Sunscreen Composition & Safe, Effective Alternatives

NAS study - Environmental Impact of Currently Marketed Sunscreens and Potential Human Impacts of Changes in Sunscreen Usage

Autumn Blum Cosmetic Chemist & CEO - Stream2Sea

Introductions

Autumn Blum

- Award winning cosmetic chemist
- Ocean advocate & technical diver
- Entrepreneur: founder of Stream2Sea, Organix-South, Scuba Girls

> *"I noticed a sunscreen 'oil slick' when diving in Palau a few years back and knew we could do better."*

FDA Revoked GRASE, 2019

Proposed GRASE Status for Sunscreen Active Ingredients

FDA

GRASE* for use in sunscreens	Not GRASE** for use in sunscreens	***Insufficient data for use in sunscreens
Zinc oxide and titanium dioxide	Aminobenzoic acid (PABA) and trolamine salicylate	Cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, avobenzone

*GRASE= Generally Recognized as Safe and Effective **These ingredients are not currently marketed. ***For those ingredients in the "insufficient data" category, FDA proposes that it needs additional data to determine that sunscreens with these ingredients would be GRASE.

Our reefs need our protection, but at what cost?

*https://www.who.int/uv/faq/skincancer/en/index1.html

Our reefs need our protection, but at what cost?

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Sunscreens: Organic vs. Mineral

Q: *What is the efficacy of different active ingredients (organic and mineral UV filters available in the United States), and application methods for protecting human health?*

Sunscreens: Organic vs. Mineral

Mineral UV Filters are comprised of “nature identical minerals” obtained by transformation of inorganic compounds mined from the earth and then processed to obtain clean and safe UV filters

Mineral / Inorganics

- ✓ Minerals are coated and dispersed to improve performance and aesthetics
- ✓ Extensively used in products marketed as reef/coral safe and formulations for sensitive skin due to no skin penetration / irritation
- ✓ Approved for use at levels up to 25% globally
- ✓ Achieve high SPF on their own

Chemical / Organics

- fossil derived in origin and are entirely synthetic chemical compounds
- Questions over environmental impact (Hawaii ban) and skin penetration (FDA)
- Permitted use levels are limited to 4 - 10% depending on regulations
- Cocktails required for high SPF

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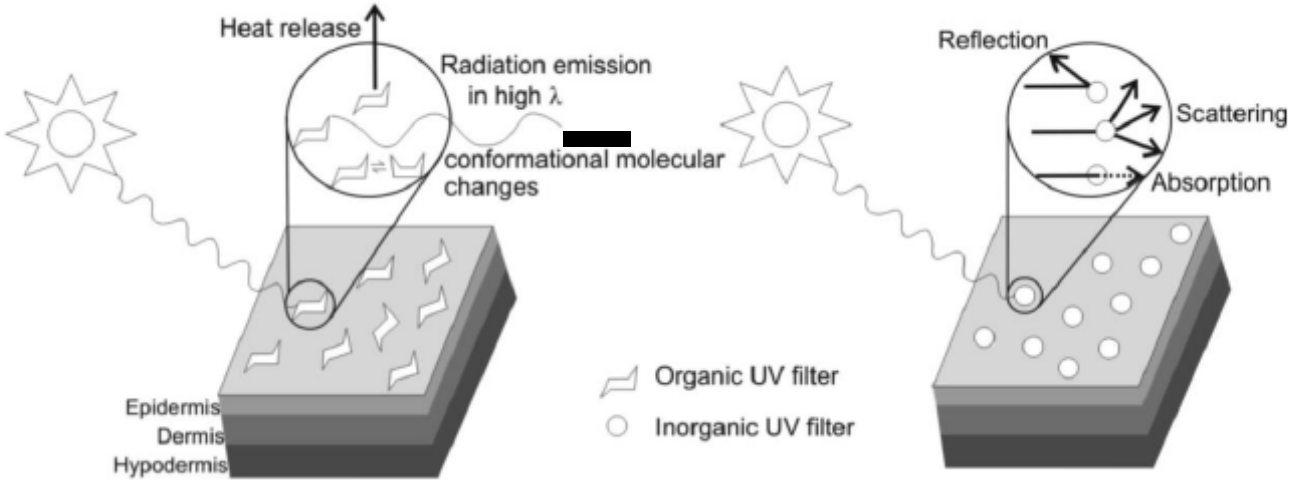
Sunscreens: Chemical Vs. Mineral

Mode of action of organic (left) and inorganic (right) UV filters



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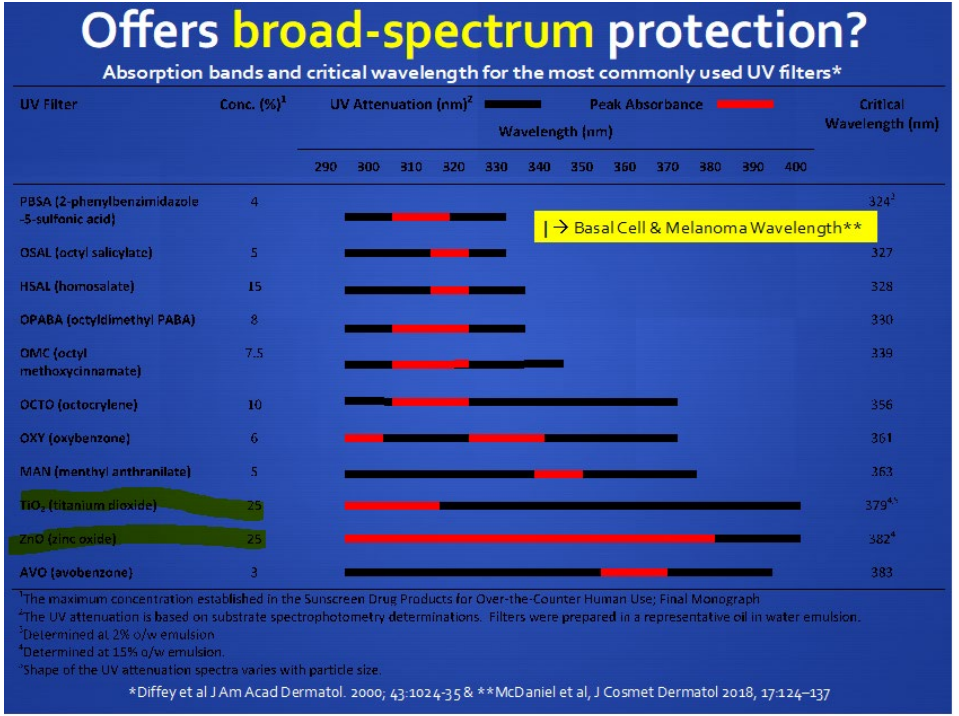
UV Absorption

