

Case Study UV filters

February 2022

We personally care



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Regulatory Situation of Sun Protection

- Cosmetics are intentional mixtures with defined use and disposal;
- Sun protection products are considered as cosmetics in the EU
- UV filters are subject to “positive list” under the Cosmetic Products Regulation
- Exposure model for safety assessment is based on full-body coverage, 365 days per year
- Currently, 32 filters are listed of which approx. 15 are widely used

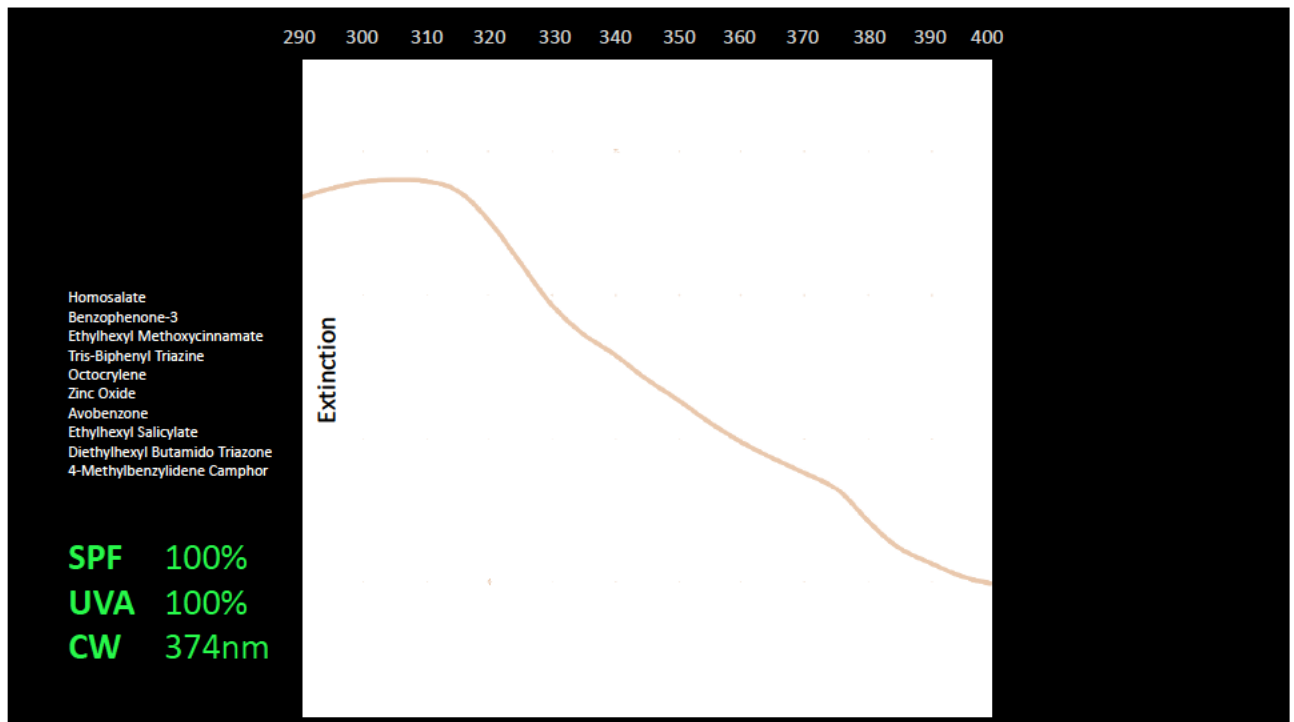
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Impact of additional mandatory safety factor under REACH

