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

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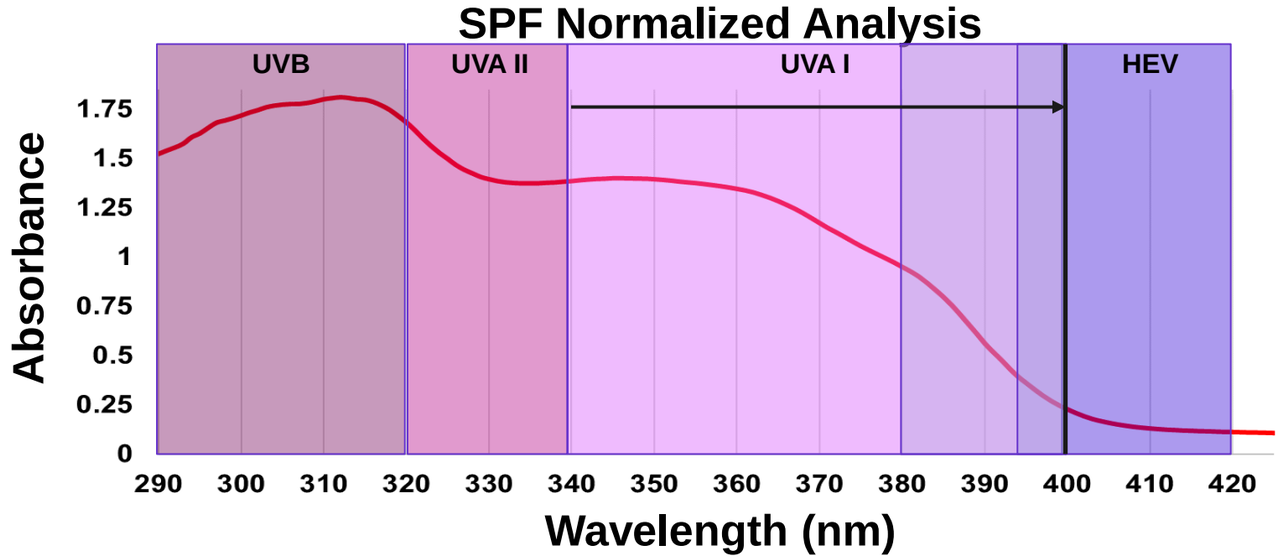
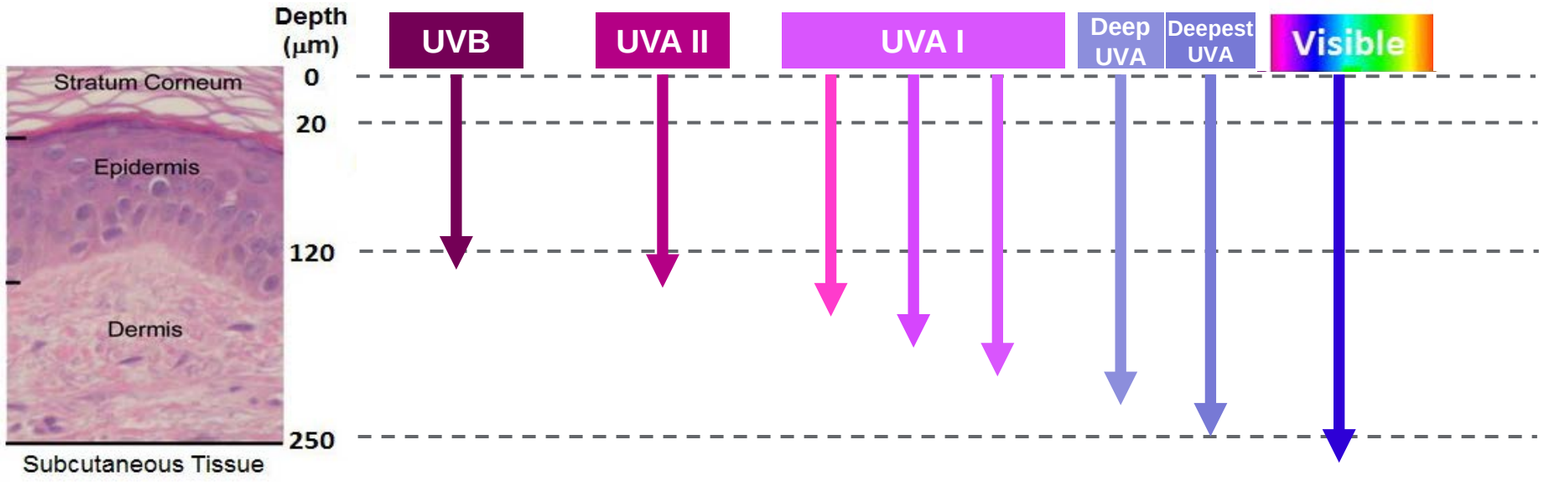
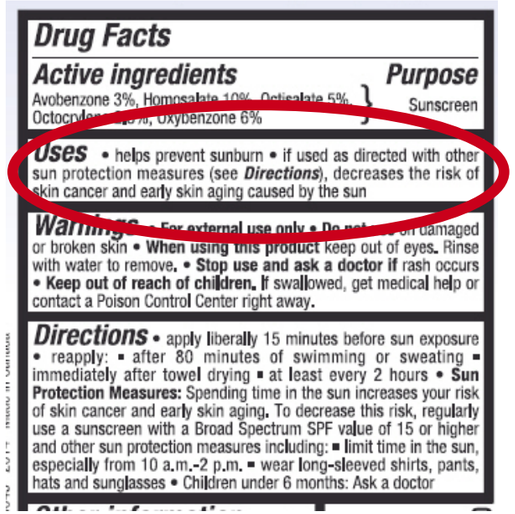
UV light can cause sunburn and skin damage and lead to an increased risk of skin cancer.