FDA Monograph Sunscreen Ingredients	Amount of Ray Protection		Chemical (C) or Physical (P)
	UVA	UVB	
Aminobenzoic acid (PABA)	○	●	C
Avobenzone	●	◔	C
Cinoxate	◔	●	C
Dioxybenzone	◐	●	C
Ecamsule	●	◔	C
Homosalate	○	●	C
Menthyl anthranilate	◐	●	C
Octocrylene	◔	●	C
Octyl methoxycinnamate	◔	●	C
Octyl salicylate	○	●	C
Oxybenzone	◐	●	C
Padimate O	○	●	C
Phenylbenzimidazole	○	●	C
Sulisobenzone	◐	●	C
Titanium dioxide	◐	●	P
Trolamine salicylate	○	●	C
Zinc Oxide	●	●	P

Protection Level: ● = extensive ◐ = considerable ◔ = limited ○ = minimal

For the most up-to-date information on approved sunscreen ingredients, visit the FDA Web site at <www.fda.gov>.



Sunscreen, The Burning Facts. EPA.gov

Drug Facts, 3-5 Actives up to 35%

Drug Facts

Active Ingredients — **Purpose**
Avobenzone 3%
Homosalate 10%
Octyl methoxycinnamate 7.5%
} 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

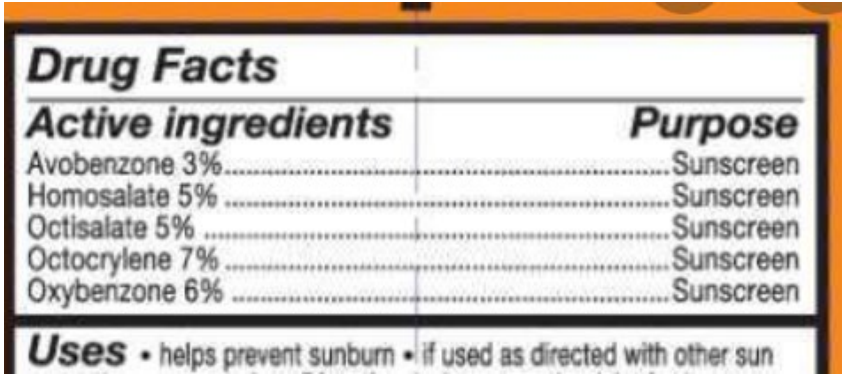
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions
- apply liberally 15 minutes before sun exposure
- reapply:
  - after 40 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 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients
aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octadecene/MA copolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E), triethanolamine, water

Other information
- protect this product from excessive heat and direct sun

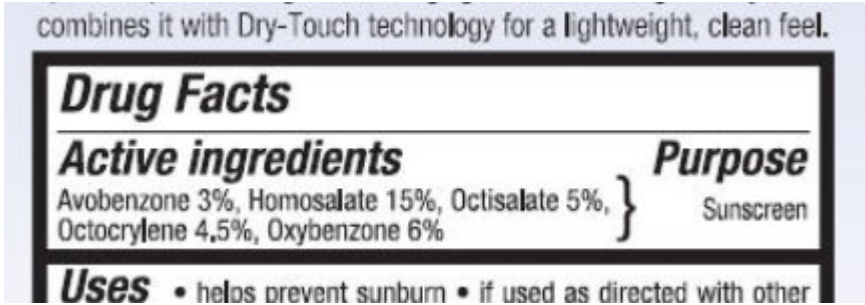
Questions or comments?
Call toll free 1-800-XXX-XXXX



Drug Facts

Active ingredients — **Purpose**
Avobenzone 3% ..... Sunscreen
Homosalate 5% ..... Sunscreen
Octisalate 5% ..... Sunscreen
Octocrylene 7% ..... Sunscreen
Oxybenzone 6% ..... Sunscreen

Uses • helps prevent sunburn • if used as directed with other sun



combines it with Dry-Touch technology for a lightweight, clean feel.

Drug Facts

Active ingredients — **Purpose**
Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 4.5%, Oxybenzone 6%
} Sunscreen

Uses • helps prevent sunburn • if used as directed with other

Drug Facts

Drug Facts

Active Ingredients	Purpose
8.8% Titanium Dioxide (Non-Nano)	Sunscreen

Uses ■ Helps prevent sunburn

Warnings ■ For external use only ■ Do not use on damaged or broken skin

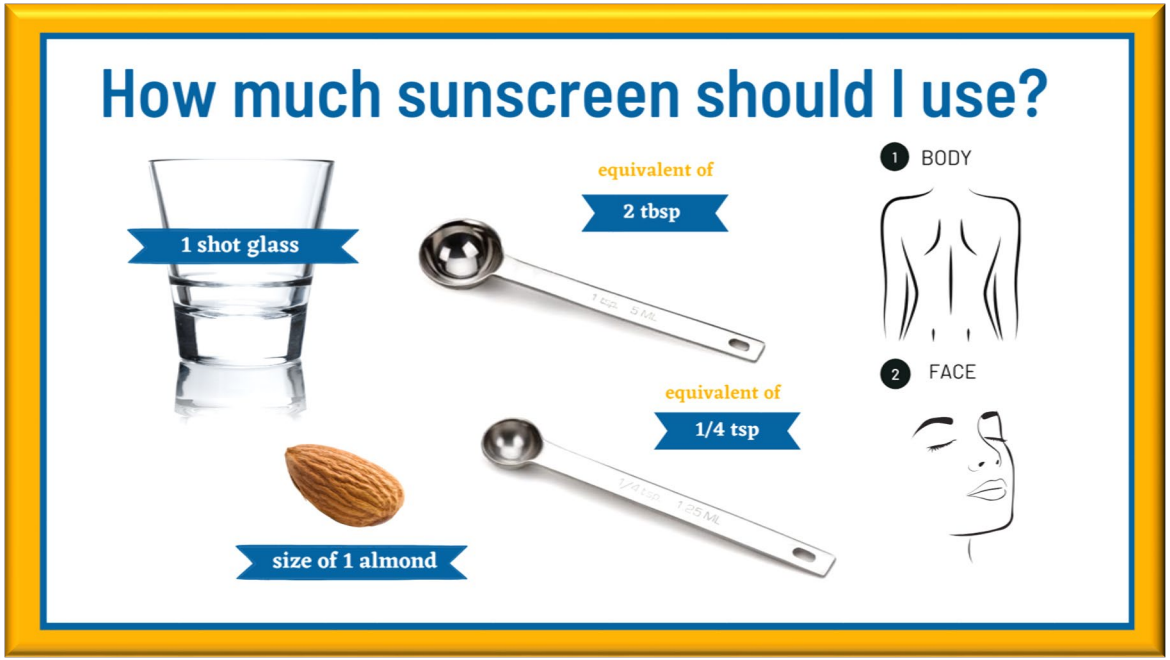
DRUG FACTS

Active Ingredients	Purpose
Titanium Dioxide, 6.0%	Sunscreen
Zinc Oxide, 6.0%	Sunscreen

