Overview of new UV-filters

Understanding Sunscreens

Uli Osterwalder[1] and Bernd Herzog[2]

1 BASF PCN, Monheim am Rhein, Germany
2 BASF Grenzach GmbH, Grenzach-Wyhlen, Germany

INTENSIVE COURSE IN
DERMATO-COSMETIC SCIENCES
BRUSSELS, 7 - 11 September 2015

Care Creations

Disclosure

Full time employee of BASF PCN, Monheim, Germany

Tinosorb® and Uvinul® are trademarks of UV filters developed and manufactured by BASF

BASF
The Chemical Company

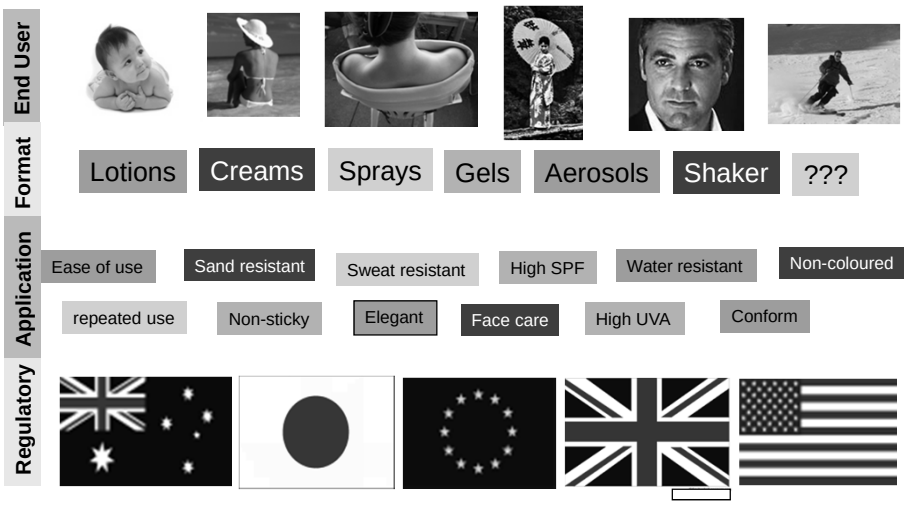
Overview of new UV-filters
Understanding Sunscreens

Contents

Manuscript

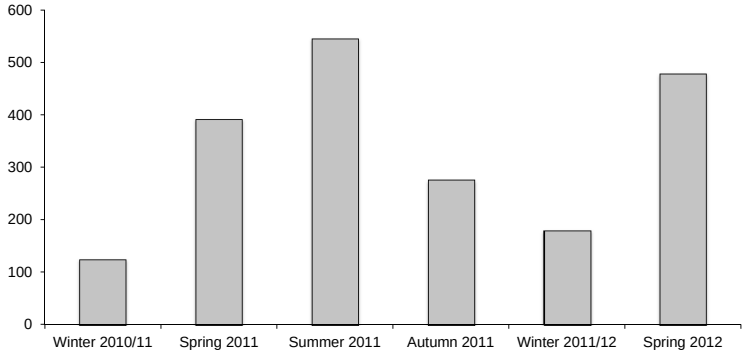
- Background
- New UV Filters
- UVA Protection
- *In silico* assessment
- Outlook
- Conclusion

The many aspects of the Sun Protection market



Sun Protection Products – Market Survey

Number of Launches of Sun Protection Products



Data from Mintel GNPD: http://www.gnpd.com/sinatra/gnpd/frontpage/:

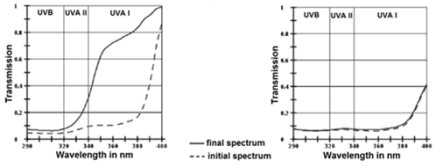
Seasonality of Sun Protection Products

Background
Glossary

- **SPF**: Sun protection factor, a number on a scale for rating the degree of protection provided by sunscreens. It is a ratio of the Minimal Erythemal Dose on product protected skin (MEDp) to the Minimal Erythemal Dose on unprotected skin(MEDu) of the same subject.

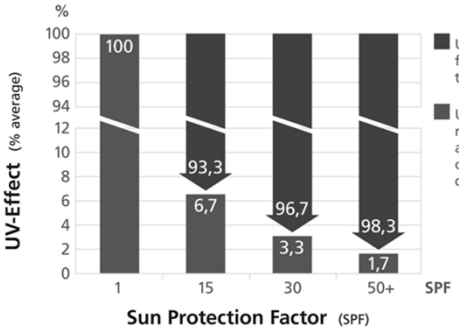
$$SPF = MEDp/MEDu$$

- **Absorption Spectrum and Transmission Spectrum**
- **Critical Wavelength (CW)** It tells consumers how far out (starting at the beginning of the UVB range) a product's 90% "protective umbrella" extends;The FDA has defined "broad spectrum" as products with a CW value of over 370nm.
- **UVA Protection:** UVA-PF/SPF ≥ 1/3(EU)
- ***In vivo, In vitro, In silico***[1]

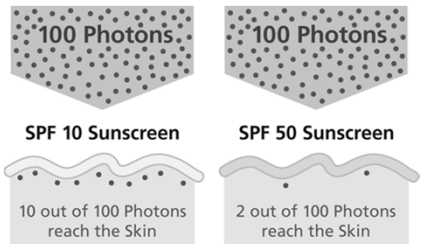


1 Sun Protection In silico with BASF Sunscreen Simulator: www.basf.com/sunscreen-simulator

Background
Glossary – SPF



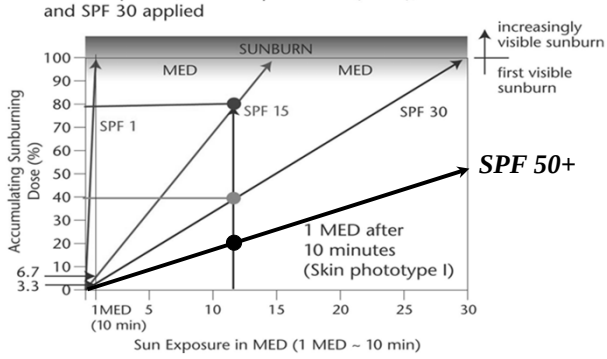
SPF 50 protects 5x better than SPF 10



Animation:
http://www.youtube.com/watch?v=8cc8qRr7oMQ

Background
Glossary – SPF Dynamic View

Accumulating sunburn dose (%) as a function of duration of sun exposure, with: no protection (SPF 1), SPF 15 and SPF 30 applied



Difference: Photo-Aging
Identical twins, Brazil, 73y

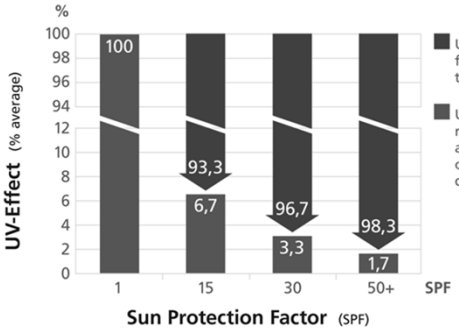
She lived in the country side, did not take any special measures to protect her skin.

(Courtesy of Ph. Masson)

She lived in urban environment, avoided sun when possible, took care of her skin

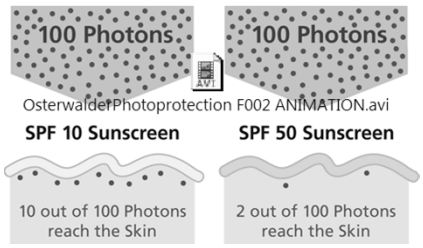
Sun protection and different SPF make the difference.

