

Aloha Aina



The Solution
Questions
The Dance
Science
Misnomers

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The Solution

- Ban Oxybenzone and Octinoxate and continue to monitor levels in Hawaiian Waters.
- Industry Scientists + Academic Scientists + Government Agencies + Non-Government Agencies “work together” to establish testing guidelines for “safe and eco-friendly” products.
- Develop new technologies that will protect people from skin cancer that are safe for aquatic life.

What Can Pollution (Chemicals) Do to Us?

- Pollution is the largest environmental cause of disease and premature death in the world today. Diseases caused by pollution were responsible for an estimated 9 million premature deaths in 2015 16% of all deaths worldwide—three times more deaths than from AIDS, tuberculosis, and malaria combined and 15 times more than from all wars and other forms of violence. In the most severely affected countries, pollution-related disease is responsible for more than one death in four.

How Many Pollutants (Chemicals) Exist in Our World?

- Division of the American Chemical Society, Chemical Abstract Service (CAS), has a database that contains more than 133 million unique organic and inorganic chemical substances.
- Updated daily with 12,000 - 15,000 new substances.
- Paracelsus (Father of Toxicology) in 1500 observed that “All things are poison and nothing is without poison; only the DOSE makes a thing not a poison”

Why Should We Care About Chemicals? (Endocrine Disruptors)

According to the World Health Organization

- Breast, endometrial, ovarian, prostate, testicular and thyroid CANCERS have been increasing over the past 40–50 years.
- The number of people with TYPE 2 DIABETES increased from 153 million to 347 million between 1980 and 2008.
- Neurobehavioral disorders (ADHD) have increased over past decades as well as ASTHMA, MENTAL RETARDATION and CHILDHOOD CANCERS.

Government and Industry History

Acetyl Ethyl Tetramethyl Tetralin (AETT)

- **Timeframe:** 1960 – 1978 (18 years)
- **Exposure:** 10+ Million Perfume/Cologne users – “Musk” Scent.
- **Impact:** Neurotoxic agent producing internal bluing of the brain, spinal cord and peripheral nerves.
- **Industry Response:** Industry conducted their own studies, slow down regulatory action, while reformulating with a similar ingredient called “Musk Ambrette”. Some 5 short years after the AETT publication, Musk Ambrette was also considered neurotoxic and removed from formulas.

Government and Industry History

Benzene

- **Timeframe:** 1960 – 1978 (18 years)
- **Exposure:** 140+ Million People Exposed Via Manufacturing Emissions (Gasoline/Coke Ovens), Industrial Jobs (Shoes/Paints) and a Variety of Consumer Products (Nail Enamels/Crafts)
- **Impact:** Aplastic Anemia/Leukemia – Death (OSHA/EPA)
- **Industry Response:** Regulations Rejected by Industry – 10 yr “Big Industry” Study (15 yrs to death); No Animal Testing (human deaths); No Doctor Monitoring

Numerous industrial chemicals with significant human impact have similar histories

Government and Industry History

P-Hydroxyanisole (PHA)

- **Timeframe:** 1970 – 1985 (15 years)
- **Exposure:** Millions of Consumers - Skin Bleaching Agent – Topical Skin Cream
- **Impact:** Cytotoxic & Causes Cancer – Started with 1970 Publication - University of London
- **Industry Response:** Industry conducted their own studies, stopped FDA ban for several years why reformulating with Hydroquinone (HQ).
 - In 1985 the Cosmetic Ingredient Review (CIR) determined that the ingredient was “not safe for cosmetic products due to it’s general toxicity and carcinogenic effects”. In 2014 CIR shifted their point of view to “safe for use in artificial nail coatings”.

