love sun body®
MAC ANNUAL MEETING
2022
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SHEER POWER
DAILY MOISTURIZING

Sunscreen Statements and Research 2019 – 2021

FDA advances new proposed regulation to make sure that sunscreens are safe and effective

February 21, 2019

In the proposed rule, the FDA makes the following proposals for sunscreens marketed without FDA-approved applications:

- Proposes that, of the 16 currently marketed active ingredients, two ingredients – zinc oxide and titanium dioxide – are GRASE for use in sunscreens; two ingredients – PABA and trolamine salicylate – are not GRASE for use in sunscreens due to safety issues. There are 12 ingredients for which there are insufficient safety data to make a positive GRASE determination at this time. To address these 12 ingredients, the FDA is asking industry and other interested parties for additional data. The FDA is working closely with industry and has published several guidances to make sure companies understand what data the agency believes is necessary for the FDA to evaluate safety and effectiveness for sunscreen active ingredients, including the 12 ingredients for which the FDA is seeking more data.

https://www.fda.gov/news-events/press-announcements/fda-advances-new-proposed-regulation-make-sure-sunscreens-are-safe-and-effective

Center for Drug Evaluation and Research – FDA Studies

May 6, 2019

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

It took just one day of use for several common sunscreen ingredients to enter the bloodstream at levels high enough to trigger a government safety investigation, according to a pilot study conducted by the Center for Drug Evaluation and Research, an arm of the U.S. Food and Drug Administration.

The study, published May 6, 2019 in The Journal of the American Medical Association (JAMA), also found that the blood concentration of three of the ingredients continued to rise as daily use continued, and then remained in the body for at least 24 hours after sunscreen use ended.

The four chemicals studied **-** avobenzone, oxybenzone, ecamsule and octocrylene are part of a dozen that the FDA recently said needed to be researched by manufacturers before they could be considered GRASE or "generally regarded as safe and effective.“

Link to study:

https://jamanetwork.com/journals/jama/fullarticle/2733085

Center for Drug Evaluation and Research – FDA Studies

January 25, 2020

According to studies by the Center for Drug Evaluation and Research, an arm of the US Food and Drug Administration after a single application, a total of seven chemicals commonly found in sunscreens can be absorbed into the bloodstream at levels that exceed safety thresholds.

The study published Tuesday, January 21, 2020 in the peer-reviewed Journal of the American Medical Association (JAMA) found that seven active ingredients in different sunscreens enter the bloodstream at levels that far exceed the FDA's recommended threshold without a government safety inspection.

This study evaluated absorption of the active ingredients avobenzone, oxybenzone, octocrylene, homosalate, octisalate, and octinoxate. The prior study evaluated absorption of avobenzone, oxybenzone, octocrylene, and ecamsule. Without further testing, the FDA does not know what levels of absorption can be considered safe.

Link to study:

https://jamanetwork.com/journals/jama/fullarticle/2759002?guestAccessKey=81a4a1e1-66d2-4f85-8d80-8d4d1aa1c56e&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=012120

FDA Takes Steps Aimed at Improving Quality, Safety and Efficacy of Sunscreens

Today's Activities Are Part of Ongoing Implementation of New Authorities for Certain Over-the-Counter Drugs

September 24, 2021

The provisions in today's proposed order are therefore substantively the same as those described in the FDA's 2019 proposed rule on sunscreens and are aimed at bringing sunscreens that are marketed without FDA-approved applications up to date with the latest science to better ensure consumers have access to safe and effective sunscreen products. For example, the order proposes to update the GRASE status for the 16 active ingredients listed in the deemed final order.

https://www.fda.gov/news-events/press-announcements/fda-takes-steps-aimed-improving-quality-safety-and-efficacy-sunscreens

UV Radiation & Your Skin
The Facts. The Risks. How They Affect You.