Background
Glossary – SPF



Animation:
http://www.youtube.com/watch?v=8cc8qRr7oMQ

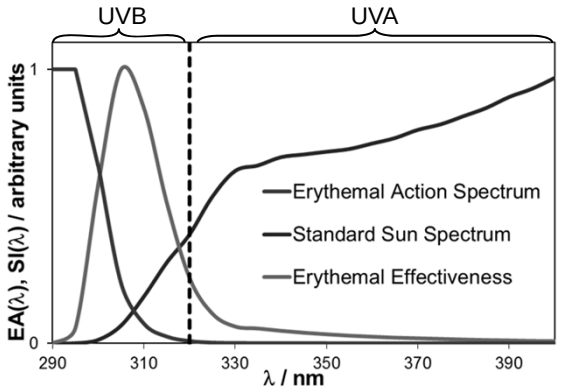
SPF50 protects five times better than SPF10



http://www.youtube.com/watch?v=8cc8qRr7oMQ

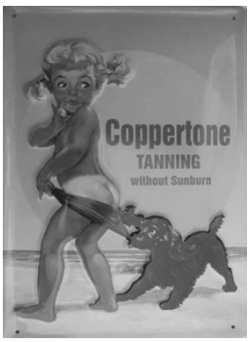
Background
Spectrum of Natural Sunlight

(Courtesy Ch. Surber/SPIRIG)

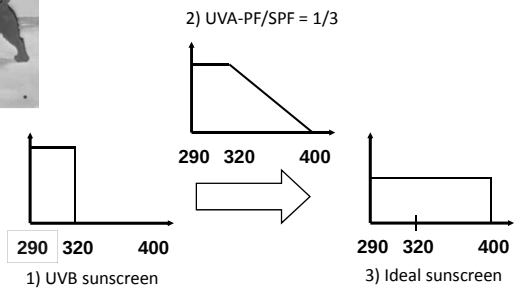


	UVB	UVA
Risk	Sun burn Skin cancer	Sunburn, Skin Cancer Accelerated Skin-Aging

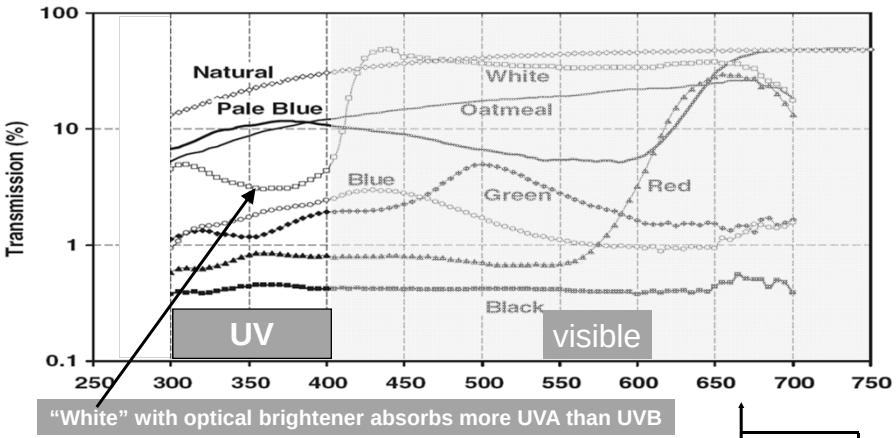
Background
History of Sunscreens



1. "UVB sunscreens" ideally suited for tanning without sunburn.
2. Better UVA protection required.
3. Spectral homeostasis as the ultimate goal.



Background
Textiles provide uniform protection



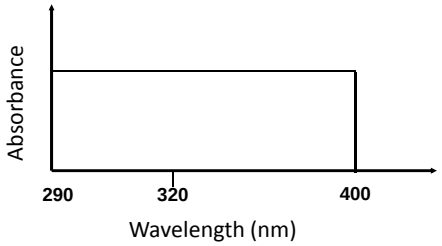
"White" with optical brightener absorbs more UVA than UVB

Spectral Homeostasis = Neutral density filter
= Uniform UVB and UVA protection
= Ideal sunscreen

Background
The Ideal Sunscreen

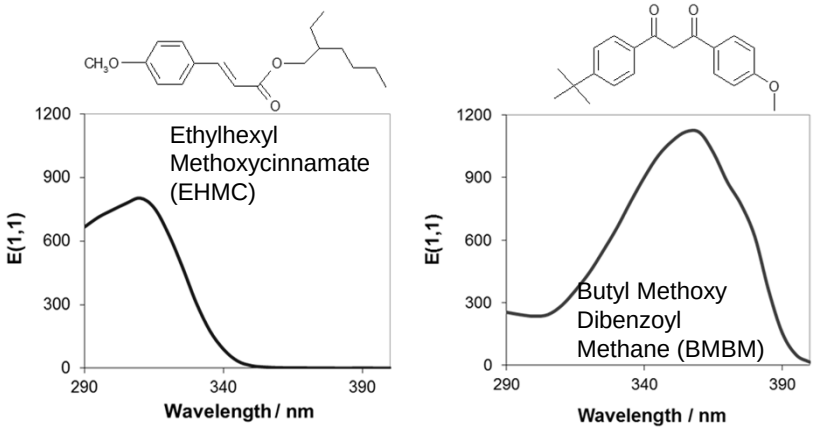
- Protects equally against UVB and UVA
- Reduces the quantity of the UV radiation
- Does not change the quality of the UV radiation that hits the skin

Spectral Homeostasis
= Neutral density filter
= Uniform UVB and UVA protection



The sun and UV radiation are not the problem; too much of them is the problem.
Gavin Greenoak

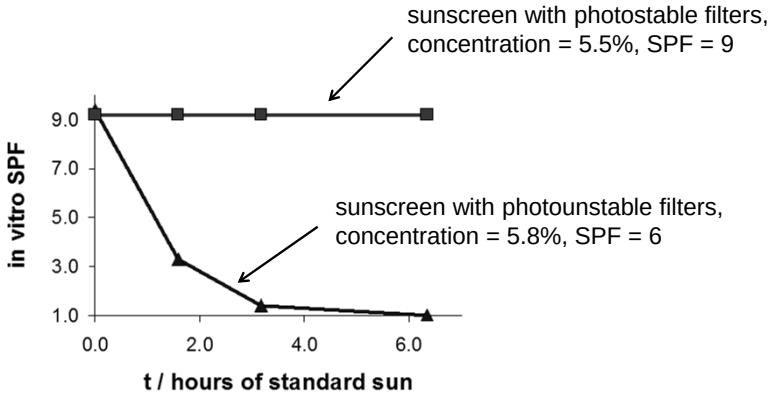
Background
The most widely used absorbers for UVB and UVA



Problem: Combination EHMC/BMBM is not photostable

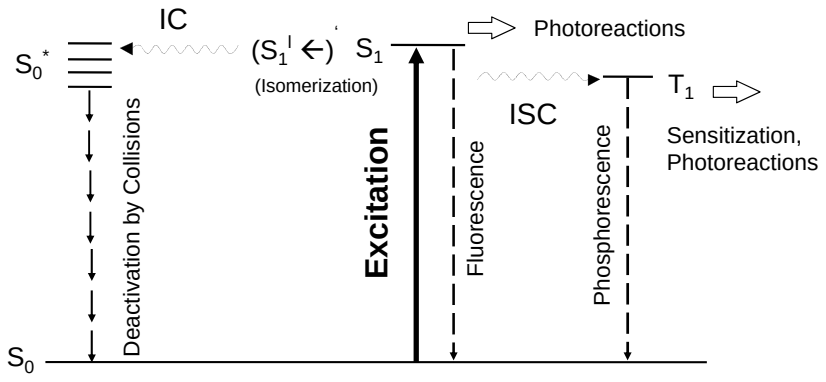
Background
Photostability (related to efficacy and safety)

UV-absorbers are photo-instable, if their chemical structure changes irreversibly upon irradiation.



