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Evaluating Hybrid Sunscreens to Meet the Needs for Inclusivity and Safety

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Objective

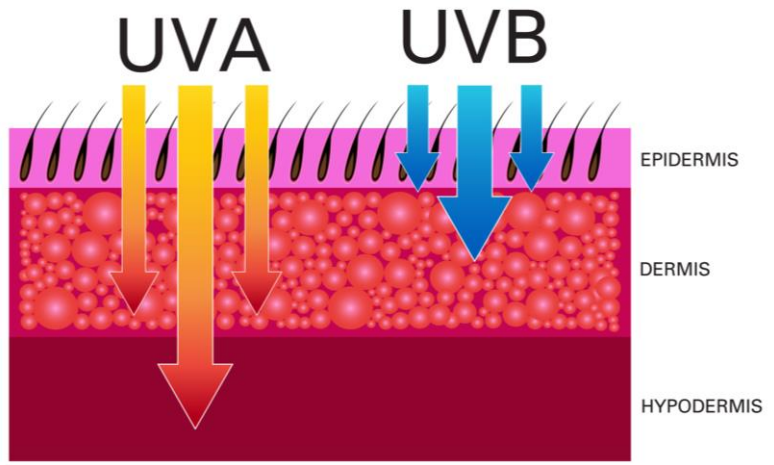
- To show hybrid sunscreens are more inclusive of all skin types
- To show hybrid sunscreens have higher SPF potential than mineral only sunscreens
- To show hybrid sunscreens have optimal formula aesthetics

Agenda

- Sun and sunscreen damage
- The need for sunscreen for diverse skin tones
- Organic sunscreens vs. Inorganic sunscreens
- Challenges of Organic and Mineral only sunscreens
- Incorporating sunscreen boosters to minimize actives and achieve SPF 50+ in Hybrid Sunscreens
- Hybrid Sunscreens - Combining minimum amounts of organic and inorganic for maximum synergy
- Exhibit aesthetically pleasing, non-whitening, inclusive formulas perfect for all skin types with high SPF

Sun Related Damage

- Sunburn
  - Sunburns are contributing factor – increases risk of developing melanoma
  - Sunburns during childhood or adolescence can increase the odds of developing melanoma later in life. Experiencing five or more blistering sunburns between ages 15 and 20 increases one's melanoma risk by 80% and nonmelanoma skin cancer risk by 68%
- Skin cancer
  - Skin cancer is the most common cancer in U.S.
  - In the USA in 2023, about 97,610 new melanomas will be diagnosed and about 7,990 people are expected to die of melanoma
- Photoaging (premature skin aging)
  - Responsible for 90% of visible changes to the skin, photoaging is a direct result of cumulative sun damage you've been exposed to throughout your life
- Environmental – degradation of coral reefs



Preventative measures include sunscreen and other sun protective measures

Skin cancer (aad.org)
Melanoma Skin Cancer Statistics | American Cancer Society
Photoaging: What You Need to Know About the Other Kind of Aging - The Skin Cancer Foundation

The Need for Sunscreen for Diverse Skin Tones

Fitzpatrick Scale

The Fitzpatrick Scale determines how easily you can burn or tan

Type I	Type II	Type III	Type IV	Type V	Type VI
Light, Pale White	White, Fair	Medium, White to Olive	Olive, Moderate Brown	Brown, Dark Brown	Black, Very Dark Brown to Black
Always burns, never tans	*Usually burns, tans with difficulty*	*Sometimes burns, gradually tans to olive*	*Rarely burns, tans with ease to a moderate brown*	*Very rarely burns, tans very easily*	*Never burns, tans very easily, deeply pigmented*

https://www.abellaskincare.com/blogs/abella-tips/know-your-skin-type-and-color-according-to-the-fitzpatrick-scale

Debunking the Myth of Type VI

MYTH → "Black and brown people are not affected because melanin provides SPF"

FACT → Even the deepest skin types only provide an SPF 13

- The minimum SPF recommended by dermatologists is SPF **30**
- Prolonged exposure to UVA rays can penetrate deep into the dermis causing photoaging and melanin alone does not protect against this even on **deeper and richer skin tones**
- African Americans have a lower survival rate of melanoma according to the Center for Disease Control and Prevention (CDC)

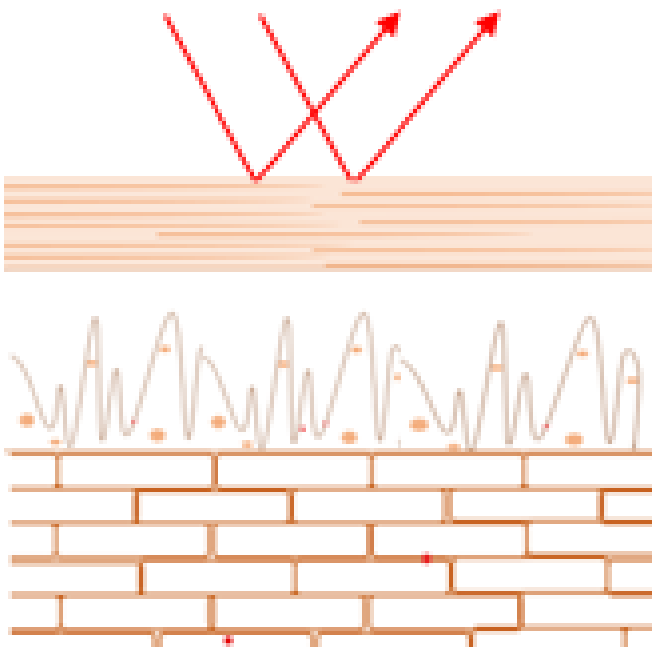
Sunscreens are Needed for all Skin Types!

https://www.nbcnews.com/news/nbcblk/sunscreen-dark-skin-tones-n1237144
https://www.cdc.gov/pcd/issues/2019/18_0640.htm

