

# Irritation Study Summary

Mölnlycke® conducted two studies to evaluate the potential of Chlorhexidine Gluconate (CHG) aqueous solutions to cause skin irritation.

A total of 56 subjects in the studies had 24-hour occlusive CHG patches applied to each upper arm every day for 14 days. Their instructions included keeping the area dry and not using any lotions or creams for the duration of the study. The trained scorer was blinded to previous scores and treatment identity. Included were five 4% CHG solutions and two 2% CHG solutions. Distilled water was used as a negative control with sodium lauryl sulfate, 0.1% w/v in distilled water, as the positive control.

Each response was scored both for irritation classification and description of observed evidence under conditions of test for cumulative irritation.

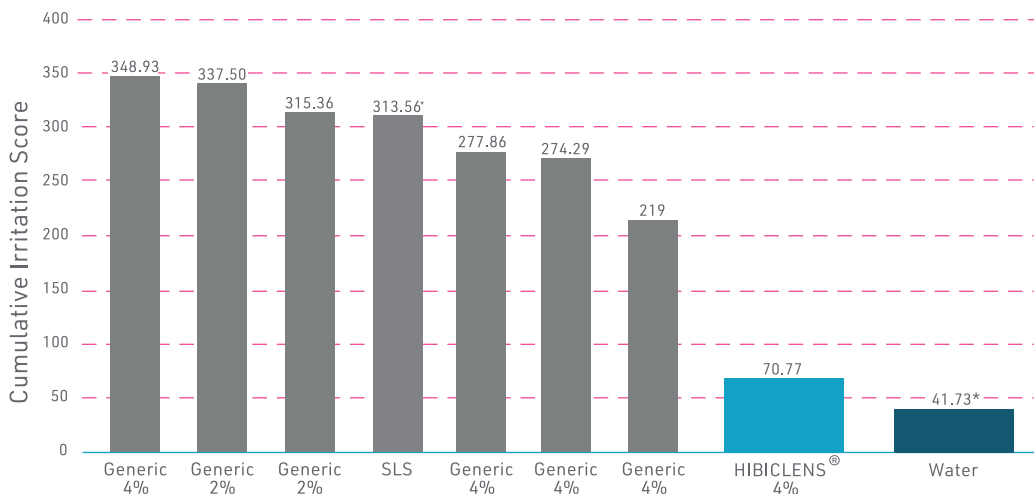
## Irritation classification included:

- Class 2 (34-133)-Probably mild in normal use
- Class 3 (134-299)-Possibly mild in normal use
- Class 4 (300-387)-Experimental cumulative irritant

## Observed evidence included:

- Slight potential for very mild irritation
- Moderate potential for mild irritation
- Strong potential for mild to moderate irritation

## Irritation study results



\*Positive and negative controls from both studies are averaged on the graph.

Results: HIBICLENS was the only CHG solution to receive a class 2 rating and had the lowest potential for cumulative irritation. The 4 remaining 4% CHG solutions received class 3 and 4 ratings respectively with evidence of moderate to strong potential for cumulative irritation. The 2% CHG solutions both received a class 4 response with evidence of a strong potential for irritation.

## Hibiclens had the lowest irritation potential of all those tested.

This summary of the studies has been compiled by Mölnlycke Healthcare US, LLC as a service to healthcare professionals. It does not contain the complete text and Mölnlycke Healthcare makes no representation as to its completeness in addressing all issues in the studies.

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