UV Filter Environmental Sources and Ecotoxicological Data Reliability Assessment

Iain A. Davies,

Personal Care Products Council (PCPC)

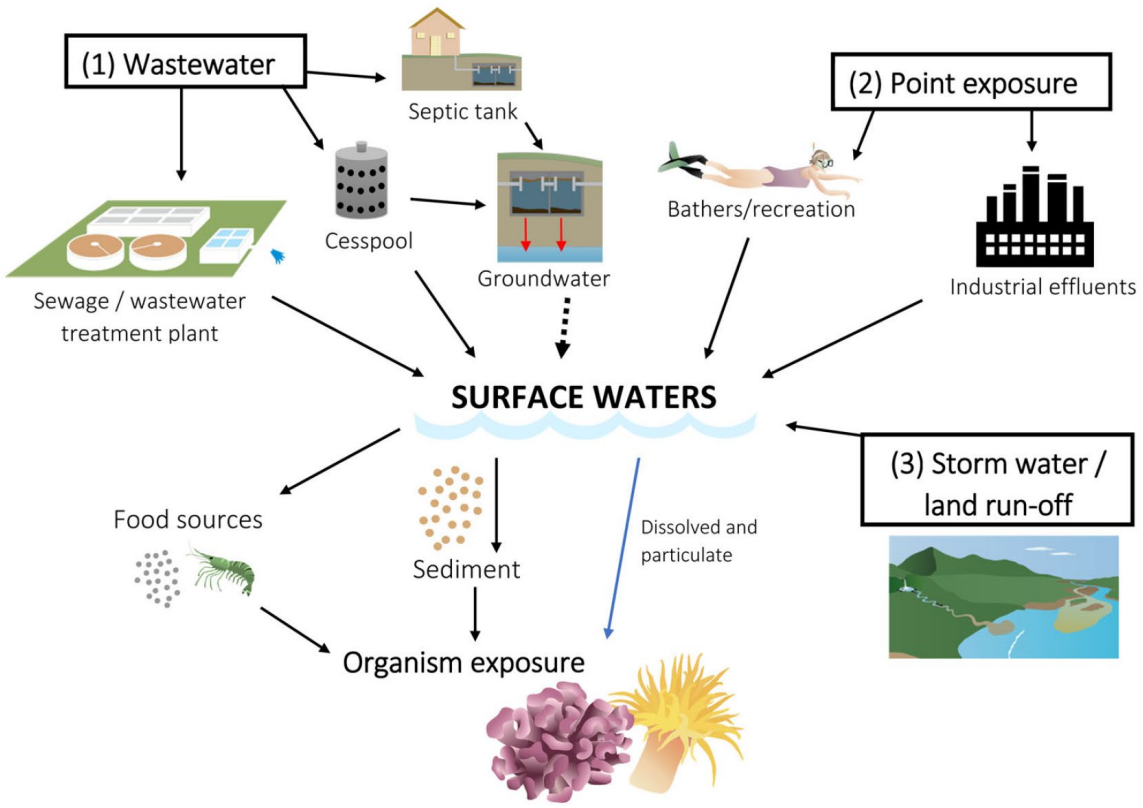
NASEM Committee Meeting,

May 27th 2020

daviesi@personalcarecouncil.org

Personal Care Products Council
Committed to Safety, Quality & Innovation

UV Filters Enter the Environment from Multiple Sources



- Marine and freshwater environments are exposed to UV filters
- It is therefore important to assess environmental exposure and evaluate UV filter ecotoxicity for exposed organisms:
  - ➢ Environmental risk assessment (ERA)
- Characterizing UV filter hazard using relevant and reliable ecotoxicity data is crucial
- Understanding UV filter usage is a critical first step in exposure assessment

