

Additional Sunscreen Studies and Information for VeganicSKN Customer Marketing

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1. TGA requirements for any claims made

*Additional restrictions may apply

TGA	CONFIRM THE ANSWER IS <u>NO</u>
Are likely to arouse unwarranted and unrealistic expectations of the product's effectiveness?	
Are false, unbalanced, unsubstantiated or likely to mislead the user? Abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress?	
Encourage or are likely to encourage inappropriate use?	
Indicate or imply that the product is infallible, unfailing, magical, miraculous, or effective in all cases?	
Indicate or imply that the product cannot cause harm?	
Indicate or imply that other competitor products are harmful or ineffectual?	
Indicate or imply that the product is endorsed by any government agency, hospital or other facility providing healthcare services, individual healthcare professional or group of healthcare professionals?	

2. Benefits of Zinc Oxide

2.2 Reef and Ocean Safe

- Zinc sunscreens are compliant with Palau Senate Bill No. 10-135, SD1, HD1¹, Thailand National Park Act B.E. 2562², Hawaii Senate Bill NO. 2571³. We are also compliant with the upcoming proposed Hawaii Senate Bill No. 132 SD2 (click [here](#) to view all our certifications).
- “Zinc (Zn) is a necessary micronutrient in the ocean”⁴
- “Dissolved Zn may therefore be an important control of distributions of surface productivity and the efficiency of the global carbon cycle.”⁵
- “The limited supply of Zn to the surface Atlantic Ocean can explain the lack of an Atlantic Zn remineralization signal and indicates Zn might play a role in phytoplankton community composition and productivity.”⁶
- Zn is still an essential nutrient element for coral growth because it is an important cofactor for many enzymes (e.g., superoxide dismutase and carbonic anhydrase)⁷.

2.3 Cell Vitality

- Zinc is an essential trace element for proper cellular function and bone formation.⁸
- Zinc is conducive to mitochondrial pyruvate transport, oxidative phosphorylation, carbohydrate metabolism, lipid metabolism and ultimate energy metabolism in both normal and toxic-induced oxidative stress conditions in vitro, and it plays an important role in restoring impaired energetic metabolism. This zinc-mediated energetic metabolism regulation could also be helpful for DNA maintenance, cryoprotection and hereditary cancer traceability. Therefore, zinc can widely adjust energetic metabolism and is essential in restoring the impaired energetic metabolism of cellular physiology.⁹

2.4 Anti-Pollution

“For anti-pollution care, maintaining skin barrier function using barrier cream seems to be sufficient in individuals sensitive to PM (particulate matter).”¹⁰

2.5 Wound Healing

“Zinc has been used during the regime of Pharaohs, and historical records show that Zinc Oxide was used in many ointments for the treatment of injuries and oils even in 2000BC.” “Of all natural and synthetic wound dressing materials, the chitosan hydrogel microporous bandages laced with zinc oxide nanoparticles developed by Kumar Etal are highly effective in treating burns, wounds and diabetic foot ulcers.”¹¹

2.6 Broad Spectrum

- “Of the available sunscreens only zinc oxide provides effective protection across the UV band range of 240 to 400 nm, covering UVC (240 to 280 nm), UVB (280 – 320nm), UVA 2 (320 to 340 nm), and UVA 1 (340 to 400 nm).”¹²
- “UVA rays account for 95% of our sun exposure. They cause skin aging and contribute to skin cancer.”¹³
- “The risk for skin cancer doubles in people who have had five or more sunburns.”¹³
- “UVA rays penetrate deeply into the skin layers, damaging collagen and cells which leads to wrinkling, hyperpigmentation and loss of elasticity.”¹⁴

2.7 Sensitive Skin/Hypoallergenic

- “In a study in which a 25% zinc oxide patch (2.9mg/cm²) was placed on human skin for 48 hours, there was no evidence of dermal irritation.”¹⁵
- One in 10 people will develop atopic dermatitis during their lifetime.¹⁶

2.8 Safety

- “A study led by two Australian universities found evidence that zinc oxide nanoparticles used in sunscreen does not cause cellular toxicity even after repeated applications.”¹¹
- “The levels we found in blood were very small,” says McCall, a research consultant on nanosafety at CSIRO. “After applications over five days, the levels of the tracer zinc in the blood were one thousandth of what is the naturally occurring total zinc levels in the blood.”¹⁷
- “In 2011, it was estimated that 116,000 child deaths per year are attributable to zinc deficiency.”¹⁸

The FDA’s release published 24/08/2021 stated “infants are at greater risk than adults of sunscreen side effects”. Zinc oxide is considered safe for infants by the [FDA](#) and is even present at up to 40% in nappy rash creams. Therefore, if there is a situation where sun protection such as protective clothing or shade is not available the safest option for babies is a Natural Zinc based 100% Organic 100% Vegan Sunscreen.

