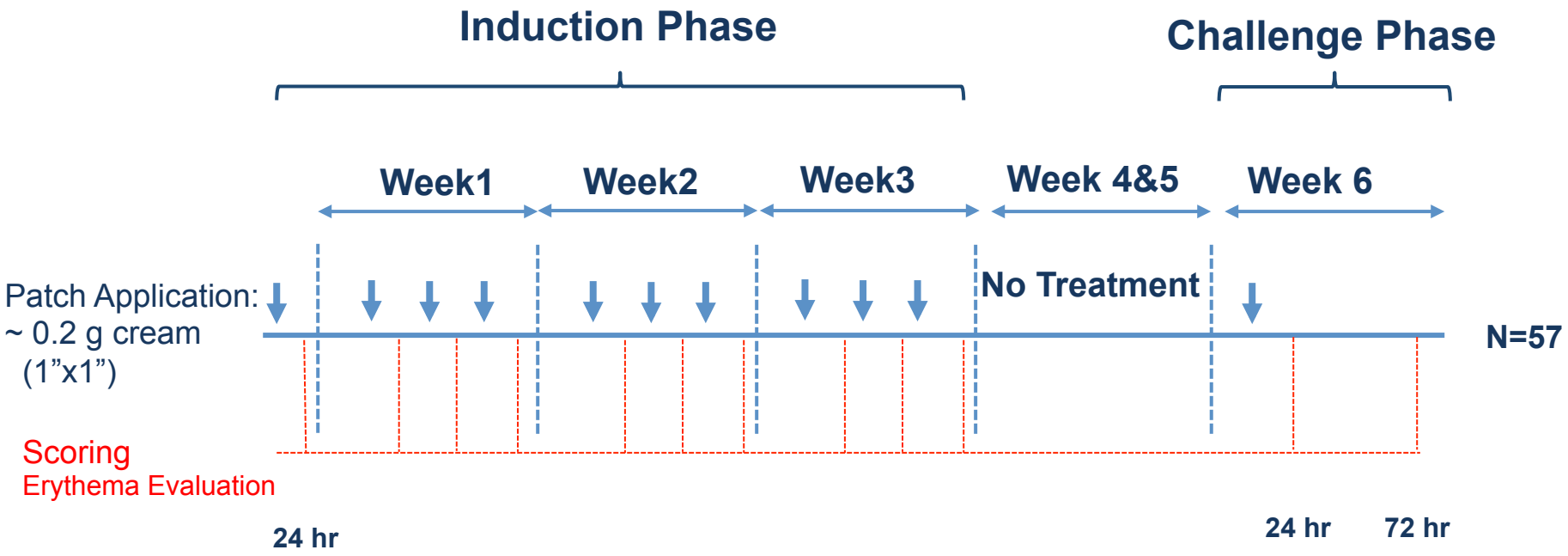
Clinical Study-Repeated Insult Patch Test in Human (Study:C11-4461.01, Consumer Product Testing Co.)

- **Objective of the study:** To determine whether Zestra Glide induce primary or cumulative irritation and /or allergic contact sensitization
- **Subjects:** 57, male and female (age 19-79) were selected for the study. 54 subjects completed the study, 3 subjects discontinued for reasons unrelated to test article.
- **Inclusion criteria:**
  - Male & female (non-pregnant or nursing) subjects (not taking drugs that influence the outcome of the study and without a history of adverse reaction to cosmetics or other personal care products), age 16 and over
  - Absence of any visible skin disease which might be confused with skin reaction from test material
  - Prohibition of use of topical or systemic steroids and/or antihistamines for at least 7 days prior to study initiation
  - Completion of medical history form, understanding and signing of an informed consent form
  - Considered reliable and capable of following directions

Clinical Study-Repeated Insult Patch Test in Human Clinical Design



Clinical Study-Repeated Insult Patch Test in Human Methodology

- **Application Site:**
  - ~ 0.2 g of Zestra Glide is applied at the upper back area between scapulae and covered with (1”x1”) absorbent pad of clear adhesive dressing