Sunscreen Filters & Mechanisms of Action

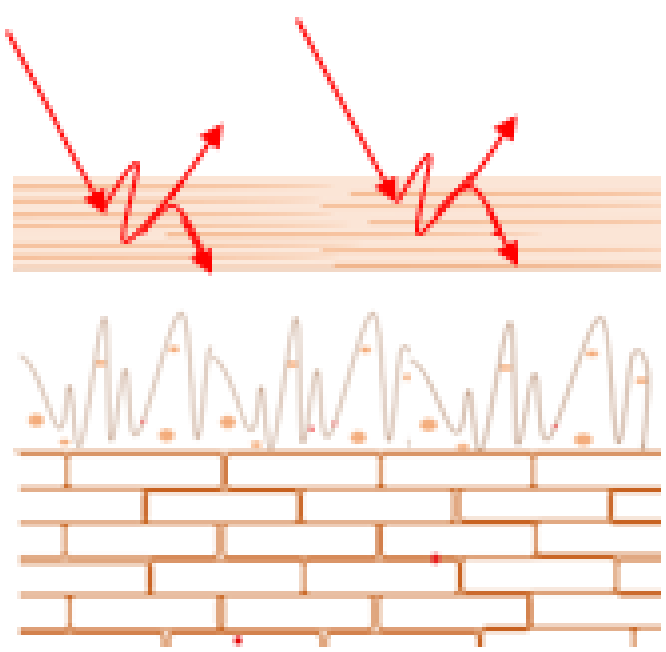
Mineral Sunscreen

Scatter/Absorb UV



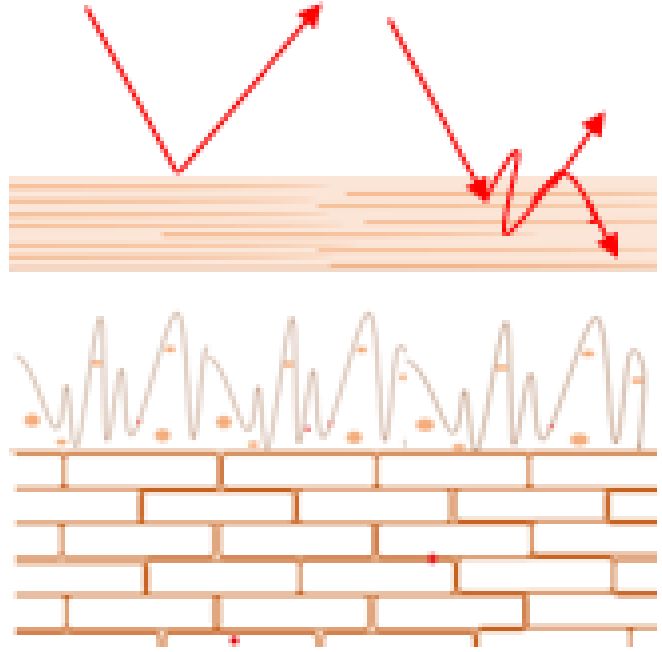
Organic Sunscreen

Absorb UV



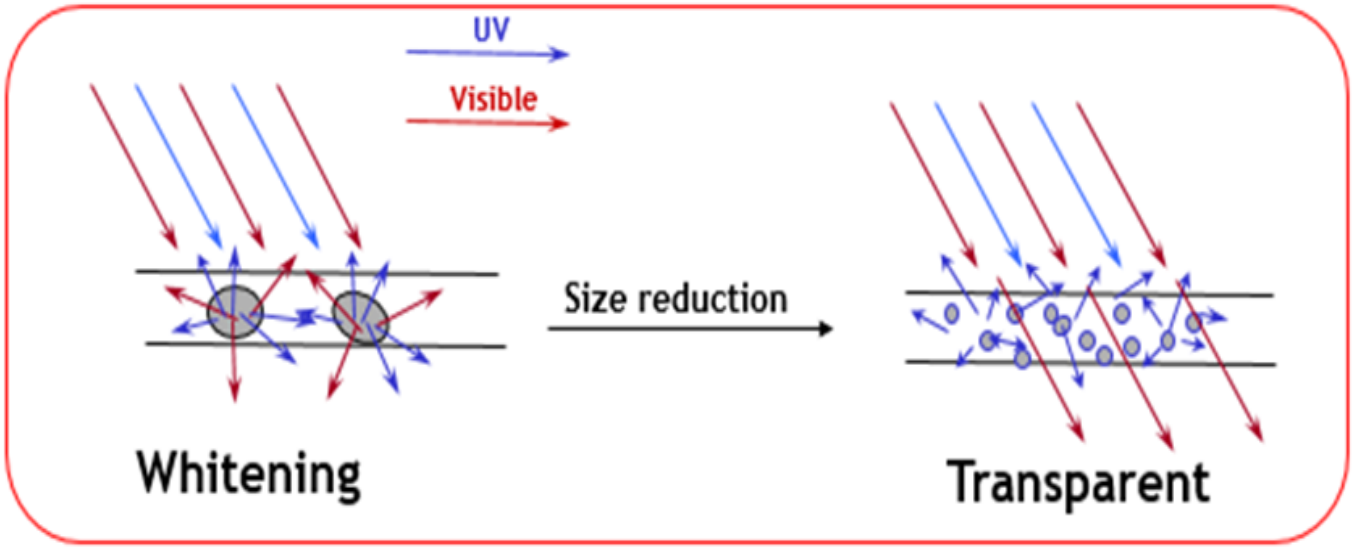
Hybrid Sunscreen

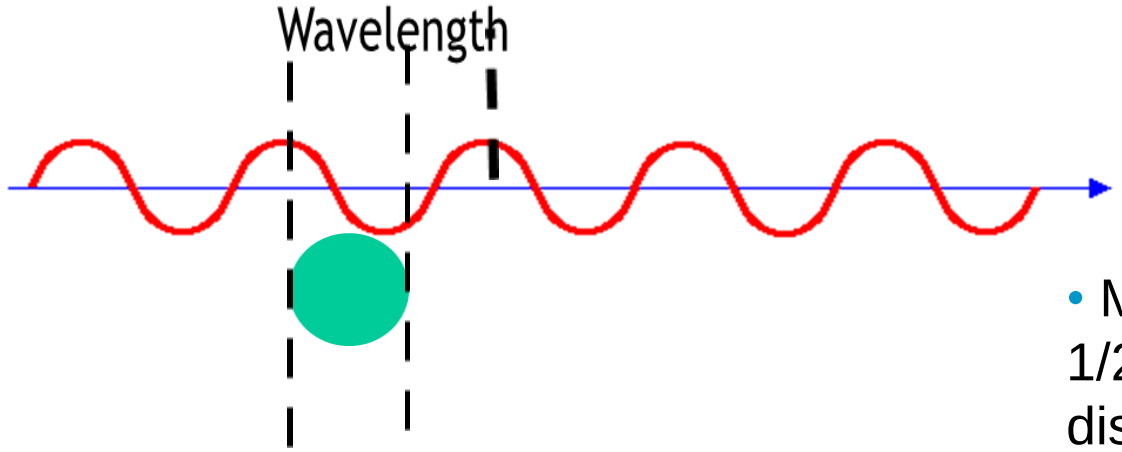
Combination



Refractive Index and Optical Path

Refractive Indices of UV Filters		
Organic		R.I.
	Octisalate	1.50
	Homosalate	1.52
	Octocrylene	1.57
Mineral		
	ZnO	**1.99**
	TiO2(rutile)	2.75