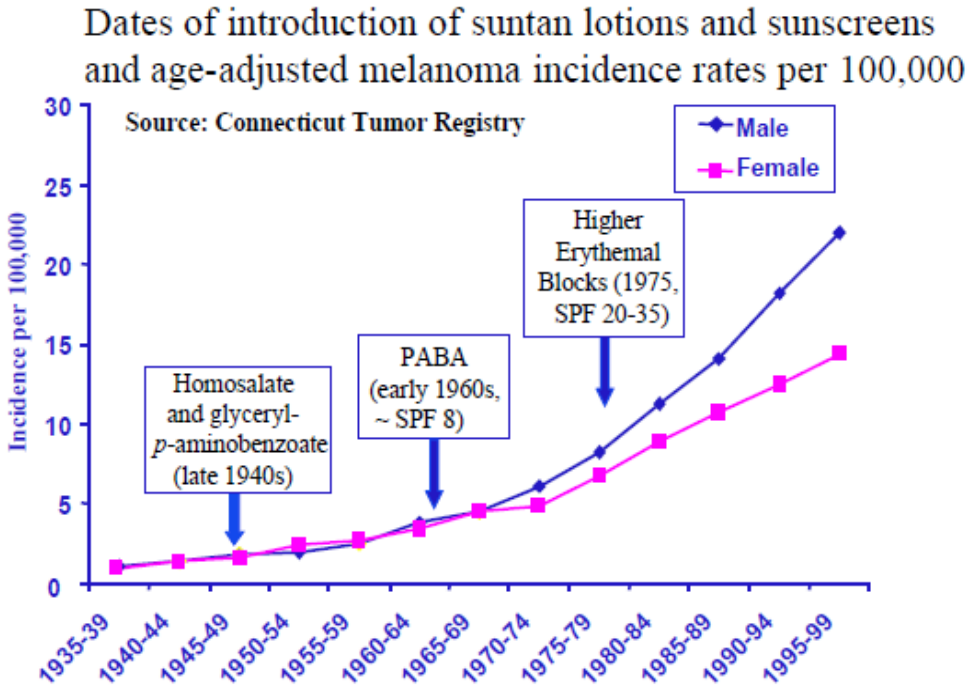
Uses: Helps prevent sunburn. If used as directed

Sunscreen Application & Types

BOTH Chemical and Mineral Sunscreens:



Sunscreen usage is on the rise



https://joshgitalis-wpengine.netdna-ssl.com/wp-content/uploads/2012/07/Introduction-of-sunscreen-and-skin-cancer-rates1.png

UV Degredation

Journal of Photochemistry and Photobiology A: Chemistry
Volume 332, 1 January 2017, Pages 241-250

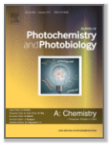


Photo-stability and photo-sensitizing characterization of selected sunscreens' ingredients

- Oxybenzone (OXB) is found to be a very stable UV filter.
- Avobenzone (AVOB) is known to be rather unstable UV sunscreen and it photodegrades with time of irradiation.
- Ecamsule (ECAM) is also found to be very photounstable sunscreen and photodegraded with irradiation of UV light.

Environment International
Volume 137, April 2020, 105495

Identification of avobenzone by-products formed by various disinfectants in different types of swimming pool waters

Albert T. Lebedev [a, c], Mojca Bavcon Kralj [b], Olga V. Polyakova [a], Elena A. Detenchuk [a], Sergey A. Pokryshkin [c], Polonca Trebše [b]

Octocrylene Degrades into Carcinogen

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Benzophenone Accumulates over Time from the Degradation of Octocrylene in Commercial Sunscreen Products

C. A. Downs*, Joseph C. DiNardo, Didier Stien, Alice M. S. Rodrigues, and Pl

Cite this: *Chem. Res. Toxicol.* 2021, 34, 4, 1046–1054
Publication Date: March 7, 2021
https://doi.org/10.1021/acs.chemrestox.0c00461

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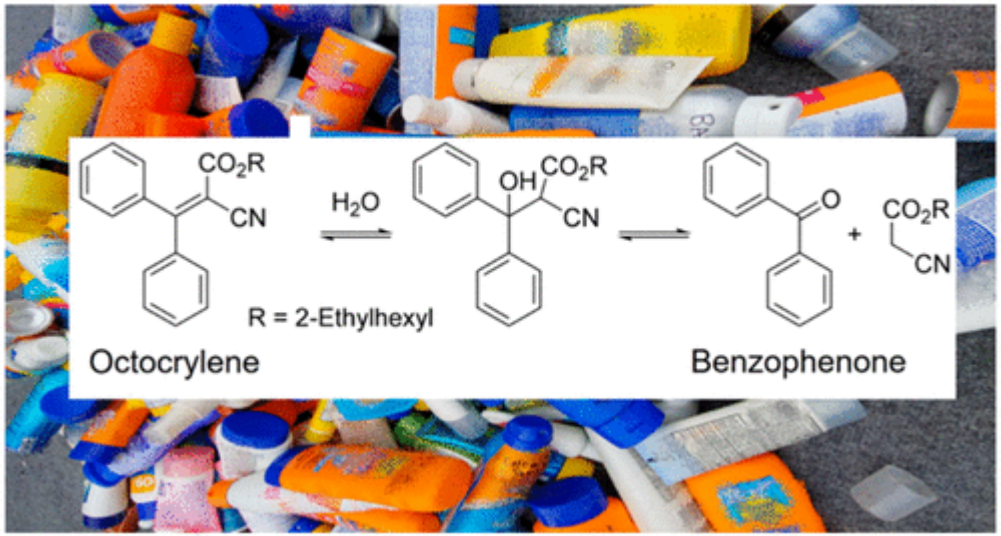