- **Induction phase:**
  - Patches were applied 3 times /week (e.g., Monday, Wednesday and Friday) for a total of 9 applications (3 weeks) at the same site.
  - Scoring is made within 24 hrs and prior to re-application

- **Challenge Phase:**
  - Start 2 weeks after the final induction patch application
  - Challenge patch is applied to a virgin test site adjacent to the original site
  - The site was scored at the clinic 24 hrs and 72 hrs post application

Clinical Study-Repeated Insult Patch Test in Human Evaluation Criteria

Erythema Score and additional Dermal Sequelae

Scoring and rating	Pathological Description of the skin
0 = No visible skin reaction	E = Edema
0.5= Barely perceptible	D = Dryness
1 = Mild	S = Staining
2 = Moderate	P = Papules
3 = Marked	V = Vesicles
4 = Severe	B = Bullae U = Ulceration Sp= Spreading

Clinical Study-Repeated Insult Patch Test in Human Results

		Induction Phase									Virgin Challenge Site	
Subjects	24 hr	1	2	3	4	5	6	7	8	9	24 hr	72 hr
All	0	0	0	0	0	0	0	0	0	0	0	0

Conclusion:

Under the condition of this study Zestra Glide did not indicate a potential for dermal irritation or allergic contact sensitization

Zestra Glide- Water-Based Formulations Competition

Product	Ingredients
Zestra Glide	Purified Water, Natural Vegetable Glycerin (Glycerine), Hydroxyethylcellulose, Xanthan Gum, Sodium Citrate, Aloe Vera Leaf Extract (Aloe Barbadensis), Potassium Sorbate, Citric Acid, Vitamin E
SYLK®	Aqua (Purified Water), Actinidia Chinensis (Kiwi) Fruit Plant Extract, Citrus Grandis (Grapefruit) Seed Extract, Xanthan Gum, Vegetable Glycerine, Citric Acid, Potassium Sorbate, Sodium Citrate
K-Y® Brand	Water (Purified), Glycerin, Sorbitol, Propylene Glycol, Hydroxyethylcellulose, Benzoic Acid, **Methylparaben,** Sodium Hydroxide
Astroglide®	Purified Water, Glycerin, Propylene Glycol, Polyquaternium 15, **Methylparaben, Propylparaben**
K-Y ® YOURS +MINE®	Water, Propylene Glycol, Polysorbate 60, Hydroxyethylcellulose, Benzoic Acid, **Menthyl Lactate, Methyl Salicylate, Fragrance**, Sodium Hydroxide
K-Y® Brand Sensitive Jelly	Water, Propylene Glycol, Sorbitol, Hydroxyethylcellulose, Benzoic Acid, Polysorbate 60, Tocopheryl Acetate
K-Y® Brand SILK-E® Vaginal Moisturizer	Water, Propylene Glycol, Sorbitol, Polysorbate 60, Hydroxyethylcellulose, Benzoic Acid, **Methylparaben,**Tocopherol Acetate, Aloe Barbadensis Leaf Juice

Zestra Glide: Preservative Efficacy Testing Results

Table 1: Mixed Bacterial Count

CPTC ID		Sampling Intervals					
		Day 0 Count (cfu/mL)	Day 2 Count (cfu/mL)	Day 7 Count (cfu/mL)	Day 14 Count (cfu/mL)	Day 21 Count (cfu/mL)	Day 28 Count (cfu/mL)
M11-4469.01	% Reduction	$6.4x10^5$	< 10	< 10	< 10	< 10	< 10
		41.8	> 99.9	> 99.9	> 99.9	> 99.9	> 99.9

Table 2: Mixed Fungal Count

CPTC ID		Sampling Intervals					
		Day 0 Count (cfu/mL)	Day 2 Count (cfu/mL)	Day 7 Count (cfu/mL)	Day 14 Count (cfu/mL)	Day 21 Count (cfu/mL)	Day 28 Count (cfu/mL)
M11-4469.01	% Reduction	$8.2x10^4$	< 10	< 10	< 10	< 10	< 10
		86.8	> 99.9	> 99.9	> 99.9	> 99.9	> 99.9