3. Concerns of UV Filters

“Nearly two-thirds of all sunscreens evaluated by the Environmental Working Group would probably not be considered safe and effective under standards proposed by the US Food and Drug Administration.”¹⁹

3.2 Pregnancy

- “Studies reported statistically significant associations between oxybenzone exposure during pregnancy and birth outcomes. One reported shorter pregnancy in women carrying male fetuses; two reported higher birth weights in baby boys; and one found lower birth weights in baby girls”¹⁸
- “Liver and kidney weights were affected after both dermal and oral exposure to BP-3”²⁰
- “Oxybenzone detected in nearly every American; found in mother’s milk; 1% to 9% skin penetration in lab studies.”²¹
- “A pregnant woman who follows the instructions for the recommended-use of sunscreen products containing 6% oxybenzone (two 1-ounce application of sunscreen) could have concentrations of oxybenzone and fetal blood levels reach as high as 3,800 part per billion in the woman, and 384 parts per billion in the fetus. These concentrations of oxybenzone can potentially cause these toxic cellular changes, and give rise to Hirschsprung’s Disease.”²²
- “Hirschsprung’s Disease is a birth defect that develops in the first trimester of pregnancy. Without surgical intervention, obstruction of the bowel may occur, which can give rise to an infancy mortality rate as high as 80%.”²²
- People who are most vulnerable to the potential health effects of UV filters are pregnant women, infants who are breast-feeding and agricultural and landscaping workers, especially those who regularly use pesticides, because some UV filters can increase the permeability of skin to certain pesticides.²³

3.3 Cancer

UV filters easily penetrate the skin and have been found throughout the breast in tissue taken from women undergoing mastectomies for breast cancer¹¹. UV filters have also been measured in human placental tissue¹⁷ and milk¹¹, as well as in adult urine and blood²⁴

“Three important observations prompted us to review the animal data and human studies on possible side effects of selected chemical UV-filters in cosmetics. (1) the utilization of sunscreens with UV-filters is increasing worldwide; (2) the incidence of the malignant disorder for which sunscreens should protect, malignant melanoma, is rapidly increasing and (3) an increasing number of experimental studies indicating that several UV-filters might have endocrine disruptive effects.”²⁰

3.4 Reef Impact

“The results show that long-term exposure to chemical ultraviolet (UV) filters -- including avobenzene, oxybenzone, and octocrylene -- is lethal for some organisms living in freshwater environments. One of the largest sources of UV-filter contamination in both marine and freshwater environments is from sunscreen leaching off of the skin while swimming.”²⁵

3.5 Swimming Pools

Chemical UV filters of concern: Avobenzene, Octocrylene, 4-MBC, Octyl methoxycinnamate, Oxybenzone. “The relatively smaller volume of these pools compared to larger pools may increase

the concentration of the UV filters in the pool and their potential interactions with materials of human origin (urine, sweat, cosmetics, skin cells, and hair) to the levels of toxicity concerns for children through the creation of disinfection by products (DBP).²⁶

3.6 FDA/Blood Stream Absorption

FDA study published 21/01/2021: The Chemical UV filters “avobenzone, oxybenzone, octocrylene, homosalate, octisalate, and Octinoxate were absorbed into the body’s bloodstream – even after a single use. An additional finding from this new study is that once absorbed, these active ingredients can remain in the body for extended periods of time.”²⁷

3.7 Benzene Contamination

- “Benzene is a petrochemical, derived from crude oil. It can also be found in a natural state as the result of volcanic activity and forest fires.”²⁸
- “It’s in the industry’s economic interests to refuse to acknowledge the relationship between benzene and childhood leukemia”²⁹
- Most chemical UV filters are derived in some form from Benzoic Acid which is derived from Toluene, as you can see below the start of this process is Benzene, and Benzoic Acid can degrade back into benzene depending on the conditions in the tube.^{30,31}
- “Toluene is produced during petroleum refining operations, directly as a by-product of styrene manufacture and indirectly as a by-product of coke-oven operations. It is produced from petroleum as an aromatic mixture with benzene and xylene primarily by catalytic reforming and pyrolytic cracking.”³²
- “Johnson & Johnson manufactured and sold Neutrogena sunscreen contaminated with unsafe levels of the cancer-causing chemical benzene, causing a woman in Georgia to develop cancer, a new lawsuit alleges. Plaintiff Kathy McCathie claims she developed cancer, including squamous cell carcinoma, basal cell carcinoma and malignant melanoma, after using Neutrogena sunscreen products that she says she didn’t know were contaminated with benzene.”³³
- “Edgewell Personal Care Company has issued a voluntary recall for three batches of its Banana Boat Hair & Scalp Sunscreen Spray SPF 30 after discovering they contained trace levels of benzene, a known human carcinogen. Consumers who purchased the recalled Banana Boat sunscreen products are also being advised to immediately stop using and appropriately discard them, according to the Banana Boat sunscreen recall.”³⁴
- Several popular sunscreen brands sold in Australia have been recalled due to the detection of a cancer causing chemical. The Therapeutic Goods Administration (TGA) on Friday issued an urgent recall notice for nine batches of sunscreen across four brands following the detection of the chemical compound benzene. Benzene is a chemical that can cause cancer in humans, depending on the level and length of exposure.³⁵
- “Based on litigation and MSDS/literature provide by manufacturers of octocrylene, it could easily be perceived that benzophenone is a contaminant from the manufacturing synthesis of octocrylene and that current manufacturing cleanup processes are unable to purify octocrylene to <1 mg/kg.”³⁶
- “Benzophenone is a mutagen, carcinogen, and endocrine disruptor. Its presence in food products or food packaging is banned in the United States. Under California Proposition 65, there is no safe harbor for benzophenone in any personal care products, including sunscreens, anti-aging creams, and moisturizers.”³⁶

