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Organic UV filters

Myriam Sohn & Marcel Schneider | May 15th, 2022

Global Requirements for Sun Protection

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Global Norms & Standards | SPF

							
SPF Range	FDA TFM 2019 **SPF 2 to 60+**	**SPF 2 - 50+**		**SPF 6 - 50+** **Claim SPF50+ → in-vivo SPF 60 or higher**		**SPF 4 - 50+**	**SPF 6 - 99**
Claims	SPF claims (from 15): 15, 20, 25, 30, 40, 50, 60+ SPF < 15: measured value SPF 2 -14 must carry a **warning** *"This product has been shown only to help prevent sunburn, not skin cancer or early skin aging."*	SPF in vivo = Claimed SPF Max. SPF 50+		SPF claim: Low: 6, 10, Medium: 15, 20, 25 High: 30, 50 Very High: >50+		SPF claims Low: 4, 6, 8, 10, Medium: 15, 20, 25, High: 30,40,50 Very High: >50+ Reference: AU AS/NZS 2604:2012 In-vivo	SPF in vivo = Claimed SPF Max. SPF99
Relevant Test Method	SPF in vivo FDA Final Rule 2011	SPF in vivo ISO 24444					

Some Countries in Asia do not require SPF in vivo measurement

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Performance Measurement of US Market Products

	UV15-093-9	UV15-093-12	UV15-093-13	UV15-093-18	UV15-093-19	UV15-093-20
UV Filter	10.0% HMS 6.0% OCR 3.0% BMDBM	10.0% HMS 6.0% B3 5.0% EHS 3.0% BMDBM 2.8% OCR	4.9% TiO2 4.7% ZnO	11.7% HMS 5.4% B3 4.5% EHS 4.5% OCR 3.0% BMDBM	10.0% HMS 5.0% B3 5.0% EHS 4.0% OCR 3.0% BMDBM	14.5% ZnO 7.5% EHMC 5.0% EHS
Claimed SPF	**50+**	**55**	**60+**	**50**	**50**	**50**
Product Type	O/W Lotion	O/W Cream	O/W Cream	O/W Lotion	Clear Spray	W/O Lotion
SPF in silico	17	24.2	13	26.5	24.6	28.5
SPF in-vivo (Europe)	**31.6**	**25.2**	**38.0**	**35.5**	**27.0**	**23.4**

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Global Norms & Standards | UVA-PF

			 				MERCOSUL	
UVA protection	UVAI/UV ratio and Critical Wavelength	UVA-PF				UVA/UVB ratio		UVA-PF
Claims	Critical wavelength AND UVAI/UV ratio ≥ 0.7 (proportional to SPF value) Allow to claim: SPF>15 → decreases risk of skin cancer	PA+ (2 – 3) PA++ (4 – 7) PA+++ (8–15) PA++++ (>16*)	PA+ (2 – 4) PA++ (4 – 8) PA+++ (8–16) PA++++ (>16*)	UVA-PF/SPF ≥ 1/3 CW >370 UVA	Allow to claim: SPF>30 → ▪ *May reduce the risk of some skin cancers* ▪ *Can aid in prevention of sunspots* SPF> 4 → *Can aid in the prevention of premature skin ageing*	Before irradiation / After irradiation 0.0 to 0.9 / 0.0 to 0.56 **NO Rating** **0.6-0.9** / **0.57-0.75** UVA GOOD **0.8 - >0.9** / **0.76-0.85** UVA SUPERIOR **>0.9** / **>0.86** UVA ULTRA		UVA-PF/SPF ≥ 1/3 CW >370
Test Method	FDA Tentative Final Monograph 2019	PPD in vivo ISO 24442		UVA-PF in vitro ISO24443 **or** PPD in vivo ISO 24442	UVA-PF in vitro ISO24443	UVA/UVB ratio (Photostability is considered)		UVA-PF in vitro ISO24443 **or** PPD in vivo ISO 24442

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Constraint on UV Filters in Different Markets

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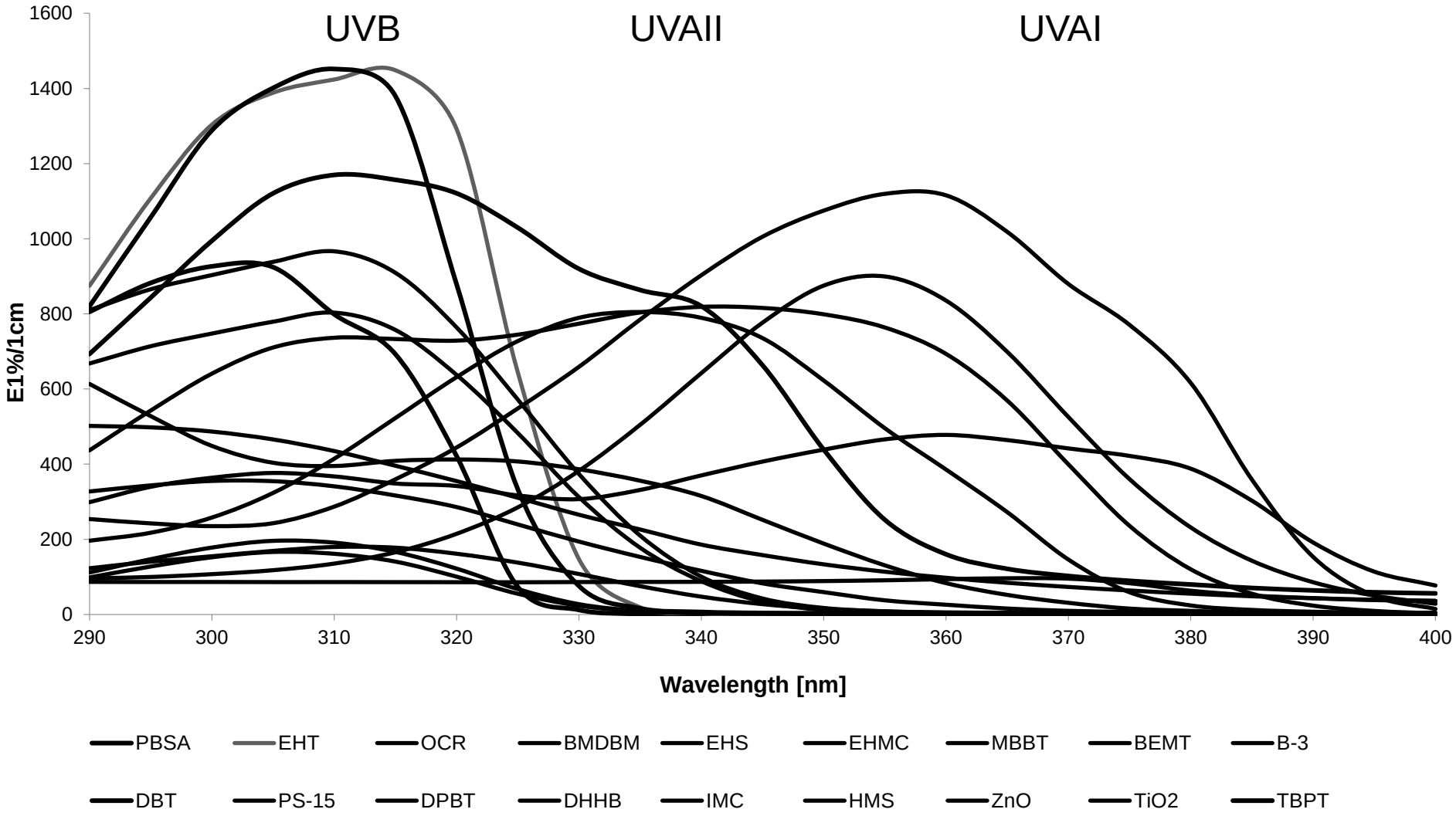
Approved UV Filters in Europe