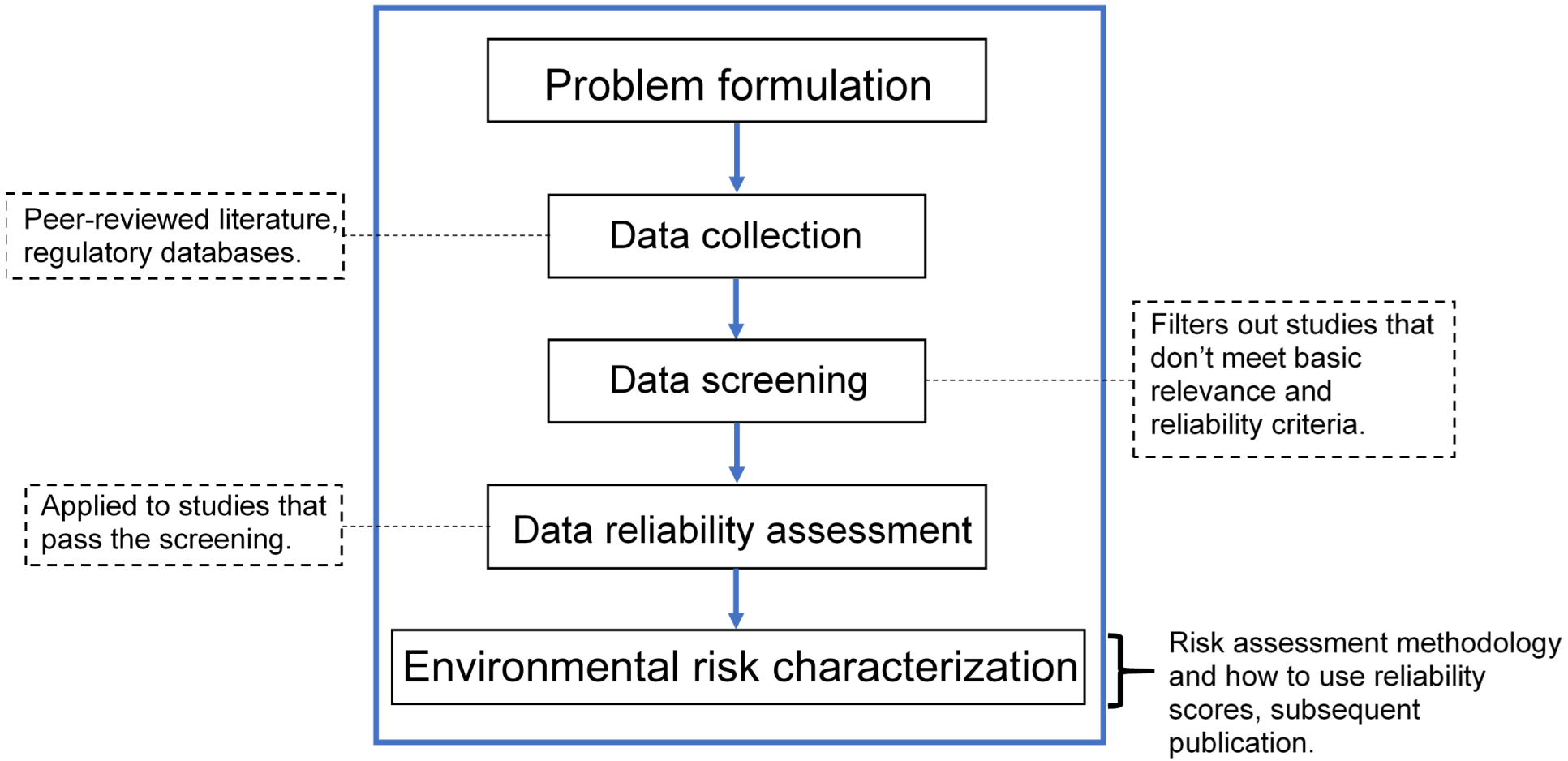
1. Mitchelmore et al. (2021)

