Standardisation of Toxicity Tests on Corals to Meet Regulatory Requirements

Dr. Sascha Pawlowski & Laura H. Lütjens

NASEM Workshop to Advance Research on Understanding Environmental Effects of UV Filters in Sunscreens
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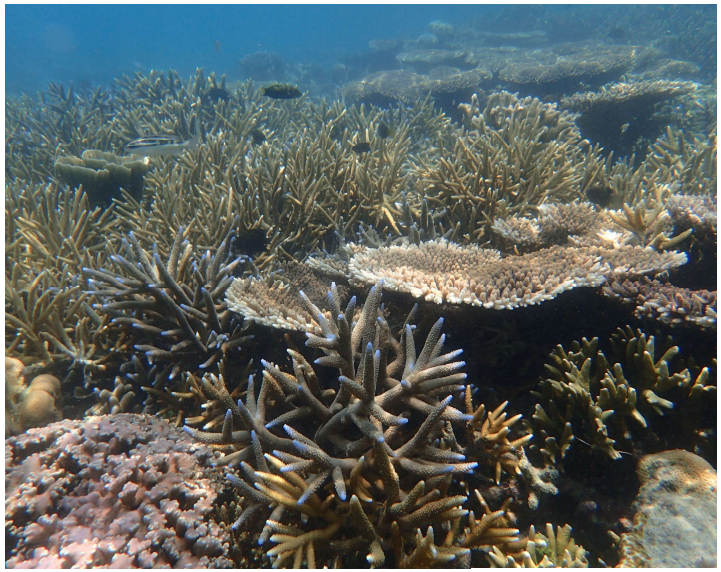
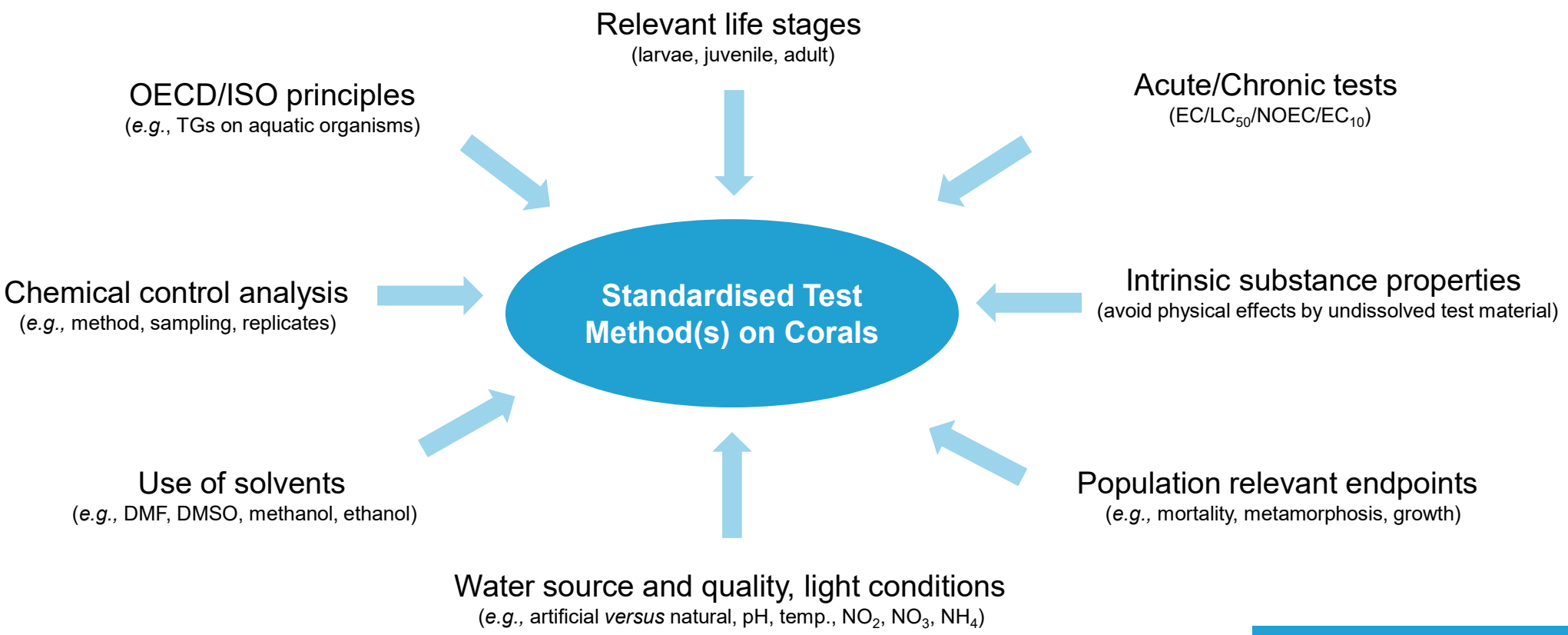