2019 & 2020 Study Leading to Change

Preliminary Communication

FREE

May 6, 2019

Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients

A Randomized Clinical Trial

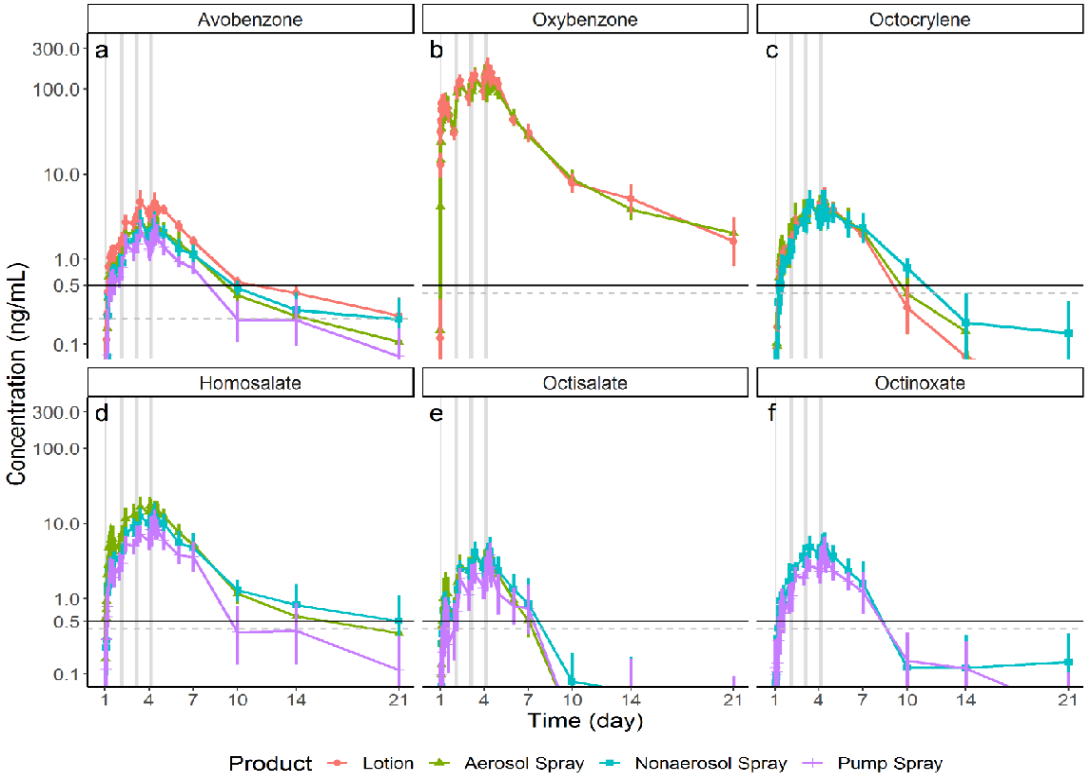
Murali K. Matta, PhD[1]; Robbert Zusterzeel, MD, PhD, MPH[1]; Nageswara R. Pilli, PhD[1]; et al

Study Results

Results showed that all four tested ingredients were absorbed into the body at amounts exceeding the FDA threshold of 0.5 nanograms per milliliter (ng/mL), for potentially waiving some additional studies for sunscreens. [2] This threshold for testing the safety of

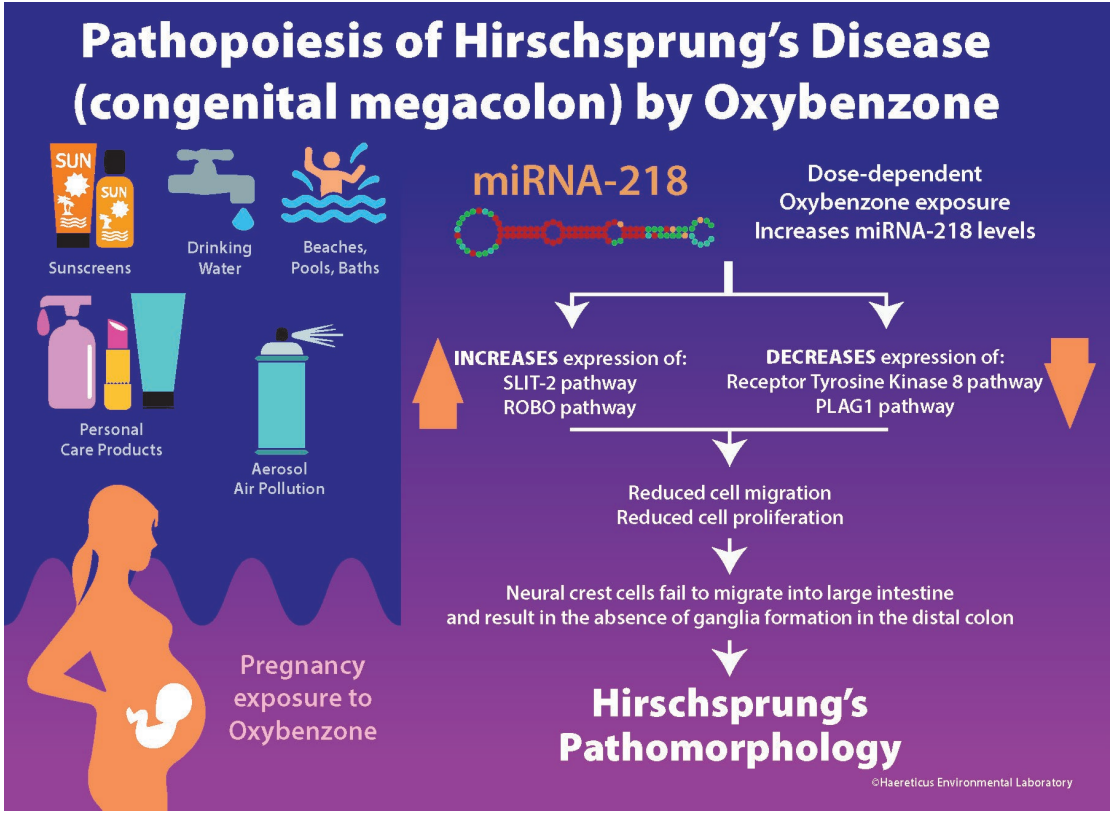
FDA Maximum Usage Trial (MUsT)

Matta data from 2020 paper: 4 applications a day for 4 days … no applications made between day 5 and 21.