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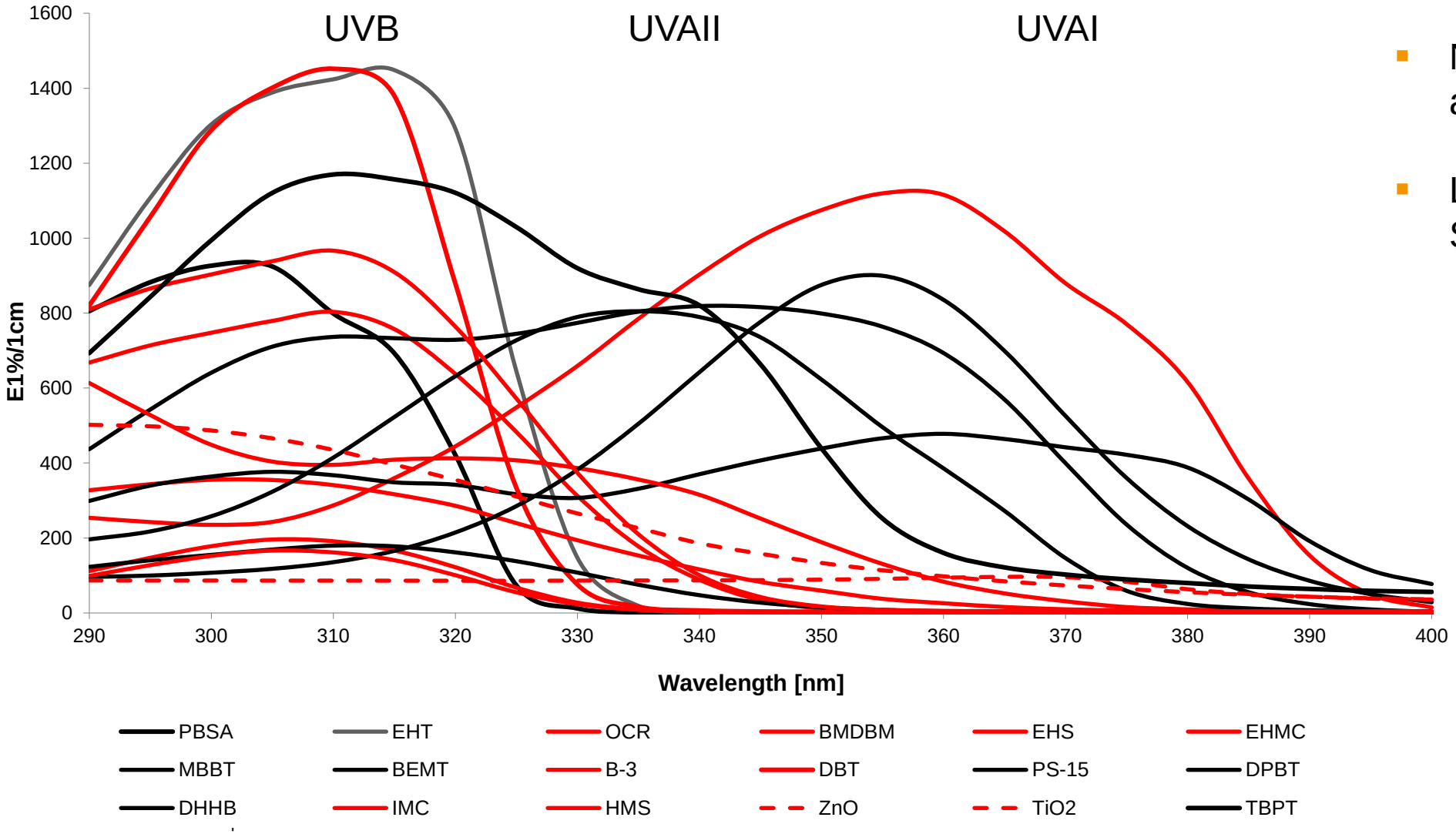
UV Filters under Evaluation in Europe (ECHA/CoRap List)



- New efficient filters are available
- Large choice for high SPF & UVA protection

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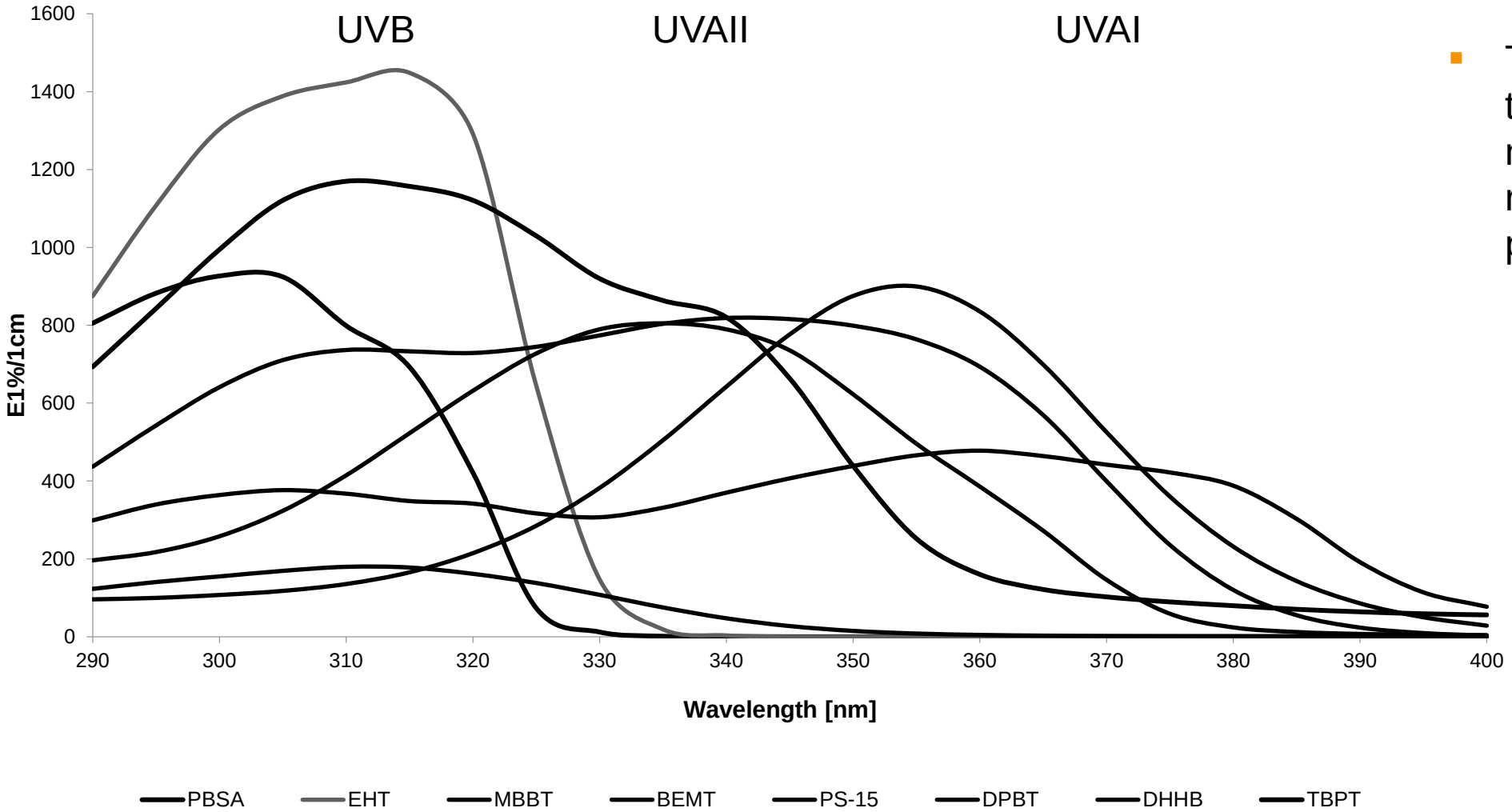
Worst Case Situation When all UV Filters on CoRap List Would Be Delisted on EU Positive List



- There is still a possibility to achieve high SPF and meet EC recommendation for UVA protection

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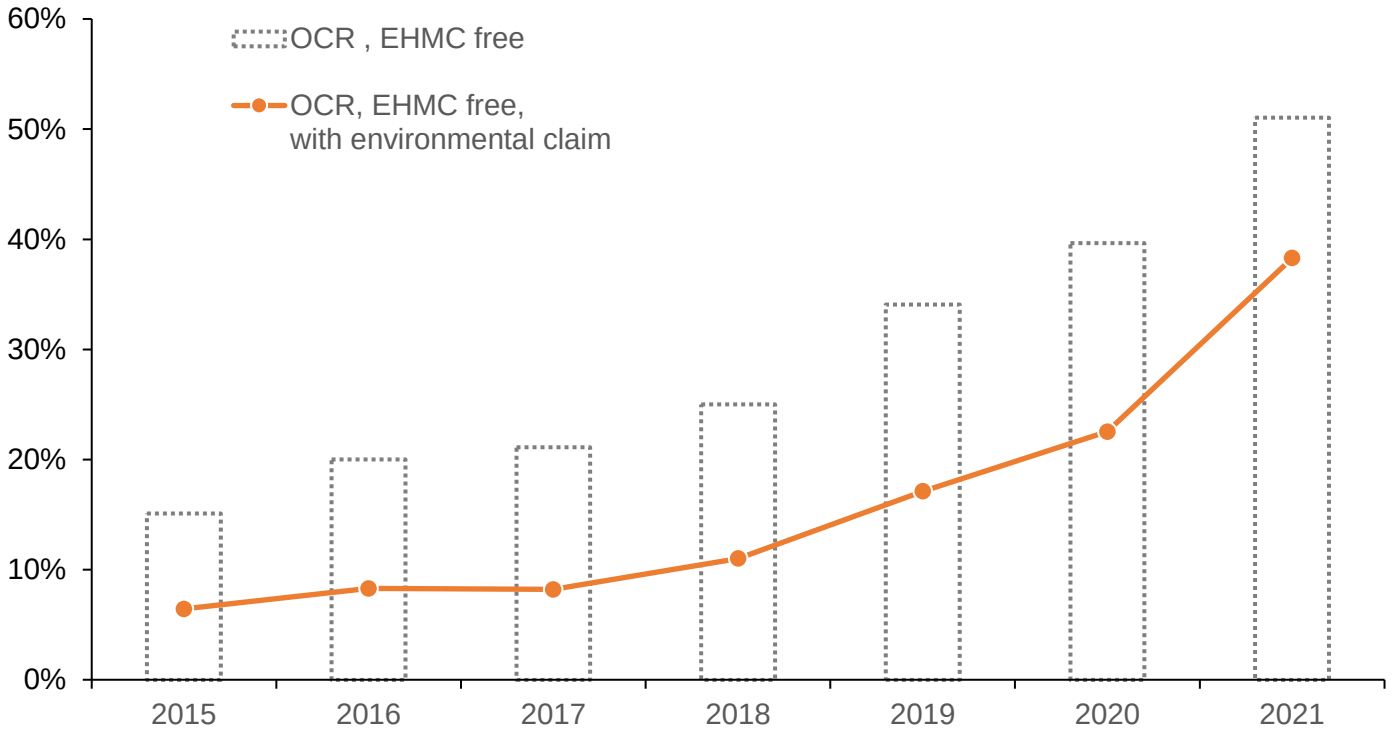
Market Reaction