When it comes to skin cancer, a major **risk factor** is prolonged exposure to **ultraviolet (UV) radiation.**

Understanding the basics about UV radiation and how it damages your skin is an important first step in learning how to safeguard yourself against skin cancer.

The good news is that the danger posed by UV radiation *can be greatly reduced* by you! Yes, you can still enjoy outdoor activities while limiting your skin cancer risk by taking simple, smart protective measures.

UV Radiation & Your Skin
The Facts. The Risks. How They Affect You.

What is UV radiation?

UV radiation is part of the natural energy produced by the sun. On the electromagnetic spectrum, UV light has shorter wavelengths than visible light, so your eyes can't see UV, but your skin can feel it. Tanning beds also emit UV radiation.

Two types of UV light are proven to contribute to the risk for skin cancer:

- **Ultraviolet A** (UVA) has a longer wavelength and is associated with skin **aging.**
- **Ultraviolet B** (UVB) has a shorter wavelength and is associated with skin **burning**.

While UVA and UVB rays differ in how they affect the skin, they both do harm. Unprotected exposure to UVA and UVB damages the DNA in skin cells, producing genetic defects, or mutations, that can lead to **skin cancer** (as well as premature aging.) These rays can also cause eye damage, including cataracts and eyelid cancers.

UV Radiation & Your Skin
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What is at stake?

UV radiation is a proven cause of basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), which often appear on sun-exposed areas of skin. Fortunately, when discovered early enough, these common forms of skin cancer are almost always curable.

UV exposure that leads to sunburn has proven to play a strong role in developing melanoma, the most dangerous of the three most common types of skin cancer. Research shows that the UV rays that damage skin can also alter a gene that suppresses tumors, raising the risk of sun-damaged skin cells developing into skin cancer.

UV Radiation & Your Skin
The Facts. The Risks. How They Affect You.

UVB facts and risks

•**UVB** penetrates and damages the outermost layers of your skin. Overexposure causes suntan, sunburn and, in severe cases, blistering.

•**UVB** is connected to the Sun Protection Factor (SPF) on labels of sunscreen products. The SPF number tells you how long the sun's radiation (including some of the UVA) would take to redden your skin when using that product compared to the time without sunscreen.

•**UVB** intensity fluctuates. While the sun's rays are strongest and pose the highest risk late-morning to mid-afternoon from spring to fall in temperate climates and even greater timespans in tropical climates, UVB rays can damage your skin year-round, especially at high altitudes or on reflective surfaces like snow or ice.

•**UVB** rays can be filtered and do not penetrate glass.

UV Radiation & Your Skin
The Facts. The Risks. How They Affect You.

UVA facts and risks

•**UVA** rays cause tanning, and the shorter wavelengths of UVA also cause sunburn. There is no such thing as a safe or healthy tan. UVA radiation is proven to contribute to the development of skin cancer.

•**UVA** is connected to the "broad-spectrum protection" you see on the labels of sunscreen products. Early sunscreens only protected your skin from UVB rays, but once it was understood how dangerous UVA rays were, sunscreen manufacturers began adding ingredients to protect you from both UVB and UVA across this broader spectrum.

•**UVA** rays, while slightly less intense than UVB, penetrate your skin more deeply. Exposure causes genetic damage to cells on the innermost part of your top layer of skin, where most skin cancers occur. The skin tries to prevent further damage by darkening, resulting in a tan. Over time, UVA also leads to premature aging and skin cancer.

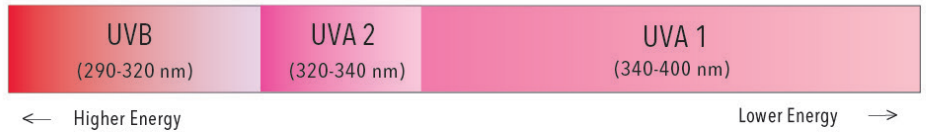
•**UVA** radiation is the main type of light used in most tanning beds. Once thought to be safe, we now know it is just the opposite.