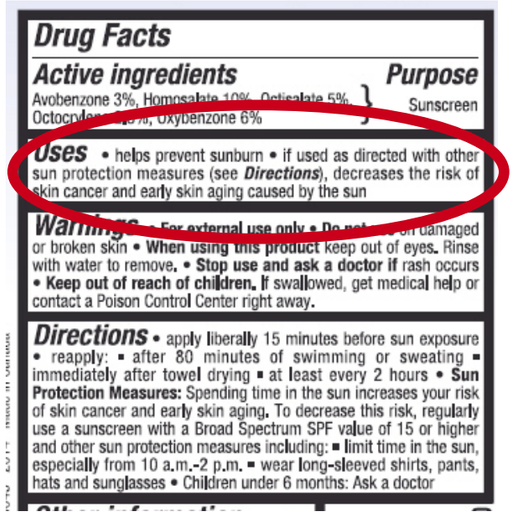


Sunscreen is the only OTC drug indicated for the prevention of cancer.



- 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.


Drug Facts

Active ingredients — **Purpose**
Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6% — Sunscreen

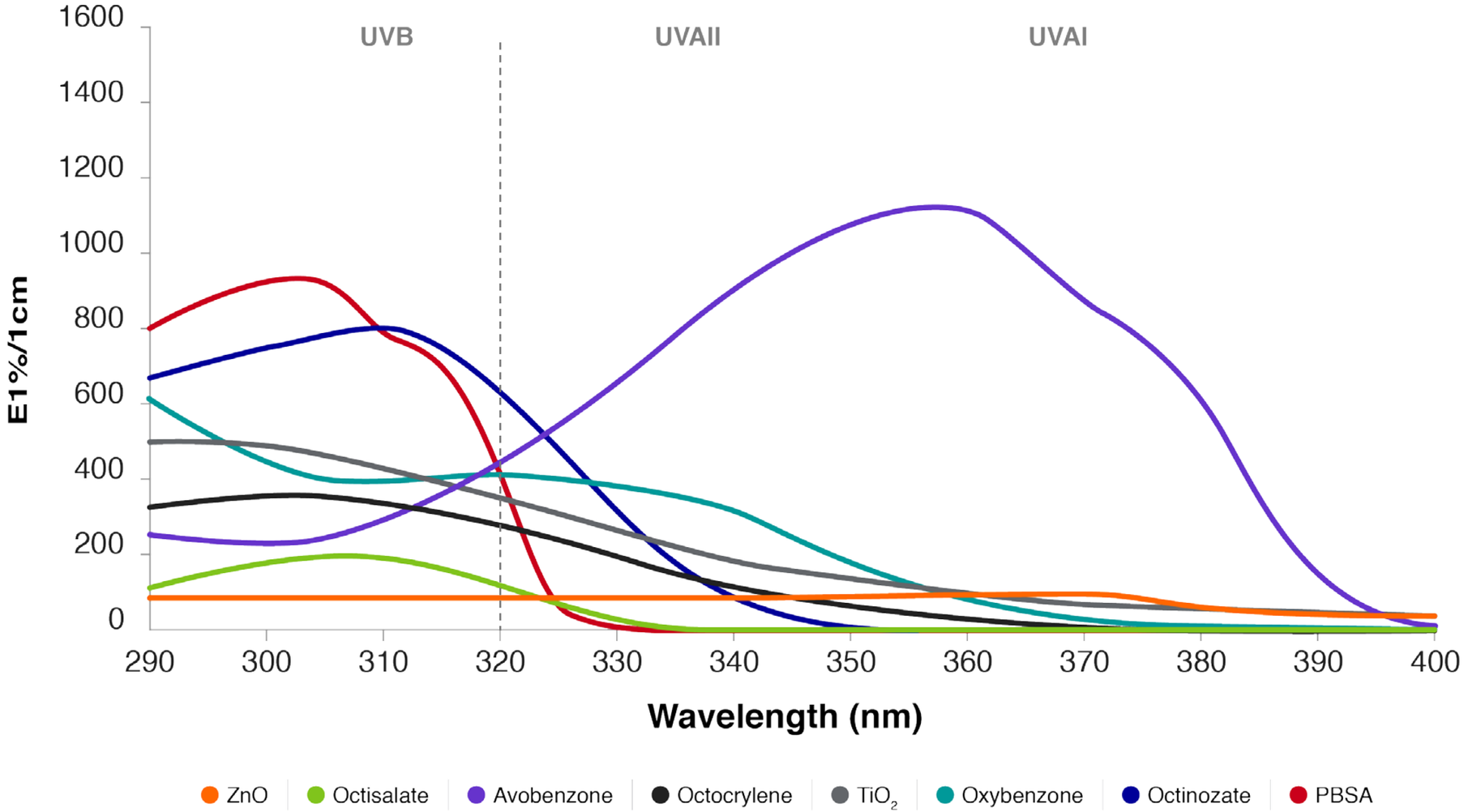
Uses • helps prevent sunburn • if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings • **For external use only** • **Do not** use on damaged or broken skin • **When using this product** keep out of eyes. Rinse with water to remove. • **Stop use and ask a doctor if** rash occurs • **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions • apply liberally 15 minutes before sun exposure • reapply: ▪ after 80 minutes of swimming or sweating ▪ immediately after towel drying ▪ at least every 2 hours • **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ▪ limit time in the sun, especially from 10 a.m.-2 p.m. ▪ wear long-sleeved shirts, pants, hats and sunglasses • Children under 6 months: Ask a doctor

- 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.