Government and Industry History

4-Methoxy-m-Phenylenediamine (4-MMPD)

- **Timeframe:** 1970's - 1980's (10+ years)
- **Exposure:** 10+ Millions of Aestheticians and Consumers - Hair Dyes
- **Impact:** Causes Cancer – Independent Epidemiology Studies and National Toxicology Program (NTP)
- **Industry Response:** FDA, believed 4-MMPD showed sufficient scientific evidence of being carcinogenic; Manufacturers disagreed and threatened to sue; FDA backed down. A few years later, manufacturers removed the chemical from their formulas, while maintaining that 4-MMPD was safe. Industry replaced the chemical with 4-Ethoxy-m-Phenylenediamine (4-EMPD) and continued selling products without Regulatory Intervention.

In toxicology very similar structured molecules produce very similar effects

Government and Industry History

Hexachlorophene/Triclosan/Triclocarban

- **Timeframe:** 1966 – 1972 (8 yrs) 1972 – 2017 (45 yrs)
- **Exposure:** 75% of US Population - Antibacterial Cleansers
- **Impact:** Infant Toxicity Multiple Deaths. In Adults Impairment Of Fertility/Reproductive Toxicity
- **Industry Response:** After 15 infant deaths in the US, FDA ban the chemical in 1972 except for Rx use based on Industry Pressure. In the consumer market, it was mainly replace with Triclosan & Triclocarban. Both were banned as Endocrine Disruptors in Sept 2017. “Industry could not demonstrate safety/efficacy of chemicals.”

Jumping from the frying pan into the fire!

Safety Data Submitted to FDA in 1978

Conclusion: *“Extensive animal and human toxicological data and wide use attest to its safety for human topical application”*

Oxybenzone:

- UV Absorption
- Oral/IP Toxicity in Rats/Mice
- Rabbit Eye & Skin Irritation
- Sub-chronic rabbit dermal toxicity

Products Containing Oxybenzone:

- 2 - Rabbit Eye Irritation Tests
- Rabbit Photosensitivity Test*
- 4 hr 14 Human Patch Test
- 48 hr 100 Human Patch Test
- Repeat Insult Patch Test 200 Humans*
- 25 Human Photosensitivity Test*
- 2 - 150 Human Repeat Insult Patch Test*
- 25 Subject Phototoxicity Test
- SPF Efficacy (UVB):
 - 3% Oxybenzone and 3% Dioxybenzone
 - 3% Oxybenzone.
- Broad Spectrum (UVA):
 - Not developed until mid 1990's
- Product Marketing Experience

Octinoxate:

- UV Absorption
- Oral Toxicity in Mice
- Rabbit Eye Irritation
- Guinea Pig Sensitization

Products Containing Octinoxate:

- 2 - 50 Human Patch Test
- Photosensitivity in Humans*
- SPF Efficacy (UVB):
 - 19 studies using natural/simulated UV on products with 2% to 7.5% concentrations.
- Broad Spectrum (UVA):
 - Not developed until mid 1990's
- Product Marketing Experience
 - 8 M units sold with 38 complaints over 2 yrs, with no clear cause/effect established.
 - No adverse reaction reports in literature.
 - Over 209 tons sold in 27 countries in 2 yrs.

*** Should detect Contact/Photo-contact Allergy**

Safety Data Needed To Establish That An OTC Sunscreen Active Is Safe & Effective

In 1978

- Animal/Human irritation and sensitization studies
- Animal/Human photosafety studies



- Postmarketing Safety Data
- Effectiveness testing (SPF)
 - UVA testing started in 90's

As of 2016*

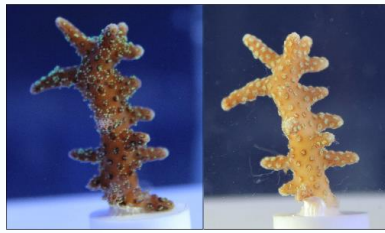
- Human irritation and sensitization studies
- Human photosafety studies
- Human Absorption Studies/Maximal Usage Trial
- **Pediatric Considerations**
- Nonclinical Safety Testing
- Carcinogenicity Studies: Dermal and Systemic
- Developmental and Reproductive Toxicity Studies
- Toxicokinetics
- Postmarketing Safety Data
- Effectiveness testing (SPF)
- Anticipated final formulation testing (UVA, Water-resistant ... etc.)