•**UVA is everywhere**. UVA accounts for up to 95 percent of the UV radiation reaching the earth. These rays maintain the same level of strength during daylight hours throughout the year. This means that during a lifetime, we are all exposed to a high level of UVA rays.

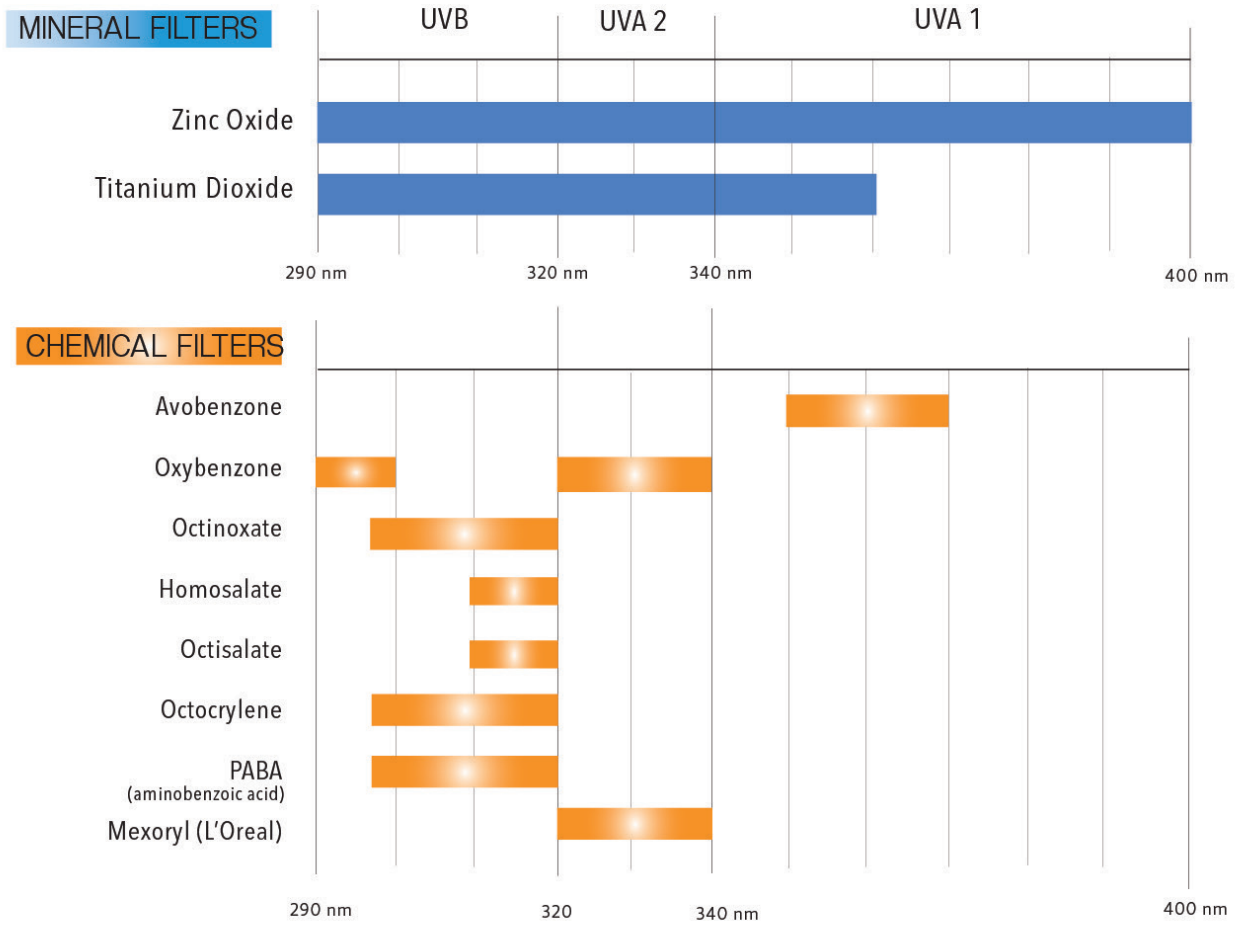
•**UVA can penetrate** windows and cloud cover.