Matta et al JAMA 2020; 323:256-267.

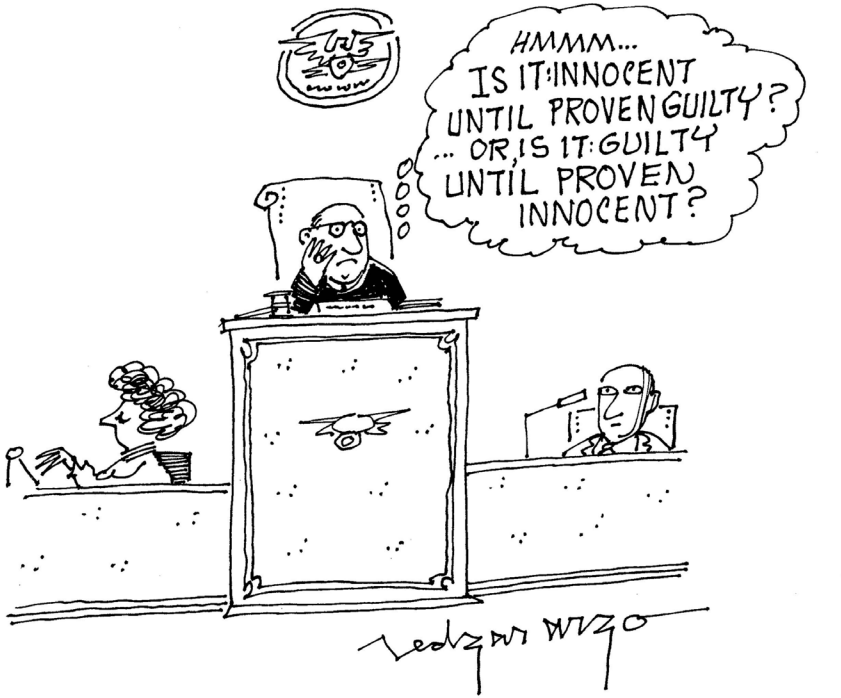
Do we need more safety testing?



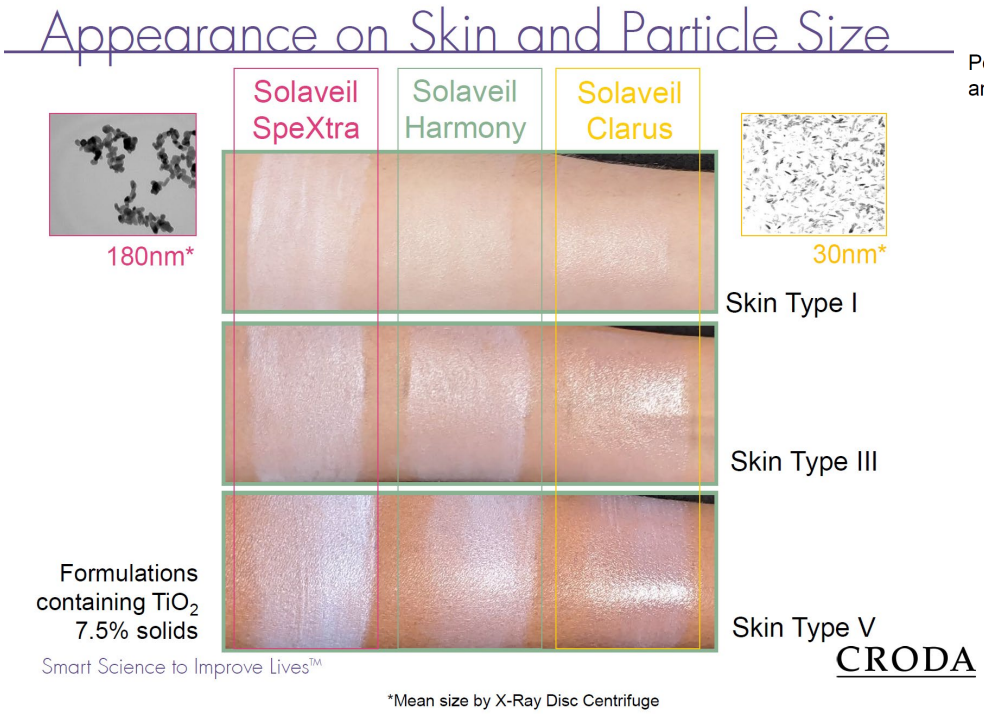
CARES Act Makes and Delays Change

- Delayed increasing UVA with increasing SPF
- SPF Towlettes, shampoos are out
- 12 organic actives are allowed to stay on the market

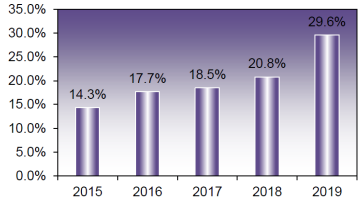
It is now up to industry to prove otherwise – or regulatory to change the monograph.

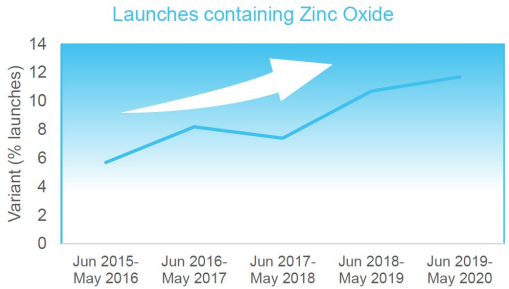


Increasing Trends – Improved aesthetics



Percentage of launches (sun care – sun protection) using TiO_2 and/or ZnO, but no organic sunscreens (2015-2019)





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UV Filters in the Environment

Question: What are the chemical properties of the UV filters that may affect their fate in the environment?

1000s of studies show that oxybenzone and/or avobenzone/octocrylene are not safe

Toxicopathological Effects of the Sunscreen UV Filter, Oxybenzone (Benzophenone-3), on Coral Planulae and Cultured Primary Cells and Its Environmental Contamination in Hawaii and the U.S. Virgin Islands

C. A. Downs[1] · Esti Kramarsky-Winter[2,3] · Roee Segal[2] · John Fauth[4] · Sean Knutson[5] · Omri Bronstein[2] · Frederic R. Ciner[1] · Rina Jeger[3] · Yona Lichtenfeld[6] · Cheryl M. Woodley[7,8] · Paul Pennington[8] · Kelli Cadenas[9] · Ariel Kushmaro[3] · Yossi Loya[2]

Toxicological effects of the sunscreen UV filter, benzophenone-2, on planulae and in vitro cells of the ... *Stylophora pistillata*

C. A. Downs · Esti Kramarsky-Win... · Omri Bronstein · Rina Jeg... · Paul Pennington ...

Natl Toxicol Program Tech Rep Ser. 2006 Feb;(533):1-264.