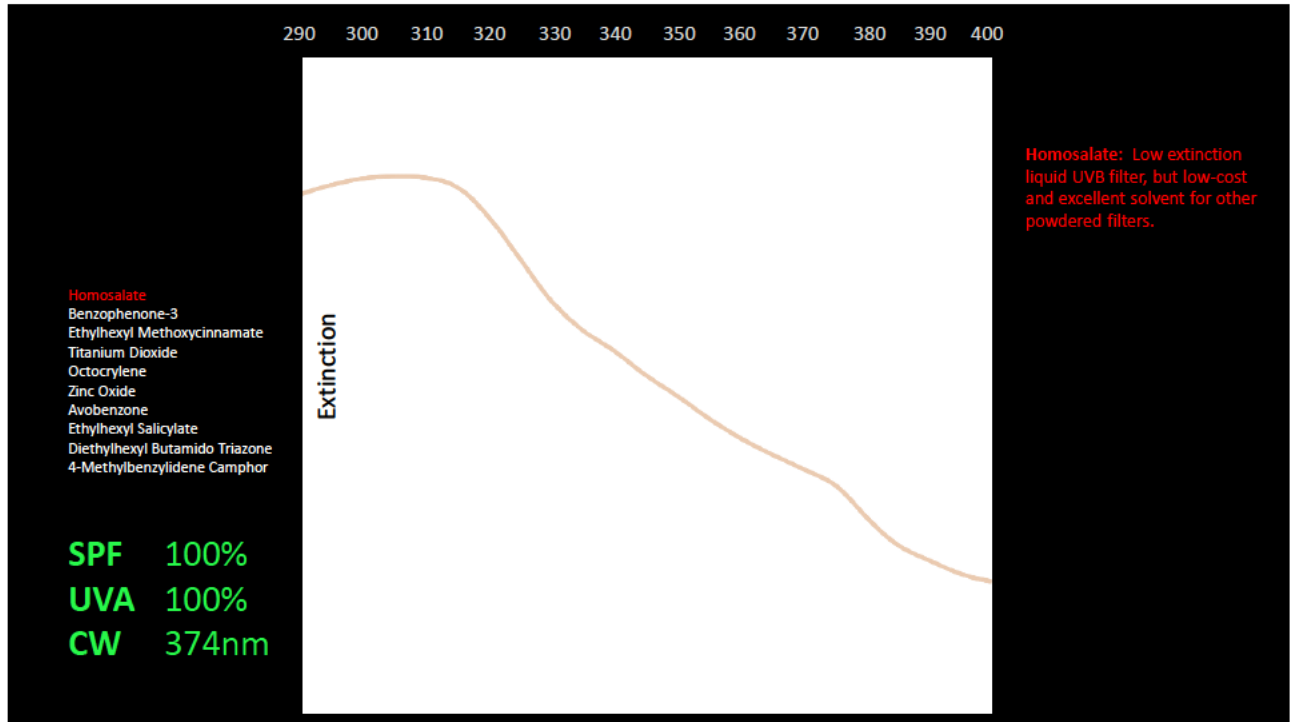
- Mandatory inclusion of an additional safety factor in substance DNEL would invalidate already conservative safety conclusions of most UV Filters;
→ 8 out of 10 UV filters could be considered as no longer safe;
- Adequate consumer protection against UV radiation would not be possible with the remaining filters;
- Impossible to rapidly 'innovate out' of artificial constraint;
- Possibly significant impact on public health in the EU;

Similar consequences expected from introduction of a safety factor into PNEC under in environmental assessment