Key Aspects to be Considered for Standardised Tests on Corals



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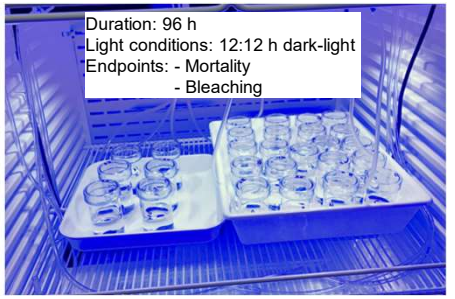
Our Work (in collaboration with University of Oldenburg, Germany)

- Acute toxicity test on adult coral fragments (lower Tier) ✓
- Toxicity test on coral larvae (higher Tier) ✓
- Effects of solvents* on corals ✓
- Further chronic toxicity test on coral fragments **– in progress**
- Bioaccumulation in corals **- planned**

Standardized test methods on corals following ISO/OECD TG principles

It´s a long way to go……(5 – 10 years)

Acute coral fragment test



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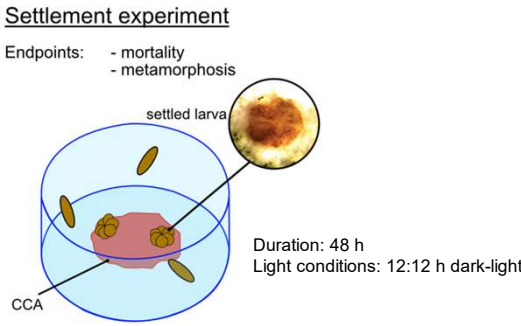
Coral larvae toxicity test



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*DMF, DMSO, ethanol, methanol,

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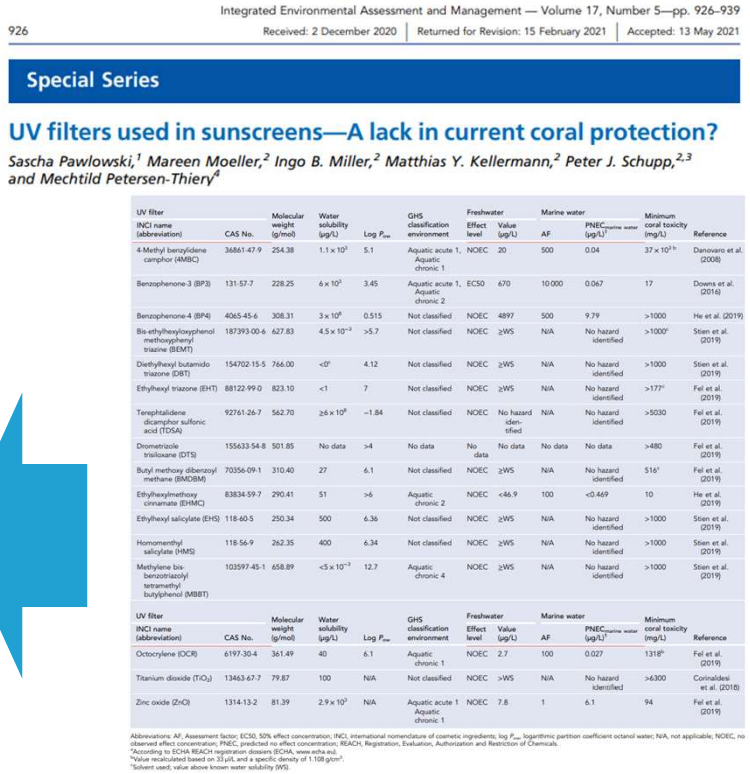
Current Safety Assessment Approach for Corals

EU REACH requires PNECs for hazardous UV filters

$PNEC_{marine\ water}$ are based on standard freshwater organisms (A, D, F) and Assessment Factors

$PNEC_{marine\ water}$ *versus* effect values on corals (literature)

- All effect levels in corals (acute, marine water) refer to already classified UV filters
- All acute effect levels in corals were above the derived $PNEC_{marine\ water}$
  - **$PNEC_{marine\ water}$ as derived within EU REACH could be used as a surrogate to protect corals until standardized methods become available**



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Special Series

UV filters used in sunscreens—A lack in current coral protection?