UV Filter Absorbance Range

UV Radiation Wavelengths (nm)



Sunscreen Filters Peak Absorbance Range



	Full UV Spectrum Protection	Visible Light/ Infrared Protection	Safe
Zinc Oxide	✓	✓	✓
Titanium Dioxide	X	✓	✓
Avobenzone	X	X	⚠
Oxybenzone	X	X	⚠ Endocrine disruptors- kill coral reefs,
Octinoxate	X	X	⚠ banned in Hawaii
Homosalate	X	X	✓
Octisalate	X	X	✓
Octocrylene	X	X	⚠
PABA (aminobenzoic acid)	X	X	⚠
Mexoryl (L'Oreal)	X	X	✓

What You Need to Know About Mineral Filters

Particle Size and Mineral Content

Particle Size

Manufacturers make the zinc oxide particles smaller to minimize the whiteness of the skin after application. This is certainly more appealing than having a chalky white face, right? Companies may enticingly label sunscreen products as **“invisible zinc”, “sheer” or “clear”**. These words give clues that these products most likely contain nanosized zinc particles.

Type of Sunscreen	Advantages	Disadvantages
Non-Nano Zinc	Broader coverage against UVB, UVA, and blue light	More white and visible
Nano Zinc	Broad coverage and less visible on the skin	The coverage is not as broad and may no cover very long wavelength UVA and blue light

Nanoparticles do work differently from non-nanoparticles. One of the reasons that nanoparticles are more clear and sheer is that they reflect less and less of visible light as the particle size becomes smaller and smaller.

Nanoparticles are not as good as blocking blue light. Blue light may have an important role in oxidative stress to the skin and in stimulating melasma more than ultraviolet radiation type A (UVA).

Mineral Content

It is important for sunscreens to contain adequate concentrations of the active ingredients zinc oxide and/or titanium dioxide. An issue that was illuminated as the EWG researched its 2017 guide, is growing SPF values with mineral sunscreens and very low concentrations of active ingredients in many of them. The majority of mineral sunscreens do not provide effective UVA and UVB protection due to low concentrations of active ingredients.

Less Than 15% Zinc Oxide	**15-20% Zinc Oxide**	**More Than 20% Zinc Oxide**
SPF 24 or less	SPF 24 to 32	At least SPF 32

It is best to avoid any sunscreens that are less than 20 percent zinc oxide. At low concentrations, the UVA protection is insufficient. A 15 percent zinc oxide formula is only about SPF 24, ideally, we want a minimum of SPF 30. For every one percent of zinc oxide, you get 1.6 SPF units. Every one percent of titanium dioxide gives you 2.6 SPF units. You want a zinc-dominant sunscreen to protect from UVA.

In the nations regulated by the European Commission, manufacturers voluntarily comply with a recommendation that broad spectrum protection by the ratio of UVA to UVB protection, requiring one third of the SPF number to be UVA protection. This provides a significantly greater amount of UVA protection than many American sunscreens, ensuring adequate UVA protection.

A Sunscreen Shake Up

Sitting on the beach in Point Pleasant, the founders **of Love Sun Body** had an idea that turned into a mission. They were discussing how difficult it was to find a healthier alternative to chemical sunscreens. Chemical filters (active ingredients) are hazardous to humans and the environment, including coral bleaching, the majority of sunscreens do not provide effective protection and many sunscreens contain hazardous synthetic ingredients.

They knew that 60% of what goes onto our skin,
is absorbed into our bodies.

The founders wanted a sunscreen that would be
safe, natural, truly effective and good for the environment.

The problem was that they just couldn't find one
and they decided to make their own
and Love Sun Body was Born!