Toxicology and carcinogenesis studies of benzophenone (CAS No. 119-61-9) in F344/N rats and B6C3F1 mice (feed studies).

The Washington Post

Energy and Environment

How we are all contributing to the destruction of coral reefs: Sunscreen

Environmental Science & Technology

Joint Effects of Multiple UV Filters on Zebrafish Embryo Development

Adela Jing Li, Japhet Cheuk-Fung Law, Chi-Hang Chow, Yanran Huang, Kaibin Li, and Kelvin Sze-Yin Leung

In Vitro and in Vivo Estrogenicity of UV Screens

Margret Schlumpf, Beata Cotton, Marianne Conscience, Vreni Haller, Bear...

Institute of Pharmacology and Toxicology, University of Zurich, Zurich, Switzerla...

Toxicology Reports

journal homepage: www.elsevier.com/locate/toxrep

ELSEVIER

Neurotoxic effect of active ingredients in sunscreen products, a

Beatriz Ferrer[a], Tanara V. Peres[a], Aristides Tsatsakis[b],

Chemicals In Sunscreen Are Harming Coral Reefs, Says New Study

america

OCTOBER 20, 2015 3:18 PM ET

OPEN ACCESS Freely available online

PLOS ONE

Sunscreen Products as Emerging Pollutants to Coastal Waters

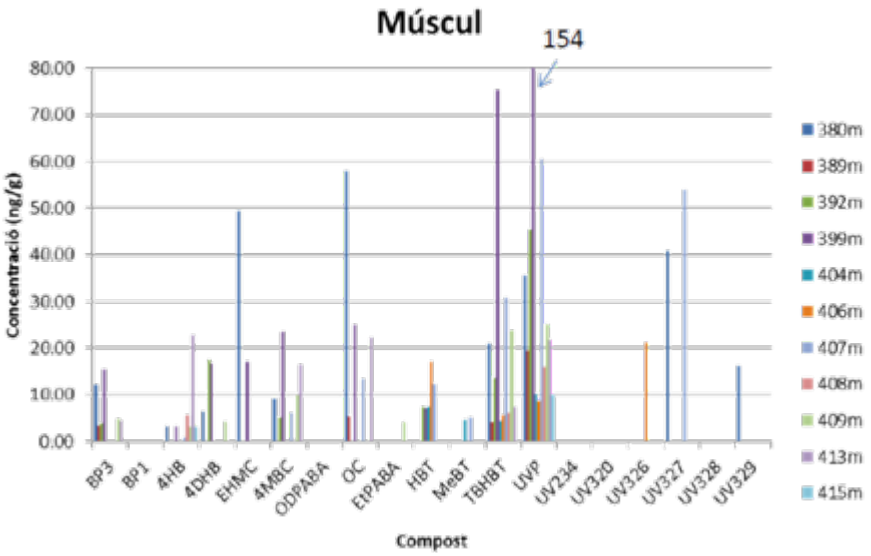
Antonio Tovar-Sánchez[1]*, David Sánchez-Quiles[1], Gotzon Basterretxea[2], Juan L. Benedé[3], Alberto Chisvert[3], Amparo Salvador[3], Ignacio Moreno-Garrido[4], Julián Blasco[4]

Unsustainable Tourism

UV Filters in the Environement

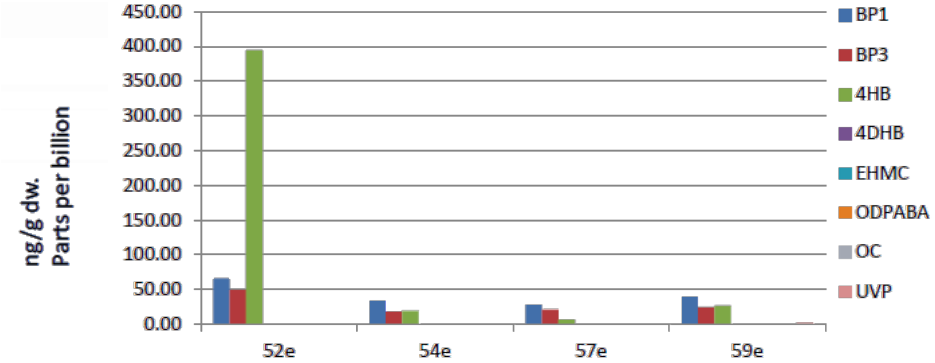
Bioaccumulation of UV Filters in Fish

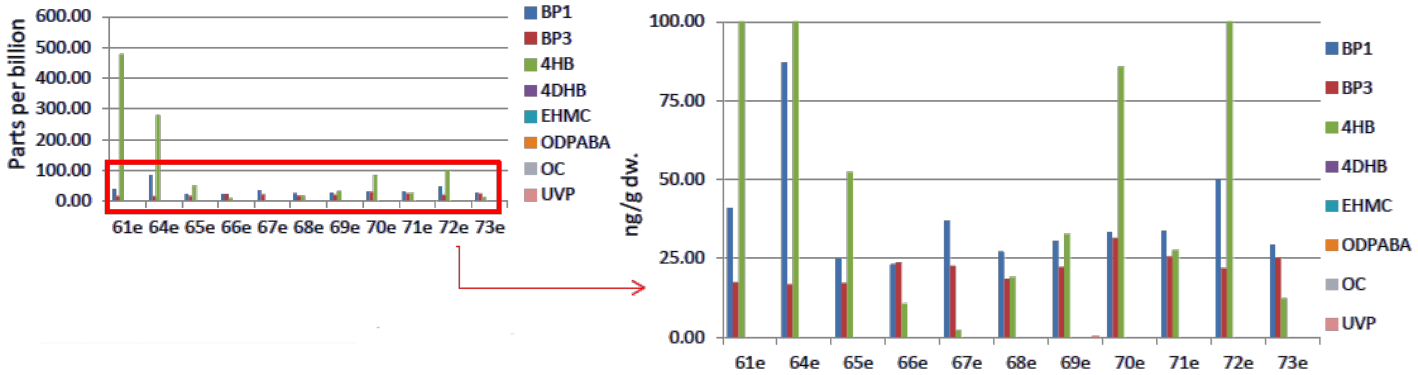
Muscle Analysis



BP3 = *oxybenzone*
BP1, 4HB, & 4DHB = *metabolites of oxybenzone*
OC = *octocrylene*
EHMC = *methoxycinnamate*