Sascha Pawlowski,[1] Mareen Moeller,[2] Ingo B. Miller,[2] Matthias Y. Kellermann,[2] Peter J. Schupp,[2,3] and Mechtild Petersen-Thiery[4]

UV filter INCI name (abbreviation)	CAS No.	Molecular weight (g/mol)	Water solubility (µg/L)	Log P_{ow}	GHS classification environment	Freshwater Effect level	Freshwater Value (µg/L)	Marine water AF	Marine water $PNEC_{marine\ water}$ (µg/L)[1]	Minimum coral toxicity (mg/L)	Reference
4-Methyl benzylidene camphor (4MBC)	36861-47-9	254.38	1.1×10^3	5.1	Aquatic acute 1, Aquatic chronic 1	NOEC	20	500	0.04	37×10^3 [b]	Danovaro et al. (2008)
Benzophenone-3 (BP3)	131-57-7	228.25	6×10^3	3.45	Aquatic acute 1, Aquatic chronic 2	EC50	670	10 000	0.067	17	Downs et al. (2016)
Benzophenone-4 (BP4)	4065-45-6	308.31	3×10^6	0.515	Not classified	NOEC	4897	500	9.79	>1000	He et al. (2019)
Bis-ethylhexyloxyphenol methoxyphenyl triazine (BEMT)	187393-00-6	627.83	4.5×10^{-3}	>5.7	Not classified	NOEC	≥WS	N/A	No hazard identified	>1000[c]	Stien et al. (2019)
Diethylhexyl butamido triazone (DBT)	154702-15-5	766.00	<0[c]	4.12	Not classified	NOEC	≥WS	N/A	No hazard identified	>1000	Stien et al. (2019)
Ethylhexyl triazone (EHT)	88122-99-0	823.10	<1	7	Not classified	NOEC	≥WS	N/A	No hazard identified	>177[c]	Fel et al. (2019)
Terephtalidene dicamphor sulfonic acid (TDSA)	92761-26-7	562.70	$\geq 6 \times 10^8$	−1.84	Not classified	NOEC	No hazard iden-tified	N/A	No hazard identified	>5030	Fel et al. (2019)
Dromotriazole trisiloxane (DTS)	155633-54-8	501.85	No data	>4	No data	No data	No data	No data	No data	>480	Fel et al. (2019)
Butyl methoxy dibenzoyl methane (BMDBM)	70356-09-1	310.40	27	6.1	Not classified	NOEC	≥WS	N/A	No hazard identified	516[c]	Fel et al. (2019)
Ethylhexylmethoxy cinnamate (EHMC)	83834-59-7	290.41	51	>6	Aquatic chronic 2	NOEC	<46.9	100	<0.469	10	He et al. (2019)
Ethylhexyl salicylate (EHS)	118-60-5	250.34	500	6.36	Not classified	NOEC	≥WS	N/A	No hazard identified	>1000	Stien et al. (2019)
Homomenthyl salicylate (HMS)	118-56-9	262.35	400	6.34	Not classified	NOEC	≥WS	N/A	No hazard identified	>1000	Stien et al. (2019)
Methylene bis-benzotriazolyl tetramethyl butylphenol (MBBT)	103597-45-1	658.89	$<5 \times 10^{-3}$	12.7	Aquatic chronic 4	NOEC	≥WS	N/A	No hazard identified	>1000	Stien et al. (2019)

UV filter INCI name (abbreviation)	CAS No.	Molecular weight (g/mol)	Water solubility (µg/L)	Log P_{ow}	GHS classification environment	Freshwater Effect level	Freshwater Value (µg/L)	Marine water AF	Marine water $PNEC_{marine\ water}$ (µg/L)[1]	Minimum coral toxicity (mg/L)	Reference
Octocrylene (OCR)	6197-30-4	361.49	40	6.1	Aquatic chronic 1	NOEC	2.7	100	0.027	1318[b]	Fel et al. (2019)
Titanium dioxide (TiO_2)	13463-67-7	79.87	100	N/A	Not classified	NOEC	>WS	N/A	No hazard identified	>6300	Corinaldesi et al. (2018)
Zinc oxide (ZnO)	1314-13-2	81.39	2.9×10^3	N/A	Aquatic acute 1 Aquatic chronic 1	NOEC	7.8	1	6.1	94	Fel et al. (2019)