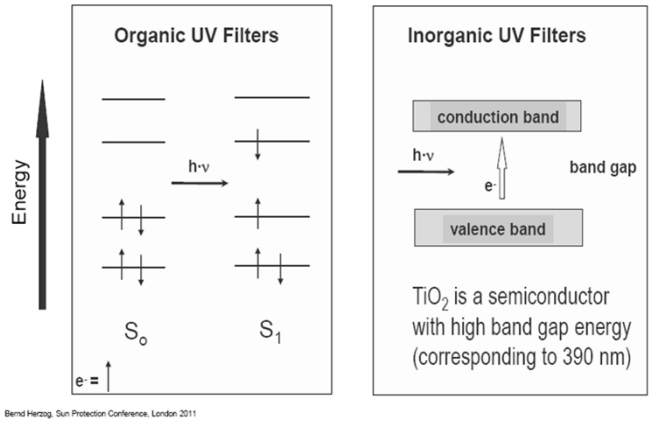
Background
Mechanism of UV Absorption

Processes after excitation in organic molecules



IC: Internal Conversion, ISC: Intersystem Crossing

Background
Mechanism of UV Filter



Bernd Herzog, Sun Protection Conference, London 2011

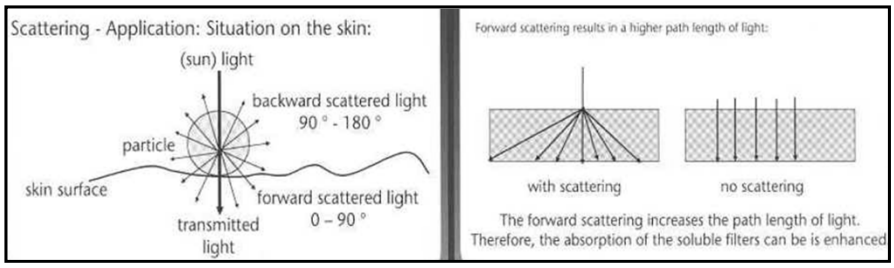
Background
The Four Basic Requirements (4BR)

1. Efficacy	**Sunscreen actives (UV Filters) must absorb UV radiation somewhere between wavelengths of 290 and 400 nm. The specific Extinction E1,1 is a measure of maximum absorption by weight (extrapolated for 1% concentration and 1 cm path length). The value of a UV filter is determined by its contribution to the SPF and UVA-PF.**
2. Safety	**Sunscreen actives should have no adverse effect on humans and the environment. Although direct comparison with a new pharmaceutical drug is not appropriate, the development of a new sunscreen active for global use is highly demanding.**
3. Registration	**In order to exploit the full economic potential of a UV filter, UV absorber manufacturers are aiming for global registration. In Europe, South America, Asia and Africa, where sunscreens are considered as cosmetics, approval is possible within 1-2 years of filing. In Australia, Japan and especially the USA it takes longer.**
4. Patent Freedom	**Patent freedom means the free use of sunscreen actives by any sunscreen manufacturer, i.e. without any uncertainty about whether any third party patent rights are infringed by the use of a particular ingredient.**

Background
Trends for improving photostability

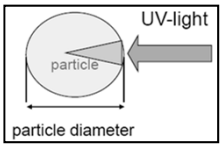
- **Photo-stabilization** of BMBM (Avobenzone) by
  - Octocrylene, MBC, MBBT, BEMT, DHHB or
  - Diethylhexyl 2,6 Naphthalate (DEHN, CORAPAN® TQ)
  - Diethylhexyl Syringylidene Malonate (DESM, Oxynex® ST)
  - Benzotriazolyl Dodecyl p-cresol (TINOGARD® TL)
- **Stabilization of TiO2** (Coating, Manganese)
- **Encapsulation** of UV Filters, e.g. UV-Pearls™ EHMC. Reaction of EHMC with BMBM thus is not possible
- **Use of New UV filters** with **inherently high photostability**

Background
Scattering of Particles (Organic and Inorganic)



Reflection = backwards scattered UVR and Light
= about 5 -15% contribution, depending on particle size

S. Mueller, B. Herzog, J. Giesinger, K. Quass, U. Osterwalder, Micronization as tool in the development of innovative UV filters SÖFW Journal, July 2005

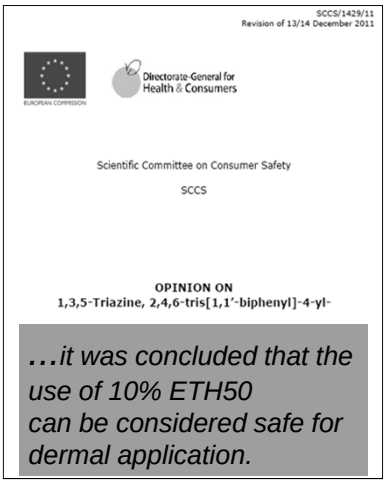


Smaller particles are more efficient in absorption (but less in scattering)
With too big particles, the UV may be blocked inside, and part of the absorbing material will stay unused.

Efficient particles are smaller than 200 nm

First UV Filter on Appendix VI as nano-form:

Tris-Biphenyl Triazine (nano)



SCCS/1429/11
Revision of 13/14 December 2011

Directorate-General for Health & Consumers

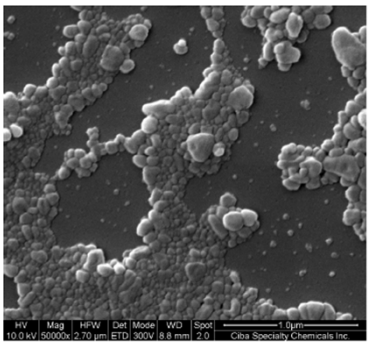
Scientific Committee on Consumer Safety

SCCS

OPINION ON
1,3,5-Triazine, 2,4,6-tris[1,1'-biphenyl]-4-yl-

…it was concluded that the use of 10% ETH50 can be considered safe for dermal application.

INCI: Tris-Biphenyl Triazine (TBPT)
A new microfine organic particles UV filter



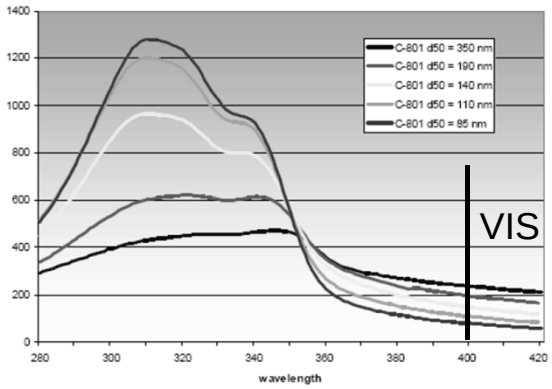
SCCS/1429/11, Revision of 13/14 December 2011

The majority of the particles are below 100 nm, but also structures larger than 100 nm can be observed.

