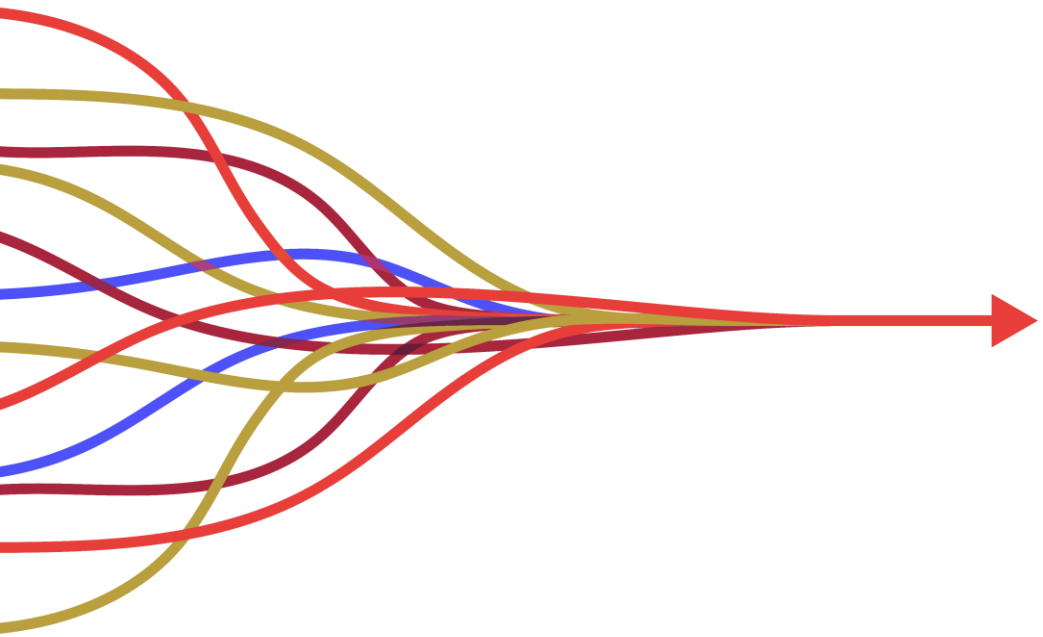


Option to increase the performance of sun care

Milano, 22-23 Novembre

Option to increase the performance of sun care

BASF
We create chemistry

Marcel Schnyder

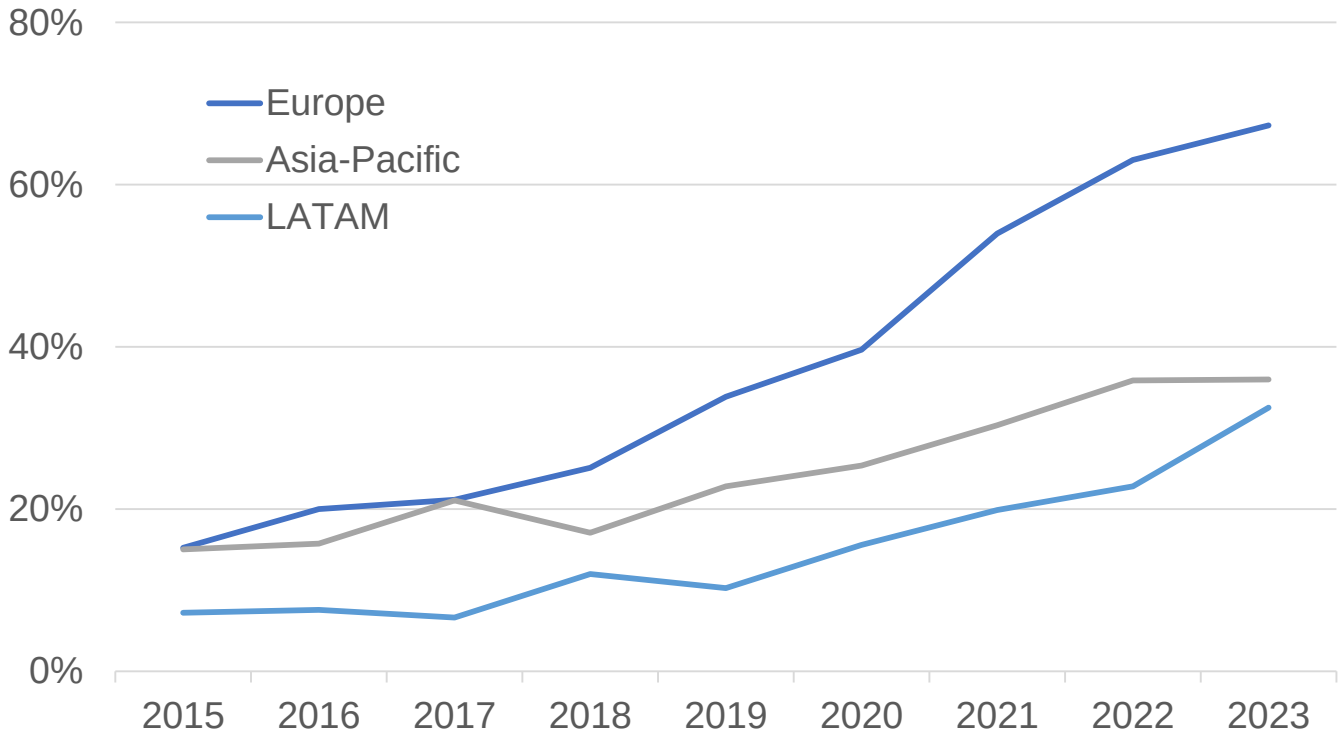
Head of global technical center sun care