Environmental Related Claims in Sun Care – Europe

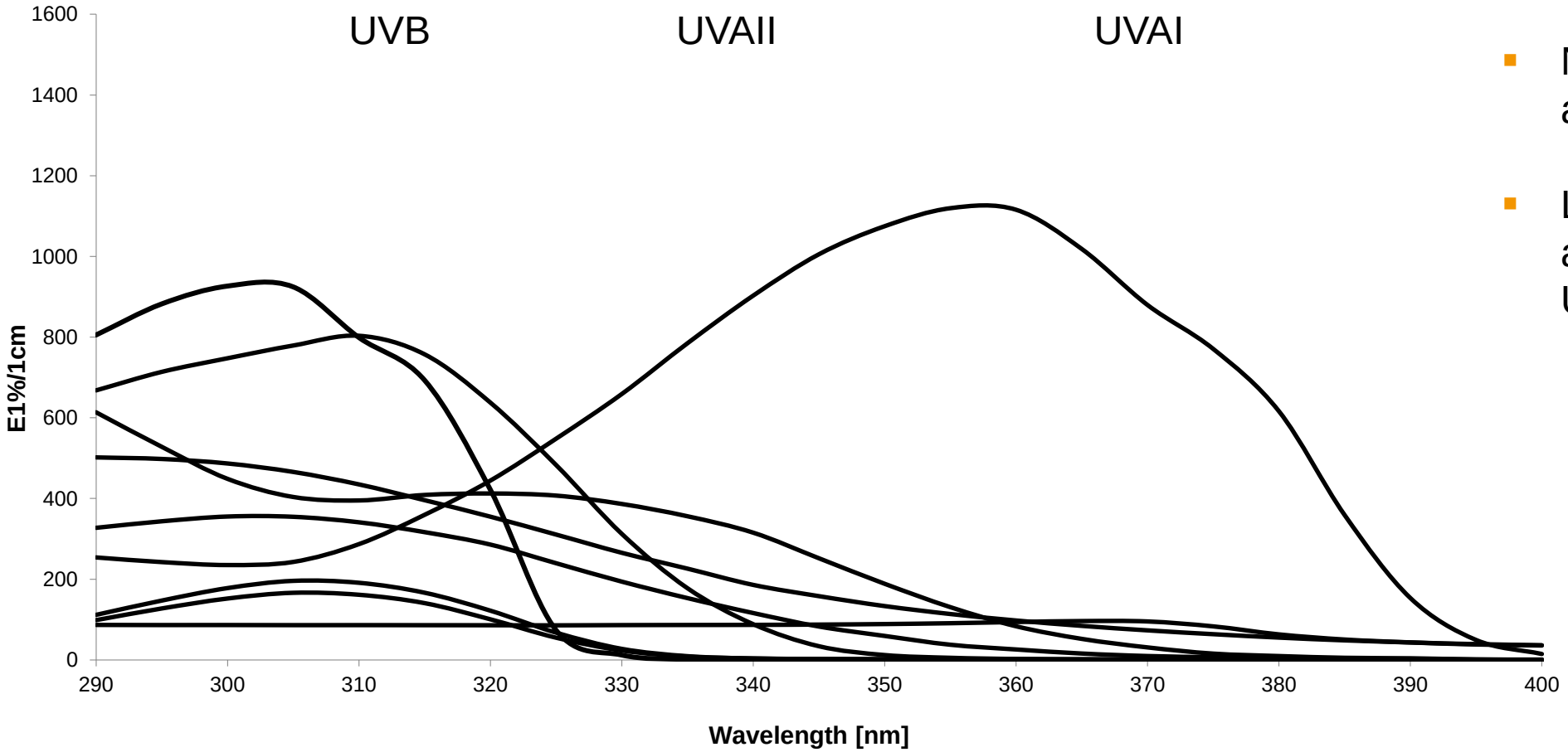
OCR and EHMC free sun care products



- Compared to 2015, number of products without OCR & EHMC increased by more than 300%
- Around 50% of the launched sun care products in 2021 (August 2021) are EHMC and OCR free
- More than 50% of the launched sun care products free from OCR and EHMC is baring environmental related claim
- A high number of environmental claims / logos appeared on the market

Reference:
Search for products, where Region matches Europe and Sub-Category matches Sun – Sun/Sunbed Exposure and Claims matches one or more of [Biodegradable; Carbon Neutral; Ethical - Environmentally Friendly Package; Ethical – Recycling; Ethical - Environmentally Friendly Product] as the claim and Date Published is between Jan xxxx and Dec xxxx.

UV Filters Approved in the US



- New efficient filters available
- Large choice for achieving high SPF & UVA protection

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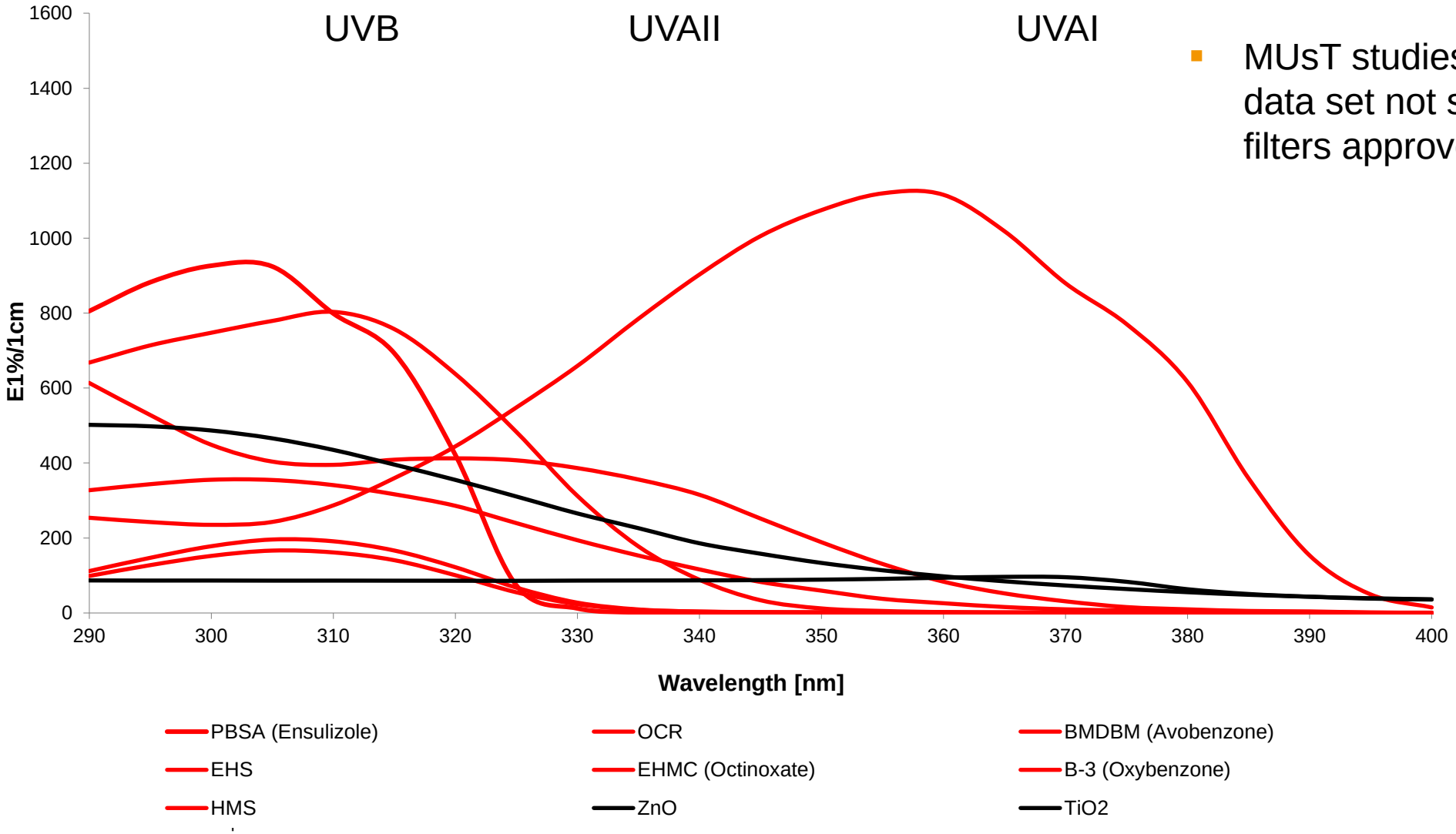
UV Filter under Evaluation by US FDA



