Case Study UV filters

February 2022
We personally care

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
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.
Homosalate: Low extinction liquid UVB filter, but low-cost and excellent solvent for other powdered filters.

SPF 100%
UVA 100%
CW 374nm

Benophenone-3
Ethylhexyl Methoxycinnamate
Titanium Dioxide
Octocrylene
Zinc Oxide
Avobenzone
Ethylhexyl Salicylate
Diethylhexyl Butamido Triazone
4-Methylbenzylidene Camphor

SPF 97%
UVA 100%
CW 374nm
Benzophenone-3: High-extinction powdered UVA-II filter.

EHMC: Industry-staple high-extinction liquid UV filter.

Tri-Biphenyl Triazine: High-extinction, broad-spectrum solid, leveraging efficiency with soluble, organic filters.

**SPF** 97%
**UVA** 100%
**CW** 374nm

**SPF** 56%
**UVA** 82%
**CW** 375nm
Octocrylene: Mid-efficiency liquid UVA filter; photostabilises Avobenzone.

ZnO: Low-efficiency solid, but excellent broad-spectrum coverage, leveraging efficiency with soluble, organic filters.

SPF 56%
UVA 82%
CW 375nm

Avobenzone
Ethylhexyl Salicylate
Diethylhexyl Butamido Triazone
4-Methylbenzylidene Camphor

SPF 35%
UVA 53%
CW 374nm
Avobenzene: Industry-staple high-extinction liquid UVA filter.
Ethylhexyl Salicylate: Low-efficiency liquid filter, but low-cost and useful UVA-II absorption.

SPF 35%
UVA 53%
CW 374nm

SPF 16%
UVA 11%
CW 329nm
DBT: Mid-efficiency powdered UVB / UVA-II filter; excellent photostability.

4-MBC: Mid-efficiency powdered UVB filter; able to photostabilise Avebenzone.

**SPF** 16%
**UVA** 11%
**CW** 329nm
Unintended consequences

Basal Cell Carcinoma  Squamous Cell Carcinoma  Malignant Melanoma


<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>No. of cases globally, 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin cancer: basal cell carcinoma</td>
<td>5,884,759</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>2,163,132</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>1,960,682</td>
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<tr>
<td>Colorectal cancer</td>
<td>1,833,451</td>
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<tr>
<td>Skin cancer: squamous cell carcinoma</td>
<td>1,778,829</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>1,334,315</td>
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<tr>
<td>Stomach cancer</td>
<td>1,220,662</td>
</tr>
<tr>
<td>Melanoma</td>
<td>308,684</td>
</tr>
<tr>
<td><strong>Total Skin Cancer</strong></td>
<td><strong>7,972,272</strong></td>
</tr>
</tbody>
</table>

Every death from skin cancer is an avoidable tragedy.

And... \textit{many more people live with skin cancer than die from it.}
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.

“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
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