UV filters under discussion in EU

Octocrylene	**Human Safety** 2005 – 2021 Potential endocrine disruptor activity; Skin sensitization due to the BP residues |degradation to BP in sun care products | 2020 SCCS opinion: OCR up to 9% in sprays **Environmental Safety** 2012 - 2020 - … ECHA CoRAp List, CLP classification Chronic Aquatic Toxic - C1 
Ethylhexyl Salicylate	**Human Safety** SCCS opinion ongoing **Environmental Safety** 2021-2022 ECHA CoRAp List, CLP classification Chronic Aquatic Toxic - C1 
Homosalate	**Human Safety** 2020 SCCS opinion: HMS up to 0.5% in sun care, 7.34% in face sun care
Ethylhexyl Methoxycinnamate	**Human Safety** 2001 - … Potential Endocrine disruptor activity | SCCS opinion ongoing **Environmental Safety** 2008 EHMC, BP3 causes coral bleaching |2016 ECHA CoRAP list, CLP classification Chronic Aquatic Toxic – C2 |9.23 Request by DE to ECHA to move to Chronic & Acute Aquatic Tox 1 classification (decision earliest end 2024)
Titanium Dioxide	**Human Safety** 2020 category 2 carcinogen classification by inhalation, 2020 EU ban as food additive **Environmental Safety** 2018 ECHA CoRAP list
Zinc Oxide	**Environmental Safety** 2022 ECHA CoRAP list (CLP classification Chronic Aquatic toxic - C1) 

Market reaction
Sun care products without UV filter under discussion

Worldwide, OCR, EHMC free SunCare



Search for products
where Region matches Europe
and Sub-Category matches Sun - Sun/Sunbed Exposure
and Date Published is between Jan xxxx and Dec xxxx

- In each of evaluated regions one can observe significant increase of products without OCR, EHMC
- Trend is the strongest in Europe, followed by Asia-Pacific and LATAM

EcoSun Pass®

an approach to calculate the environmental **impact of SunCare formulations**

The BASF EcoSun Pass

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

The EcoSun Pass® is calculated depending on:

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

- Acute aquatic toxicity
- Chronic aquatic toxicity
- Bio-degradation
- Bio-accumulation
- Endocrine suspicion
- Terrestrial toxicity
- Sediment toxicity

EcoSun Pass® in BASF Sunscreen Simulator

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:	

Consequence of removal of EHMC, HMS, EHS and OCR

Solubility:

Excellent solubility capacity for crystalline UV filters by liquid UV filters

INCI Name	BMDBM	BEMT	EHT	DHHB
Ethylhexyl Salicylate	17,0	20,0	4,0	34,0
Ethylhexyl Methoxycinnamate	22,8	16,3	13,8	39,0
Octocrylene	20,6	7,8	4,2	39,4
Homosalate		15,9	4,0	36.0

Need to be compensated by polar emollients

INCI Name	BMDBM	BEMT	EHT	DHHB
C12-15 Alkyl Benzoate	13,8	11,7	4,4	21,6
Dibutyl Adipate	18,0	10,4	15,9	31,0
Dicaprylyl Carbonate	11,0	8,8	5,9	18,3
2-Propylheptyl Caprylate	11,8	6,3	6,1	11,5

Replacement of oil soluble UV filters by:

- UV filter particles (MBBT (nano), TBPT (nano), TiO2 (nano), ZnO (nano))
- Water soluble UV filters (PBSA, TDSA, DPDT)
- Encapsulated UV filters (BEMT encapsulated)

Photostability:

- A main function of OCR was the efficient stabilization of BMDBM (Avobenzone)
- Alternatives are:
  - Stabilization of Avobenzone with BEMT (1:1 ratio needed)
  - Use of photostable UVA filters (DHHB, BEMT, MBBT, ZnO)
- Lack of photostability results in:
  - Radical formation with an increased irritation potential and destabilization of other ingredients (i.e. even triazines)

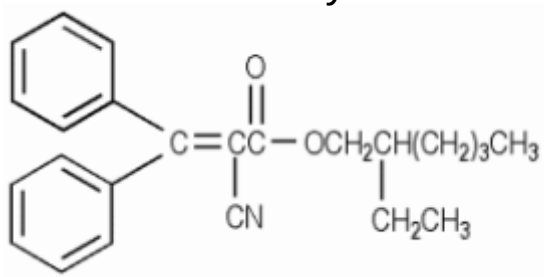
Identical performance for identical cost is not achievable

How to increase the performance of UV filters further?

- Use of stabilizers / boosters?
- Improve film formation?
- Use particles that lengthen the pathway of UV light?