Benzene Contamination

The Department of Health and Human Services (DHHS) has determined that benzene causes cancer in humans

May 24, 2021:

Valisure Petitions FDA to recall 78 different lots of sunscreen and after sun care products

July 14, 2021:

Major brands sold in mass & masstige issues voluntary recall of sunscreens

September 30, 2021:

Major brand sold in mass issues voluntary recall of sunscreens

valisure

May 24, 2021

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care Products

Dear Sir or Madam:

The undersigned, on behalf of Valisure LLC ("Valisure" or "Petitioner"), submits this Citizen Petition ("Petition") pursuant to Sections 301(21 U.S.C. § 331), 501 (21 U.S.C. § 351), 502 (21 U.S.C. § 352), 505 (21 U.S.C. § 355), 601 (21 U.S.C. § 361), 602 (21 U.S.C. § 362), 702 (21 U.S.C. § 372), 704 (21 U.S.C. § 374), and 705 (21 U.S.C. § 375) of the Federal Food, Drug and Cosmetic Act (the "FDCA"), in accordance with 21 C.F.R. 10.20 and 10.30, to request the Commissioner of Food and Drugs ("Commissioner") to issue a regulation, request recalls, revise industry guidance, and take such other actions set forth below.

A. Action Requested

Sunscreens are considered drugs that are regulated by the U.S. Food and Drug Administration ("FDA").[1] Valisure has tested and detected high levels of benzene in specific batches of sunscreen products containing active pharmaceutical ingredients including avobenzone, oxybenzone, octisalate, octinoxate, homosalate, octocylene and zinc oxide. The Centers for Disease Control and Prevention ("CDC") states that the Department of Health and Human Services has determined that benzene causes cancer in humans.[2] The World Health Organization ("WHO") and the International Agency for Research on Cancer ("IARC") have classified benzene as a Group 1 compound thereby defining it as "carcinogenic to humans."[3] FDA currently recognizes the high danger of this compound and lists it as a "Class 1 solvent" that "should not be employed in the manufacture of drug substances, excipients, and drug products because of their unacceptable toxicity ... However, if their use is unavoidable in order to produce a drug product with a significant therapeutic advance, then their levels should be restricted" and benzene is restricted under such guidance to 2 parts per million ("ppm").[4] Because many of the sunscreen products Valisure tested did not contain detectable levels of benzene, it does not appear that benzene use is unavoidable for their manufacture, and considering the long history and widespread use of these products, it also does not appear that they currently constitute a

[1] Certain sunscreens may also be dually regulated as cosmetics under the FDCA, and the designations "drug" and "cosmetic" are not mutually exclusive.
[2] Centers for Disease Control and Prevention, *Facts About Benzene* (2018) (https://emergency.cdc.gov/agent/benzene/basics/facts.asp)
[3] International Agency for Research on Cancer and World Health Organization, *IARC Monographs on the Identification of Carcinogenic Hazards to Humans* (https://monographs.iarc.who.int/list-of-classifications)
[4] Food and Drug Administration, *Q3C – Tables and List Guidance for Industry* (2017) (https://www.fda.gov/media/71737/download)

Benzene Contamination

Why Is Benzene Showing Up in Some Sunscreens and Not Others?

Valisure's petition suggests that the findings are a result of contamination somewhere in the manufacturing process. There are a lot of theories and some of them seem logical based on how raw ingredients are processed, how compounds are made and how formulas are manufactured. The experts tend to agree that some form of accidental or oversight left these companies (and the products) vulnerable to a cross-contamination that resulted in benzene ending up where it shouldn't.

This risk of a cross-contamination becomes much higher for any company using synthetic ingredients, chemical compounds and petroleum-based ingredients in their sunscreen because of all the processing and manufacturing of those ingredients. When a raw ingredient is manufactured in large tanks, cleaning products might leave a residue before or after a batch is made. Something similar could happen when a formula is manufactured. Ultimately, several chemical raw materials could be combined and manufactured into a new compound chemical that could also have become compromised or contaminated in that process. Benzene is also a natural part of crude oil, so crude based ingredients like silicone, dimethicone and other petroleum-based ingredients may also be the source of contamination. Whether its processing, cleaning, manufacturing of raw ingredients or formulas -- there's basically room for error here.