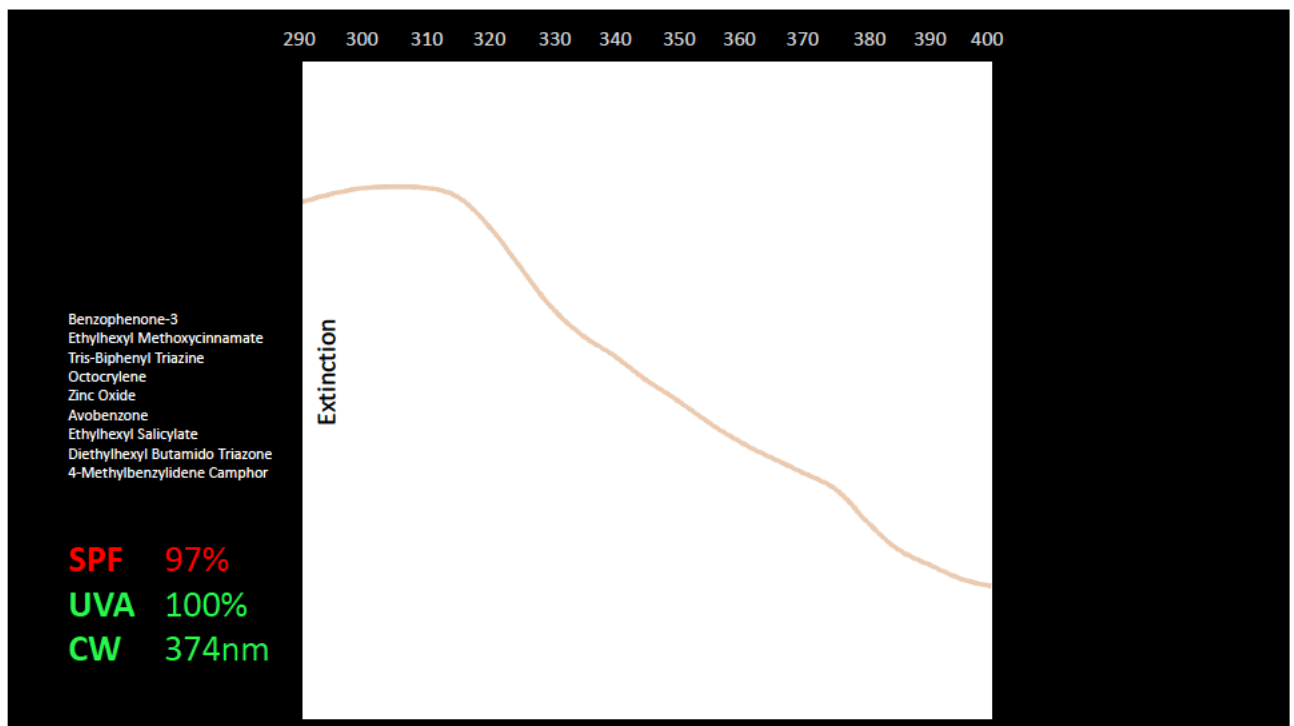
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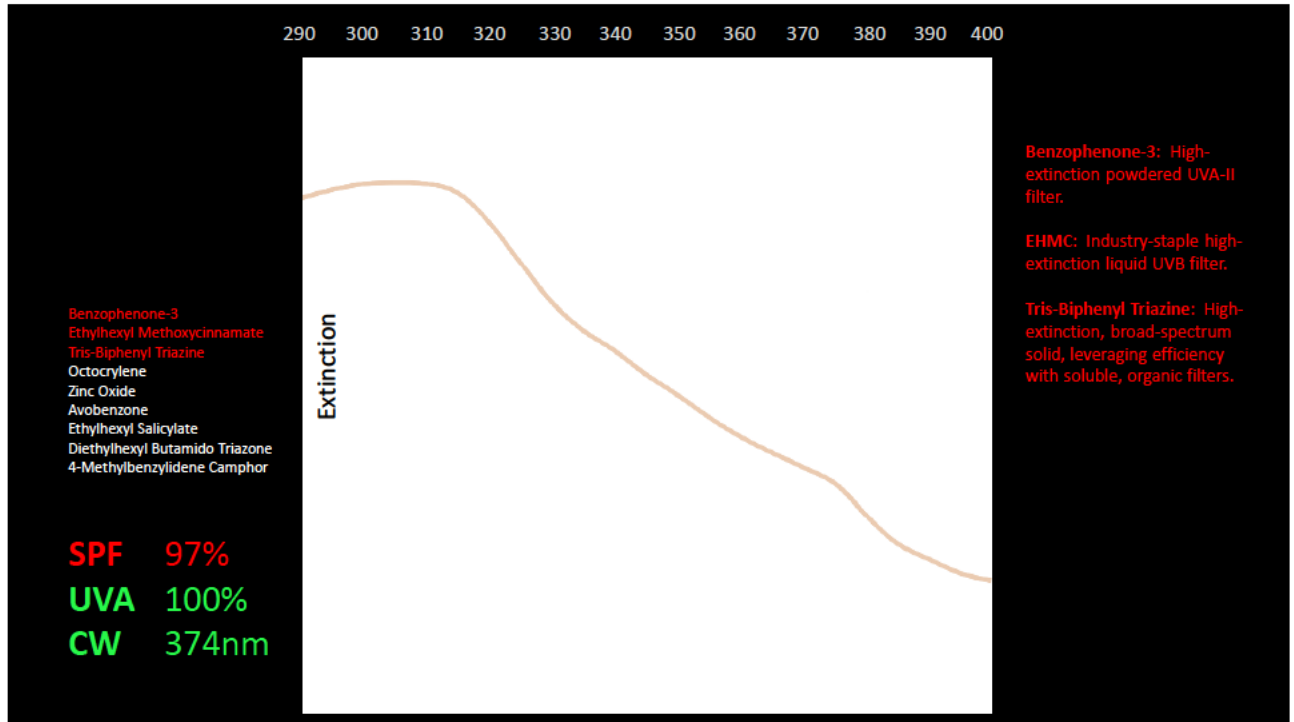
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