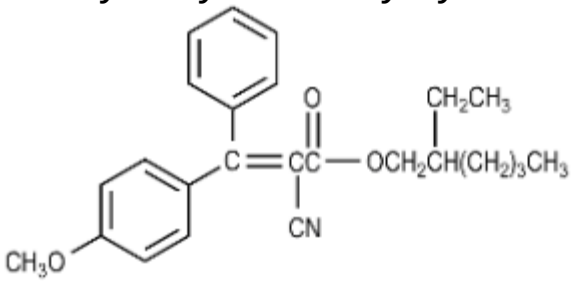
Comparison of Absorption UV filter vs “Stabilizer / Booster”

Octocrylene

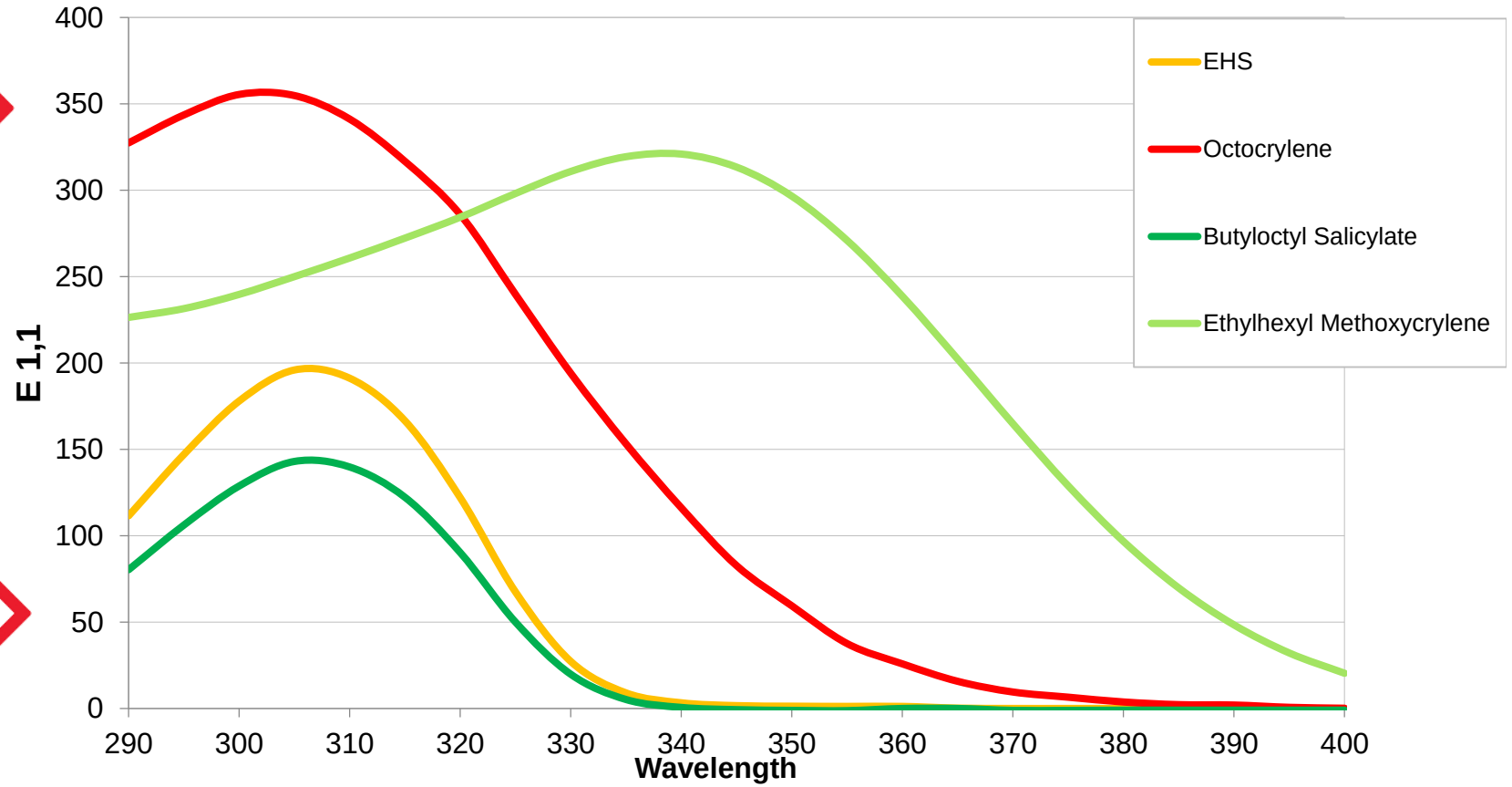


Registered UV filter under focus by US FDA due to MuST data

Ethylhexyl Methoxycrylene



The use of non registered UV filters is not legal in most markets



“Stabilizers” of photoinstable UV filters / EU Cosmetic Regulation

- 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

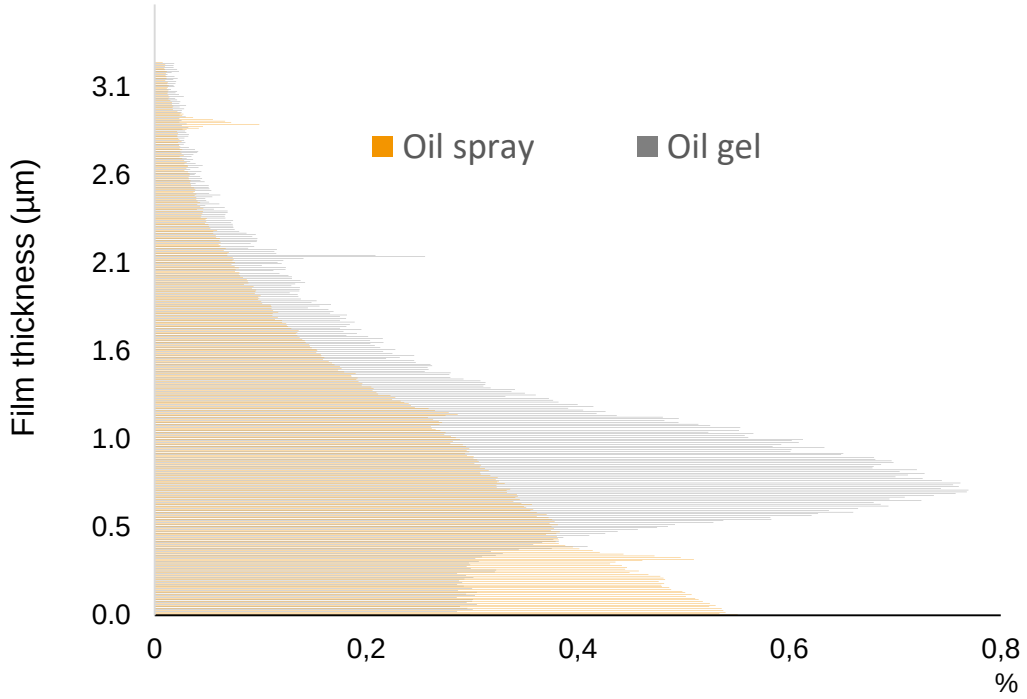
(i) UV-filters other than those listed in Annex VI and UV-filters which are listed there but not used in accordance with the conditions laid down in that Annex;

