Efficacy and Substantivity Evaluation of a Sunscreen Formulation for People Conducting Sporting Activities in a High-UV Intensity Locale

Darrell S. Rigel, M.D. • Hao Ouyang, Ph.D. • Yohini Appa, Ph.D.

*New York University Medical Center, New York, NY, USA • Neutrogena Corporation. Los Angeles, CA, USA

BACKGROUND
It has been reported that moderate physical activities outdoors, sweat or heat can facilitate skin erythema reaction. Sunscreens designed for people conducting sport activities should provide sufficient protection level to compensate for these changes in skin physiology. In addition, sweating or water immersion and rub-off can also compromise the performance of a sunscreen and a sport sunscreen needs to withstand these factors. A consumer use sunscreen test was conducted on subjects during sport activities at high altitude and extreme UV conditions to evaluate these properties.

MATERIALS & METHODS

Materials
SPF 70+ sunscreen designed for sport activities containing 15% homosalate, 5% octisalate, 4%, octocrylene, 5% oxybenzone and 3% avobenzone

Study Location and Design
The SPF 70+ sport sunscreen was tested under the real-world conditions in a single-blinded clinical study in the summer of 2008 at Vail, CO (elevation 2,500 meters above sea level) for subjects playing golf (average exposure was about 4.5 hours). The sunburning UVB of sunlight at this elevation is approximately 65% higher than the intensity at sea level (every 305 meters above sea level, increases the UVB fluence rate increases by 8%). The study location and design represent the extreme UV condition that people may experience during outdoor sporting activities. Subjects applied sunscreen to their whole faces at the beginning of the study. Upon completion of the sport activity, dermatological evaluation was conducted on the next day. Subjects also self-assessed the SPF 70+ sunscreen.

Study Population
Out of 43 subjects who participated in both cells, 22 had Fitzpatrick skin type I-II, 17 had skin type III and 4 had skin type IV. The average age was 45.7 for the study population including 34 males and 9 females.

UV Conditions During the Study
UV conditions during the entire study period of the day were monitored and estimated to be roughly 5 Joule/cm² of UVB and 83 Joule/cm² of UVA for total exposure dose. Therefore virtually all subjects were expected to get sunburn in unprotected skin areas. The total UV dose is estimated to be more than 20 MED for skin type I subject.

Re-Application Subgroup
To test the substantivity of the sunscreen, one subset of the subjects (21) applied the SPF 70+ sport sunscreen on the whole face at the baseline and reapplied the sunscreen in the middle of the activities (about 2 hours into the UV exposure) to only one half of the face.

Results

Location
Fig. 1 Shows The Study Location

Dermatologist Grading
For the 21-subject reapplication group, none of the subjects could be differentiated in terms of increased erythema on one side by clinical examination at the end of the exposure. No post-exposure sunburn was noted clinically although one subject had a slight increase in erythema.

Subject Self-Assessment
Table 1 shows the percentage of the subjects (N=43) that agree with the statement describing the SPF 70+ sport sunscreen.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect my skin during intensive sport activities</td>
<td>91%</td>
</tr>
<tr>
<td>Does not sting my face</td>
<td>93%</td>
</tr>
<tr>
<td>Does not run into my eyes and sting</td>
<td>93%</td>
</tr>
<tr>
<td>Gentle formula</td>
<td>98%</td>
</tr>
<tr>
<td>Non-irritating</td>
<td>93%</td>
</tr>
<tr>
<td>Resists rub-off</td>
<td>77%</td>
</tr>
<tr>
<td>The skin is still breathable when wearing the sunscreen</td>
<td>91%</td>
</tr>
<tr>
<td>Non-greasy</td>
<td>86%</td>
</tr>
<tr>
<td>Rate the overall sunscreen experiences as excellent or good</td>
<td>95%</td>
</tr>
</tbody>
</table>

Figure 2 pie chart shows 95% (20/21) of the subjects had no later difference, indicating excellent substantivity to skin for the SPF 70+ sunscreen and that re-application was not necessary for the prevention of sunburn.

CONCLUSIONS
- The tested formulation is substantive and reapplication was not needed to prevent sunburn to the skin.
- The high performance of the SPF 70+ sport sunscreen was very effective in protecting skin from sunburns under extreme UV and real sporting conditions.

REFERENCES