Robust Environmental Chemical Management Requires Reliable Scientific Data

- Relevant and reliable ecotoxicity data should be used for ERA:
  - Decreases uncertainty and improves robustness of ERAs
- Studies undergo a data reliability assessment to ensure they are relevant and reliable for ERA:
  - Particularly important for non-standard tests where guidelines that help generate robust and repeatable data are not followed or available
- PCPC developed an ecotoxicity data reliability tool based on existing methods:
  - U.S. Environmental Protection Agency guidelines
  - Klimisch Scoring (used by the European Chemicals Agency)
  - Eco-QESST (used by Environment Canada and Health Canada)
  - CRED (methods from the published literature)

2. USEPA (2011)
3. Klimisch et al. (1997)
4. Breton et al. (2009)
5. Mormond et al. (2016a)

Overview of PCPC's Ecotoxicity Data Reliability Assessment Tool



6. Burns & Davies (2021)

PCPC's Ecotoxicity Data Reliability Tool Screens and Assesses Studies

5 screening questions (pass/fail)

- Two relevance questions ← Must pass both
- Three reliability questions ← Must pass two or more

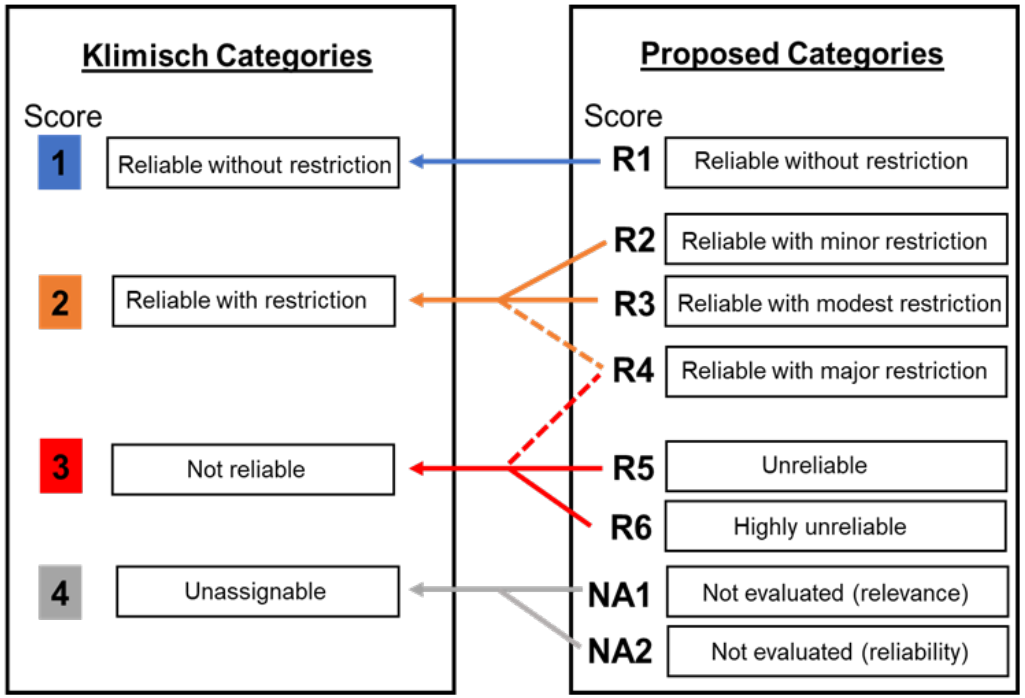
Passing studies progress to the data quality assessment

Data quality assessment

- 23 questions, points awarded based on fulfilment
- Questions weighted by importance for study reliability

Screening + data quality assessment = reliability score

Toxicity Data Reliability Categories Provide Guidance on How Studies Should be Used for ERA