4. Concerns with Chemical UV-filters

4.2 Octocrylene

- “Octocrylene by itself is an endocrine disruptor, a developmental toxicant, and a metabolic stressor, both to mammal receptor models and to various wildlife models, including fish and coral. Preliminary evidence potentially suggests that octocrylene may have a role in the behavior of tumorigenesis and carcinogenesis.”³⁶
- “Based on litigation and MSDS/literature provide by manufacturers of octocrylene, it could easily be perceived that benzophenone is a contaminant from the manufacturing synthesis of octocrylene and that current manufacturing cleanup processes are unable to purify octocrylene to <1 mg/kg.”³⁶
- “One of the UV-filters, BP-3, has been found in 96% of urine samples in the US and several UV-filters in 85% of Swiss breast milk samples. It seems pertinent to evaluate whether exposure to UV-filters contribute to possible adverse effects on the developing organs of fetuses and children.”²⁰

5. Concerns of Titanium Dioxide

5.2 Ingestion Concerns

Because sunscreen can be used on the lips and incidentally ingested by infants, we do not use Titanium dioxide due to the below ingestion concerns.³⁷

5.3 EU Ban

- “After conducting a review of all the relevant available scientific evidence, EFSA concluded that a concern for genotoxicity of TiO₂ particles cannot be ruled out. Based on this concern, EFSA’s experts no longer consider titanium dioxide safe when used as a food additive. This means that an Acceptable Daily Intake (ADI) cannot be established for E171.”³⁸

Titanium Dioxide Banned as Food Additive in EU from 8 August, 2022: In May 2021, the European Food Safety Authority (EFSA) published an opinion that stated that titanium dioxide can no longer be considered safe when used as a food additive. Based on this opinion, the European Commission and the Member States agreed to remove all uses of titanium dioxide as an additive in food. In January 2022, a Regulation withdrawing the authorisation to use titanium dioxide as a food additive in food products was adopted i.e. Commission Regulation (EU) 2022/63.³⁹

5.4 Cancer Concern

- January 1st, 2020: France banned titanium Dioxide in all food products due to cancer concerns.⁴⁰

6. Ingredient Claims

6.2 Zinc Oxide

According to the WHO, Zinc is a vital mineral needed in almost every cell of humans, plants and animals. Globally around a third of people don't get enough Zinc, risking and/or increasing the possibility of serious disease. Zinc Oxide is a miracle mineral that blocks the sun, heals wounds, boosts the immune system, and regenerates skin.⁴¹

6.3 Sunflower Seed Oil

Reinforces the skin barrier and improves skin hydration whilst providing anti-inflammatory and soothing antioxidants.⁴²

6.4 Jojoba Seed Oil

Moisturising and antioxidant, the omegas in the oil make it a near match for the natural healing oils our skin produces.⁴³

6.5 Vitamin E

A well-known antioxidant that keeps the skin healthy. It is a great anti-inflammatory that is also essential in preventing UV-induced free radical damage to the skin.⁴⁴

6.6 Candelilla Wax

6.7 Polyglyceryl-3 Polyricinoleate

6.8 Cetyl Acetate

6.9 Thuja Plicata

A strong but gentle ingredient that has excellent anti-aging, antioxidant and anti-inflammatory properties that limits skin damage. For more information click [here](#).

6.10 Isosteric Acid

6.11 Calendula Extract

6.12 Xanthum Gum

6.13 Glycerine

6.14 Maltodextrin

6.15 Potassium Cetyl Phosphate

6.16 Sodium Chloride

6.17 Vanillin

A soothing anti-inflammatory rich in antioxidants.⁴⁵

6.18 Iron Oxide

6.19 Oat Kernel Flour

A soothing and moisturizing anti-inflammatory, mattifies the skin, rich in antioxidants.⁴⁶

6.20 Hyaluronic Acid

A powerful moisturizer that smooths, hydrates, repairs, and regenerates damaged skin.⁴⁷

6.21 Vitamin C

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