* Additional testing/warning labels are required for Aerosol Spray Sunscreens
[fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm473464.pdf](https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm473464.pdf)

Safety - Pediatric Considerations

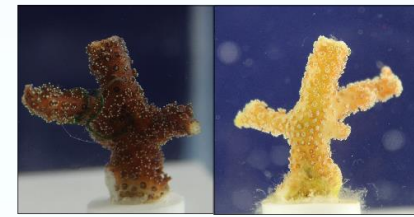
- **Food Drug Administration: Sunscreens are not recommended for infants.** The FDA recommends that infants be kept out of the sun during the hours of 10 a.m. and 2 p.m., and to use protective clothing if they have to be in the sun. **Infants are at greater risk than adults of sunscreen side effects**, such as a rash. The best protection for infants is to keep them out of the sun entirely. Ask a doctor before applying sunscreen to children under six months of age.
- **Swedish Research Council: Determined that sunscreens with Oxybenzone are unsuitable for use in young children** because children under the age of two years have not fully developed the enzymes that are believed to breakdown oxybenzone. This suggests, in theory, that small children will not be able to get rid of the substance as easily as adults.
- **Switzerland:** In a study involving 1,196 human subjects, **Octinoxate** aggregate exposure levels for adults were below the NOEL. However, during summer months, the predicted aggregate **exposure levels for children aged 4 years or less exceed the NOEL for reported thyroid endocrine disrupting effects.**

Oxybenzone/Octinoxate In The Environment



Time 0

500 ppt
Oxybenzone
14 days



Control

1 ppBillion
Octinoxate
14 days

152 Papers Reviewed

- 150+ scientists from 15 countries on 4 continents found significant levels in drinking water/wastewater treatment plants/sewage/sludge, swimming pools, fresh or salt water streams, rivers, lakes, bays, gulfs, seas, and oceans – virtually all sources of water.
- Identified in: invertebrates (including coral), fish, turtle & bird eggs, aquatic mammals/fetuses as well as in human urine, blood, semen, and breast milk which transfers to and was measured in infants.
- Edible portions of - mussels, clams, mullet, carp, catfish, eel, white fish, trout, barb, chub, perch and mahi-mahi.

Photos Above: Coral Toxicity Oxybenzone = 500 ppt and Octinoxate = 1 ppb

Sources of Oxybenzone/Octinoxate

Plastic Bottles



Pharmaceutical



Plastic Bags



Fish Based Live Stock Meal



UV Coatings/Adhesives



Agricultural



Printing Inks



Fish Based Fertilizers



Oxybenzone/Octinoxate

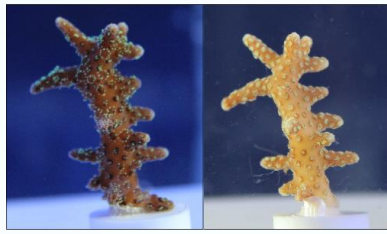
General Toxicity



152 Papers Reviewed

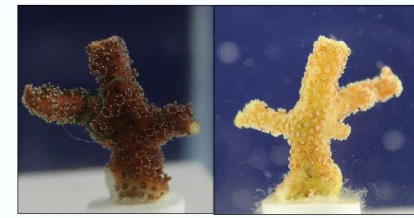
- 100+ Scientists from Argentina, Australia, China, Czech Republic, France, Germany, Greece, Italy, Japan, Korea, Norway, Poland, Slovenia, Spain, United Kingdom and United States.
 - Toxicity observed in various bacterial/mice/human cell lines, algae, planktonic crustaceans, sea urchins, coral, zebrafish, clown fish and rats.
- Oxybenzone (China/Europe/United States):
 - Hirschsprung's Disease – neonatal intestinal abnormality.
 - Contact/photo-contact allergen, urticaric/anaphylactic reactions.
 - Frequent allergen in sunscreens + 2014 Allergen of the Year.