Are All Mineral or Natural Sunscreens Benzene Free?

A mineral sunscreen with zinc oxide and/or titanium dioxide may contain synthetic chemicals in its formula and it may also contain chemical filters such as Oxybenzone, Octinoxate, Octocrylene, Homosalate and Avobenzone and still market itself as natural when mixed with a mineral filter.

As highlighted above, brands that use a lot of synthetic ingredients, chemical compounds and petroleum-based ingredients in their formulas inherently open themselves up to more risk of contamination with harmful chemicals like benzene versus those who don't use these ingredients.

With that said, Love Sun Body is absolutely a safe sunscreen option today for several reasons.

Truly Conscientious

Supply Chain and Production

Reliable guarantees around the world

A historical player in the world of **organic farming certification**, Ecocert is renowned for its **competence, independence and impartiality.**

Ecocert® Cosmos Natural Certified

Validation of Raw Materials

- Ingredient manufacturers only use approved raw ingredients sourced from plants and minerals without any Genetically Modified Organisms (GMOs)
- Must comply with strict limitations of toxicity and biodegradability
- We use non-nano zinc oxide and non-nano titanium dioxide, the only sunscreen filters approved as safe according to the FDA and Cosmos-standard.

Validation of Branding and Labeling

- Ecocert COSMOS Natural symbol must be used on your retail label and visible at point of sale.
- Must indicate the natural percentage as “xx% natural origin of total”. For products that are 100% natural, this indication of the percentage natural origin is not required but may be used.

Validation of Formulas

Certified to Cosmos Natural requirements:

Generalities

- Process specificity: Adjustment of pH, viscosity, etc.
- Process specificity: Weighting
- Process specificity: Evaporation of water

Specific cases

- Plant Extracts
- Liquid and/or solid soaps

Purchased ingredients

- Aqueous extracts
- Non-aqueous extracts
- Soaps

Validation of Packaging

- Minimized packaging
- Environmentally friendly, maximizing reusable or recyclable amount
- Labeling clear and not misleading to consumer, accurately represents ingredients and formulas

Validation of Production

- Annual inspections of facility, plus audits and tracking of raw ingredients
- Cleaning materials used before and after manufacturing certified compliant with **GREEN CHEMISTRY** respecting environment and human health, without residue
- Environmental and waste management plan at factories

Cosmos certification includes branding and labeling to state the formulas percent of Natural Origin of Total.
All Love Sun Body Formulas are certified 100% Natural Origin of Total.

revolution

Love Sun Body was founded in 2012 and after 6 years of R&D launched in 2018 the first and only sunscreens in the U.S. certified by Ecocert Cosmos Natural

Clients Love

- **All formulas are 100% Natural Origin and Certified by Ecocert Cosmos Natural**
- **All formulas are truly effective, meeting the FDA Monograph and EU recommendation for UVA protection**
- **All formulas contain only non-nano-mineral filters and plant based inactive ingredients**
- **All formulas are Hypoallergenic, Non-Comedogenic, Gluten free, Cruelty free and Vegan**
- **All facial formulas have no eye-stinging ingredients and are safe for eye area**
- **Reef Safe, No Chemical Filters, No Synthetic Ingredients & Water Resistance 80 Minutes**

We listened to our consumers & buyers discovering challenges

- **Some white cast with SPF 50 formulas**
- **Thickening of formulas over time**
- **Bottles difficult to dispense sunscreen formulas**

evolution

Clients are in Love with

SHEER PERFECTION SHEER POWER GLOW NATURAL

- **All new formulas are thin, easy to apply**
- **All new formulas are stable over time**
- **All new formulas utilize new crimp tubes manufactured with over 50% PCR (Post-consumer recycled content) that are ecofriendly and easy to dispense sunscreen formulas**

SHEER PERFECTION
MINERAL BODY SUNSCREEN
100% Natural Origin of Total

NEW Launching March 2022

Sheer Perfection is our beloved year-round 100% natural origin mineral body sunscreen in a new rapid rub-in formula, so it's easy to apply, lightweight and quick-drying. Sheer Perfection is America's first and only Cosmos-certified 100% natural origin mineral body sunscreen.