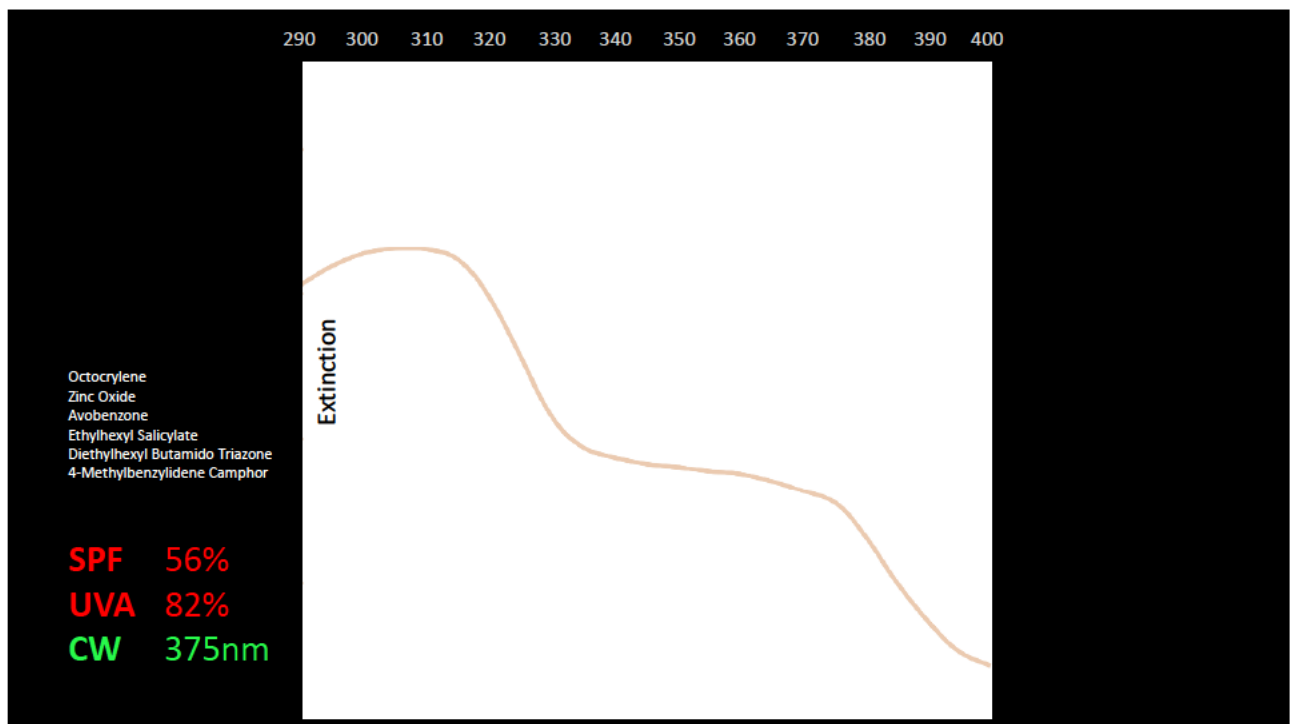
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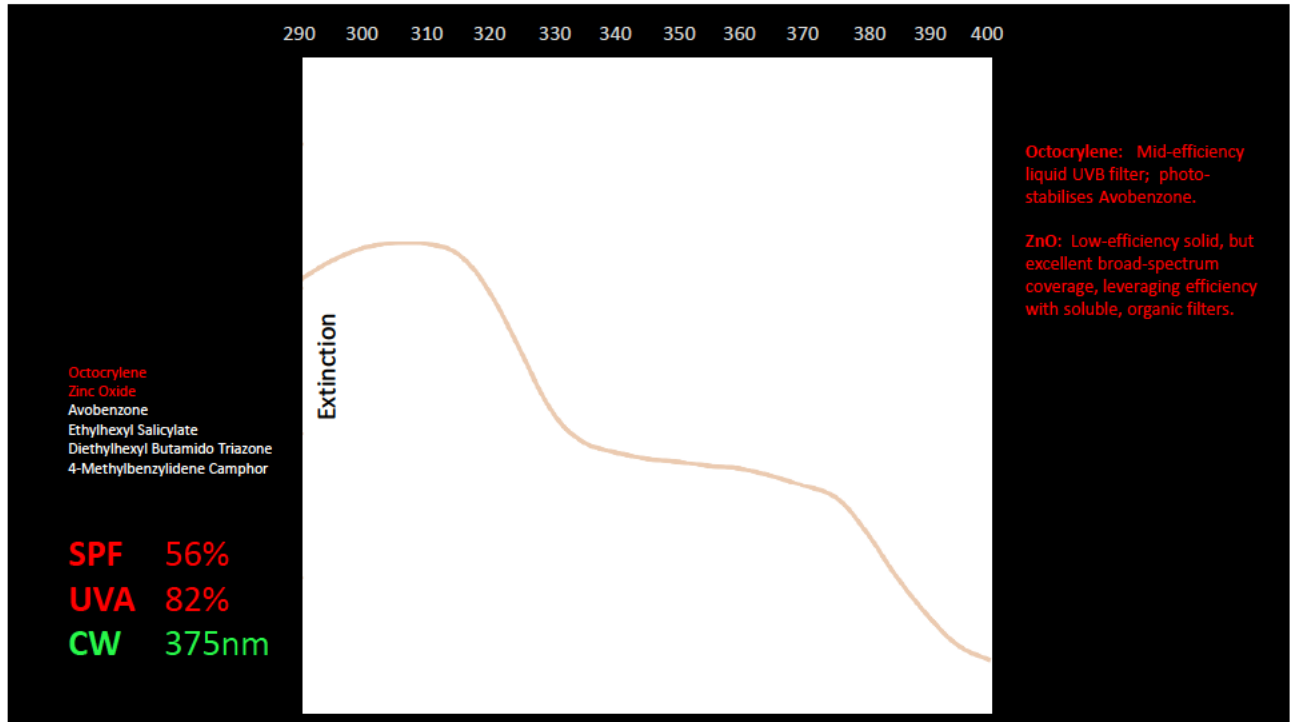