21

New UV Filter: Tris-Biphenyl Triazine (nano), TBPT

Influence of particle size on efficacy



SCCS/1429/11, Revision of 13/14 December 2011

- Absorption in UVAII and UVB region increases with the decreasing particle size
- Larger particles are less efficient and less transparent (i.e.visible)

22

Overview of new UV-filters
Understanding Sunscreens

Contents

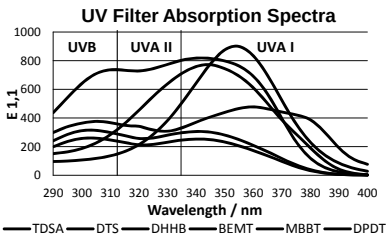
Manuscript

- Background
- New UV Filters
- UVA Protection
- *In silico* assessment
- Outlook
- Conclusion

New UV Filters
Global View

Table 2 Common UV Filters Approved in Australia, Europe, Japan and USA

INCI	COLIPA Nr. [0]	USAN	Trademark	INCI Abbr.	Concentration Limits in Sunscreen (%)			
					AU S	EU	JP	U SA
Broad- Spectrum and UVAI (340-400nm)								
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	S 81	Bemotrizinol	Tinosorb® S	BEMT	10	10	3	[1]
Butyl Methoxydibenzoylmethane	S 66	Avobenzone	Parsol 1789	BMBM	5	5	10	3
Diethylamino Hydroxybenzoyl Hexyl Benzoate	S 83		Uvinul® A Plus	DHHB	10	10	10	-
Disodium Phenyl Dibenzimidazole Tetrasulfonate	S 80	Bisdisulizole Disodium	Neo Heliopan AP	DPDT	10	10	-	-
Drometrizole Trisiloxane	S 73	-	Mexoryl XL	DTS	15	15	-	-
Menthyl Anthranilate	-	Meradimate		MA	5			5
Methylene Bis-Benzotriazolyl Tetramethylbutylphenol	S 79	Bisoctrizole	Tinosorb M (active)	MBBT	10	10	10	[1]
Terephthalylidene Dicamphor Sulfonic Acid	S 71	Ecamsule	Mexoryl SX	TDSA	10	10	10	[1, 2]
Zinc Oxide	S 76	Zinc Oxide	ZnO (Nanox)	ZnO	no limit	[3]	no limit	25
UVB (290-320nm) and UVAII (320-340nm)								
4-Methylbenzylidene Camphor	S 60	Enzacamene	Eusolex 6300	MBC	4	4	-	[1]
Benzophenone-3	S 38	Oxybenzone		BP3	10	10	5	6
Benzophenone-4	S 40	Sulisobenzone	Uvinul MS40	BP4	10	5	10	10
Polysilicone-15	S 74	-	Parsol SLX	PS15	10	10	10	-
Diethylhexyl Butamido Triazone	S 78	-	Uvasorb HEB	DBT	-	10	-	[1]
Ethylhexyl Dimethyl PABA	S 08	Padimate O	Eusolex 6007	EHDP	8	8 [4]	10	8
Ethylhexyl Methoxycinnamate	S 28	Octinoxate	Uvinul MC 80	EHMC	10	10	20	7.5
Ethylhexyl Salicylate	S 13	Octisalate	Neo Heliopan OS	EHS	5	5	10	5
Ethylhexyl Triazone	S 69	Octyltriazone	Uvinul T 150	EHT	5	5	3	[1]
Homomenthyl Salicylate	S 12	Homosalate	Eusolex HMS	HMS	15	10	10	15
Isoamyl p-Methoxycinnamate	S 27	Amiloxate	Neo Heliopan E1000	IMC	10	10	-	[1]
Octocrylene	S 32	Octocrylene	Uvinul N 539 T	OCR	10	10	10	10
Phenylbenzimidazole Sulfonic Acid	S 45	Ensulizole	Eusolex 232	PBSA	4	8	3	4
Titanium Dioxide	S 75	Titanium Dioxide	Eusolex T2000	TIO2	25	25	no limit	25
Tris Biphenyl Triazine	(S 84)	-	Tinosorb A2B	TBPT	-	10	-	-



[0] Cosmetics Europe (former COLIPA): http://www.cosmeticseurope.eu/, oeder number shows chronology of UV filter development
[1] Time and Extent Application (TEA), Proposed Rule on FDA approval expected 2013
[2] Approved in certain formulations up to 3% via New Drug Application (NDA) Route
[3] Currently under EU-review by Scientific Committee on Consumer Safety (SCCS), opinion on non-nano grade positive
[4] Not being supported in the EU and may be delisted

New UV Filters
Spectral Properties: UVB-absorbers

S 74 (BMP)

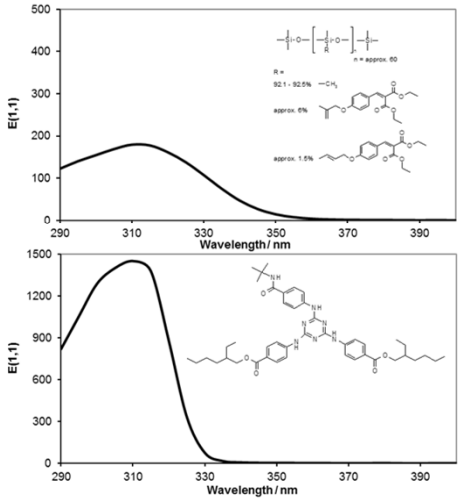
Benzylidene Malonate Polysiloxane (Polysilicone 15)

→ Oil-soluble

S 78 (DBT)

Diethylhexylbutamido Triazone

→ Oil-soluble



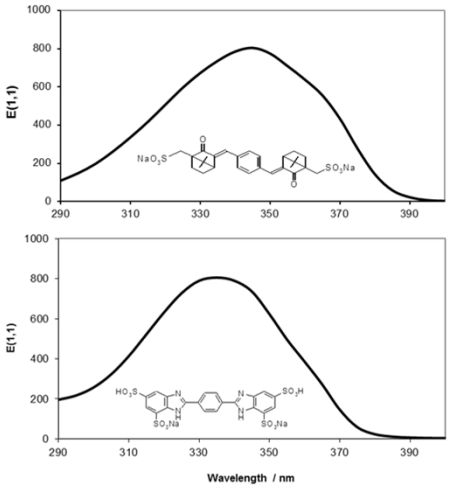
New UV Filters
Spectral Properties: UVA-absorbers

S 71 (TDSA)
Terephthalidene Dicamphor Sulfonic Acid

→ Water-soluble

S 80 (DPDT)
Disodium Phenyl Dibenzimidazole Tetrasulfonate

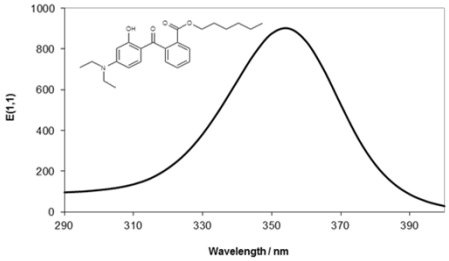
→ Water-soluble



New UV Filters
Spectral Properties: UVA-absorbers

S 83 (DHHB)
Diethylamino Hydroxylbenzoyl Hexyl Benzoate

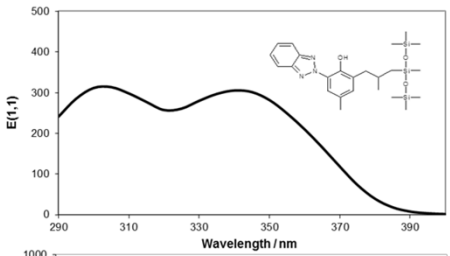
→ Oil-soluble



New UV Filters
Spectral Properties: Broad-Spectrum-absorbers

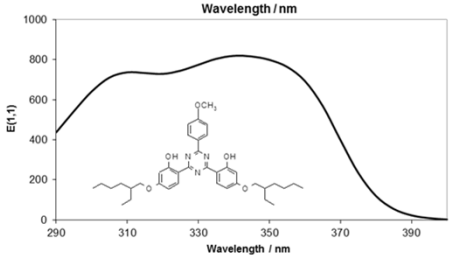
S 73 (DTS)
Drometrizole Trisiloxane

→ Oil-soluble



S 81 (BEMT)
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine

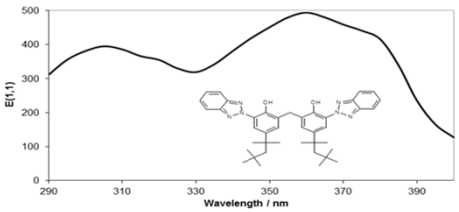
→ Oil-soluble



New UV Filters
Spectral Properties: Broad-Spectrum-absorbers

S 79 (MBBT)
Methylene Bis-Benzo-triazolyl Tetramethyl-butyl-phenol (nano)