Oxybenzone/Octinoxate Endocrine Disruption



Time 0

500 pptillion
Oxybenzone
14 days



Control

1 ppBillion
Octinoxate
14 days

152 Papers Reviewed

- 275+ Scientists from the Argentina, China, Demark, France, Germany, Hungary, Italy, Japan, Korea, Mexico, Netherlands, Spain, Switzerland, Thailand, United Kingdom and United States.
- Report a variety on Endocrine Disruption Effects (estrogen and testosterone) in various human and non-human cells as well as in coral, harlequin fly, snails, zebrafish, japanese rice fish, fathead minnows and rats.



Oxybenzone/Octinoxate



It takes 40 years to reach a toxic dose

- Oxybenzone NOEL < 100 parts per trillion (aquatic life) and 200 parts per million (warm-blooded animals) for reproductive toxicology.
- Octinoxate NOEL <1 part per billion (aquatic life) and 500 parts per million (warm-blooded animals)) for reproductive toxicology.
- American Academy of Dermatology recommends people use 1 oz of sunscreen/2 hrs. In 4 hours a 75 Kg/165 lb adult exposure is:
 - 6.0% Octinoxate = 48 parts per million or roughly 1/4 of the NOEL level (Adults).
 - 7.5% Octinoxate = 60 parts per million or roughly 1/8 of the NOEL level (Adults).
- World Health Organization (Endocrine Disrupting Chemicals):
 - **800+ chemicals that are known/suspected of being endocrine disruptors.**
 - **Additive - doses below the NOEL can work together to cause an effect.**
 - **Endocrine receptors are not species dependent (wildlife = humans).**
 - **Minimizing exposure, by banning substances, is a proven method to reduce the risk of toxicity.**

Sunscreens Stop People from Getting Skin Cancer

- **FDA**, Sunscreens labeled Broad Spectrum “help prevent sunburn and decreases the risk of skin cancer and early skin aging caused by the sun”
- **Health and Human Services**, skin cancer increased from 3.4 million in the 2002–2006 to 4.9 million between 2007– 2011.
- **Cornell University** = 87,110 estimated people will get melanoma (2017).
- **University of Melbourne (Australia)**, non-melanoma skin cancers increased from 412,493 (1997); 767,347 (2010); estimated 938,991 (2015).
- **International Agency for Research on Cancer (IARC)**, “No conclusion can be drawn about the cancer-preventive activity of sunscreens against basal cell carcinoma and melanoma ... Use of sunscreens extend sun exposure ... which increases the risk of melanoma.”
- **Director, Education and Research at Cancer Council Western Australia** “It’s important to understand that sunscreen is a useful adjunct to other sun protection measures (sun avoidance/protective clothing). Rather than being our first line of defense, it should be the last.”

Misnomers

Oxybenzone/Octinoxate

- Global warming is killing coral not sunscreens!
- Doesn't come off in the water!
- Doesn't absorb into humans/aquatic life!
- They're safe – no data exists – unclear ED effects – fake studies have been debunked numerous times!
- It takes 40 years to reach a toxic dose or they are below the limit of concern!
- Sunscreens stop people from getting skin cancer!

The Solution and “You”

- Ban Oxybenzone and Octinoxate and continue to monitor levels in Hawaiian Waters.
- Industry Scientists + Academic Scientists + Government Agencies + Non-Government Agencies work together to establish testing guidelines for “safe and eco-friendly” products.
- Develop new technologies that will protect people from skin cancer that are safe for all forms of life.

!What Can We Do Now!

Sun Avoidance/Protective Clothing/Minimize Exposure to
Oxybenzone/Octinoxate