- MUsT studies required by FDA as data set not sufficient for organic UV filters approved in the US

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Dermal Penetration: MUsT
Maximal Use Trial (MUsT), New Requirement of US-FDA

- New requirement for UV filters in USA, even for grandfathered filters
- Already standard requirement for topically applied pharmaceuticals
- Triggered by life-long and frequent use of sunscreens
- Looks for blood plasma concentration after repeated dose
- Includes all different skin types of human body
- Includes different formulation compositions
- Will have to be conducted under maximum use conditions: max. concentration, max. application frequence, max. surface area
- Was performed as a small scale pilot study by FDA after industry had not committed to do so
- FDA will require additional carc studies, when a threshold of 0.5 ng filter/ml blood plasma is exceeded

Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients
A Randomized Clinical Trial

published on May 6, 2019 Journal of American Medical Association

Original Investigation

January 21, 2020

Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients
A Randomized Clinical Trial

Murali K. Matta, PhD[1]; Jeffry Florian, PhD[1]; Robbert Zusterzeel, MD, PhD, MPH[1]; et al

Author Affiliations | Article Information

JAMA. 2020;323(3):256-267. doi:10.1001/jama.2019.20747

Sunscreens – US FDA Studies on Dermal Penetration

- Already after one application, the systemic absorption exceeds 0.5 ng/ml blood plasma for all UV filters
- The concentrations of UV filters in blood were still above the threshold limit of 0.5 ng/mL up to 21 days after study start.
- Concentrations in blood and on the skin relatively independent of formulation type (spray, lotion,…)
- Oxybenzone with highest concentrations, followed by homosalate
- Analytical results comparable to those of the 1st MUsT study of FDA (= good reproducibility)
- Study results will be used by FDA to request more systemic toxicity data (carcinogenicity, reproduction, ADME), because a safety assessment based on available studies not possible

- **FDA explicitly comments, that the presence of UV filters in blood does not mean, that the filters are toxic!**

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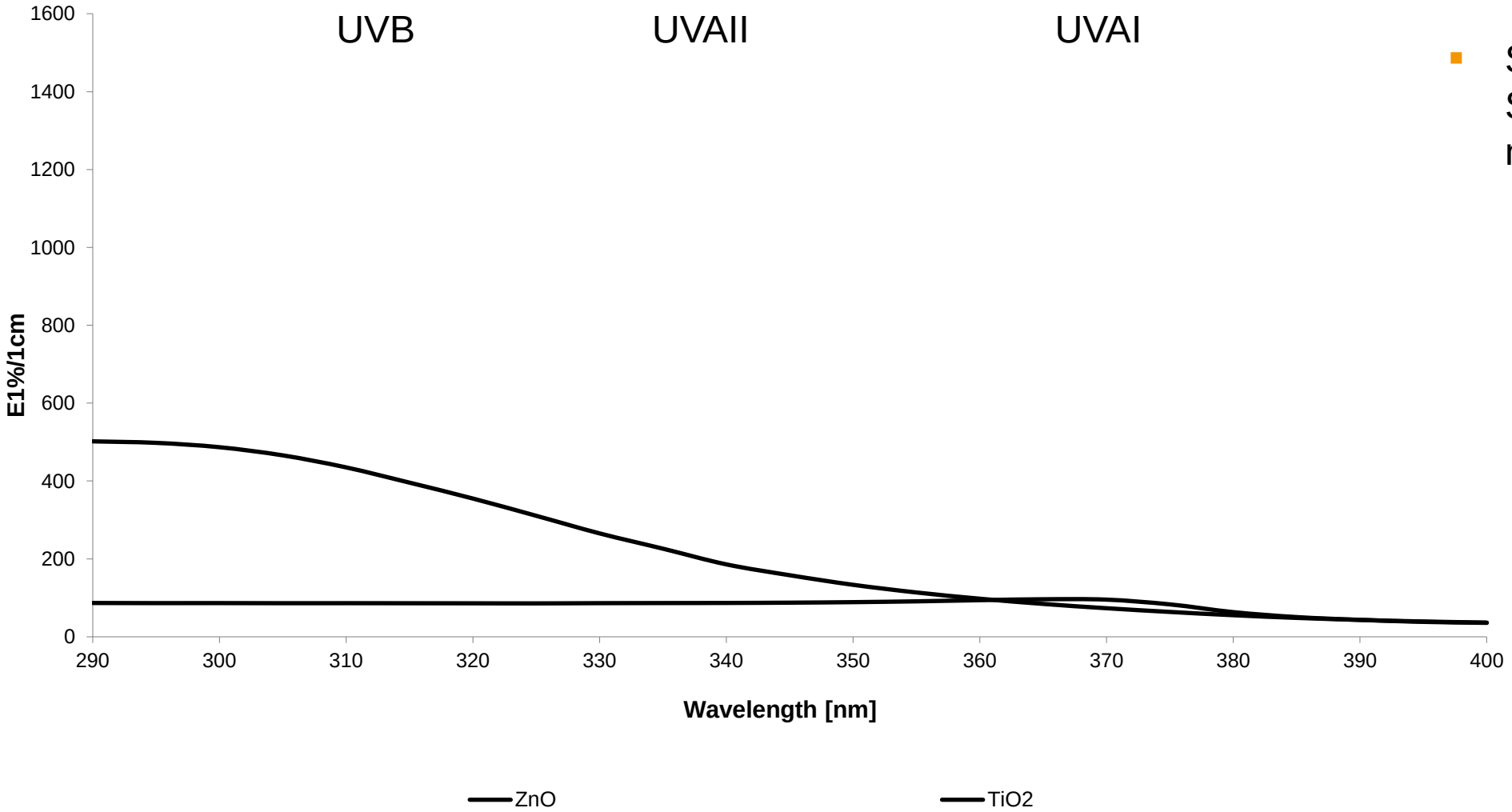
UV Filter Listed as GRASE by US FDA



- Sun Protection with high SPF and UVA-PF seems not feasible anymore

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Reaction of the Industry

Problem:

- **Difficult to achieve high performance with Titanium Dioxide and / or Zink Oxide only**
- **Sensory disadvantages due to high load of inorganic particles**

Potential solution:

- **The use of boosters to reach the desired performance with acceptable sensory**
- **Boosters can be scattering particles or film formers, but also non registered UV filters or stabilizers with UV absorber function**

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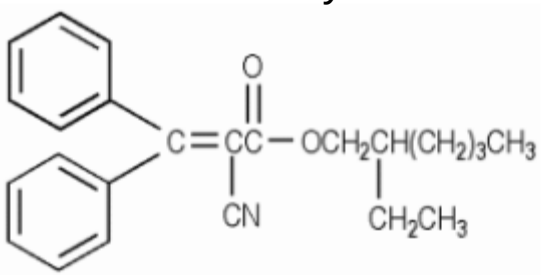
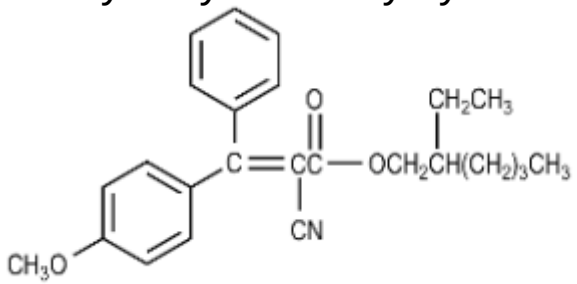
Comparison of Absorption UV Filter vs Stabilizer