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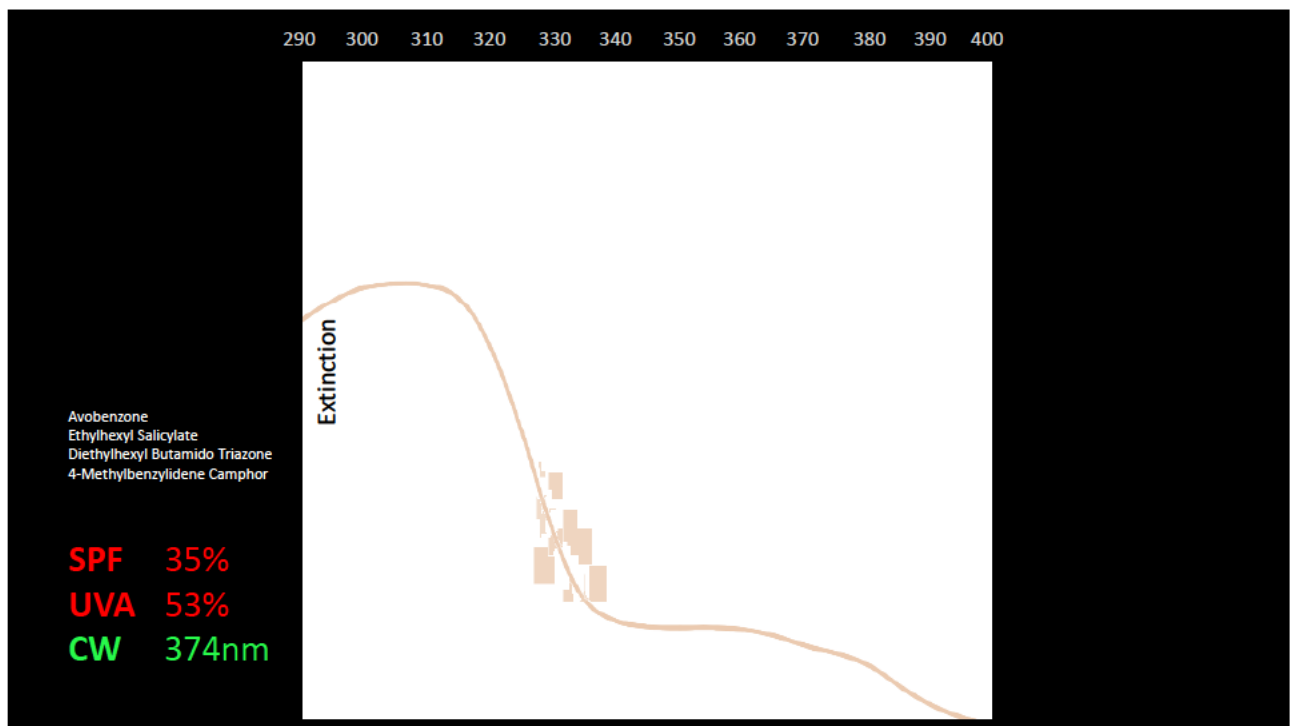
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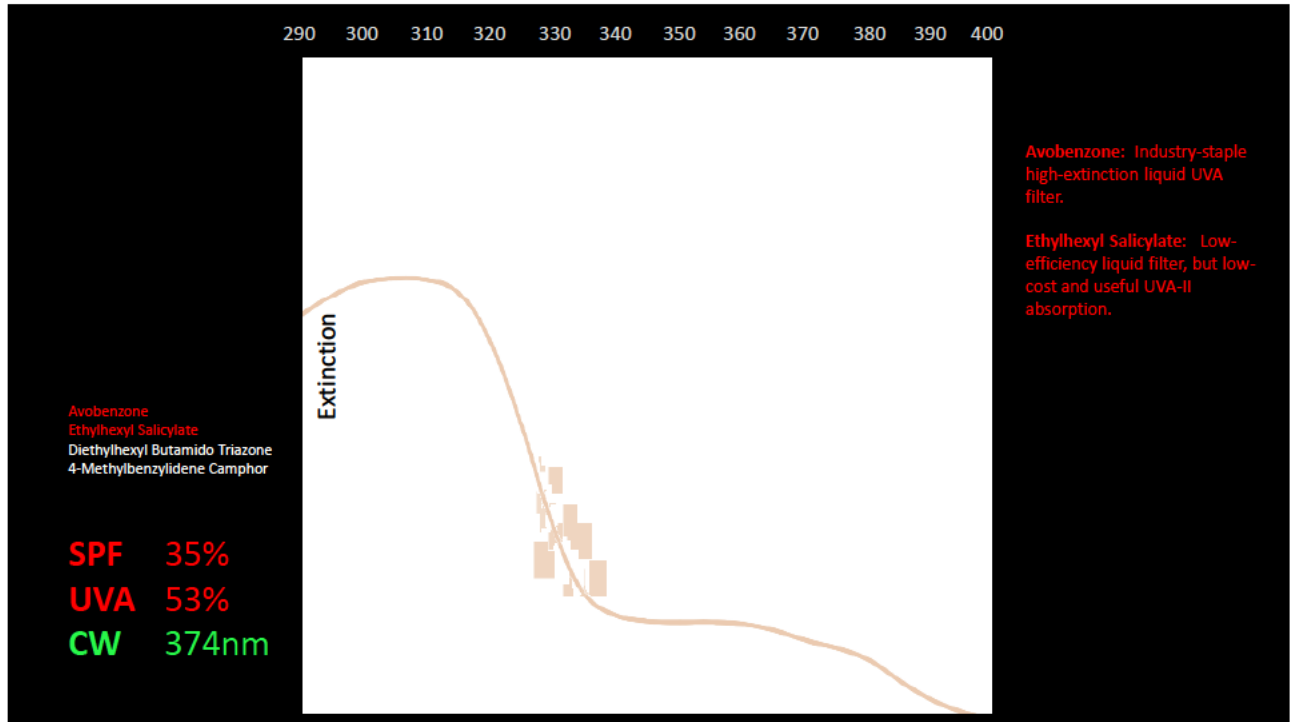