- Maximum scattering occurs when size equals 1/2 the wavelength and particles are uniformly dispersed **(Mie theory)**

Organic Sunscreens vs Inorganic Sunscreens

Organic vs Inorganic Sunscreen Actives

Organic (Carbon-Containing)

- All are synthetic and act by absorbing UV radiation and converting to heat energy
- Most organic filters are aromatic compounds conjugated with carbonyl groups
- Some actives have been shown to penetrate the skin; suspected allergens
- Concerns about negative impact on the environment (coral reefs)

Mineral

- Reflect, scatter, and absorb UV rays
- Titanium Dioxide (TiO_2) and Zinc Oxide (ZnO) are equivalents of naturally occurring minerals
- The only 2 actives considered GRASE (Generally Recognized as Safe and Effective) in the 2019 FDA proposed sunscreen monograph

Regulation on Sunscreen Actives is complex and changes worldwide. For a good summary, please see: Global Regulations of Inorganic UV Filters – Dr. Yun Shao

UVA Filters

UVA Filters (320-400 nm)					
Organic					
	U.S	**EU**	**AUS**	**China**	**Japan**
Avobenzone (Butyl Methoxydibenzoylmethane)	3.00%	5.00%	5.00%	5.00%	10.00%
Mineral / Inorganic / Physical					
	U.S	**EU**	**AUS**	**China**	**Japan**
Zinc Oxide	25.00%	25.00%	100.00%	25.00%	100.00%
Titanium Dioxide	25.00%	25.00%	25.00%	25.00%	100.00%

UVB Filters

UVB Filters (290-320 nm)						
Organic						
	U.S.	**EU**	**AUS**	**China**	**Japan**	**Peak Absorption**
Octisalate (Ethylhexyl Salicylate)	5.00%	5.00%	5.00%	5.00%	10.00%	305 nm
Homosalate (Homomenthyl Salicylate)	15.00%	10.00%	15.00%	10.00%	10.00%	305 nm
Octocrylene	10.00%	10.00%	10.00%	10.00%	10.00%	303 nm
Octinoxate (Ethylhexyl Methoxycinnamate)	7.50% (BANNED IN HAWAII)	10.00%	10.00%	10.00%	20.00%	308 nm
Oxybenzone (Benzophenone-3)	6.00% (BANNED IN HAWAII)	6.00%	10.00%	10.00%	5.00%	
Ensulizole (Phenylbenzimidazol Sulfonic Acid)	4.00%	8.00%	4.00%	8.00%	3.00%	306 nm
Mineral / Inorganic / Physical						
	U.S.	**EU**	**AUS**	**China**	**Japan**	
Titanium Dioxide	25.00%	25.00%	25.00%	25.00%	100.00%	
Zinc Oxide	25.00%	25.00%	100.00%	25.00%	100.00%	

Organic Filter Properties

UVB Absorbers (290-320 nm)

Organic

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Octisalate (Ethylhexyl Salicylate)	5.00%	5.00%	5.00%	5.00%	10.00%	305 nm
Homosalate (Homomenthyl Salicylate)	15.00 %	10.00%	15.00%	10.00%	10.00%	305 nm
Octocrylene	10.00 %	10.00%	10.00%	10.00%	10.00%	303 nm

- Oil Soluble
- Excellent Photostability
- Can be used in water resistant formulas
- Cold Processing Possibility
- Easy to incorporate into emulsions
- Excellent solvent for crystalline and oil-soluble UV absorbers

GRASE Categories

Category I

- Generally recognized as safe and effective (GRASE)
  - Mineral sunscreens – Titanium Dioxide and Zinc Oxide

Category II

- Not GRASE
  - Sunscreens containing active ingredients aminobenzoic acid (PABA) and trolamine salicylate