Octocrylene

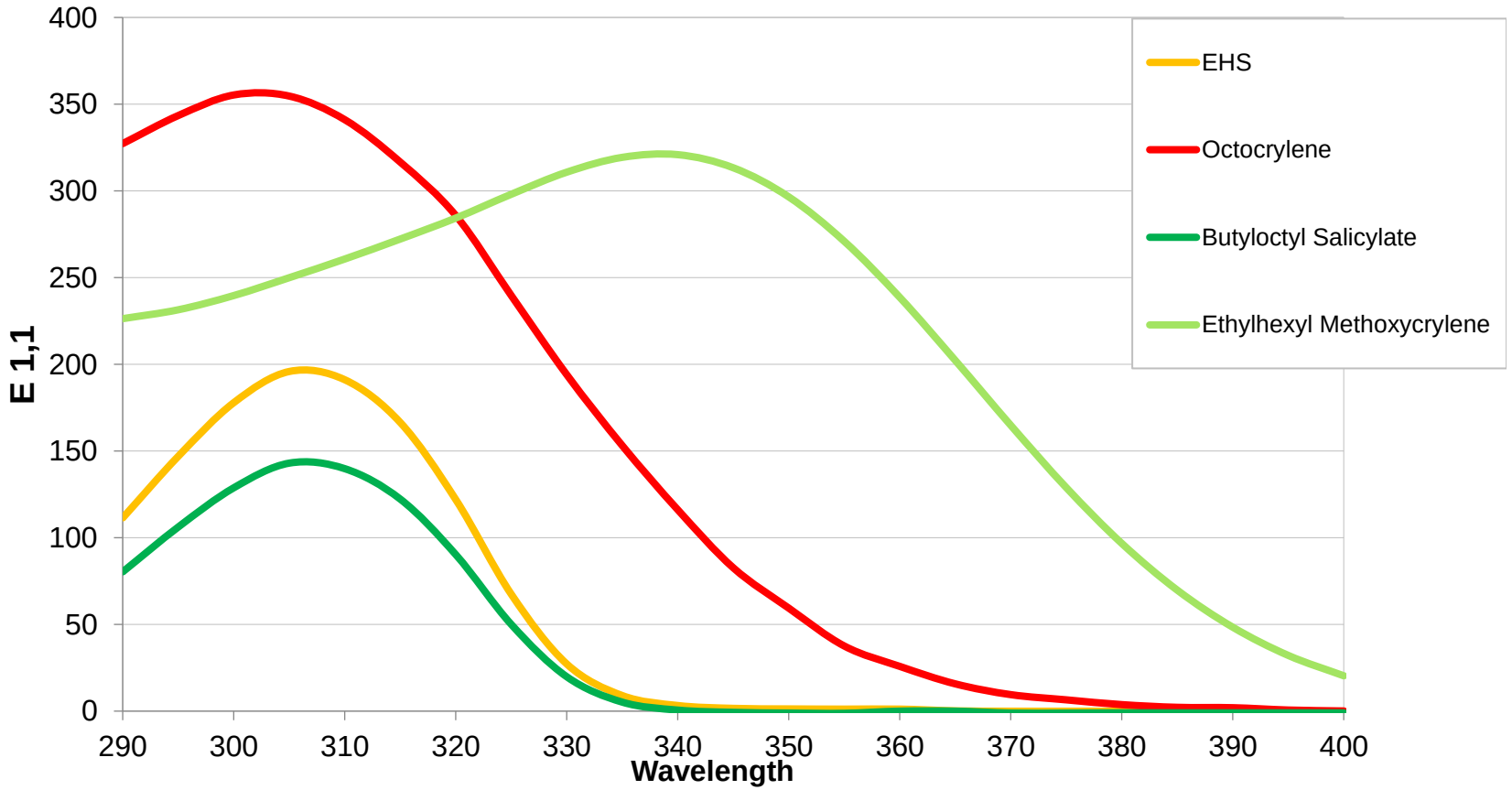


Registered UV filter under focus by US FDA due to MuST data

Ethylhexyl Methoxycrylene



Non registered UV filter no focus as not seen as UV filter



US Market Product Examples

Mineral only sunscreen SPF50

active ingredients:
zinc oxide (24.08%)

inactive ingredients:
water, C12-15 alkyl benzoate, isopropyl palmitate, butyloctyl salicylate, ethylhexyl isononanoate, cetyl PEG/PPG-10/1 dimethicone, propylene glycol, cyclopentasiloxane, bis-octyldodecyl dimer dilinoleate/propanediol copolymer, dimethicone, ethylhexyl methoxycrylene, polyester-27, TEA, Camellia sinensis (leaf) extract*, giant kelp (Macrocystis pyrifera) extract*, sacred lotus (Nelumbo nucifera) extract*, triethoxycaprylylsilane, beeswax, PEG-12 dimethicone crosspolymer, tocopherol, 1,2-hexanediol, caprylyl glycol, sodium chloride
*botanical extracts

100% mineral sunscreen SPF50

active ingredients:
titanium dioxide (4.5%), zinc oxide (6.5%)

inactive ingredients:
water, caprylic/capric triglyceride, isohexadecane, butyloctyl salicylate, octyldodecyl citrate crosspolymer, cetyl PEG/PPG-10/1 dimethicone, lauryl PEG-8 dimethicone, C30-38 olefin/isopropyl maleate/MA copolymer, sodium chloride, ethylhexyl methoxycrylene, dimethicone, phenoxyethanol, caprylyl glycol, PEG-8, alumina, glycerin, sodium citrate, tocopheryl acetate

Mineral sunscreen SPF50

active ingredient:
zinc oxide (12%)

inactive ingredients:
allantoin, bisabolol, butyloctyl salicylate, C12-15 alkyl benzoate, caprylyl glycol, caprylyl methicone, dimethicone, dimethiconol/propylsilsesquioxane /silicate crosspolymer, ethylhexylglycerin, hexylene glycol, isododecane, lauryl PEG-10 tris(trimethylsiloxy) silylethyl dimethicone, lauryl PEG-8 dimethicone, niacinamide, octyldodecyl neopentanoate, PEG-10, phenoxyethanol, polymethylsilsesquioxane, propanediol , sodium chloride, sodium hydroxide, tetrasodium glutamate diacetate, tocopherol (vitamin E), trilaureth-4 phosphate, water

Was this the intension of FDA when asking for additional data to prove safety of organic UV filters?

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“Stabilizers” of Photoinstable UV Filters / EU Cosmetic Directive

- Some ingredients are promoted as Avobenzone photostabilizers by quenching its photoexcited state.
- These ingredients show inherent absorbance exceeding the one of registered UV filters BUT are NOT LISTED in the annex VI of EC regulation and have no SCCS opinion
- This issue of using non official registered UV filters was addressed by several organizations
- Market products had to be removed from the market due to the use of non-registered molecules showing UV absorbance

CHAPTER IV

RESTRICTIONS FOR CERTAIN SUBSTANCES

Article 14

Restrictions for substances listed in the Annexes

1. Without prejudice to Article 3, cosmetic products shall not contain any of the following:

“ …

(e) UV-filters

(i) UV-filters other than those listed in Annex VI and UV-filters which are listed there but not used in accordance with the conditions laid down in that Annex;

(ii) without prejudice to points (b), (c)(i) and (d)(i), substances listed in Annex VI but which are not intended to be used as UV-filters and which are not used in accordance with the conditions laid down in that Annex.

Skin Penetration – Dependencies

What ffects skin penetration?

- Formulation/vehicle which is presented to the skin
- **Lipophilicity of test substance**
- **Molecular weight of test substance**
- **Charge of test substance**
- **Concentration of the test substance**
- Area and time of exposure
- Quality of the outermost layer of the skin
- Thickness and integrity of the *stratum corneum*
- Temperature, blood flow

….

Best possible practice for low skin penetration

Parameter	Rule	Effect
Size	500 Dalton rule	Large molecules don‘t penetrate
Hydrophobicity	Log POW < 1or > 4	Very polar or very unpolar molecules don‘t penetrate
Polarity	Low to no functional groups	No interaction with skin
Melting point	Substances with mp > 50 °C	Low to no penetration

Wiechers, J.W., et al., Predicting Skin Penetration of Actives from Complex Cosmetic Formulations: an Evaluation of Inter Formulation and Inter Active Effects during Formulation Optimization for Transdermal Delivery. International Journal of Cosmetic Science, 2012. 34(6): p. 525-35.
Bos, J.D. and Meinardi. M., The 500 Dalton Rule for the Skin Penetration of Chemical Compounds and Drugs. Experimental Dermatology, 2000. 9(3): p. 165-9.