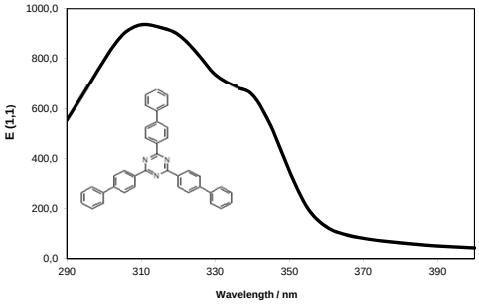
→ Water-dispersible



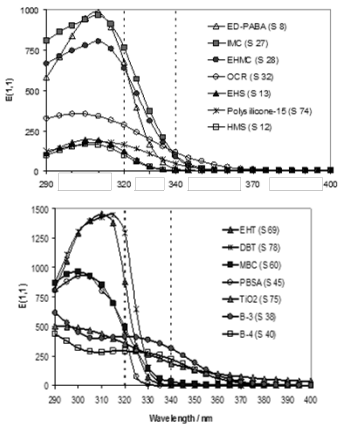
S 84 (TBPT)
Tris-Biphenyl Triazine (nano)

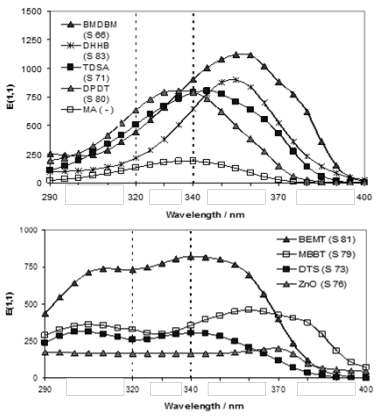
→ Water-dispersible

(Annex VI since 8.8. 2014)



Sunscreen Actives (Summary)

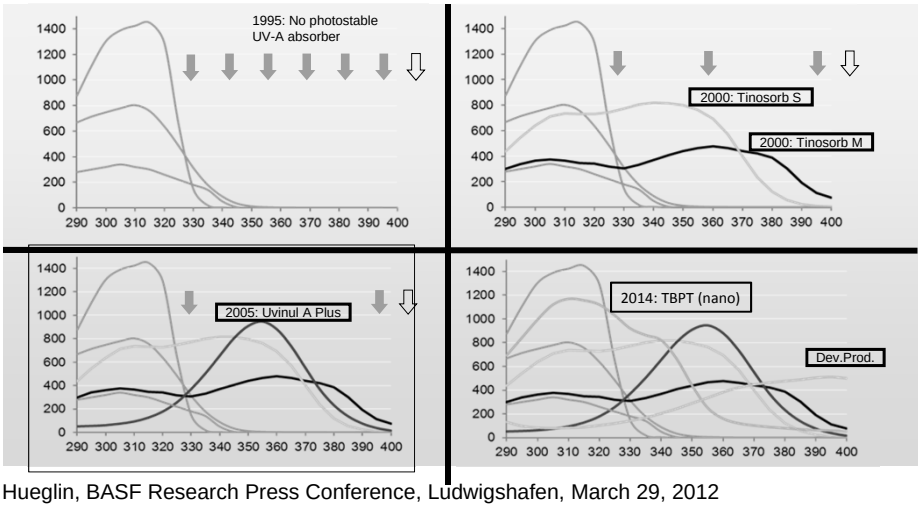




Osterwalder U and Herzog B, Chemistry and Properties of Organic and Inorganic UV Filters, Clinical Guide to Sunscreens and Photoprotection, edited by HW Lim and ZD Draelos, informa healthcare, New York 2009

BASF's approach:

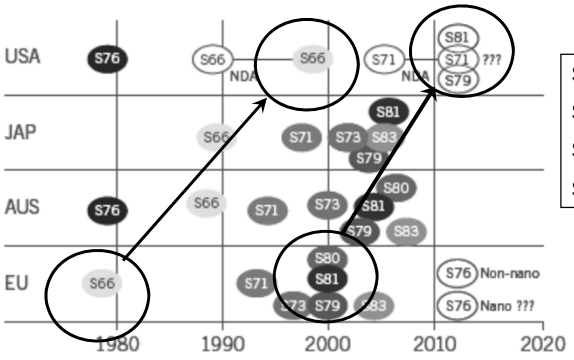
"Closing the gaps" in UV-A protection



Hueglin, BASF Research Press Conference, Ludwigshafen, March 29, 2012

UV Filters

Time frame to achieve global approval (especially USA)



S66 avobenzone
S71 ecamsule
S79 bisoctrizole
S81 bemotrizinol

Unfilled circles = pending

Hopefully it will take less than 20 years to achieve full global approval for the new broad-spectrum UV filters

UV Filters
Risk Assessment - Humans and Environment

RISK = EXPOSURE x HAZARD

- **Exposure: Humans, Environment**
  (defined by application, use pattern,
  physico-chemical properties, specific preparations ...)
  ⇨ can be modified

- **Hazard:**
  (defined by toxicologial / ecotoxicological profile)
  ⇨ cannot be modified ⇨ inherent properties

Potential risks should be compared with benefits of sun protection

UV Filters
EU: Safety Requirements

Data on the compound, specification, analytical methods, stability and photostability, and safety include:

Dossier preparation

- Acute oral toxicity
- Acute dermal toxicity
- Repeated dose oral toxicity
- Irritation (skin)
- Irritation (mucous membranes)
- Sensitisation
- Dermal absorption
- Teratogenicity
- Mutagenicity/Genotoxicity
- Phototoxicity; Photoallergenicity
- Photomutagenicity
- Safety evaluation
- Additional studies depending upon the results of the dermal absorption test and the outcome of the other studies

Note: endocrine effects are evaluated in vivo from affected systems; e.g., in Teratology study sex ratio or ano-genital distance.

approx. 2 years

costs 350.000 to 400.000 € per compound

Approval process

- Application for inclusion in Annex VII of Dir. 76/768 EEC (2013-07:Annex VI)
- Safety evaluation by SCCP (Scientific Committee on Consumers Products)
- Ad-hoc Working Party proposes new Adaptation to Technical Progress (ATP) Directive
- Committee of ATP agrees
- Publication in Official Journal

1-2 years

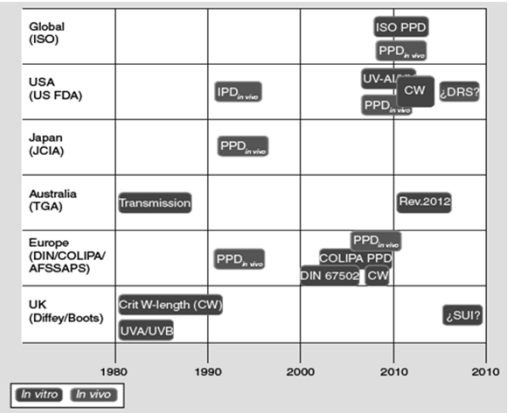
Overview of new UV-filters
Understanding Sunscreens

Contents

Manuscript

- Background
- New UV Filters
- UVA Protection
- *In silico* assessment
- Outlook
- Conclusion

UVA Protection
Evolution of UVA-Methods



Osterwalder et al., Evolution of UVA Protection, Cosm Manuf Yearbook 2010

Trend towards *in vitro* testing for UVA protection.