Category III

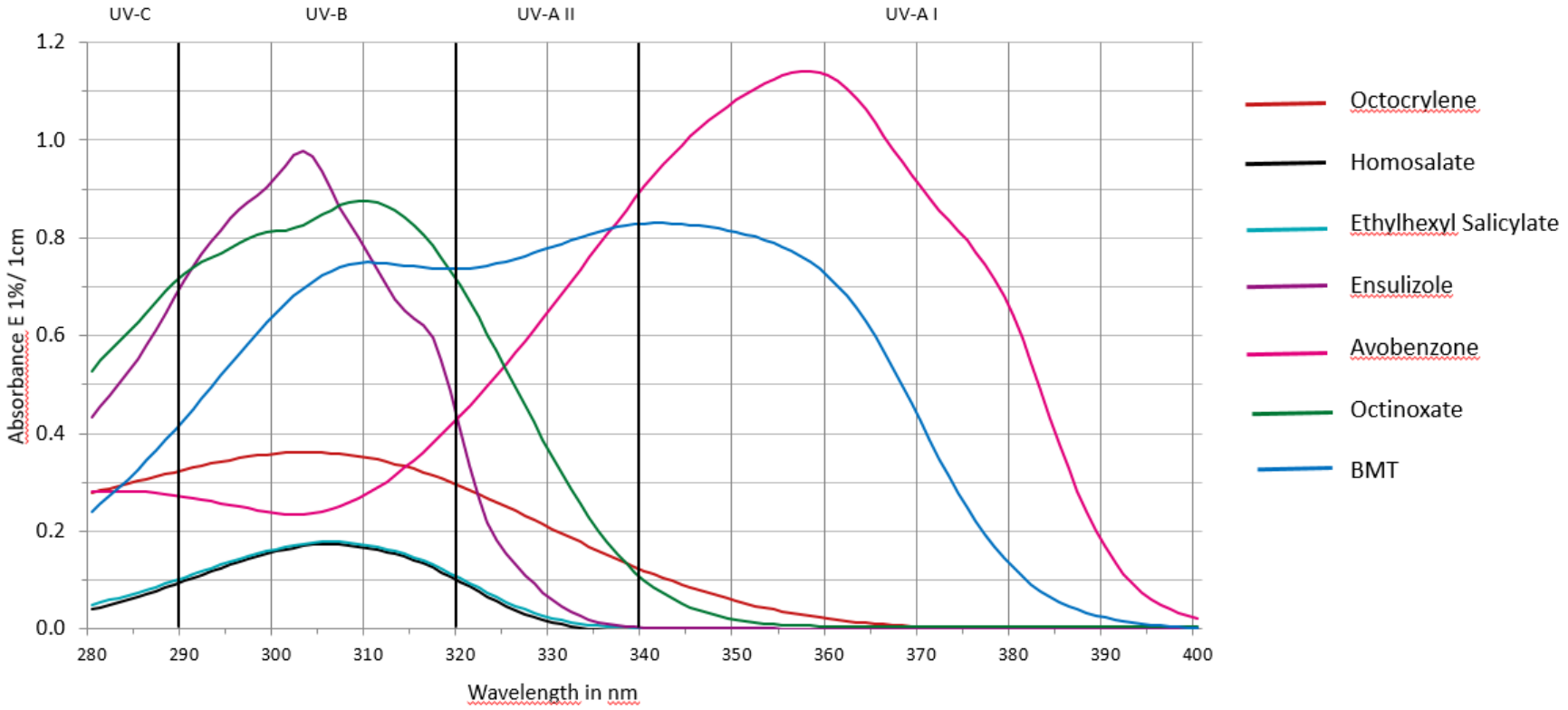
- Insufficient data available to determine if GRASE
  - Sunscreens containing Oxybenzone, Octinoxate, Cinoxate, Dioxybenzone, Ensulizole, Homosalate, Meradimate, Octisalate, Octocrylene, Padimate O, Sulisobenzone, and Avobenzone

Questions and Answers: FDA posts deemed final order and proposed order for over-the-counter sunscreen | FDA