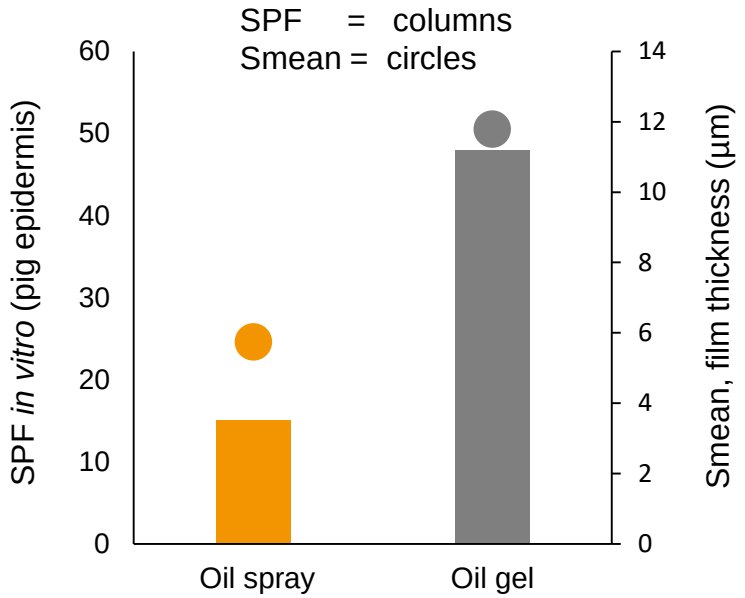
(ii) without prejudice to points (b), (c)(i) and (d)(i), substances listed in Annex VI but which are not intended to be used as UV-filters and which are not used in accordance with the conditions laid down in that Annex.

How to increase the performance of UV filters further?

- Use of stabilizers / boosters?
- Improve film formation?
- Use particles that lengthen the pathway of UV light?

Impact of formulation on film forming and performance





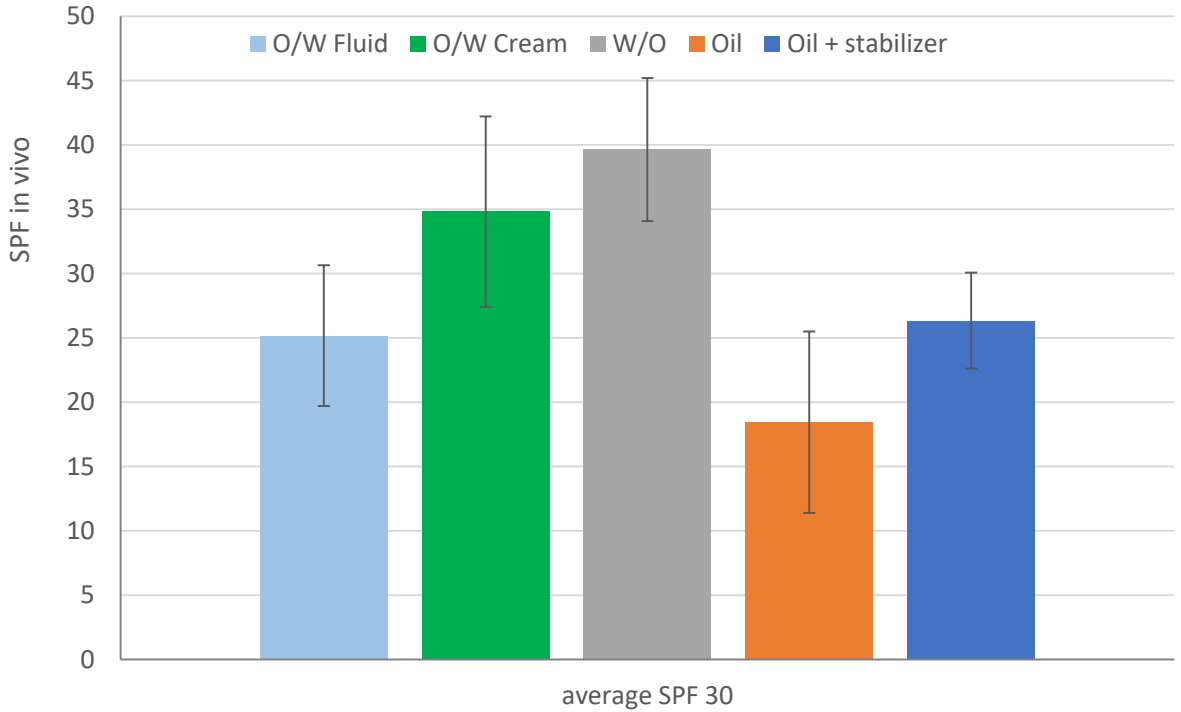
Film thickness frequency distribution differs between both formulations.
Greater proportion of small film thicknesses leads to lower SPF.