UVA Protection (e.g. @ SPF 15)

Critical Wavelength 370 nm is not enough

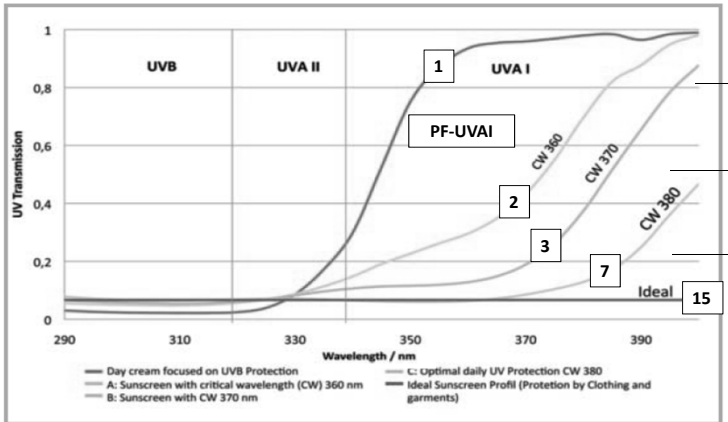


Fig. 8 UV protection profile of optimal daily care compared with other day creams/ sunscreens (All SPF 15) (18)

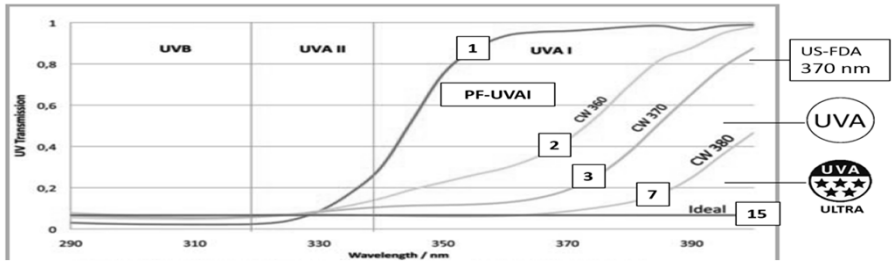
Osterwalder U, Herzog B, Wang SQ, Expert Rev. Dermatol. 6 (5), 479-491 (2011)

37

UVA Protection (e.g. @ SPF 15)

Critical Wavelength 370 nm is not enough (ca. UVA-PF 3)

Sunscreen SPF 15	SPF	CW (nm)	Transmission (%) UVB/UVAII	Transmission (%) UVAI	Protection Factor UVAI (= 1/T)	Normalized Transmitted UV Dose at 1 MED
UVB biased	15	333	2.9 / 17	92	1	8.0
A	15	360	5.6 / 11	56	2	5.3
B	15	370	6.5 / 9.2	34	3	3.6
C	15	380	6.8 / 6.7	14	7	1.6
Ideal Profile (Garments)	15	389 (max.)	6.7 / 6.7	6.7	15	1.0 (7.9 J/cm2)



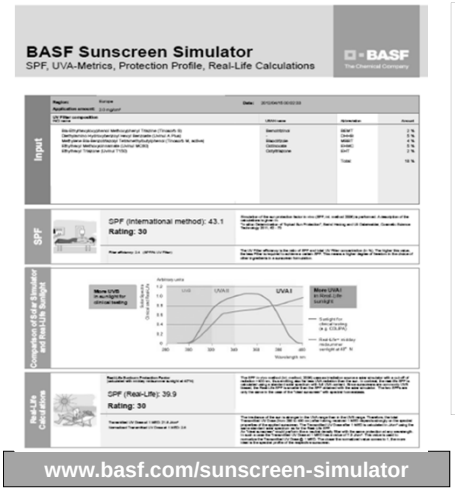
Overview of new UV-filters
Understanding Sunscreens

Contents

Manuscript

- Background
- New UV Filters
- UVA Protection
- *In silico* assessment
- Outlook
- Conclusion

In Silico Assessment
BASF Sunscreen Simulator - the innovation tool for formulators



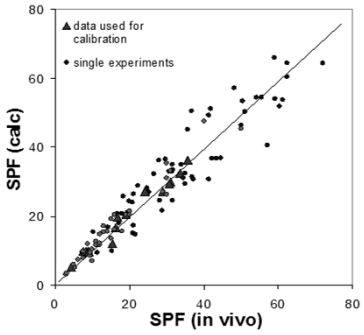
www.basf.com/sunscreen-simulator

Reducing time to market by rapid prototyping:

- Explore formulation space to develop different sunscreens
- Check UVA protection metrics of all major regions
- Check photostability and closeness to ideal sunscreen
- Test *in silico* before expensive *in vitro* or *in vivo* testing

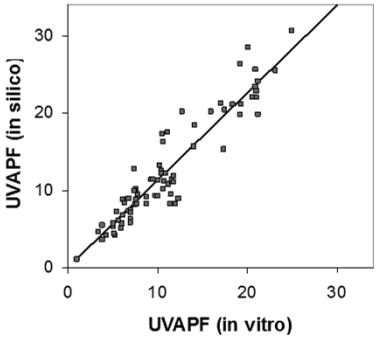
In Silico Assessment
Reliability of BASF Sunscreen Simulator

SPF



n = 110, slope = 0.98, r = 0.958

UVA-PF



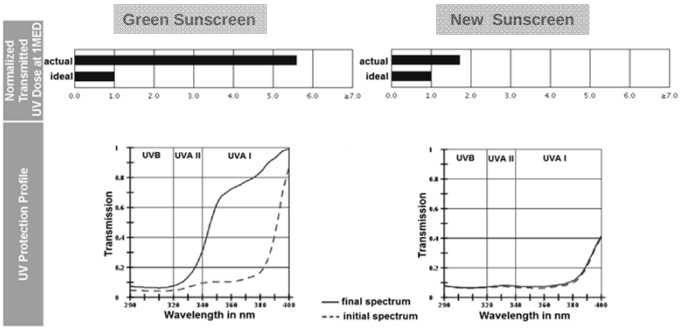
n = 81, slope = 1.13, r = 0.948

In silico does not replace actual formulation work and *in vivo* SPF testing of the final product

In Silico Assessment
Example by using BASF Sunscreen Simulator

SPF 15

	Active ingredients (%)						
		UVB / UVA2		UVA 1 / Broad spectrum			
Product	EHMC	OCR	PBSA	BEMT	BMBM	MBBT	Total
Green Sunscreen	8				2		10,00
New Sunscreen		2	1	1.5	1.5	1.5	7.5