Water

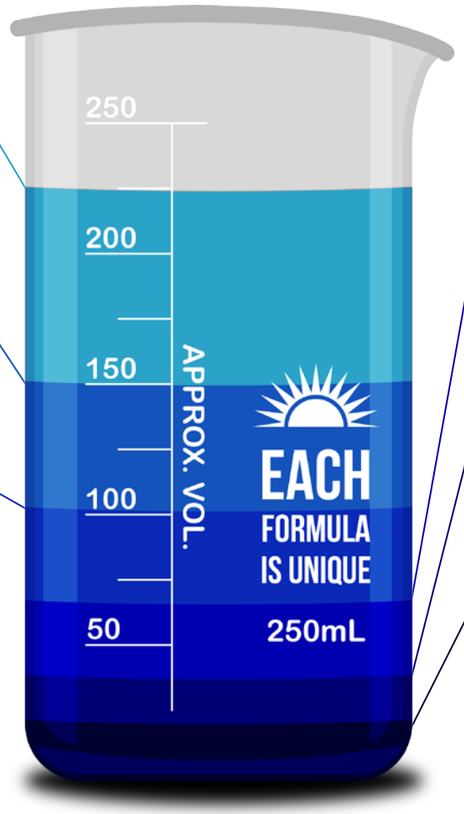
Lotions

Film Formers

Evenly distribute filters, create structural matrix, improve SPF, and water resistance

Emollients

Surface distribution, improve droplet size and texture



Emulsifiers

Solubilize filters

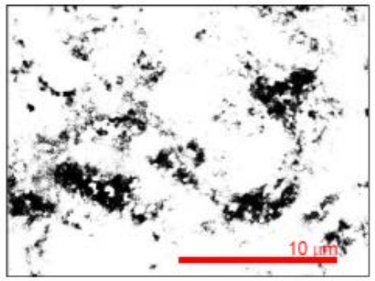
Thickeners

Waxes

UV filter system

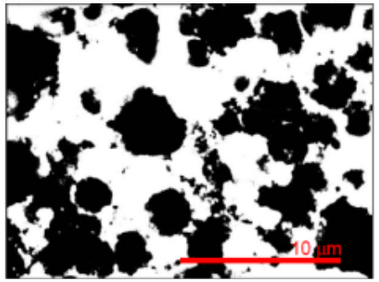
UVA + UVB filters to achieve specified SPF, photostability, and broad-spectrum coverage