Feels great on and features non-nano zinc oxide with shea butter, jojoba esters, sunflower oil, glycerin and natural vitamin E. Clinically proven to be effective, even after 80 minutes in the water. Suitable for all skin types, including sensitive skin.

The ideal mineral sunscreens:

- SPF 30 formulated with non-nano zinc oxide and SPF 50 with non-nano zinc oxide and non-nano titanium dioxide for truly effective broad spectrum UVA/UVB protection
- Thin, easy to rub in
- No white cast
- Hypoallergenic, non-comedogenic and gluten-free
- Reef Safe, No Chemical Filters & Water Resistance 80 Minutes
- No synthetic ingredients
- Cruelty Free & Vegan
- Recommended for children and babies 6 months or older
- SPF 30 Fragrance-Free 90 ml, SPF 30 Tiare & Vanilla 90 ml, SPF 50 Fragrance-Free 90 ml, SPF 50 Tiare & Vanilla 90 ml, $28

SHEER POWER
DAILY MOISTURIZING MINERAL FACE SUNSCREEN
100% Natural Origin of Total

NEW Launching March 2022

Sheer Power is our beloved 100% natural origin daily moisturizing mineral face sunscreen in a new lightweight, rapid rub-in formula. Love Sun Body Sheer Power is America's first and only Cosmos-certified 100% natural origin mineral face sunscreen. It feels great on, all day long! Suitable for all skin types, including sensitive skin.

- Ideal sunscreen and everyday moisturizer in one.
- Formulated with non-nano zinc oxide for truly effective broad spectrum UVA/UVB protection.
- Raspberry seed and sunflower oils, shea butter, jojoba esters, glycerin and vitamin E to hydrate, fight wrinkles and helps prevent premature aging, phytosterols and essential fatty acids to nourish, hydrate & boost moisture retention, antioxidants defend against environmental aggressors and free radicals.
- Thin, easy to rub in
- No white cast
- Quick drying
- Hypoallergenic, non-comedogenic and gluten-free
- Reef Safe, No Chemical Filters & Water Resistance 80 Minutes
- No synthetic ingredients
- Cruelty Free & Vegan
- No-eye-stinging ingredients
- SPF 30 Fragrance-Free 90 ml, $42

Packaging
Post Consumer Resin (PCR)

May 2021
All New Packaging to Incorporate PCR

Post consumer recycled resin (PCR resin) is a material made from recycled plastic, such as water and beverage bottles and other packaging.

Among all of the potential packaging options, PET plastic is by far the most popular for a variety of reasons. It leads the pack with overwhelming durability, but the environmental impacts of plastic disposal is a major drawback for the industry and concern among the growing environmental impact.

That's where post-consumer resin (PCR) comes in. Improvements in the recycling/reprocessing of material result in higher quality post-consumer material which allows higher levels of PCR to be used effectively.

- Our new Glow Natural Tinted Mineral Sunscreen & Moisturizer launched in May 21' on QVC. This is our first product line to launch with over 50% PCR material in our new packaging.

- All new production will utilize over 50% PCR material for all packaging components.

BREAKTHROUGH SUNSCREEN
& APPLICATION TECHNOLOGY

Retailers

Love Sun Body

Follain

The Detox Market

Amazon

Dr. Terry Zickerman
Founder & CEO
zickerman@lovesunbody.com

love sun body®

BREAKTHROUGH SUNSCREEN
& APPLICATION TECHNOLOGY