Physico-chemical Parameters and Dermal Absorption
Examples of Different UV Filters

Filter	Water solubility	Log POW	Melting point °C	Molecular mass (Da)	Dermal Penetration
BP-3 (Oxybenzone)	3 mg/L	**3.45**	62.5	**228**	3-4 %
BMDBM (Avobenzone)	< 1 mg/L	6.1	84	**310**	< 0.5%
TDSA (Ecamsule)	> 600 g/L	**1.35**	255	562	0.16%
OCR (Octocrylene)	<< 1 mg/L	6.1	**< 30**	**361**	0.12%
EHMC (Octinoxate)	<< 1 mg/L	> 6	**< 30**	**290**	4 %
EHS (Ethylhexyl salicylate)	< 1 mg/L	> 6	**< 30**	**250**	1.1 %
MBBT(Bisoctrizole)	<< 1 mg/L	> 12	195	659	< 0.1 %
BEMT (Bemotrizinol)	<< 1 mg/L	>>6	80	627	< 0.1 %
TBPT (Tris-biphenyl Triazine)	<< 1 mg/L	10.4	281	537	< 0.1%
EHT (Ethylhexyl Triazone)	<< 1 mg/L	>>6	130	823	< 0.1%

* dermal penetration ex-vivo human skin / EU registration SCCS dossier

Marked UV filters were part of MUsT Studies

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Comparison Inorganic / Organic UV Filters

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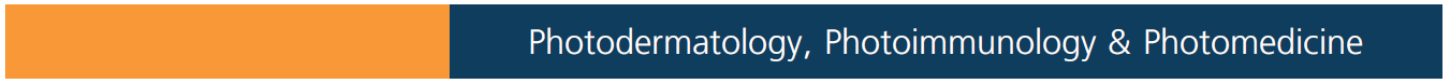
Importance of Scattering Effect

UV Filter Particles provide:

1. Absorption ⇔ approx. **85%** of performance
2. Reflection ⇔ approx. **15%** of performance
3. Multiple Scattering ⇔ **boosting** effect of soluble filters



ORIGINAL ARTICLE

Metal oxide sunscreens protect skin by absorption, not by reflection or scattering

Curtis Cole[1], Thomas Shyr[2] & Hao Ou-Yang[2]

The main function of organic and inorganic particles is identical.

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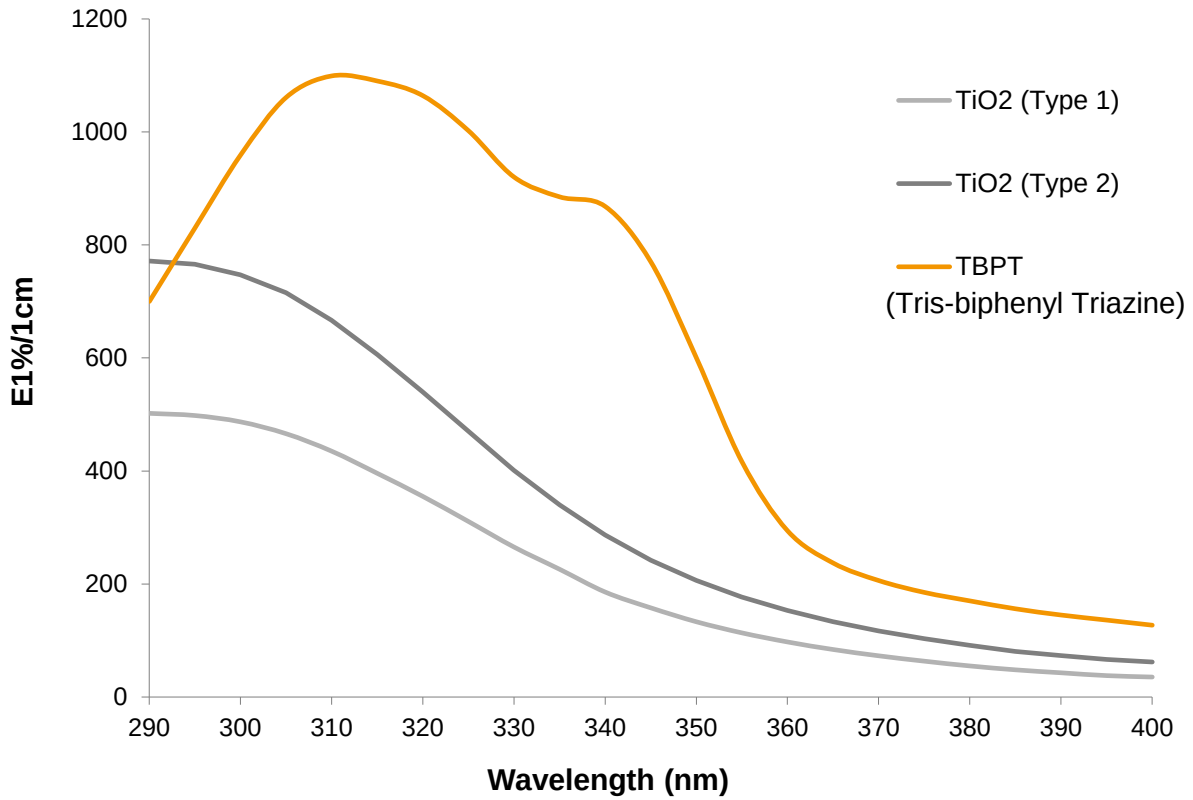
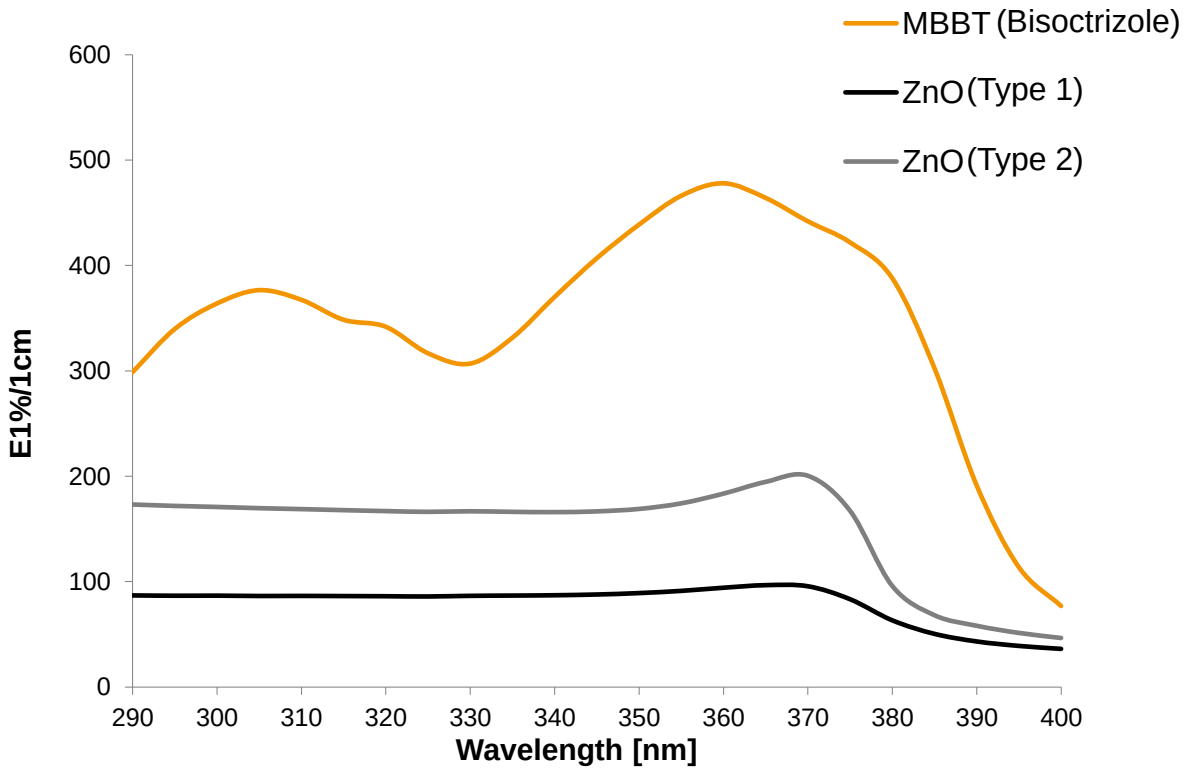
Comparison to Inorganics Particulates UV Filters





Organic particles are 2-3 times more efficient than inorganic particles.