Minimal UV transmittance

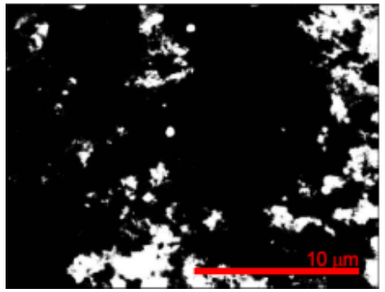


Good Coverage

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



Uneven Coverage



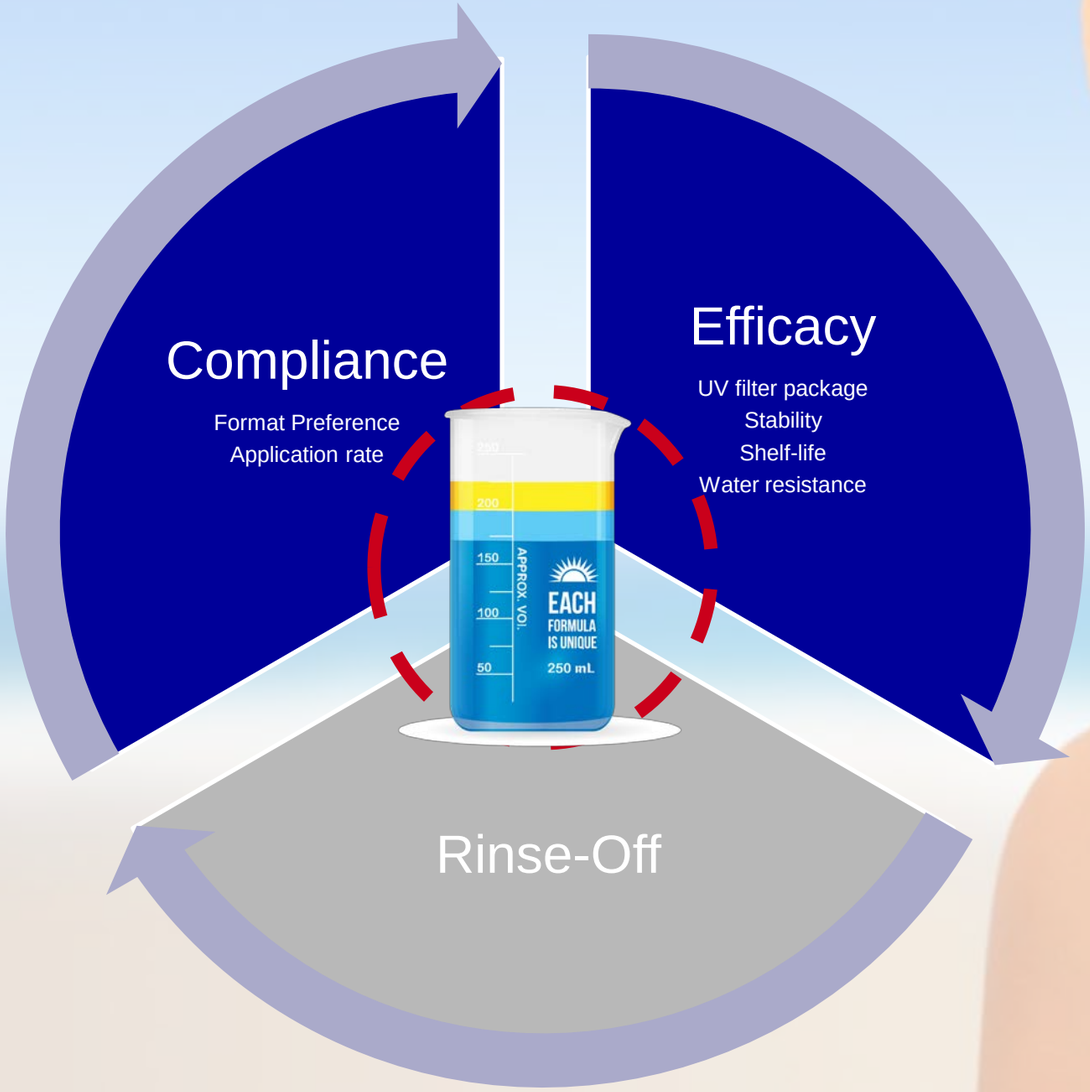
Poor Coverage