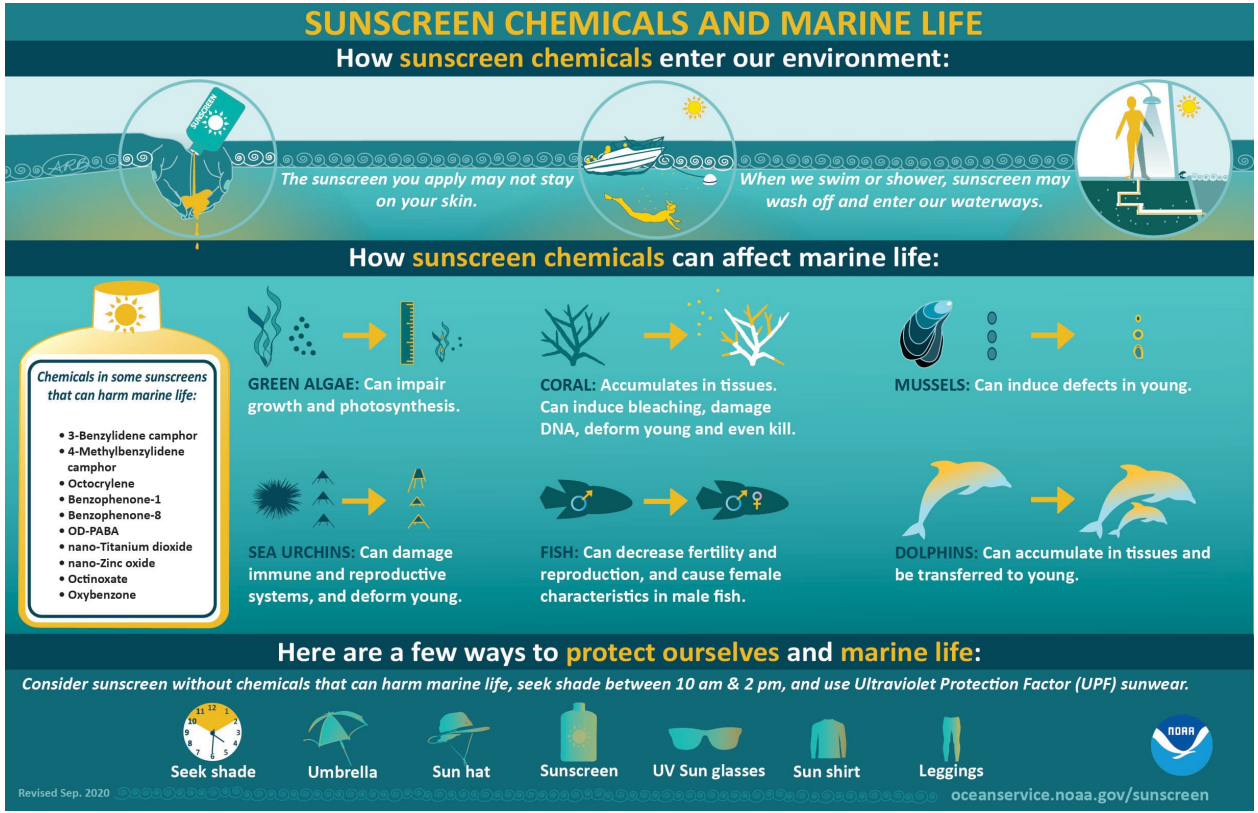
UV Filters in Eggs of Birds from a Preserved Natural Area





Sea Turtle Nests

UV Filters in the Environement



Waterproof?

Question: What is the expected waterproof efficacy and rinse off rate of sunscreen actives?

Guidance for Industry

Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-The-Counter Human Use — Small Entity Compliance Guide

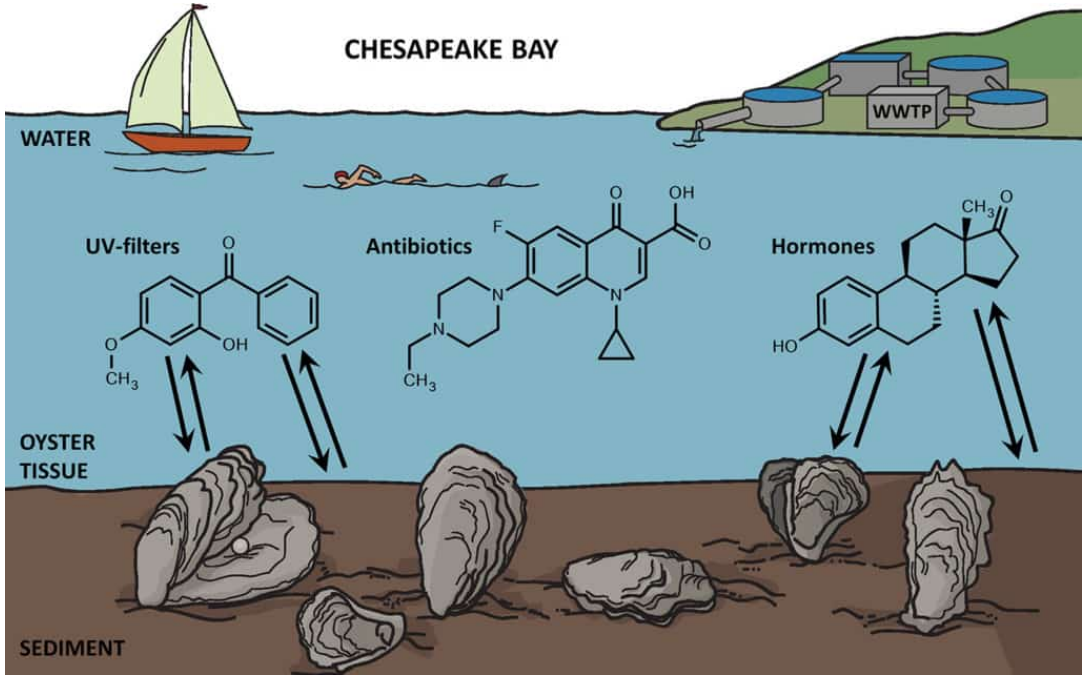
For sunscreen drug products that provide 40 or 80 minutes of water resistance according to the test in 21 CFR 201.327(i)(7):