Rough translation to Klimisch data reliability categories

Decision-making quality

R1 Pass all screening, data quality ≥85%

R2 Pass all screening, data quality ≥70%

Preliminary assessment quality

R3 Fail 1 screening, data quality ≥70%

R4 Fail 1 screening , data quality ≥60%

Supporting evidence only

R5 Fail 1 screening , data quality ≥50%

Disregard study

R6 Fail 1 screening , data quality <50%

The Reliability of Published UV Filter Coral Toxicity Data is Insufficient for Decision-Making

Reliability score	Screening assessment	Data quality score	Study
NA1/NA2	Failed	-	Danovaro et al. (2008)
R6	Passed	45%	Downs et al. (2016)
R3	Passed	73%	Fel et al. (2019)
R4	Passed	66%	He et al. (2019a)
R4	Passed	63%	He et al. (2019b)[1]
R3	Passed	74%	He et al. (2019b)[2]
NA1/NA2	Failed	-	McCoshum et al. (2016)
NA1/NA2	Failed	-	Stein et al. (2019)
NA2	Failed	-	Wijgerde et al. (2020)

*All studies failed at least 1 screening question

NA1 = Failed relevance screening
NA2 = Failed reliability screening

No studies suitable for decision-making (R1 & R2)

Four assays suitable for preliminary assessment (R3 & R4)

One study disregarded (R6) and four failed the screening

PCPC Identified Accurate and Reliable Usage Data/Information Sources

Data/information source	Category	Description
ECHA[1]	ECHA use category	Reported chemical use types (e.g., sunscreens)
	ECHA annual tonnage band	Chemical tonnages reported in ranges per annum
USEPA[2]	CDR[3] product category (company)	Reported use of chemicals in commerce
	CDR inventory (tonnage)	Reported manufactured/imported > 11.3 metric tonnes
USFDA[4]	VCRP[5]	No. formulations an INCI[6] name is used in
Euromonitor International	Total ingredient tonnages by sector	Ingredient tonnages calculated from sales data
	Product category tonnages	Ingredient tonnages by product category

[1]ECHA = European Chemicals Agency.
[2]USEPA = United States Environmental Protection Agency.
[3]CDR = Chemical Data Reporting.
[4]USFDA = United States Food & Drug Administration.
[5]VCRP = Voluntary Cosmetic Reporting Program.
[6]INCI = International Nomenclature of Cosmetic Ingredients.

7. ECHA (2021)
8. ECHA (2021)
9. USEPA (2021)

NOTE: All publicly available data and analysis will be provided to the NASEM Committee

UV Filter Usage Case Study 1: Octocrylene

ECHA USAGE CATEGORIES
(Tonnage band = 1000 – 10000 metric tonnes per annum)

- Cosmetics
- Personal care products
- Perfumes and fragrances
- Washing and cleaning products
- Automotive care products
- Paints and coating or adhesives
- Air fresheners
- Long-life materials: outdoor (metal, wooden and plastic construction/building materials)
- Long-life materials: miscellaneous (flooring, furniture, construction materials, curtains, footwear, leather products, electronic equipment)
- Long-life materials: plastic (food packaging and storage, toys, mobile phones)
- Long-life materials: paper (tissues, feminine hygiene products, nappies, books, magazines, wallpaper, cardboard products)

Different Data Sources Report Octocrylene Usage within the Same Range

Total and category-specific volume of use data reported by USEPA and Euromonitor

USEPA usage data	
CDR product category (company)	CDR inventory (metric tonnes)
Personal care products (Symrise)	53.6
Personal care products (Symrise)	421.4
CBI (BASF)	CBI[1]
CBI (3M)	CBI
2014 aggregate volume	**454.6 - < 9071.8**

[1]CBI = confidential business information.

Euromonitor U.S. data[1]	
Category	Volume of use (metric tonnes)
Skin care	238.5
Sun care	1120.1
Color cosmetics	6.5
All categories	**1365.1**

[1]Based on 2019 sales data.