The same SPF may lead to completely different UV exposure

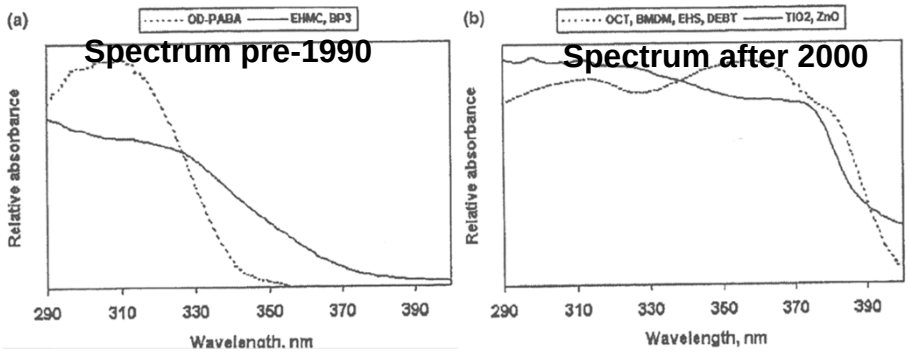
Overview of new UV-filters
Understanding Sunscreens

Contents

Manuscript

- Background
- New UV Filters
- UVA Protection
- *In silico* assessment
- Outlook
- Conclusion

Outlook
"Suncreens and Melanoma: The future looks bright" (Diffey)



Diffey BL, British Journal of Dermatology 2005 153, pp 378-381

Early advocacy for broad-spectrum sunscreens (Diffey 2005)

Outlook
US-FDA, Final Rule, 2011-06-17

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures, **decreases the risk of skin cancer** and early skin aging caused by the sun

FDA rule based on Green et al, 1999, 2010

Outlook
Evolution towards ideal sunscreen

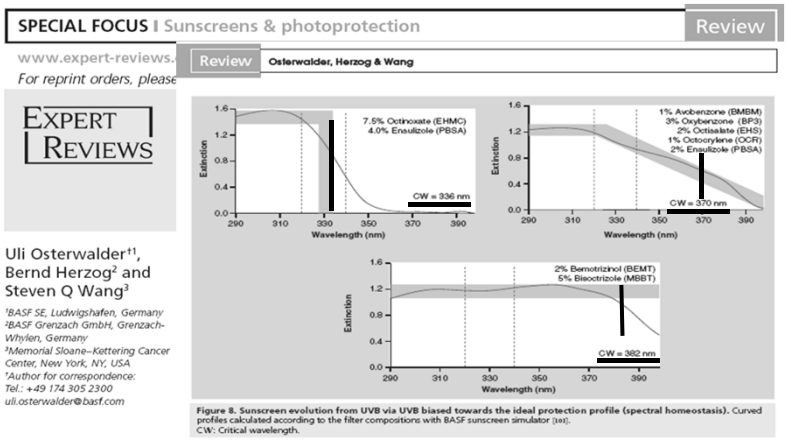
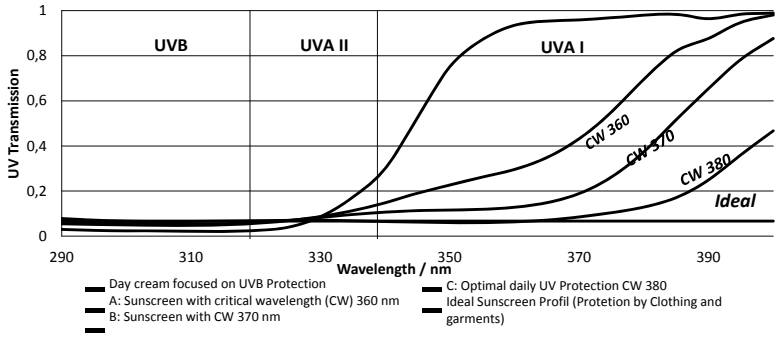


Figure 8. Sunscreen evolution from UVB via UVB biased towards the ideal protection profile (spectral homeostasis). Curved profiles calculated according to the filter compositions with BASF sunscreen simulator [101]. CW: Critical wavelength.

Future sunscreens should have CW values > 380 nm

Outlook
The Ideal Sunscreen

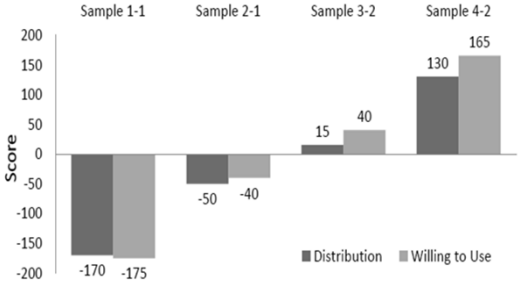
- Uniform protection profile
- Good skin feel – pleasing to use
- Long lasting, photostable, safe, accepted (by NGOs)…….



Outlook
Survey about sunscreen and skin feel

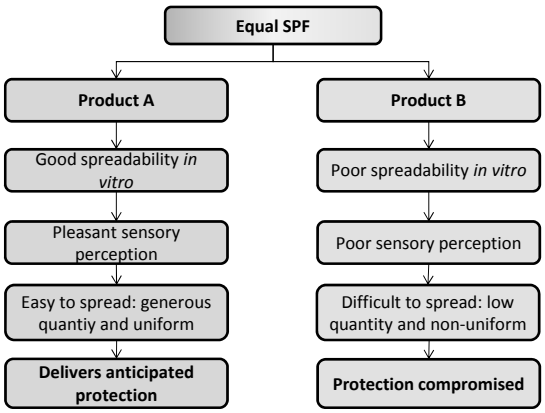
Formulation number		UV12031-1-1	UV12031-2-1	UV12031-3-2	UV12031-4-2
Emulsion type		W/O	W/O	O/W	O/W
Spreadability		Low	Low	Low	High
Filters in %	Titanium Dioxide (and) Aluminum Hydroxide (and) Stearic Acid	16.0	-	-	-
	Zinc Oxide	9.0	-	-	-
	Octocrylene	-	10.0	10.0	10.0
	Butyl Methoxydibenzoylmethane	-	5.0	5.0	5.0
	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	-	2.0	2.0	2.0
	Methylene Bis-Benzotriazolyl Tetramethylbutylphenol	-	2.0	2.0	2.0
Emollients in %	Isocetyl Palmitate	8.0	8.0	8.0	-
	Caprylic/Capric Triglyceride	8.0	8.0	8.0	-
	Dicaprylyl Carbonate	-	-	-	8.0
	Coco-Caprylate	-	-	-	5.0
	Cyclohexasiloxane (and) Cyclopentasiloxane	-	-	-	3.0

Distribution and Willingness to use the Sunscreen



Sunscreen formulation has influence on acceptance by consumer

Outlook
Compliance is crucial



Pissavini M, Diffey B, Marguerie BS, Carayol T and Doucet O, Predicting the efficacy of sunscreens in vivo veritas, Intl J of Cosm. Sci., 1–5, (2011)

Compliance determines the protection result/effect of a sunscreen

Overview of new UV-filters
Understanding Sunscreens

Contents

Manuscript

- Background
- New UV Filters
- UVA Protection
- *In silico* assessment
- Outlook
- Conclusion

Conclusion

- **New UV filters that came to market in the last decade that allow manufacturing of photostable sunscreens with good UVA protection**
- **Latest positive opinion for UV filter TBPT – UVB & UVA II range with high effectiveness**
- **CW 370 does not provide sufficient UVA protection**
- ***In silico* method helps understanding sunscreens and helps accelerate innovation**

Further Reading

- Osterwalder U, Sohn M and Herzog B, **Global state of sunscreens**, Photodermatol Photoimmunol Photomed; 30: 62–80 (2014)
- Jansen R, Osterwalder U, Wang SQ, Burnett M and Lim HW, **Photoprotection, Part II. Sunscreen: Development, efficacy, and controversies**, J AM ACAD DERMATOL VOLUME 69, NUMBER 6 (2012)
- Osterwalder U, He Q, Sohn M and , Herzog B, **Sustainable Sun Protection with Sunscreens Requires the Right Technology and Good Compliance**, SOFW-Journal, 138(7), 2-18 (2012)
- Osterwalder U, Herzog B, and Wang SQ, **Advance in Sunscreens to Prevent Skin Cancer**, Exp. Rev. Dermatol 6(5), 479–491 (2011)
- Osterwalder U and Herzog B, **The long way towards the ideal sunscreen—where we stand and what still needs to be done**, Photochem. Photobiol. Sci., 2010, 9, 470
- Osterwalder U and Herzog B, **Sun protection factors: world wide confusion,** British Journal of Dermatology 2009 161 (Suppl. 3), pp13–24