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/cm^2 density utilized by standard SPF testing.[6]

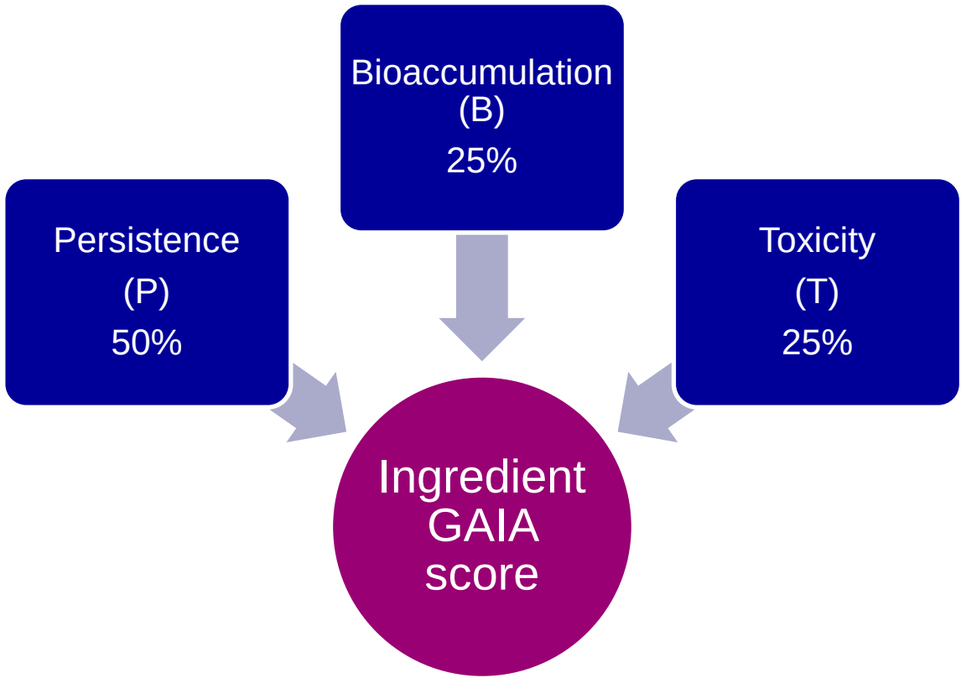
Formulation determines water resistance and skin adherence.