Organic UV Absorbers

FDA approved Chemical UV Absorbers

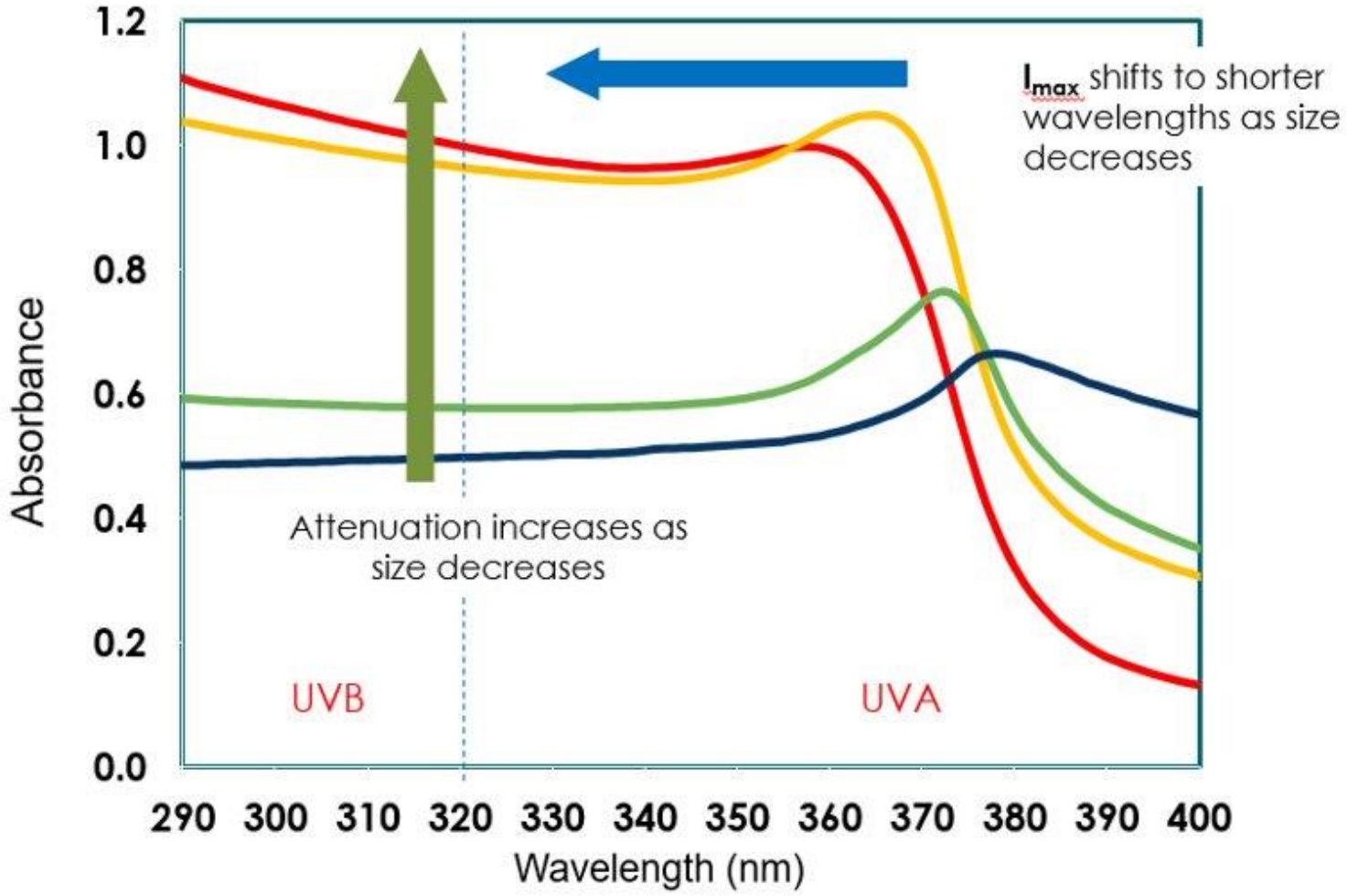
*Absorbance curves in methanol**



* Ensulizole : measured in water neutralized with sodium hydroxide,

Image ref: Symrise

UV Attenuation by ZnO



	PPS	PS
	20 nm	130 nm
	20 nm	228 nm
	60 nm	226 nm
	200 nm	320 nm

Sample: Dispersions were diluted in Chloroform to 0.005% of ZnO

Unit: Hitachi U3010 UV/Vis Spectrophotometer

Smaller size results in higher attenuation and a shift to shorter wavelength

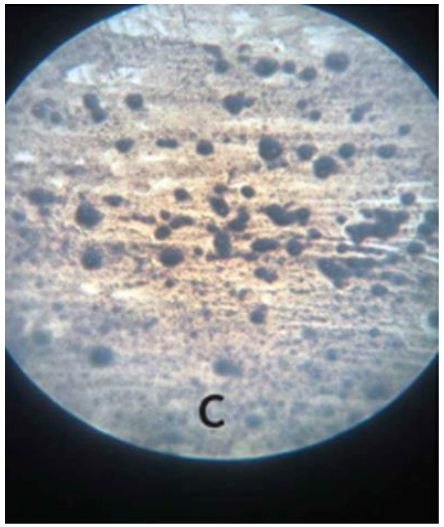
Challenges of Organic and Mineral Sunscreens

Challenges of Organic Sunscreen Actives Today

- Not always suitable for those with sensitive skin
- Aesthetics (too oily)
- Photostability issues (specifically with avobenzone)
- Oxybenzone and Octinoxate banned in Hawaii, since they were deemed detrimental to aquatic life

Challenges of Mineral Sunscreen Actives Today

- White cast on deeper skin tones
- Consumer acceptable aesthetics (heavy feel/too thick)
- Stability and ease of formulating; incompatibilities
- Health and environmental concerns of nano particles