Abbreviations: AF, Assessment factor; EC50, 50% effect concentration; INCI, international nomenclature of cosmetic ingredients; log P_{ow}, logarithmic partition coefficient octanol water; N/A, not applicable; NOEC, no observed effect concentration; PNEC, predicted no effect concentration; REACH, Registration, Evaluation, Authorization and Restriction of Chemicals.
[a]According to ECHA REACH registration dossiers (ECHA, www.echa.eu).
[b]Value recalculated based on 33 µL and a specific density of 1.108 g/cm³.
[c]Solvent used; value above known water solubility (WS).

REACH – Registration
PNEC – Predicted no-effect concentration
A, D, F – algae, daphnids, fish

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Safety Assessment Approach for other Environmental Organisms

- Comparing EU REACH derived PNECs for all environmental compartments* with effect values on other non-standard test species** (literature)
- PNECs were usually based on standard test organisms (freshwater, freshwater sediment, terrestrial) and Assessment Factors

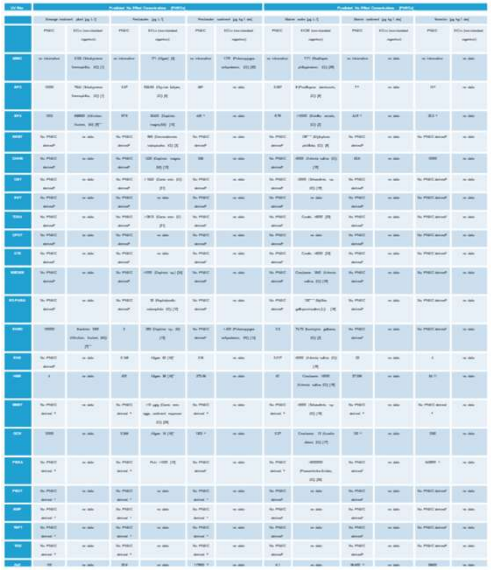
- Majority of literature data refer to fresh- and marine water species
- All comparable effect values (e.g., LC_{50}) from non-standard organisms were above the derived PNECs

  - **Derived PNECs for all environmental compartments were protective for other non-standard test organisms**

Cosmetic UV filters in the environment - state of the art in EU regulations, science and possible knowledge gaps

Sascha Pawlowski, Laura Henriette Lütjens, Alina Preibisch, Stephanie Acker, Mechtild Petersen-Thiery

Int. J. Cosm. Sci. Special series Sun Protection (submitted)



*Sewage treatment plant (STP), fresh- and marine water, fresh- and marine sediment, terrestrial
**included taxonomic groups: bacteria, algae, corals, annelids, mollusks, crustacea, arthropods, echinodermata, fish

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Summary

- Short term toxicity texts on adult corals (acute) and larvae (chronic) are ready for pre-validation under ISO/OECD
- Further long-term (chronic toxicity) tests on adult corals are in progress
- Bioaccumulation tests in corals are planned
- However, standardization of coral toxicity tests is a long way to go
- $PNEC_{marine\ water}$ as derived within EU REACH could be used as a surrogate to protect corals until standardized methods become available
- Furthermore, EU REACH derived PNECs for all environmental compartments were protective for other non-standard test organisms

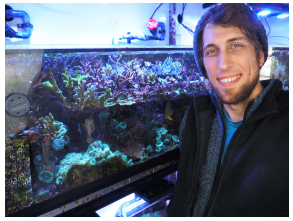
The Team

University of Oldenburg (UOL)


Valentina Di Mauro


David Brefeld


Dr. Mareen Möller


Dr. Samuel Nietzer


Dr. Matthias Y. Kellermann


Prof. Dr. Peter J. Schupp

Former UOL members: Dr. Elham Kamyab, Ingo B. Miller

BASF


Laura H. Lütjens


Dr. Mechtild Petersen-Thiery


Dr. Sascha Pawlowski

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