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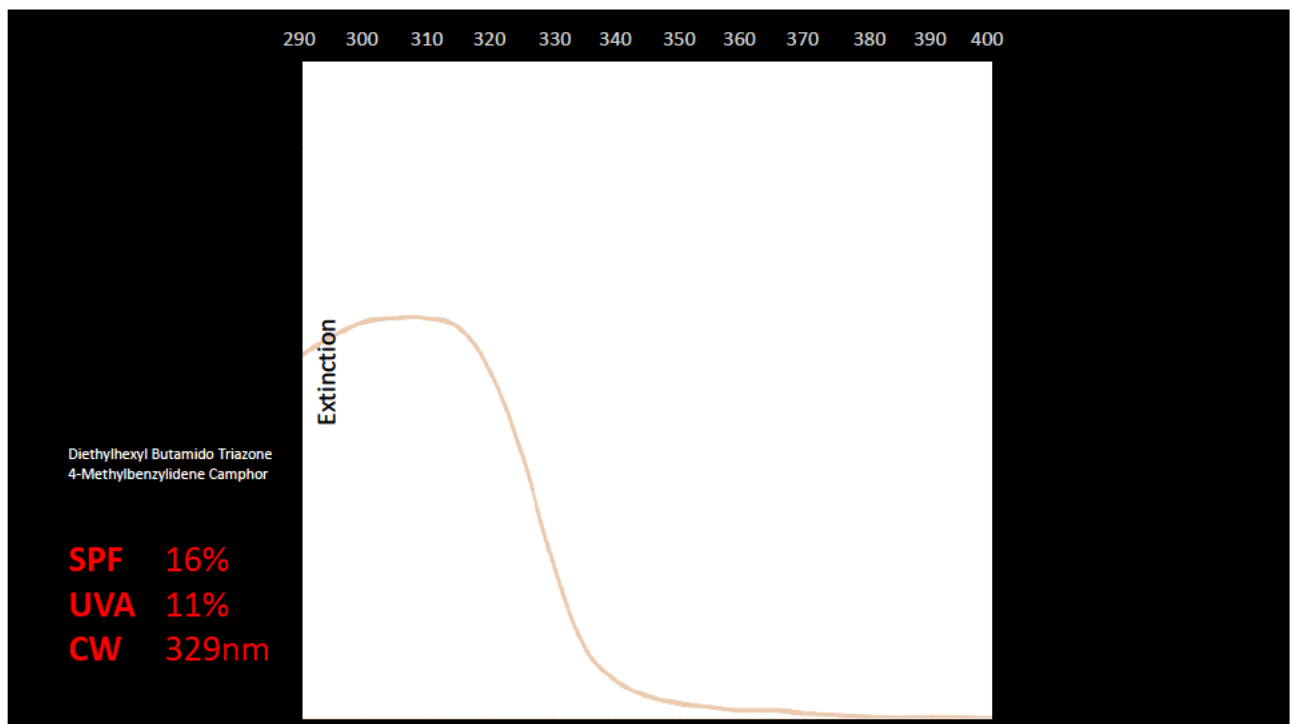
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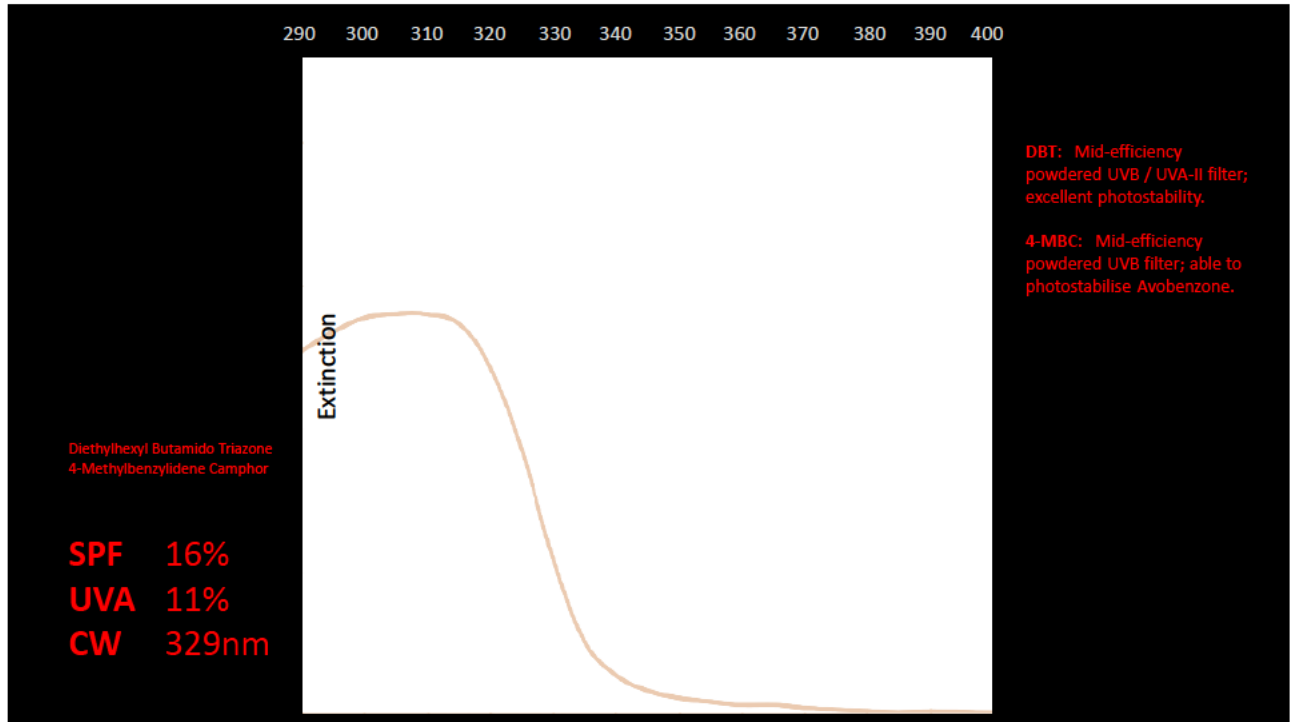
