The critical role of sunscreen formulation in efficacy & environmental exposure.

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UV light can cause sunburn and skin damage and lead to an increased risk of skin cancer.
Sunsunscreen is the only OTC drug indicated for the prevention of cancer.

- Skin cancer is the most common form of cancer in the U.S., with more annual cases than breast, prostate, lung and colon cancers combined.¹
- Approximately 9,500 Americans are diagnosed with skin cancer every day. More than two people die of the disease every hour.¹⁻³
- According to the WHO, following sun-safe practices can help prevent 4 out of 5 cases of skin cancer.⁴
- Sunscreens are critical to protecting skin from the sun – even one bad childhood sunburn can double your chance of developing melanoma later in life.⁵
Sunscreens are regulated by the FDA to ensure they meet safety and effectiveness standards.

• OTC sunscreen drug products must follow Drug Facts labeling content and format requirements in § 201.66 (21 CFR 201.66).

• Labeling requirements for marketed OTC sunscreen drug products are set forth in § 201.327 (21 CFR 201.327).

• SPF, broad spectrum, and water-resistant testing requirements and the indications and claims allowed based upon the results of these tests are in § 201.327(i) and (j).

• “Sunblock” and “Water-proof” are NOT allowed.

• Other claims like “reef-safe,” “biodegradable” and “environmentally-friendly” are unregulated.
A diverse palette of UV filters is necessary to provide broad-spectrum coverage for all skin types.

- UV filters are not interchangeable.
- There are only 8-9 commonly-used FDA-approved filters in the US. Any new filters would require FDA approval prior to use.
- Most US filters are effective UVB filters.
- Only Oxybenzone and Zinc oxide are broad-spectrum (covering UVB & UVA).
- Avobenzone is the only organic UVA filter.
Proper formulation is a critical factor for protection with sunscreens. Each filter has unique properties (light-stable, biodegradable, compatibility, hydrophobic/hydrophilic, mineral/organic) that affect overall formula performance.

**UV filter system**
- UVA + UVB filters to achieve specified SPF, photostability, and broad-spectrum coverage

**Water**
- Lotions

**Film Formers**
- Evenly distribute filters, create structural matrix, improve SPF, and water resistance

**Emollients**
- Surface distribution, improve droplet size and texture

**Emulsifiers**
- Solubilize filters

**Thickeners**
- Waxes

Minimal UV transmittance
- Good Coverage

Partial UV transmittance from uneven or heterogeneous deposition of UV filter leaves consumers poorly protected
- Uneven Coverage

Consumers poorly protected
- Poor Coverage
Consumer needs are personal.
Stable, aesthetically pleasing formulas are created to meet the needs of all consumers.

- Dermatologists agree the best sunscreen is the one people prefer to use.
- A variety of choice in sunscreen is important to meet consumer needs, helping them to follow sun protection guidelines.
- People consider several factors in choosing a sunscreen including:
  - SPF
  - Product form, e.g. stick, lotion or spray
  - How it feels, ease of spread, mineral/organic
  - Special needs, e.g. sensitive or acne-prone skin, sports, wet skin, fragrance/no-fragrance
- People are routinely observed to apply 25-50% of the 2 mg/cm² density utilized by standard SPF testing.⁶
Formulation determines water resistance and skin adherence.
Global Aquatic Ingredient Assessment (GAIA) is an internal J&J Consumer Health tool used to evaluate ingredients and formulations end of life impacts on aquatic ecosystems and waterways after use.

- Ingredients/ formulas are given scores from 0-100 based on published and/or modeled data on persistence, bioaccumulation and ecotoxicity.
- Over 1400 ingredients currently scored and integrated into our R&D systems.
- Ingredient scores can be aggregated for a product formula score.

A refined environmental risk assessment requires an accurate exposure model.

• Legislation has been enacted that is not based on robust ERAs

• Previously published ERAs use assumptions or poorly controlled studies that have led to exposure models that overestimate the risk of sunscreen actives in the environment.\textsuperscript{7-10}

• More refined exposure models should be based on rigorous experimental methods and empirical evidence.

• Habits & practices studies to understand consumer use can also be used to build exposure models.\textsuperscript{6}

• Environmental monitoring cannot determine source and suffers from collection and analytical challenges.\textsuperscript{10}
Development of a novel rinse-off method for improved sunscreen exposure assessment*

Jennifer K. Saxe,1 Stacy Dean,2 Randy L. Jones,2 Larry A. Mullins,2 Kurt A. Reynertson

• We sought to develop a novel, reproducible, and reliable method coupled with robust analytical methods to measure UV filter elution from sunscreen formulas applied to skin in a simulated marine environment.

• Objective:
  – Use the rinse-off method in the development of a more refined environmental risk assessment for key UV filters, and
  – Help make more informed formulation choices for future product development.

1EcoSafety Sciences; 2Battelle Memorial Institute. *Manuscript accepted in Integrated Environmental Assessment and Management (IEAM)
Rinse-off study methods were based on FDA water resistance criteria to simulate recreational bathing.

• Skin specimens were sectioned into small pieces and placed into custom holders. Sections were stored at 60-70% relative humidity in a saturated magnesium nitrate salt box.

• A positive displacement pipet was used to dispense a standard volume of sunscreen (0.5 & 2 mg/cm²). Sunscreen formulations (stick, spray, & 2 lotions) were analyzed in triplicate.

• After 20 min, sections were dipped into a containers with 250 mL of ~28 °C seawater* (T=0), and then removed and incubated sequentially with gentle oscillation (100 RPM) to new containers for 10 min (T=10), 10 min (T=20), air dried for 20 min, & final 20 min rinse (T=60). Skin sections and glass jars were rinsed with ethyl acetate for a mass balance.

• After SPE clean-up, a GC-MS/MS method was used for organic analysis, ICP-MS for mineral analysis. LODs and LOQs for each target compound were determined.

*Natures Ocean seawater contains live marine bacteria, trace elements, and other nutrients that approximates natural seawater. Method adopted from US FDA test method 352.76, Determination if a product is water resistant or very water resistant.
Lotions, sticks and sprays were tested.

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<th>Octocrylene</th>
<th>Avobenzone</th>
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<th>ZnO</th>
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</table>

O = organic; M = mineral; all formulas are SPF 50-55

Results for organic sunscreens are included in IEAM manuscript; mineral results not yet peer-reviewed.

Spray formulations were very hydrophobic, presenting some analytical challenges. Results are not included, but UV filter retention appears similar to sticks.
UV filter rinse-off is driven by formulation and application rate.

- This model is suitable for preparing replicate test samples to evaluate UV-filter removal in seawater. **This is the first well-controlled study of its kind.**
- Overall, stick formulations had the lowest rinse-off recoveries (0-5% for most analytes).
- Rinse-off was not a linear function of application rate or formula concentration.
- The factors that drive formulation efficacy, stability, and consumer acceptance also drive potential rinse-off.
UV filters applied to skin & rinsed into seawater is formula, ingredient and application dependent

O = organic; M = mineral. Results for organic sunscreens included in IEAM paper; mineral results not yet peer-reviewed.
To meet the needs of consumers and manage environmental exposure, a diverse palette of UV actives, excipient choices, and sunscreen formats is critical.
References Cited


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Questions?