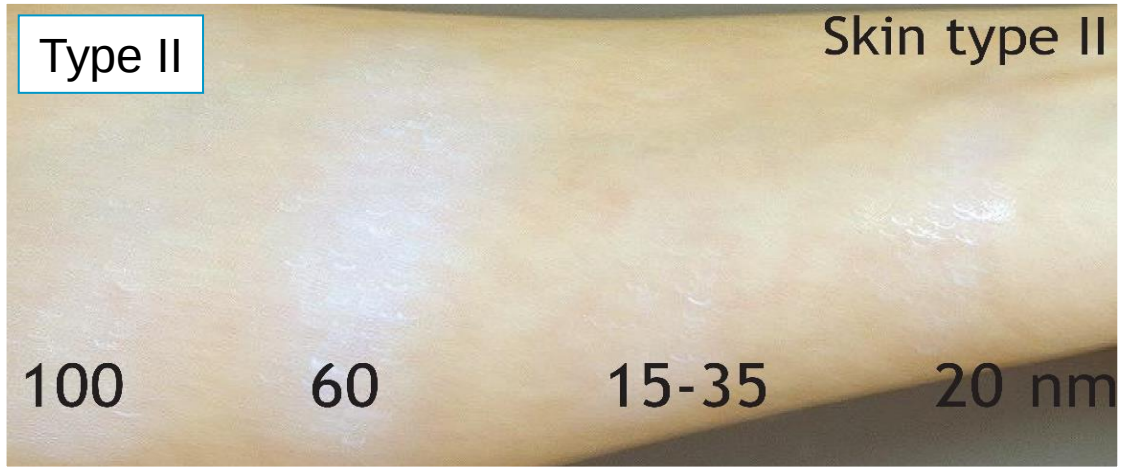


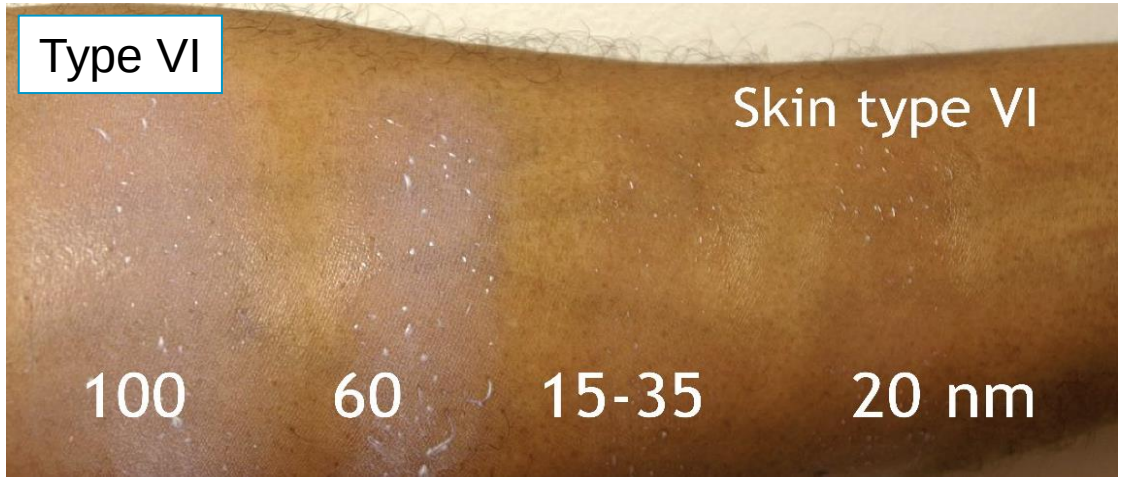
Formula instability

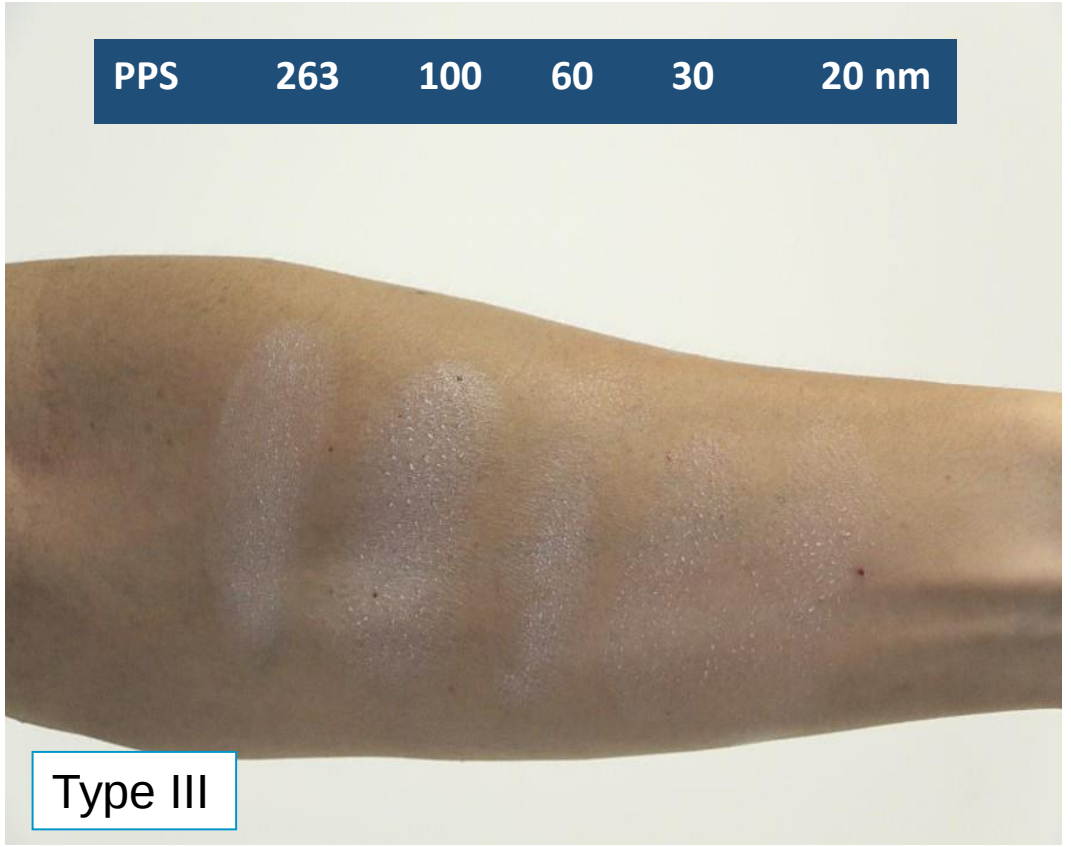
Agglomeration of mineral actives

White/blue cast on deeper skin tones

Influence of ZnO Particle Size on Transparency





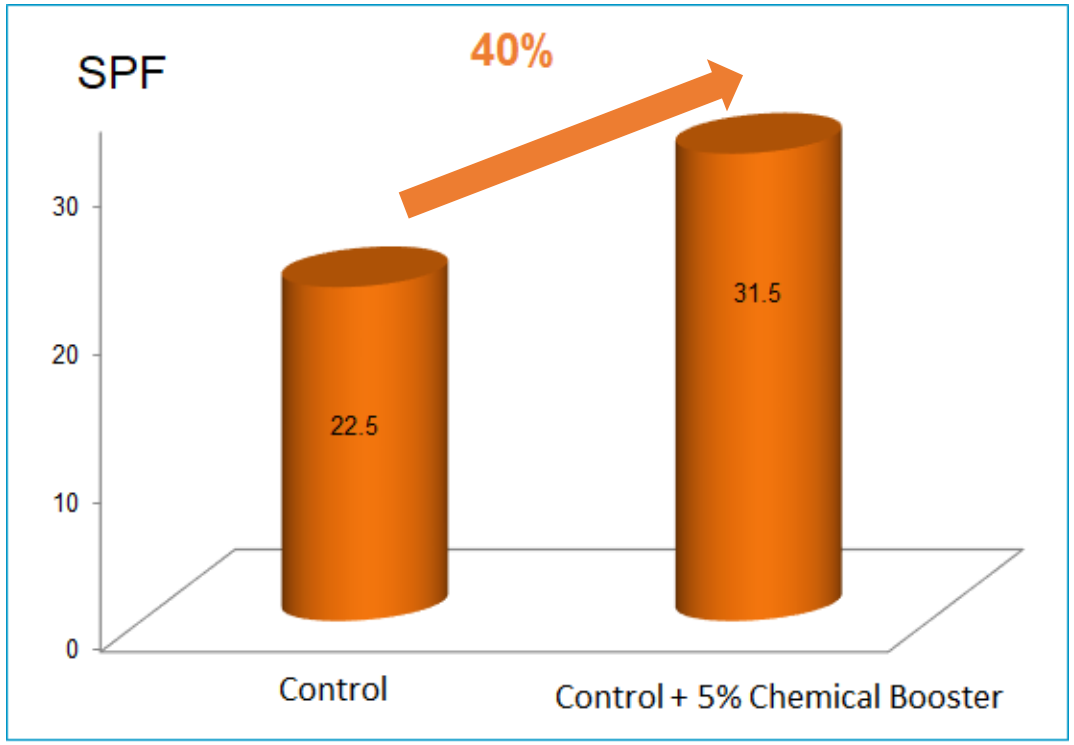


All dispersions diluted in Caprylic/Capric Triglyceride (to 20% active)