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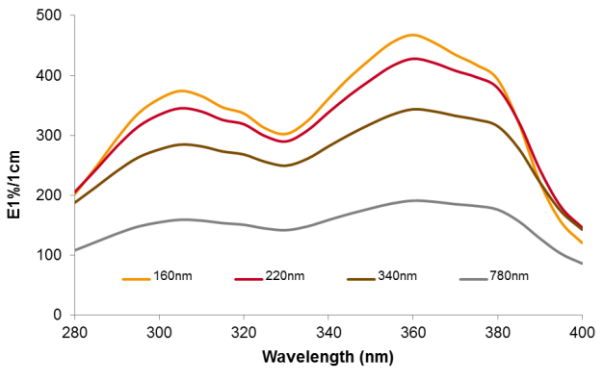
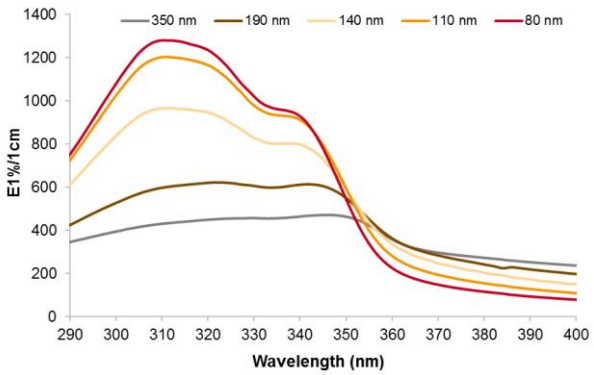
Particulate UV Absorbers

Relevance of Particle Size on Absorption

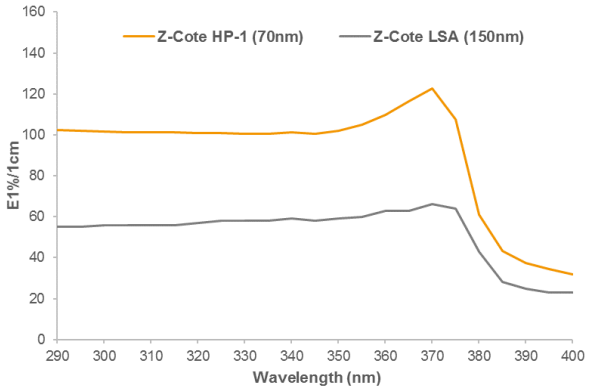
Bisoctrizole (nano)



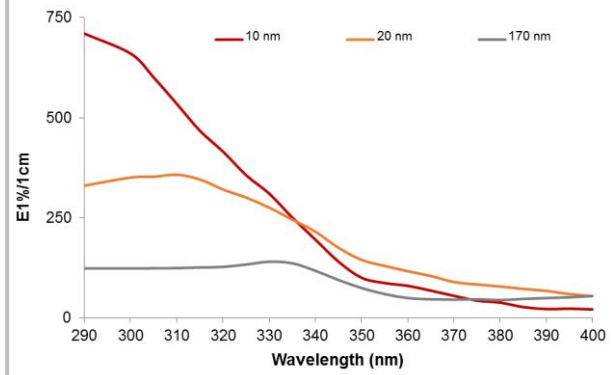
Tris-biphenyl Triazine (nano)



ZnO (nano)



TiO_2 (nano)



Taken from: Technical information sheet of TiO_2 producer

Performance linked to particle size, as smaller the particles as higher the performance.

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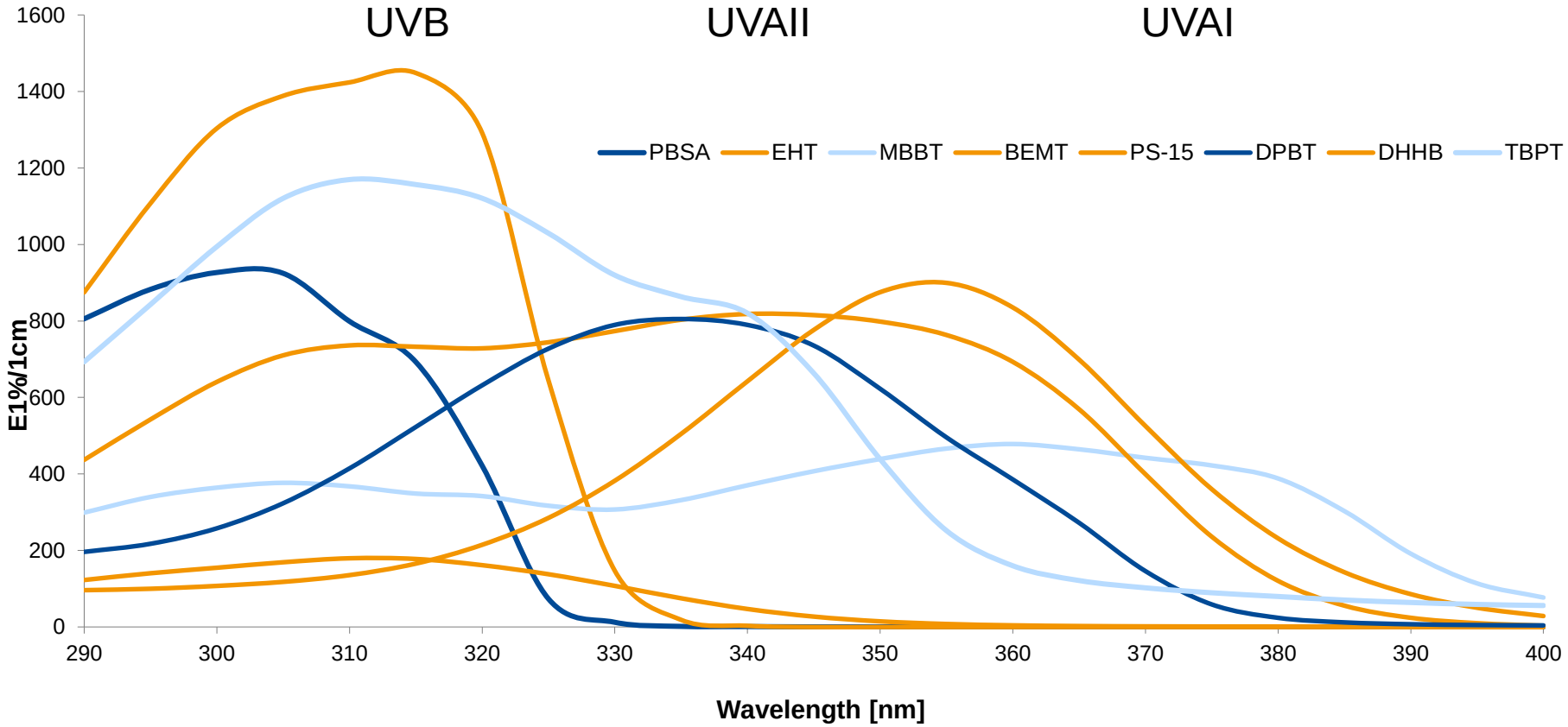
Organic UV Filters Offer More Flexibility



Oils or oil soluble

Water soluble

Water dispersible

As bigger the choice of approved UV filters as better the protection of consumers.

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Environmental Aspects

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Limitation of UV Filter Choice in Some Market Driven by Environmental Aspects

Hawaii US

- Ban of Benzophenone 3 and Ethylhexyl Methoxycinnamate / **Oct 2022 ban of all organic UV filters approved in the US (i.e. Ethylhexyl Salicylate, Homosalate, Ocrocrylene and Butyl methoxydibenzoylmethane**

Palau

- Ban of Benzophenone 3, Ethylhexyl Methoxycinnamate, Octocrylene, 4-Methyl-Benzylidene Camphor

Key West Florida US

- Ban of Benzophenone 3 and Ethylhexyl Methoxycinnamate

US Virgin Islands

- Ban of Benzophenone 3 and Ethylhexyl Methoxycinnamate

Brazil

- Ban of Benzophenone 3, Ethylhexyl Methoxycinnamate, Octocrylene, 4-Methyl-Benzylidene Camphor under discussion

Europe

- Currently 11 UV filters on CoRap list with open requests for further evaluation