=> Octocrylene is used across multiple sectors, although some data are not publicly available

UV Filter Usage Case Study 2: Zinc Oxide

ECHA USAGE CATEGORIES
(Tonnage band = ≥ 100000 - < 1000000 metric tonnes per annum)

- Cosmetics
- Fillers
- Putties
- Plasters
- Modelling clay
- Coating products
- Metal treatment products
- Finger paints
- Polymers
- Washing & cleaning products
- Automotive care products
- Paints and coating or adhesives
- Fragrances or air fresheners
- Long-life materials: indoor (flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment)
- Long-life materials: outdoor (metal, wooden and plastic construction materials)
- Complex articles: vehicles, machinery, mechanical appliances (computers, cameras, lamps, refrigerators, washing machines), metal (jewelry, cutlery, pots, toys), plastic (food packaging and storage, mobile phones), wood (floors, furniture, toys) and fabrics, textiles and apparel (e.g., clothing, mattress, curtains or carpets, textile toys)

The Use of Zinc Oxide in Sunscreens is Relatively Minor

Total and category-specific volume of use data reported by USEPA and Euromonitor

USEPA usage data			
CDR Product category	Number of entries per category	CBI per category	CDR inventory per category (metric tonnes)
Non-TSCA[1] use	2	0	102422
Electrical and electronic products	6	3	94354
None reported	30	16	64555
Adhesives and sealants	2	0	51227
Chemical manufacturing and feed Material	1		51211
Paints and coatings	11	2	48652
Metal products not covered elsewhere	6	0	44812
+ 26 additional categories			
Personal care products	4	1	5055
2014 aggregate total			**226796 - < 340195**