Sunscreen Boosters

Sunscreen Boosters

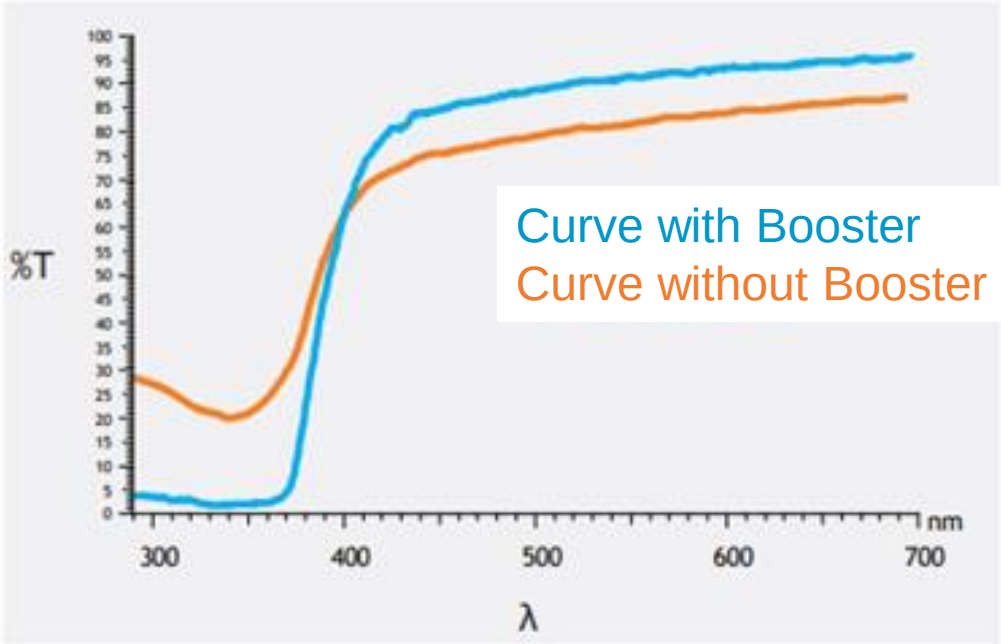
- Can boost product SPF over 30%
- Various kinds
  - Emollients (esters and oils)
  - Anti-oxidant, anti-inflammatory, and/or anti-irritant agents (Bisabolol, tocopheryl acetate, allantoin, etc.)
  - Polymers (oil soluble and hydrophilic) -- film formation
  - Powders
- Benefits:
  - Less use of sunscreen actives for better aesthetics and better transparency
  - Skincare benefits



*Chemical booster experiment

Sunscreen Boosters Functionalities

- Help increase UV absorption max for a higher critical wavelength
- Help increase UV absorption/scattering ability of sunscreens
- Help increase sunscreen uniformity and film on the skin (film former booster)
- Help reduce UV induced skin damage



Sunscreen Booster Substantiation

Formula	Actives	In Vivo SPF	PFA	% Boost on SPF	% Boost on PFA
Control 1 O/W Base	Organic 31%	40	13	Control	
Exp 1	Organic 31% Natural Booster 5%	54	17	35%	31%
Control 2 W/O Base	TiO_2 5.78% ZnO 3.74%	19	7	Control	
Exp 2	TiO_2 5.78% ZnO 3.74% Natural Booster 3.6%	30	10	58%	43%
Control 3 W/O Base	TiO_2 7.13%	22	4	Control	
Exp 3	TiO_2 6.85% Natural Booster 3.58%	32	7	45%	75%

Hybrid Formulations

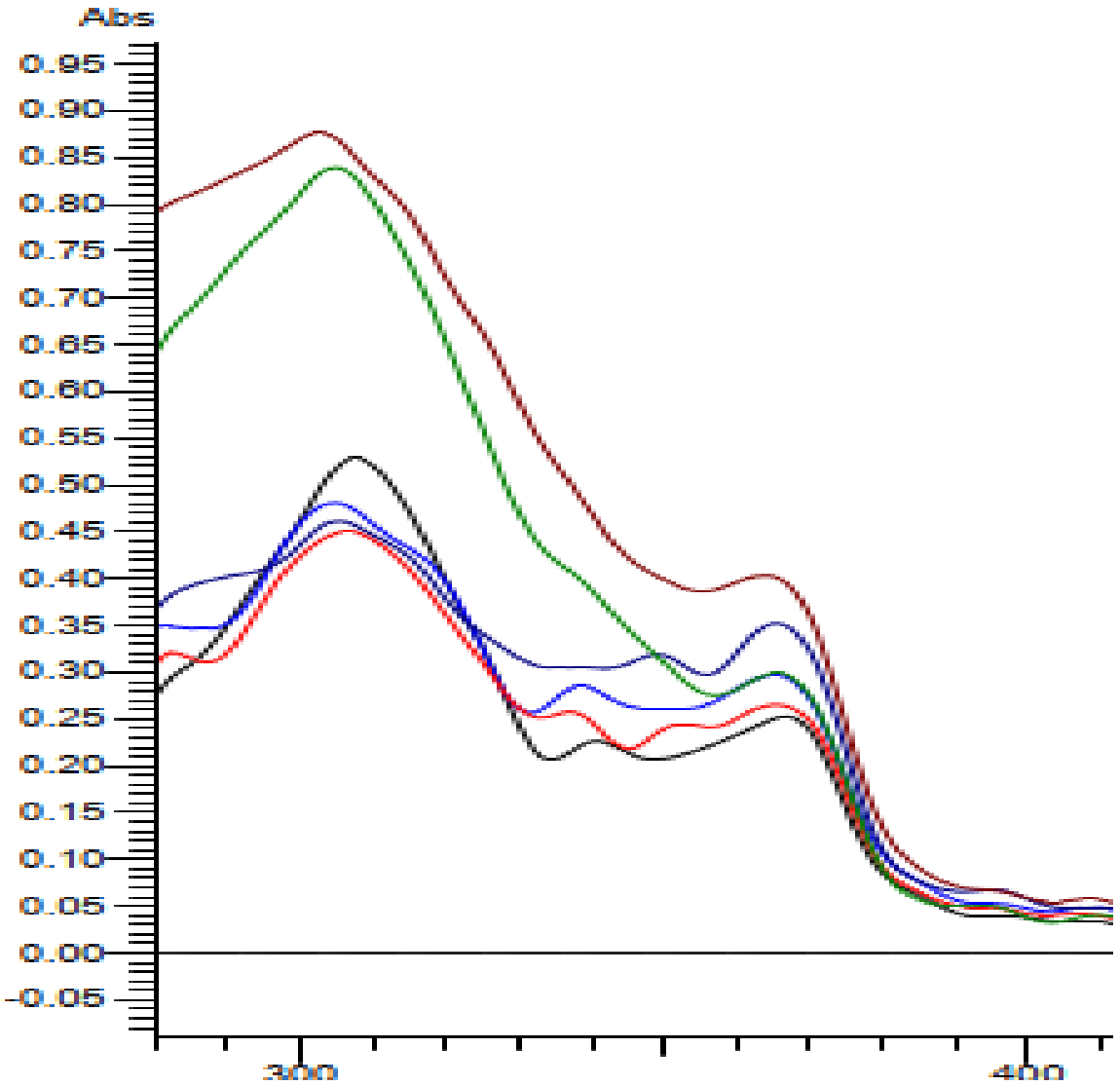
Benefits of Hybrid Formulations

- Inclusivity - greater transparency on all skin tones vs mineral only
- Higher SPF potential
- Optimal aesthetics vs mineral only sunscreens