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.



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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.[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.[6]
- Environmental monitoring cannot determine source and suffers from collection and analytical challenges.[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.**

[1]EcoSafety Sciences; [2]Battelle 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/cm^2). 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.

	Octisalate	Homosalate	Octocrylene	Avobenzone	Oxybenzone	ZnO	TiO_2	Water Resistant
Stick O	5%	15%	10%	3%		-	-	Yes
Lotion O1	5%	10%	2.8%	3%	6%	-	-	Yes
Lotion O2	5%	9%	9%	2.7%	4.5%	-	-	Yes
Stick M	-	-	-	-	-	21.6%	-	Yes
Lotion M1	-	-	-	-	-	6%	7%	No
Lotion M2	-	-	-	-	-	21.6%	-	Yes
Lotion M3	-	-	-	-	-	25%	1%	N/A

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

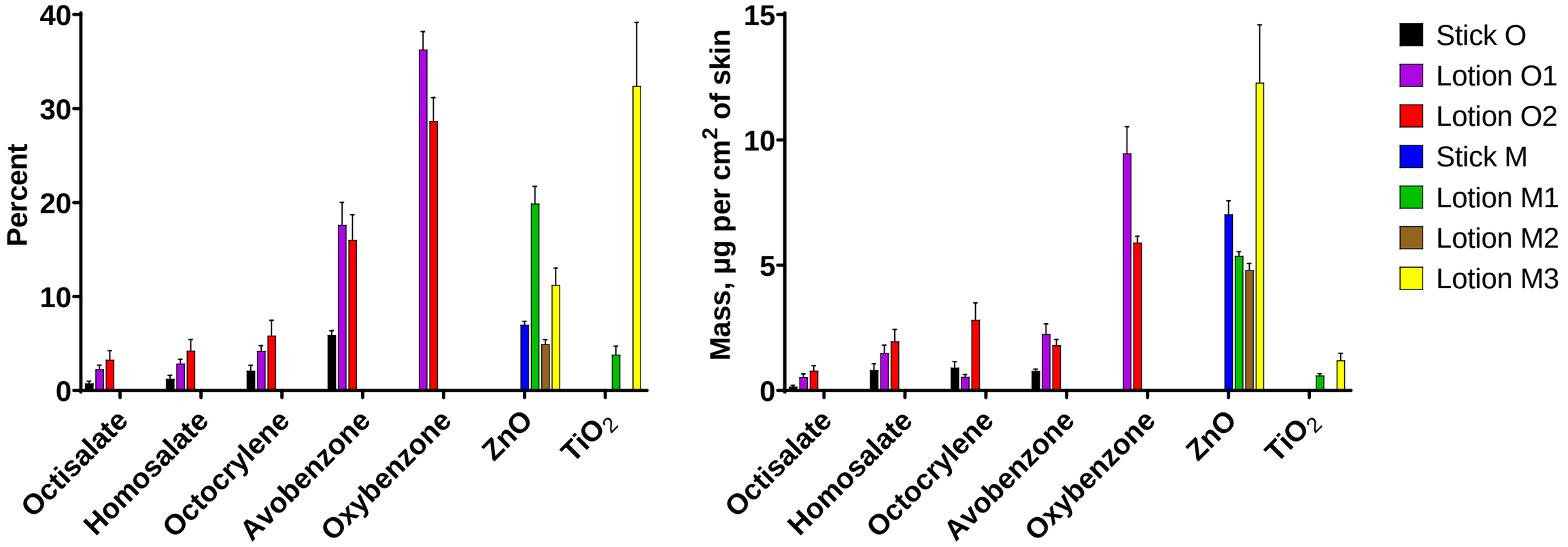
Results for organic sunscreens are included in IEAM manuscript; mineral results not yet peer-reviewed.

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



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To meet the needs of consumers and manage environmental exposure, a diverse palette of UV actives, excipient choices, and sunscreen formats is critical.

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Questions?