Impact of formulation format on performance

Identical UV Filter combination

Abbr.	INCI	SPF expected 30
EHS	*Ethylhexyl Salicylate*	5,00
EHT	*Ethylhexyl Triazone*	2,00
DHHB	*Diethylamino Hydroxybenzoyl Hexyl Benzoate*	5,00
DBT	*Diethylhexyl Butamido Triazone*	2,50
BEMT	*Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine*	2,50

Different in-vivo SPF depending on formulation format



Formulation type has a direct impact on the performance

Improvement of the film formation by synthetic polymer alternatives

INCI
Hydrogenated Castor Oil
Octyldodecanol (and) Irvingia Gabonensis Kernel Butter (and) Hydrogenated Coco-Glycerides
Glyceryl Oleate
Hydrogenated Palm Glyceride
Cetyl Palmitate
Myriystyl Myristate
Hydrogenated Coco-Glycerides
Cera Alba
Sorbitol/Sebacic Acid Copolymer Behenate
Tribehenin
C18-38 Alkyl Hydroxystearoyl Stearate
Glyceryl Rosinate (and) Octyldodecanol
Oleic/linoleic/linolenic Polyglycerdies
Cera Alba (Bees Wax), Sodium Stearoyl Lactylate
Copernicia Cerifera (Carnauba) Wax (and) Oryza Sativa (Rice) Bran Wax
Oryza Sativa Wax
Helianthus Annuus Seed Wax, Ascorbyl Palmitate, Tocopherol, Helianthus Annuus Seed Oil
Carnauba Wax
Lauryl Laurate
Dicocoyl Pentaerythrityl Distearyl Citrate
Bis-Diglyceryl Polyacyladipate-2
Polyhydroxystearic Acid
Sucrose Polystearate, Glyceryl Stearate, Cetearyl Alcohol, Sodium Stearoyl Glutamate, Myristyl Myristate

INCI
Capryloyl Glycerin/Sebacic Acid Copolymer
Trimethylpentanediol/Adipic Acid/Glycerin Crosspolymer
Adipic Acid/Diglycol Crosspolymer
Trimethylpentanediol/Adipic Acid/Glycerin Crosspolymer
Trimethylpentanediol/Adipic Acid Copolymer
Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate (and) Caprylic/Capric Triglyceride
VP/Dimethiconylacrylate/Polycarbamyl Polyglycol Ester
Triacontanyl PVP
Maleated Soybean Oil Glyceryl/Octyldodecanol Esters
Polyglyceryl-3 Stearate/Sebacate Crosspolymer
Hydrolyzed Corn Starch
Corn Starch
Poly C10-30 Alkyl Acrylate
Silica Caprylyl silylate
Silica cetyl Silylate
Microcrystalline Cellulose
Dicaprylyl Carbonate, Stearalkonium Hectorite, Propylene Carbonate
Ethylcellulose
Hydrogenated Castor Oil/Sebacic Acid Copolymer
Hydrogenated Castor Oil/Sebacic Acid Copolymer
Castor Oil/IPDI Copolymer (and) Caprylic/Capric Triglyceride
Caprylic/Capric Triglyceride (and) Castor Oil/IPDI Copolymer

Evaluation of alternatives for currently used synthetic film formers:

- >50 different ingredients have been tested in the identical formulation base

- Evaluation of SPF in-vitro
- Water resistance in-vitro

- The candidates with promising performance have been tested in-vivo

Impact of alternative film formers on performance in-vivo

	Ingredient	INCI	% (by weight)
A	Eumulgin Prisma	Disodium Cetearyl Sulfosuccinate	0,20
	Cutina GMS-SE	Glyceryl Stearate SE	2,00
	Lanette O	Cetearyl Alcohol	1,50
	Cetiol B	Dibutyl Adipate	12,00
	Eutanol G	Octydodecanol	3,00
	Cetiol Sensoft	Propylheptyl Caprylate	2,00
	Cetiol CC	Dicaprylyl Carbonate	5.00
	Cetiol OE	Dicaprylyl Ether	2,00
	Euxyl PE 9010	Phenoxyethanol and Ethylhexylglycerin	1,00
	WR agent		Qs
	Verdessence Xanthan	Xanthan Gum	0,50
	Uvinul A Plus	Diethylamino Hydroxybenzoyl Hexyl Benzoate	6,00
	Uvinul T 150	Ethylhexyl Triazone	3,00
	Tinosorb S	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	2,00
B	**Water**	**Aqua**	Qs
	Glycerine	Glycerin	3,00
C	Eusolex 232	Phenylbenzimidazole Sulfonic Acid	0,70
	Water	Aqua	Qs
	Tris Amino Ultra PC	Tromethamine	Qs
D	Tinosorb A2B	Tris-Biphenyl Triazine (nano), Aqua, Decyl Glucoside, Disodium Phosphate, Butylene Glycol, Xanthan Gum	4,00