Experimental Findings

Formula	Contributing to SPF	In silico SPF result (actives only, no boosters)	In Vivo SPF (5 Subjects)	CW (nm)	UVA I / UV Ratio
KSL-521	24.80% ZnO 5.00% Octisalate 4.00% natural booster	**41.50**	**57**	371.79	0.79
KSL-521A	24.80% ZnO 10.00% Homosalate 4.00% natural booster	**42.90**	**58**	371.37	0.74
KSL-521B	24.80% ZnO 10.00% Octocrylene 4.00% natural booster	**48.90**	**62**	370.01	0.69
KSL-521C	20.15% ZnO 5.00% Octisalate 5.00% chemical booster 4.00% natural booster	**34.40**	**49**	371.61	0.74
KSL-521D	20.15% ZnO 10.00% Homosalate 5.00% chemical booster 4.00% natural booster	**35.80**	**45**	371.24	0.70
KSL-521E	20.15% ZnO 10.00% Octocrylene 5.00% chemical booster 4.00% natural booster	**41.80**	**49**	369.14	0.65
KSL-531	20.58% ZnO 5.00% Octisalate 5.00% chemical booster 4.00% natural booster	**30.70**	**57**	371.49	0.76

Absorption Curves showing Synergy Between Actives



KSL-521D
KSL-521A
KSL-521C
KSL-521
KSL-521B
KSL-521E

Transparency on Diverse Skin Types

24.80% ZnO
5.00% Octisalate
4.00% natural booster
SPF= 57
CW= 371 nm

KSL-521

KSL-521A

24.80% ZnO
10.00% Homosalate
4.00% natural booster
SPF= 58
CW= 371 nm

Transparency on Diverse Skin Types

24.80% ZnO
10.00% Octocrylene
4.00% natural booster
SPF= 62
CW= 370 nm

KSL-521B

KSL-521C

20.15% ZnO
5.00% Octisalate
5.00% chemical booster
4.00% natural booster
SPF= 49
CW= 371 nm

Transparency on Diverse Skin Types

20.15% ZnO
10.00% Homosalate
5.00% chemical booster
4.00% natural booster
SPF= 45
CW= 371 nm

KSL-521D

KSL-521E

20.15% ZnO
10.00% Octocrylene
5.00% chemical booster
4.00% natural booster
SPF= 49
CW= 369 nm

Transparency on Diverse Skin Types

24.80% ZnO
5.00% Octisalate
4.00% natural booster
SPF= 57
CW= 371 nm

Slight white cast

KSL-521

KSL-531

20.58% ZnO
4.99% Octisalate
4.00% natural booster
5% chemical booster
SPF= 57
CW= 371nm

KSL-531

Hybrid Sunscreen SPF 57

PART	%	INCI NAME
1	**33.33**	***C12-15 Alkyl Benzoate (And) Zinc Oxide (And) Ethylhexyl Salicylate (And) Polyhydroxystearic Acid (And) Triethoxycaprylylsilane***
	8.00	*Octyldodecyl Neopentanoate*
	6.75	*Polyglyceryl-6 Polyricinoleate (and) Polyglyceryl-2 Isostearate (and) Disteardimonium Hectorite*
	5.00	***Butyloctyl Salicylate***
	5.00	*Glyceryl Hydrogenated Rosinate (And) C9-12 Alkane*
	4.00	*Polyglyceryl-3 Polyricinoleate (And) Polyglyceryl-3 Diisostearate*
	4.00	***Argania Spinosa Kernel Oil (And) Tocopheryl Acetate (And) Bisabolol***
	1.50	*Silica*
2	23.72	*Water*
	6.50	*Butylene Glycol*
	0.90	*Sodium Chloride*
	0.80	*Phenoxyethanol (and) Ethylhexylglycerin*
	0.50	*Trisodium Ethylenediamine Disuccinate*

Formula versions KSL-521 A-E

PART	% for KSL-521	% for KSL-521A	% for KSL-521B	% for KSL-521C	% for KSL-521D	% for KSL-521E	INCI NAME
1	**40.00**	**40.00**	**40.00**	**32.50**	**32.50**	**32.50**	***Zinc Oxide (And) C12-15 Alkyl Benzoate (And) Polyhydroxystearic Acid (And) Triethoxycaprylylsilane***
	6.50	6.50	6.50	6.50	6.50	6.50	*Polyglyceryl-6 Polyricinoleate (and) Polyglyceryl-2 Isostearate (and) Disteardimonium Hectorite*
	6.00	6.00	6.00	6.00	3.00	3.00	*Neopentyl Glycol Diheptanoate*
	5.00	**-**	**-**	**5.00**	**-**	**-**	***Ethylhexyl Salicylate***
	-	**10.00**	**-**	**-**	**10.00**	**-**	***Homosalate***
	-	**-**	**10.00**	**-**	**-**	**10.00**	***Octocrylene***
	-	**-**	**-**	**5.00**	**5.00**	**5.00**	***Butyloctyl Salicylate***
	4.00	4.00	4.00	4.00	4.00	4.00	*Polyglyceryl-3 Polyricinoleate (And) Polyglyceryl-3 Diisostearate*
	4.00	**4.00**	**4.00**	**4.00**	**4.00**	**4.00**	***Argania Spinosa Kernel Oil (And) Tocopheryl Acetate (And) Bisabolol***
	3.00	3.00	3.00	4.00	3.25	3.25	*Caprylyl Methicone*
	1.00	1.00	1.00	1.50	1.25	1.25	*Silica*
2	22.15	22.15	22.15	23.15	22.15	22.15	*Water*
	6.50	6.50	6.50	6.50	6.50	6.50	*Butylene Glycol*
	1.00	1.00	1.00	1.00	1.00	1.00	*Magnesium Sulfate*
	0.85	0.85	0.85	0.85	0.85	0.85	*Phenoxyethanol (And) Ethylhexylglycerin*

Conclusion

- Ability to achieve full inclusivity for all skin types
- Chemists can formulate high protection sunscreens for all skin tones by combining a minimum load of organic sunscreens with Zinc Oxide
- Octisalate and Homosalate (at maximum global levels) when combined with Zinc Oxide, provide the best UVA protection with high SPF factor
- Aesthetics of Hybrid Sunscreens are highly favored

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