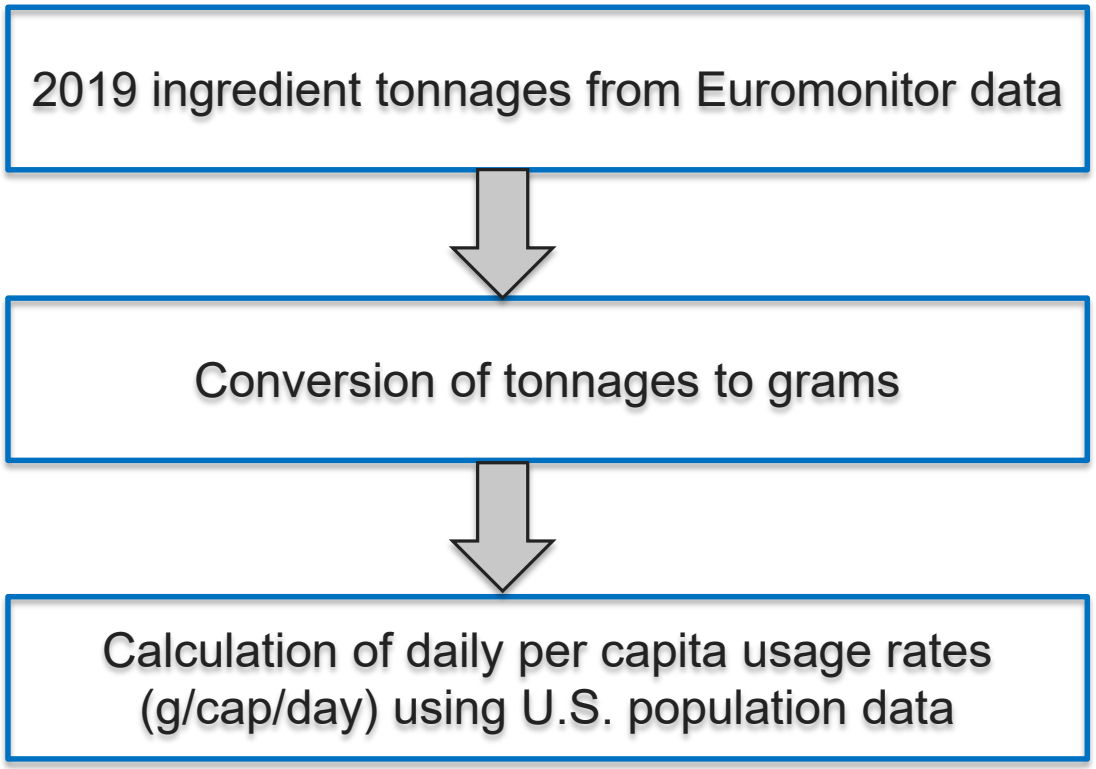
[1]Toxic Substances Control Act

Euromonitor U.S. data[1]	
Category	Volume of use (metric tonnes)
Sun care	303.4
Skin care	15.8
Color cosmetics	29.6
Baby and child-specific products	501.7
All categories	**850.4**

[1]Based on 2019 sales data.

=> Zinc oxide is used across multiple sectors at relatively high levels

Calculation of Daily Per Capita UV Filter Usage Rates

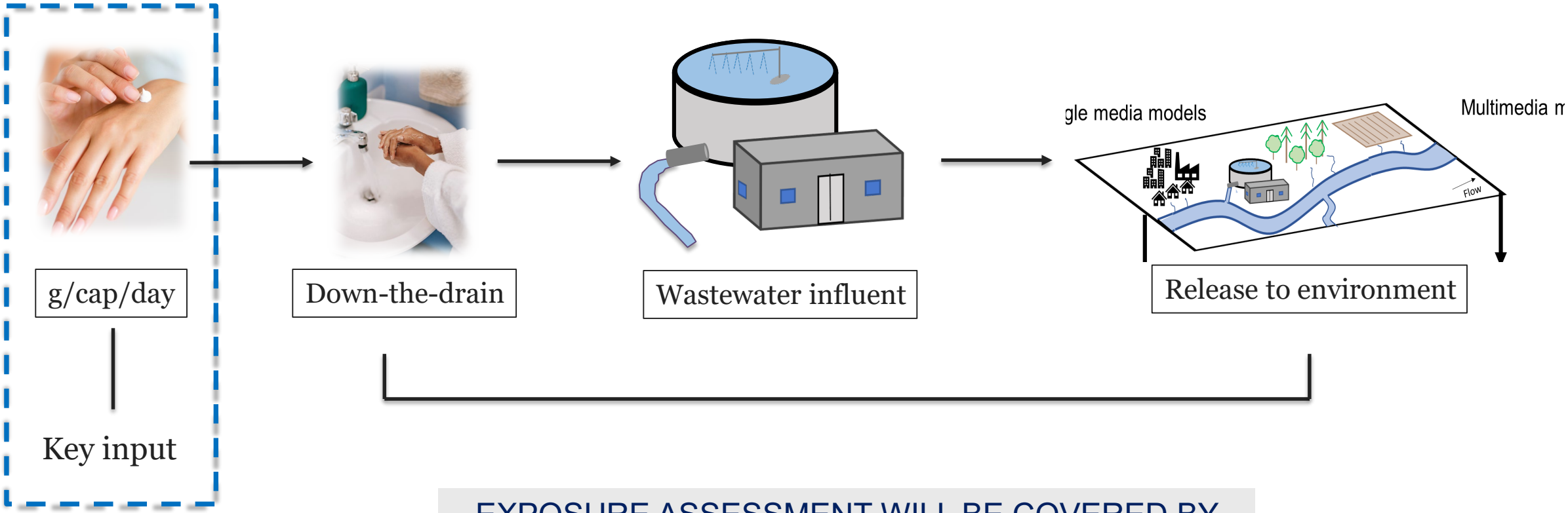


INCI sunscreen active name (INN/USAN/ANN)[1]	g/cap/day[2]
Avobenzone (Butyl methoxydibenzoylmethane)	0.008
Homosalate	0.027
Octinoxate (ethylhexyl methoxycinnamate)	0.009
Octisalate (ethylhexyl salicylate)	0.012
Octocrylene (octocrilene)	0.011
Zinc oxide	0.007
Titanium dioxide	0.003
Oxybenzone (benzophenone-3)[3]	0.011
Sulisobenzone (benzophenone-4)[3]	0.011
Dioxybenzone (benzophenone-8)[3]	0.011
Meradimate (menthyl anthranilate)[3]	0.0002
Cinoxate[3]	0.0002
Ensulizole (phenylbenzimidazole sulfonic acid)[3]	0.0002
Trolamine salicylate (triethanolamine salt of salicylate)[3]	0.0002

