mild, 2 = moderate, 3 = severe). The study was double-blind, randomized, and carried out under controlled temperature and humidity conditions. The inclusion of Floraesters 20, 30, and 60 and Floraesters K-100 Jojoba resulted in directionally significantly ( $p < 0.10$ ) less erythema (Mexameter) than the vehicle and than petrolatum and dimethicone. (Clinical Study 17-072 - Phase I and IV report available upon request.)