Performance	
SPF in silico	43
UVA-PF in silico	22,1

Performance enhancer	SPF in vitro	SPF in vivo	WR in vivo	WR in vitro
Placebo	30	37	27%	60%
Addition of 1% Hydrogenated Castor Oil 1% Carnauba Wax	79	54	40%	76%
Addition of 1% Hydrogenated Castor Oil 1% Tribehenin	27	48	75%	69%
Addition of 3% Dicocoyl Pentaerythrityl Distearyl Citrate	49	60	57%	85%
3% Triacontanyl PVP (Benchmark)	48	44	61%	79%

Dicocoyl Pentaerythrityl Distearyl Citrate (Cutina Shine)
Hydrogenated Castor Oil (Cutina HR)
Triacontanyl PVP (Antaron WP660)

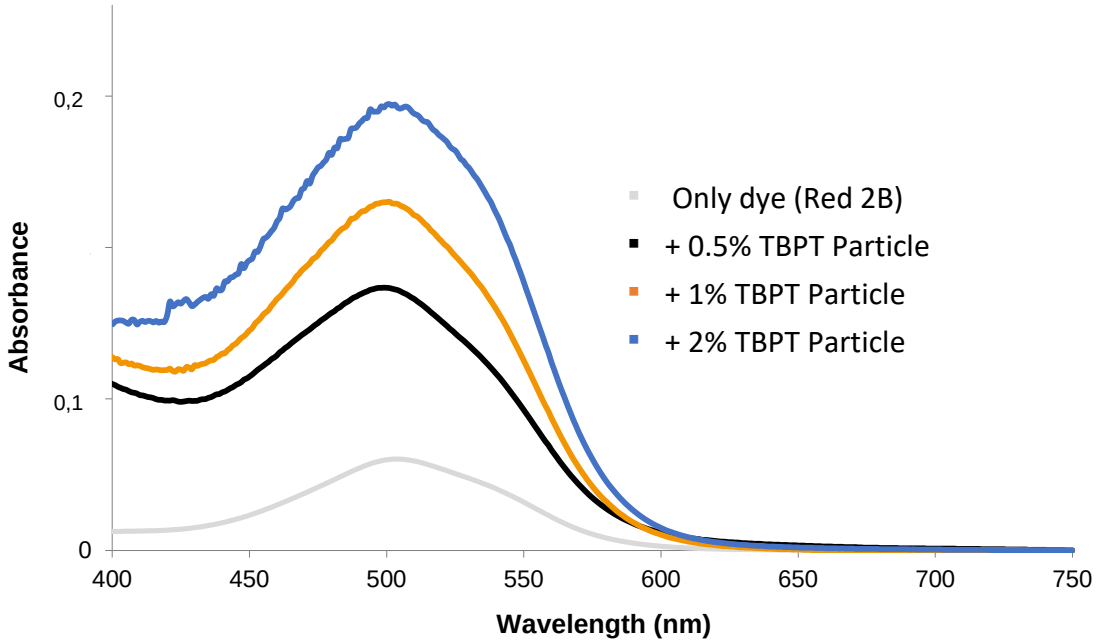
SPF / WR in-vivo tested at identical test institute

How to increase the performance of UV filters further?

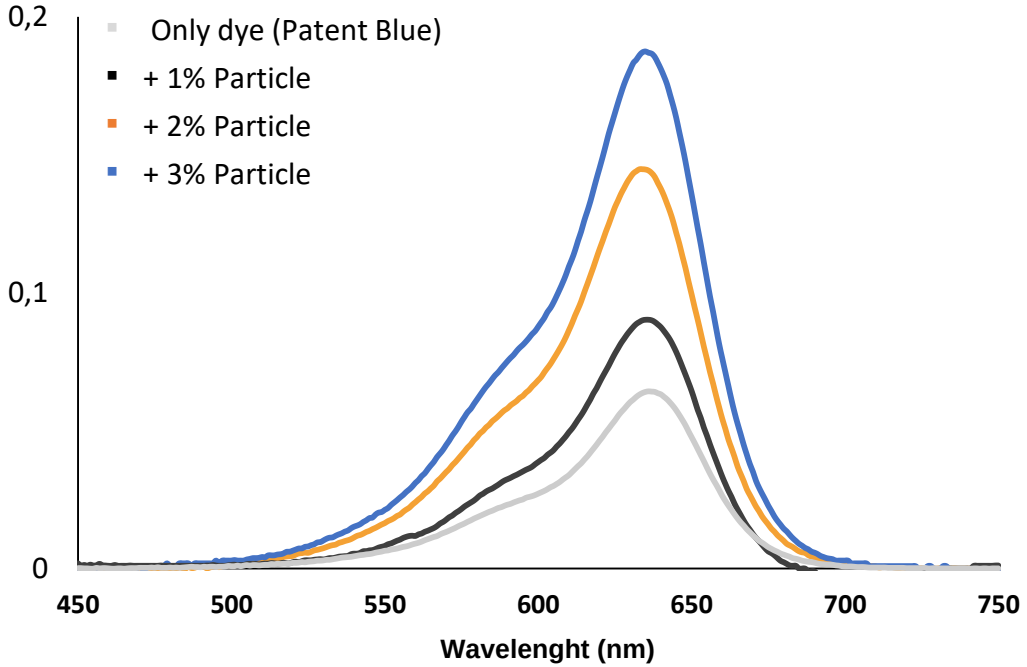
- Use of stabilizers / boosters?
- Improve film formation?
- Use particles that lengthen the pathway of UV light?