[1]INN/USAN/ANN = International nonproprietary name/United States adopted name/Australian approved name.
[2]Based on 2019 tonnage data: U.S. population of 328 239 523; 365 days
[3]Conservatively assumed from category total for each ingredient.

10. Burns et al. (2021)

Use of Daily Per Capita Usage Rates in Exposure Assessment



EXPOSURE ASSESSMENT WILL BE COVERED BY DR. EMILY BURNS TOMORROW

Summary

- PCPC developed an ecotoxicity data relevance and reliability tool which was used to evaluate published coral toxicity studies
- No published coral ecotoxicity studies were found to be suitably reliable for decision-making, while four studies were identified as being suitable for preliminary assessment
- PCPC has developed methods to evaluate use categories and volumes of use for UV filters
- Considerable UV filter usage has been reported for a wide array of non-cosmetic, personal care and over-the-counter (OTC) drug products
- Volume of use data collected, compiled and analyzed by PCPC is being used to assess the environmental exposure of UV filters in the United States

References

1. Mitchelmore, C. L., Burns, E. E., Conway, A., Heyes, A., & Davies, I. A. (2021). A critical review of organic UV filter exposure, hazard, and risk to corals. Environmental Toxicology and Chemistry 40(4), 967–988. https://doi.org/ 10.1002/etc.4948.
2. US Environmental Protection Agency, 2011. Evaluation guidelines for ecological toxicity data in the open literature. Procedures for screening, viewing, and using published open literature toxicity data in ecological risk assessments. Washington DC.
3. Klimisch, H.J., Andreae, M., Tillmann, U. 1997. A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data, Regulatory Toxicology and Pharmacology 25(1), 1-5.
4. Breton, R.L., Gilron, G., Thompson, R., Rodney, S., Teed, S., 2009. A new quality assurance system for the evaluation of ecotoxicity studies submitted under the new substances notification regulations in Canada. Integrated Environmental Assessment and Management 5, 127–137. https://doi.org/10.1897/IEAM_2008-026.1.
5. Mormond, C.T.A., Kase, R., Korkaric, M., Ågerstrand, M., 2016a. CRED: Criteria for reporting and evaluating ecotoxicity data. Environmental Toxicology and Chemistry 35, 1297–1309. https://doi.org/10.1002/etc.3259.
6. Burns, E.E., Davies, I.A. 2021. Ecotoxicological data evaluation for the environmental risk assessment of cosmetic and personal care ingredients: UV filter and coral case study. Manuscript *in prep.*
7. European Chemicals Agency (ECHA). (2021). Substance Infocard, octocrilene. https://echa.europa.eu/substance-information/-/substanceinfo/100.025.683.
8. European Chemicals Agency (ECHA). (2021). Substance Infocard, zinc oxide. https://echa.europa.eu/substance-information/-/substanceinfo/100.013.839.
9. United States Environmental Protection Agency (USEPA). (2021). Chemical Data Reporting, Access CRD Data. https://www.epa.gov/chemical-data-reporting/access-cdr-data.
10. Burns, E.E., Csiszar, S.A., Roush, K, Davies, I.A. 2021. National-scale down-the-drain environmental risk assessment of oxybenzone in the US. Integrated Environmental Assessment and Management, DOI: 10.1002/ieam.4430.

Thank you for your attention!

Personal Care Products Council

Committed to Safety, Quality & Innovation

Iain Davies
daviesi@personalcarecouncil.org