Review of Environmental Working Group® Sunscreen Testing

• Introduction
The Environmental Working Group (EWG) has produced evaluations of EltaMD sunscreens. To understand EWG’s rating, three key facts must be considered:

1. EltaMD sunscreens are clinically tested and evaluated by an independent laboratory, as required by the FDA and other international rules governing sunscreen safety and performance claims.

2. EWG does not actually test the sunscreen ingredients and products they evaluate.

3. EWG created and implements a proprietary modeling and scoring system to evaluate on sunscreen ingredients and products.¹

• Executive Summary
EWG’s sunscreen evaluation methodology is based on estimates and produces inconsistent results. By creating and employing their own proprietary test methods, explained below, EWG does not apply FDA-required clinical product evaluations. The outcome of this can be confusion and serve to undermine consumer confidence in products proven to be safe and reliable.

Testing Methodology
EWG states that it performs no product testing. “The (sunscreen) ratings are based on an in-house compilation of standard industry, government and academic data sources, models we constructed over the past nine years…”

Because EWG creates and administers its own proprietary model to determine sunscreen evaluations, EWG is not held to the same standards the FDA requires of sunscreen manufacturers. What’s more, EWG does not indicate that it validates its scoring of products with any outside source. EWG produces its own proprietary sunscreen evaluations and solicits organizational contributions through their publication.
As an example of how EWG’s proprietary methodology is flawed, EWG places a heavy reliance on Monochromatic Protection Factor (MPF) testing of ingredients and products. EWG states that, “…MPF is a…key component in EWG’s evaluation of sunscreen effectiveness.” “We computed the MPF transmission spectra following the method detailed by Herzog and implemented by the BASF Sunscreen Simulator.”

MPF testing as established by BASF with their Sunscreen Simulator is not a true measure of the UV protection of an ingredient or product. According to BASF, “The BASF Sunscreen Simulator is a tool enabling the estimation² of the Sunburn Protection Factor (SPF) as well as various common UVA-Metrics. This tool helps the formulator planning the composition of active ingredients in a sunscreen formulation, but it does not replace the actual formulation work and in vivo SPF testing of the final product.”³

Nowhere does EWG indicate that it’s scoring of sunscreen products are “estimations”³. EWG simply states that the MPF values produced by the BASF Sunscreen Simulation evaluation are a “…key component in EWG’s evaluation of sunscreen effectiveness.”

A tool used by formulators for planning is far from a rigorous in vivo evaluation process, a fact EWG’s methodology fails to point out. No country or product governance organization allows for MPF testing to be used in lieu of reliable and accepted clinical evaluations.

**Irregular Evaluation Results**

Over time EWG’s evaluations of ingredients and products has shifted, but there has been no published reason for these shifts.

**Ingredients**

In 2013 EWG published the list of various ingredients used in sunscreens, including octinoxate or OMC, a commonly used UV protector. EWG rated OMC a 5.

However, in 2016, EWG’s rating of OMC had dropped to a rating of 6.

It might be reasonable to conclude that this change was based on clinical evidence that had come to light since the 2013 evaluation. However, almost all of the 23 clinical studies on EWG’s web-site that served as the basis for the rating of 6, were conducted prior to or during 2013.

All of the studies on OMC conducted in 2013 were performed by the European Commission (EU). Only abstracts of these studies are listed on the EWG website. However, one must conclude that OMC performed safely in these studies because OMC in the EU is an acceptable sunscreen active ingredient, and can be used up to a 10% concentration in any sunscreen product rather than the 7.5% usage percentage allowed in any US sunscreen.

This type of seemingly arbitrary evaluation of ingredients with no new evidentiary facts suggests an irregularity not consistent with a disciplined clinical evaluation process.
**Products**
In 2011 EWG published an evaluation of EltaMD sunscreens. The results are depicted in the table below:

<table>
<thead>
<tr>
<th>2011 EWG Sunscreen Ratings</th>
<th>UV Clear</th>
<th>UV Lotion</th>
<th>UV Shield</th>
<th>UV Sport</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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Per the data in the table above taken from EWG’s 2011 website, EWG ranked the four EltaMD products listed above as a 2.4

In its 2016 report EWG demoted the ratings of three of these same sunscreens by as much as 6 points.5 Considering that none of the formulations for the EltaMD products listed above have changed since the 2011 rating, the validity of the EWG testing protocol that produces such a wide-ranging evaluation discrepancy becomes questionable.

By creating its own methodologies and standards EWG seems to be free to randomly "move the goal posts" regarding sunscreen product performances independent of FDA-required clinical product testing.

- **Summary**
EltaMD believes that EWG has a meaningful role in helping consumers make safe decisions regarding sunscreen purchases. However, relying on self-conceived ingredient and product testing methodologies defy the regulatory and clinical standards set down worldwide to which sunscreen manufacturers are held helps no one, and can serve to confuse consumers.

**References**

2. - *Authors emphasis*