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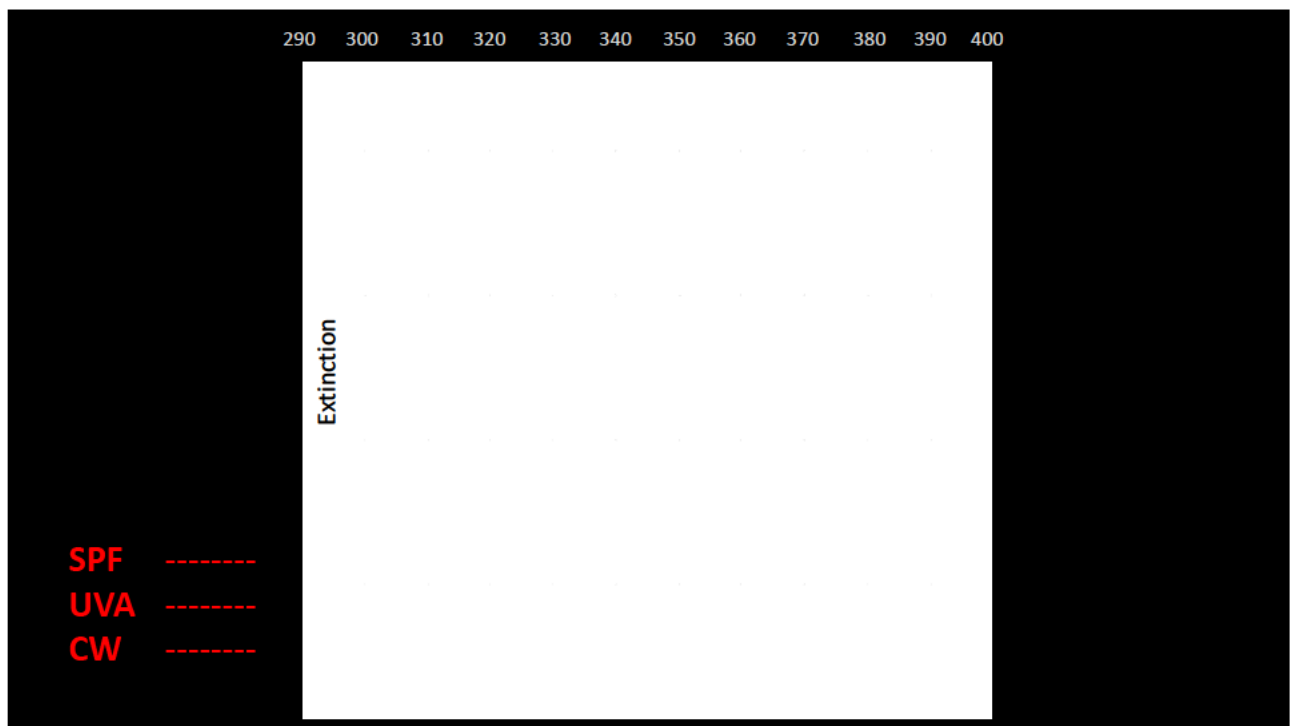
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Unintended consequences