Boosting effect of soluble UV filters by particles

UV absorbing particle (example TBPT)



Particle without UV absorber function (Calcium carbonate, Hydroxyapatite)

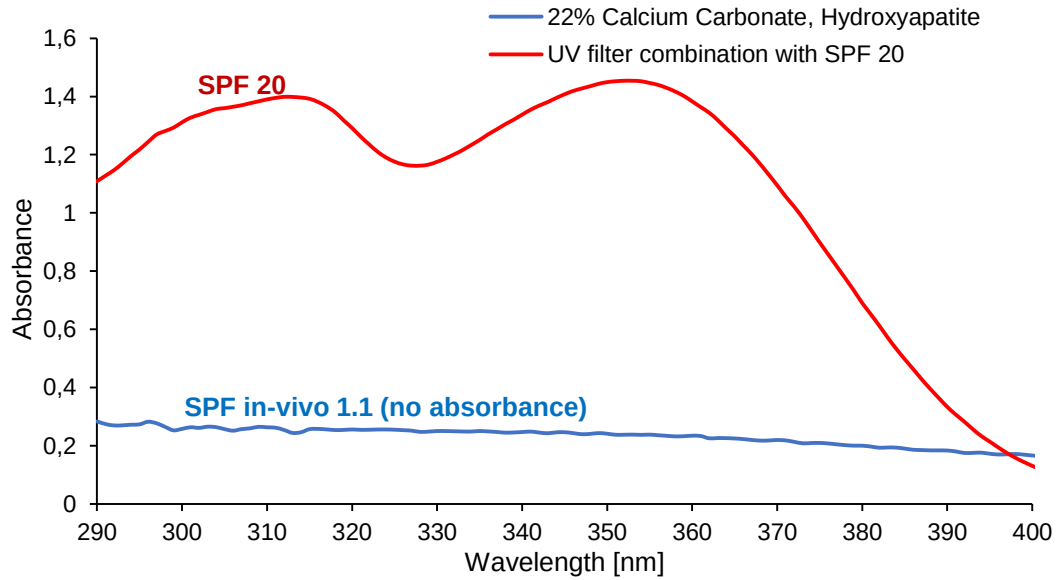


Particles independent whether UV absorbing or not, increase the performance of soluble dyes / UV filters

Calcium Carbonate, Hydroxyapatite particles

SEM images (**10k magnification**)

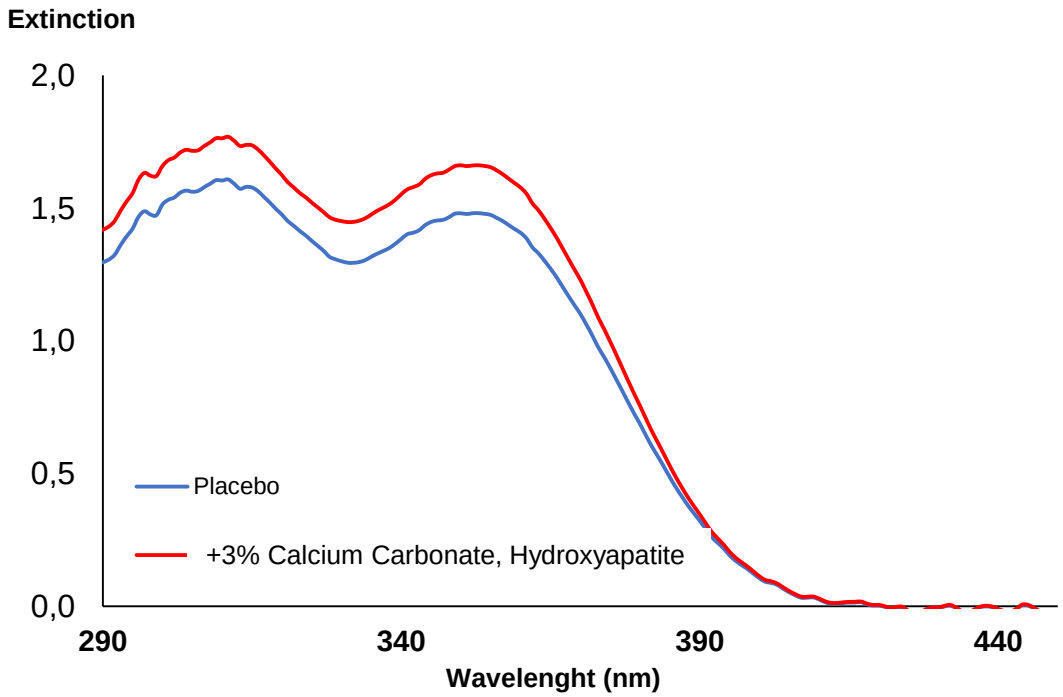
ECO status	Cosmos & Natrue approved
Appearance	Off-white fine powder
Particle size (d50%)	3 - 4 µm
Preservative	Free
Recommended use level	3.0%