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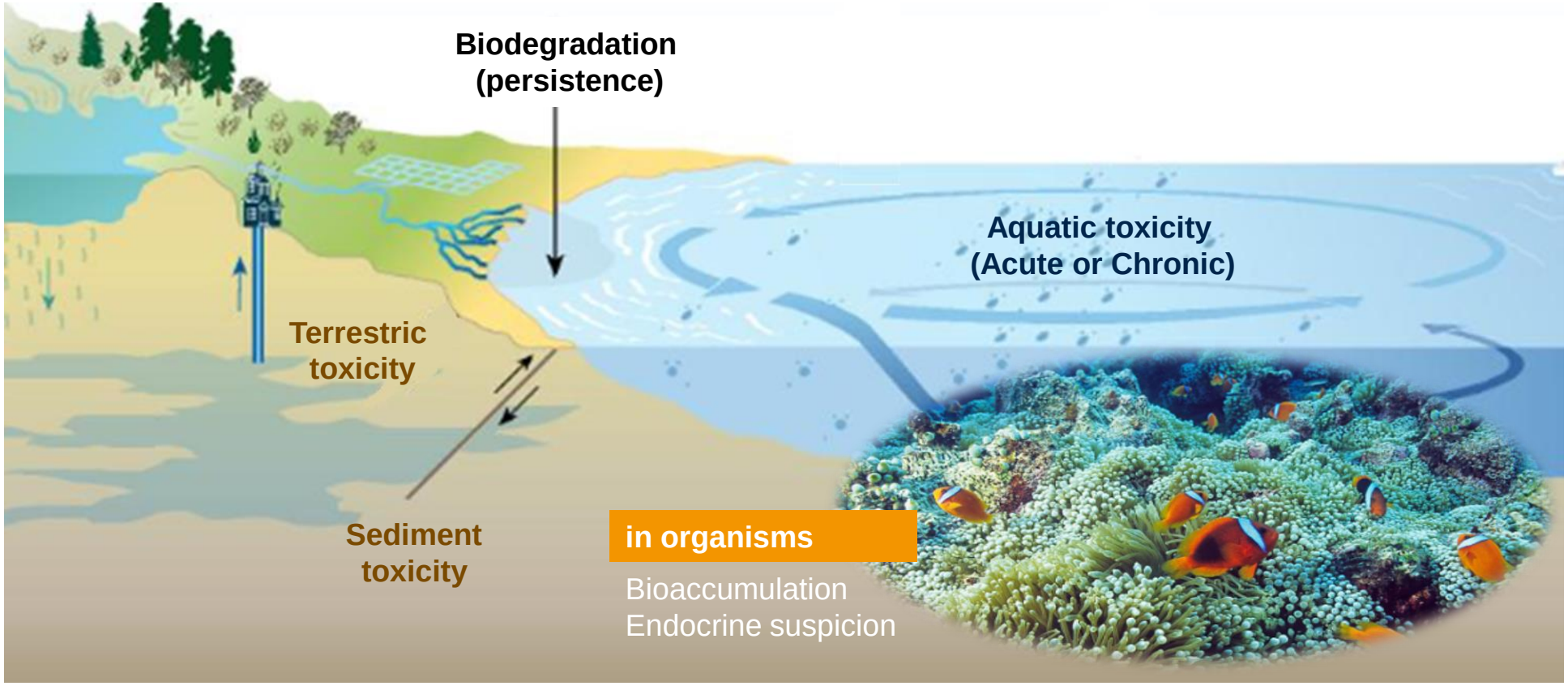
Environmental Effect



Environmental effect of UV filter has to be considered in holistic way.

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Environmental Effect of UV Filters

Different Parameters Are Evaluated to Define Their Environmental Footprint

- Biodegradation
- Acute aquatic toxicity
- Chronic aquatic toxicity
- Bioaccumulation
- Terrestrial toxicity
- Sediment toxicity

Data basis

- Study reports
- ECHA-website
- Literature
- QSAR (quantitative structure-activity relationship models)
- Expert Judgements

The EcoSun Pass is calculated depending on:

- SPF & UVA-PF value
- UV filter type used in formulation
- Quantity of UV filter used

The BASF EcoSun Pass

By considering all these parameters, more eco-compliant sunscreen formulation can be developed.

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Classification of UV Filters for EcoSun Pass

Biodegradation	Factor	Trigger
readily biodegradable	0.25	not P
biodegradable	0.5	not P
partly biodegradable	0.75	potential P (incl. Metabolites)
poorly biodegradable	1	P
Bioaccumulation	**Factor**	**Trigger**
logPow < 4.5	0.25	not P
LogPow >= 4.5	0.5	potential B
BCF < 2000	0.25	B
BCF > 2000 < 5000	0.75	B
BCF >= 5000	1	vB
acute aquatic toxicity	**Factor**	**Trigger**
EC50 > 100 mg/L or > WL	0.25	no C & L
EC50 < 100 > 10 mg/L	0.5	A3
EC50 < 10 > 1 mg/L	0.75	A2
EC50 < 1 mg/L	1	A1
EC50 < 0.1 mg/L	1.25	A1
Chronic aquatic toxicity	**Factor**	**Trigger**
NOEC/EC10 > 10 mg/L	0.25	no C & L
NOEC/EC10 < 10 > 1 mg/L	0.5	"C3"
NOEC/EC10 < 1 > 0.1 mg/L	0.75	"C2"
NOEC/EC10 < 0.1 > 0.01 mg/L	1	"C1"
NOEC/EC10 < 0.01 > 0.001 mg/L	1.25	"C1"

Chronic terrestrial toxicity	Factor
NOEC/EC10 > 1000 mg/kg	0.25
NOEC/EC10 < 1000 > 100 mg/kg	0.5
NOEC/EC10 < 100 > 10 mg/kg	0.75
NOEC/EC10 < 10 > 1 mg/kg	1
NOEC/EC10 < 1 mg/kg	1.25

Sediment toxicity	Factor
NOEC/EC10 > 1000 mg/kg	0.25
NOEC/EC10 < 1000 > 100 mg/kg	0.5
NOEC/EC10 < 100 > 10 mg/kg	0.75
NOEC/EC10 < 10 > 1 mg/kg	1
NOEC/EC10 < 1 mg/kg	1.25

- Each UV filter was ranked according to its ecotox profile.
- Each class of effects was given the same level of concern
- In case no data or no reliable data is available for a specific criteria the maximum value was applied.

Substances with only a minimum data set available may be at the lower end of the ranking, similar to substances with a bad ecotox profile.

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EcoSun Pass Calculation

Sun Care SPF 50

	SPF 50 (UV-DE-15-124-2-2)	SPF 50 (UV-DE-15-124-1-4)	SPF 50 (UV-DE-17-099-2-6)	SPF 50 (UV-DE-15-124-7-3)
	10.0% Octocrylene 5.0% Ethylhexyl Salicylate 3.0% Tris-biphenyl Triazine 4.0% Avobenzone 2.0% Bemotrizinol	10.0% Octinoxate 2.5% Ethylhexyl Triazone 5.0% Ethylhexyl Salicylate 8.0% DHHB 2.0% Bisoctrizole	2.5% Ethylhexyl Triazone 5.0% Ethylhexyl Salicylate 3.0% Tris-biphenyl Triazine 4.0% DHHB 2.0% Bisoctrizole 1.0% Bemotrizinol	2.0% Ethylhexyl Triazone 3.0% Tris-biphenyl Triazine 6.0% Bisoctrizole 2.5% Bemotrizinol
UV Filters concentration	24.0%	27.5%	17.5%	13.5%
SPF in vivo	53	54	53	57
UVA-PF in vitro	23.8	18.2	17.7	18.1
The BASF EcoSun Pass	0 (cut off criteria applied OCR chronic aquatic toxic)	160	228	272

DHHB = Diethylamino Hydroxybenzoyl Hexyl Benzoate

Improvement of environmental compatibility of UV filter system is possible.

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EcoSun Pass in BSSS

FILTER

Region* Europe | Application amount 2 mg/cm² | Show INCI-Name

* Please select the relevant region for your calculation

BROAD-SPECTRUM / UVA I FILTERS

INCI-Name

- **Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine (Tinosorb® S)**
- Bis-Ethylhexyloxyphenol Methoxyphenyl Triazineaq, active amount (Tinosorb® S Lite Aqua)
- Butyl Methoxydibenzoylmethane
- **Diethylamino Hydroxybenzoyl Hexyl Benzoate (Uvinul® A Plus)**
- Disodium Phenyl Dibenzimidazole Tetrasulfonate
- Drometrizole Trisiloxane
- **Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano), active amount (Tinosorb® M)**
- Terephthalylidene Dicamphor Sulfonic Acid
- Zinc Oxide (nano) oil or aq (Z-Cote®)
- Zinc Oxide (nano) oil (Z-Cote® HP1)

FILTER SELECTION

	Max.	
BEMT	10%	2.5
DHHB	10%	4
EHT	5%	3
MBBT (nano)	10%	2
TBPT (nano)	10%	3
Total:		14.5%

SPF (SUN PROTECTION FACTOR)

SPF:	50.7
Rating:	50
Filter Efficiency:	3.5

ECOSUN PASS VALUE

EcoSun Pass Value	260
Rating:	

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Summary

- The requirements in sun protection are globally well harmonized (after US FDA tentative final monograph 2019 is finally implemented)
- UV filters need a dedicated registration and need to be positive listed in most markets
- The choice of UV filters is reduced globally due to open questions of authorities regarding environmental and/or human safety
- The lack of performance is sometimes filled by flexible interpretations of boosters
- Even when all organic UV filters approved in the US showed penetration over the FDA threshold for drugs it does not mean that all UV filters show penetration under MuSt conditions as no data is available for the new UV filters
- Modern organic UV filters are designed for highest UV absorption and best safety profile. They outperform inorganic UV filters
- EcoSun pass offers a possibility to calculate the environmental impact of the UV filter combination used
- Reduced choice of possible UV filters will finally negatively impact the protection of end consumers which results in another health concern

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