Basal Cell Carcinoma



Squamous Cell Carcinoma



Malignant Melanoma

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The global burden of skin cancer: A longitudinal analysis from the Global Burden of Disease Study, 1990–2017

No. of cases globally, 2017

Skin cancer: basal cell carcinoma	5,884,759
Lung cancer	2,163,132
Breast cancer	1,960,682
Colorectal cancer	1,833,451
Skin cancer: squamous cell carcinoma	1,778,829
Prostate cancer	1,334,315
Stomach cancer	1,220,662
Melanoma	308,684
Total Skin Cancer	7,972,272

J Amer Acad Dermatol International, Volume 2, 98-108, 2021

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Every death from skin cancer is an avoidable tragedy.

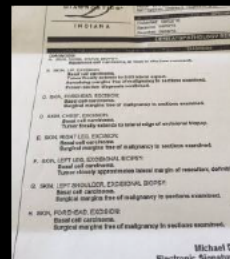
And... *many more people live with skin cancer than die from it.*

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In 2015, 49, shared her series of BCC surgeries publicly on Facebook.

Ms Cloud was left with permanent facial scarring, numbness and some immobility.



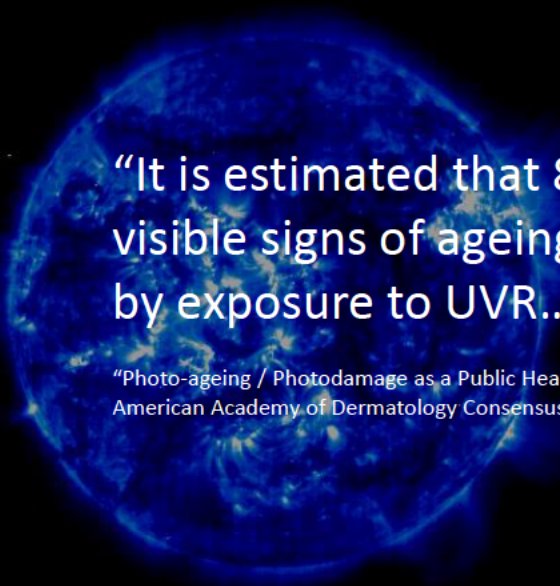
"I'm really hoping the thought of going to a tanning bed no longer sounds quite so attractive to you..."

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A minority will develop skin cancer.

And... ***100% of humans look older, less healthy and less attractive than they should because of chronic UVR exposure.***

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“It is estimated that 80% of the visible signs of ageing... are caused by exposure to UVR...”

“Photo-ageing / Photodamage as a Public Health Concern”
American Academy of Dermatology Consensus Conference, March 3-4, 1988

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Conclusions

- Impact for cosmetics is not limited to UV filters but can affect other ingredient classes (e.g. preservatives, hair dyes, ...);
- Addition of a simplistic default safety factor can have significant unintended consequences for whole product categories and even for public health;
- MAF concept should be limited to unintentional environmental mixtures of substances of high concern;
- Any application should be done at the level of risk assessment, not at the level of hazard characterisation
- Conservatisms already built into risk assessment should be considered
- Detailed data should always be accepted to overrule Tier 1 default values