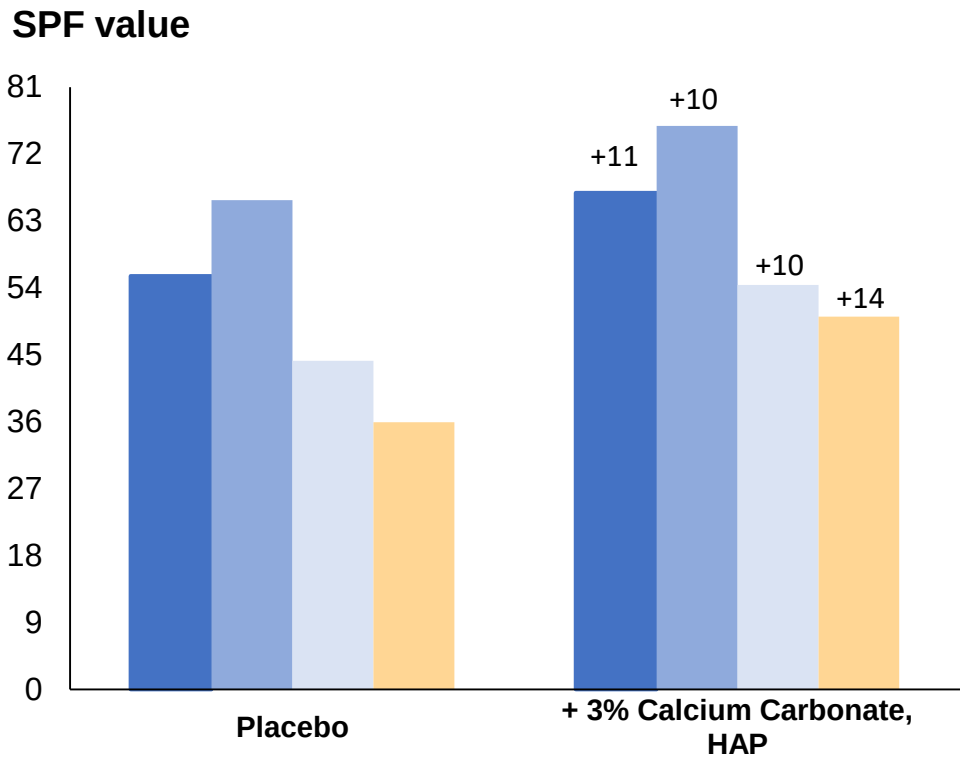
No direct absorption, just boosting of soluble UV filters

Performance with oil and water soluble UV filters

INCI	UV-20-034-21-1	UV-20-034-21-2
Lauryl Glucoside (and) Polyglyceryl-2 Dipolyhydroxystearate (and) Glycerin	1,50	1,50
Sodium Stearoyl Glutamate	1,00	1,00
Dibutyl Adipate	5,00	5,00
Coco -Caprylate	5,00	5,00
Caprylic/Capric Triglyceride	5,00	5,00
Dicaprylyl Ether	2,00	2,00
Phenoxylethanol & Ethylhexylglycerin	1,00	1,00
Ethylhexyl Triazone	**2,00**	**2,00**
Ethylhexyl Salicylate	5,00	5,00
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	**3,00**	**3,00**
Diethylamino Hydroxybenzoyl Hexyl Benzoate	**5,00**	**5,00**
Aqua	42,80	39,80
Glycerin	5,00	5,00
Xanthan Gum	0,10	0,10
Microcrystalline Cellulose	1,00	1,00
Calcium Carbonate, Hydroxyapatite	**-**	**3,00**
Aqua	10,00	10,00
Phenylbenzimidazole Sulfonic Acid	**2,50**	**2,50**
Sodium Hydroxide	1,10	1,10
Undecane Tridecane	2,00	2,00



Performance increase in-vivo SPF



	Placebo	+ 3% Calcium Carbonate, HAP
SPF in vivo Institute 1	55,6	66,8
SPF in vivo Institute 2	65,8	75,8
SPF in vivo Institute 3	44,2	54,4
SPF in vitro	35,9	50,1

- SPF in-vivo increase confirmed by all test institutes
- By addition of 3% Calcium Carbonate, Hydroxyapatite approx. 10 SPF units are added
- Positive impact on sensory (reduction of stickiness and oiliness)
- No white painting effect
- Best performance in combination with soluble UV filters
- More flexibility when liquid UV filters (OCR, EHMC, EHS, HMS) are removed

Summary

- More UV filters are under discussion regarding environmental and human safety (MBC, B3, EHMC, OCR, HMS and EHS)
- With EcoSun Pass a tool based on scientific environmental safety data is available which allows to calculate the environmental impact of UV filter combinations and their improvement
- Solubility and photostability is becoming an issue when liquid UV filters are removed
  - UV Filter particles, encapsulated UV filters or water soluble UV filters can be of help
- To get the maximum performance from the remaining UV filters different approaches can be used
  - The use of not registered UV filters (stabilizers, boosters) is legally not an option
  - Improve of the film formation by traditional synthetic polymers or alternatively hydrophobic waxes or natural polymers is an option
  - The use of particles that lengthen the pathlength of UV light in the sunscreen can help to increase the performance of soluble UV filters

BASF

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BASF has performed no inhalation safety assessments either on the example compositions from the example formulations, on any possible conditions of application of these formulations, or the use of any of the individual ingredients in other personal care formulations designed for similar intended and foreseeable uses.

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