Public Access to SunScreens (PASS) Coalition

- The PASS Coalition is a multi-stakeholder coalition formed to advocate for a transparent and timely review by the U.S. FDA of over-the-counter sunscreen ingredients.
- On a bipartisan, bicameral basis, Congress enacted reforms to the U.S. sunscreen application process to expedite the approval of new and innovative sunscreen ingredients. The *Sunscreen Innovation Act* (Public Law 113-195) amends the Food Drug & Cosmetic Act to ensure all sunscreen ingredients receive a transparent and timely review.
- Despite this legislation, the U.S. Food and Drug Administration (FDA) has yet to make a final decision on eight pending sunscreen ingredients that have been awaiting review for up to 13 years in some cases.
- On May 22, a petition to President Obama was filed calling for action to fight skin cancer and ensure access to the latest sunscreens. The petition can be accessed here: http://wh.gov/iKss3

WE the PEOPLE
YOUR VOICE IN OUR GOVERNMENT

@PASScoalition
http://www.passcoalition.com
https://www.facebook.com/PASSCoalition

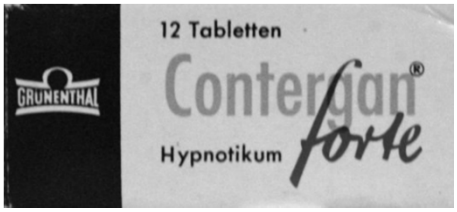
pass coalition
PUBLIC ACCESS TO SUNSCREENS

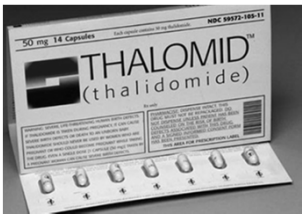
US Registration
Understanding the FDA

Reasons for delay of US approval:

- Not protectionism (urban legend)
- Regulated as OTC drug
- **Thalidomide**
  - One scientist at FDA avoided damage in US
  - **Paradigm change at FDA**

Europe: Early 60´s





US Registration
Reasons for delay of US approval: **Thalidomide**

50 Years after Thalidomide: Why Regulation Matters

Posted on **February 7, 2012** by **FDA_Voice**

By: Margaret Hamburg, M.D.

Fifty years ago, the vigilance of FDA medical officer Dr. Frances Kelsey prevented a public health tragedy of enormous proportion by ensuring that the sedative thalidomide was never approved in the United States. As many remember, in the early 1960's, reports were coming in from around the world of countless women who were giving birth to children with extremely deformed limbs and other severe birth defects. They had taken thalidomide. Although it was being used in many countries, Dr. Kelsey discovered that it hadn't even been tested on pregnant animals.

Dr. Kelsey's reaction to thalidomide exemplifies the FDA's mission: protecting and promoting the health of the American people, using science for regulatory decision-making.

1962: Frances Kathleen Oldham Kelsey receiving the President's Award for Distinguished Federal Civilian Service from President John F. Kennedy

US Registration
Reasons for delay of US approval: ***Thalidomide***

Kelsey (age 87) at the FDA Reception commemorating her induction into the National Women's Hall of Fame

Legacy and awards [edit]

- 1962 • President's Award for Distinguished Federal Civilian Service[6]
- 1963 • Gold Key Award from University of Chicago, Medical and Biological Sciences Alu
- In 1994, the Frances Kelsey Secondary School in Mill Bay, British Columbia is named in
- 2000 • Inducted into the National Women's Hall of Fame[7]
- 2001 • Named a Virtual Mentor for the American Medical Association[8]
- 2006 • Foremother Award from the NRC for Women & Families[9]

In 2010 the FDA honored Kelsey by naming one of the awards, Center Director Steven K. Galson, M.D. Kelsey Drug Safety Excellence Award and to recog important aspect of drug regulation."[10] Kelsey rece annually.[11]

Kelsey received an honorary doctor of science deg Kelsey turned 100 in July 2014.[12] Asteroid 6260 Kelsey is named in her honour.[13]

See also [edit]

European Medicines Agency

the drug detective

WIKIPEDIA

Shedding some light on FDA's review of sunscreen ingredients and the Sunscreen Innovation Act

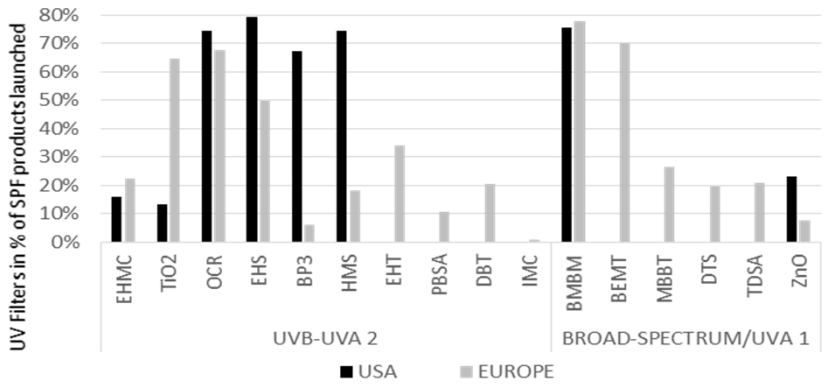
Posted on **February 24, 2015** by **FDA Voice**

By: Theresa M. Michele, M.D.

At this time there is not enough generally available data to determine whether any of the ingredients under review meet FDA's safety and effectiveness standards.

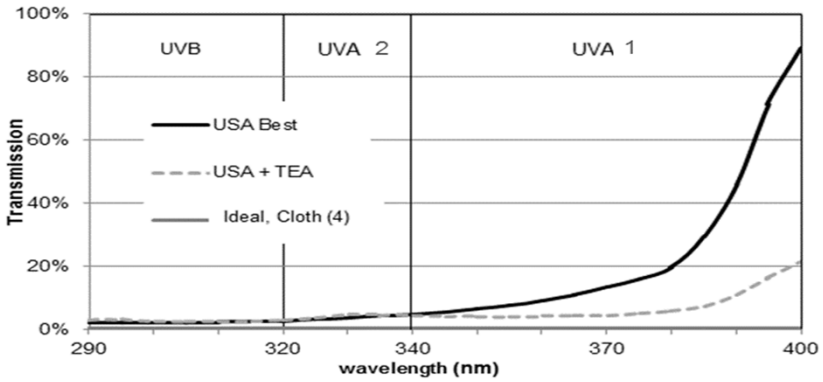
Successful implementation of the SIA will require a cooperative effort with industry and other stakeholders. We look forward to continuing this important work.

UV Filter use USA vs Europe
(Launches 2012-14, GNPG/Mintel)



U Osterwalder and L Hareng, **Global UV filters: current technologies and future innovations**, in Principles and Practice of Photoprotection, Wang/Lim (Eds.), Springer 2015

UV Filter use USA vs Europe
(Contribution of new UV filters to US sunscreens)



U Osterwalder and L Hareng, **Global UV filters: current technologies and future innovations**, in Principles and Practice of Photoprotection, Wang/Lim (Eds.), Springer 2015