"Water Resistant ([insert length of time drug product is proven to be water resistant, either 40 minutes or 80 minutes, according to 21 CFR 201.327(i)(7)])"

Sewage

- 30 minutes after application, detect in urine
- Residue on skin, wash off in shower

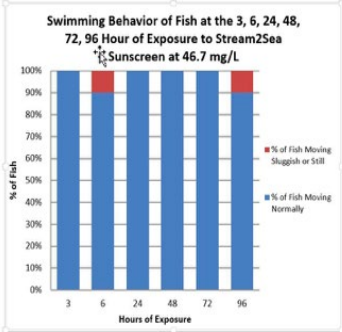
Chesapeake Bay

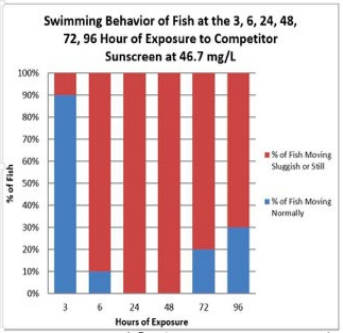


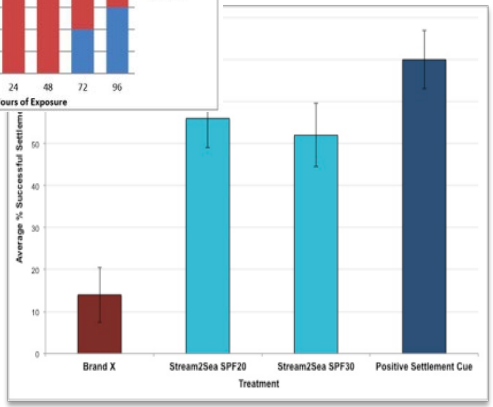
Graphic as appears in Science of the Total Environment
https://www.sciencedirect.com/science/article/abs/pii/S0048969718338944

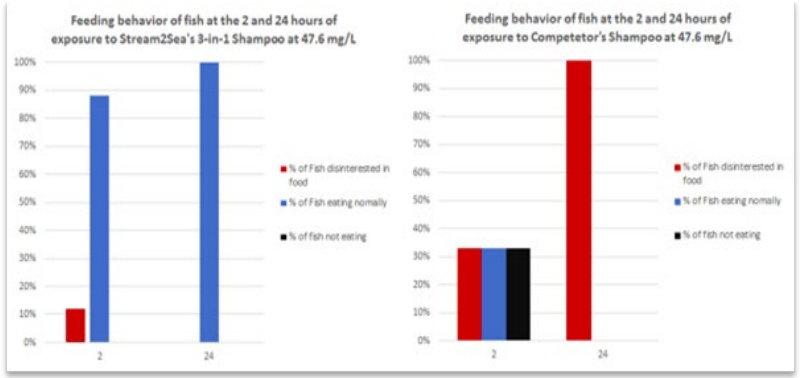
Test Results – What is reef safe?

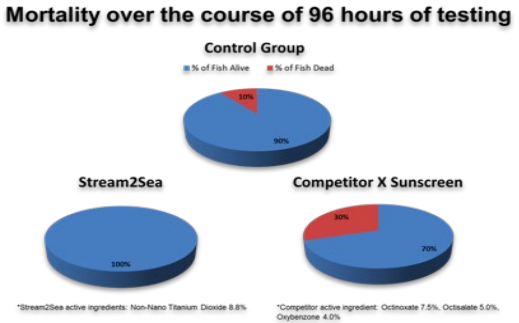
Removing banned ingredients does NOT mean a product is REEF SAFE











Our reefs need our protection!

Photo on the left of Autumn taken by Frazier Nivens in 2016.
On the right taken 5 months later. It is just rubble on the bottom of the ocean today.

Sunscreen Legislation

Hawaii
January 2021: ban of oxybenzone and octinoxate

Key West
~~January 2021: ban of oxybenzone and octinoxate~~

Bonaire
2021: ban of reef-killing sunscreens

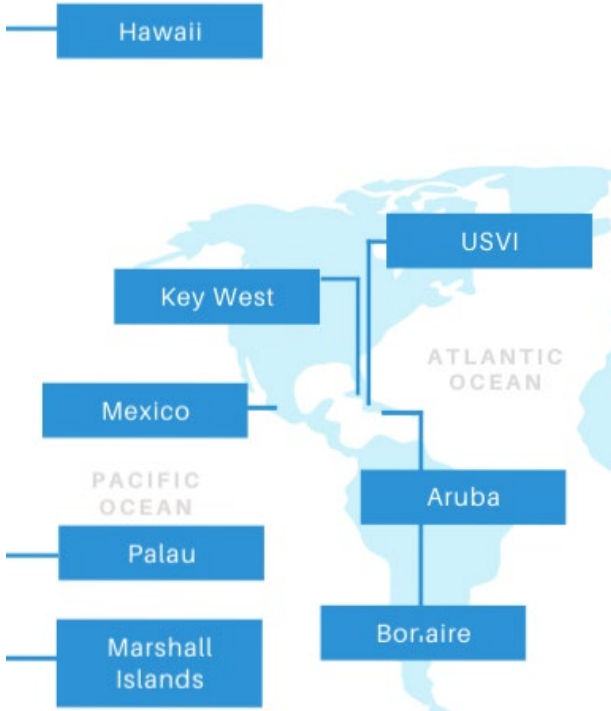
Aruba
2020: ban of oxybenzone and octinoxate

Palau
Ban of sunscreen with any of 13 toxic ingredients, enforces fines for vendors

Mexico
Ecotourism preserves and natural water parks are asking visitors to use only biodegradable sunscreens

USVI
In effect: ban of oxybenzone, octinoxate and octocrylene

Marshall Islands
In effect: ban of 28 toxic ingredients & 10 Preservatives, fines enforced for vendors and tourists



Together, we can do better!

“Government must be more effective in protecting the environment, and industry must be its top partner.”

- President Tommy E. Remengesau, Jr.
Republic of Palau

STREAM2SEA

Reef-Friendly • Biodegradable

REFERENCES, CITATIONS AND DIALOG AVAILABLE UPON REQUEST:

Autumn Blum
autumn@stream2sea.com