ASSOCIATION FOR THE ADVANCEMENT OF ALTERNATIVES ASSESSMENT

International Symposium on Alternatives Assessment Virtual 2020

Current Practices and Future Prospects

October 27-29, 2020

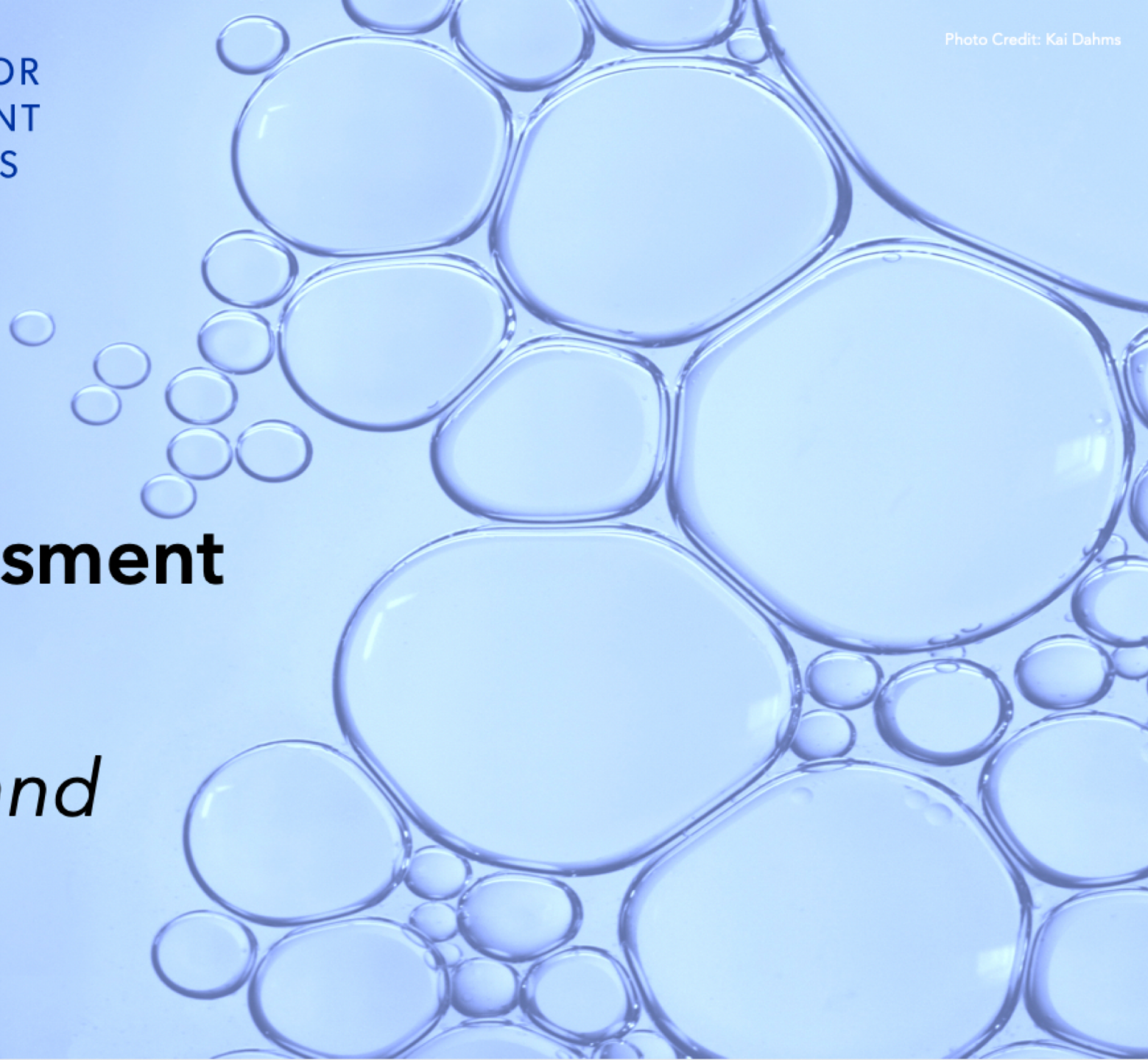

Photo Credit: Kai Dahms

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- During the Q&A portion of the session, if you wish to ask a question or offer a comment, please raise your hand
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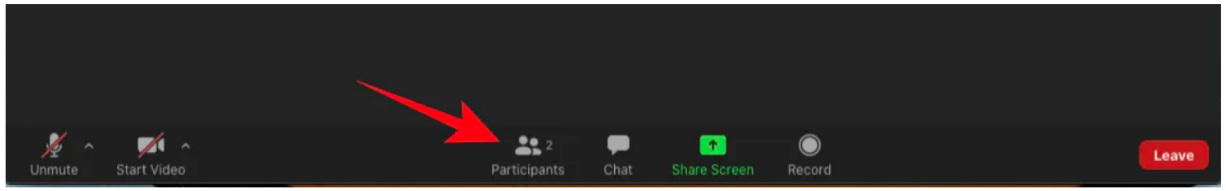
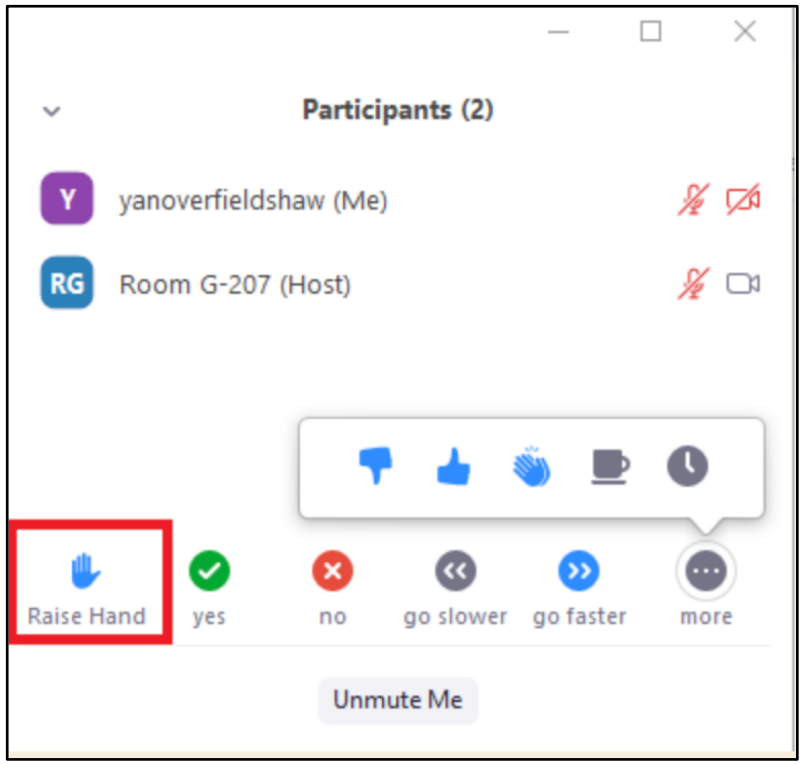
Raising your hand in Zoom





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  - first open the participants icon on the bottom of your computer screen
  - When the participants view opens, you’ll find the “raise hand” icon in the icon list at the bottom.
  - Help us by lowering your hand (toggle the icon) when you finished with your question/comment
- The chat will work too

Symposium Session 6

Part II: Considering Trade-offs:
Real-world strategies to make decisions

Questions? Comments?

- What do you do to address trade-offs in your assessments?
- What are the lessons would you pass on to this community?
- Is our alternatives assessment practice coalescing around specific strategies to navigate trade-offs in decisions about alternatives?
    - Should it?

Moderator & Panelists

MOLLY JACOBS

University of Massachusetts Lowell

MATTEO KAUSCH

Cradle to Cradle Products Innovation Institute

TOM LEWANDOWSKI

Gradient

HEATHER MCKENNEY

The Honest Co.

MALLORY MCMAHON

The Honest Co.

MARTIN WOLF

Seventh Generation

Decision Making Considering Trade Offs

29 October 2020

Outline

- Introduction to Seventh Generation
- Sustainable Product Design
- Product Standards
- The Problem
- The Decision
- Q&A and Discussion

WE DO BUSINESS *differently*

Certified B Corporation

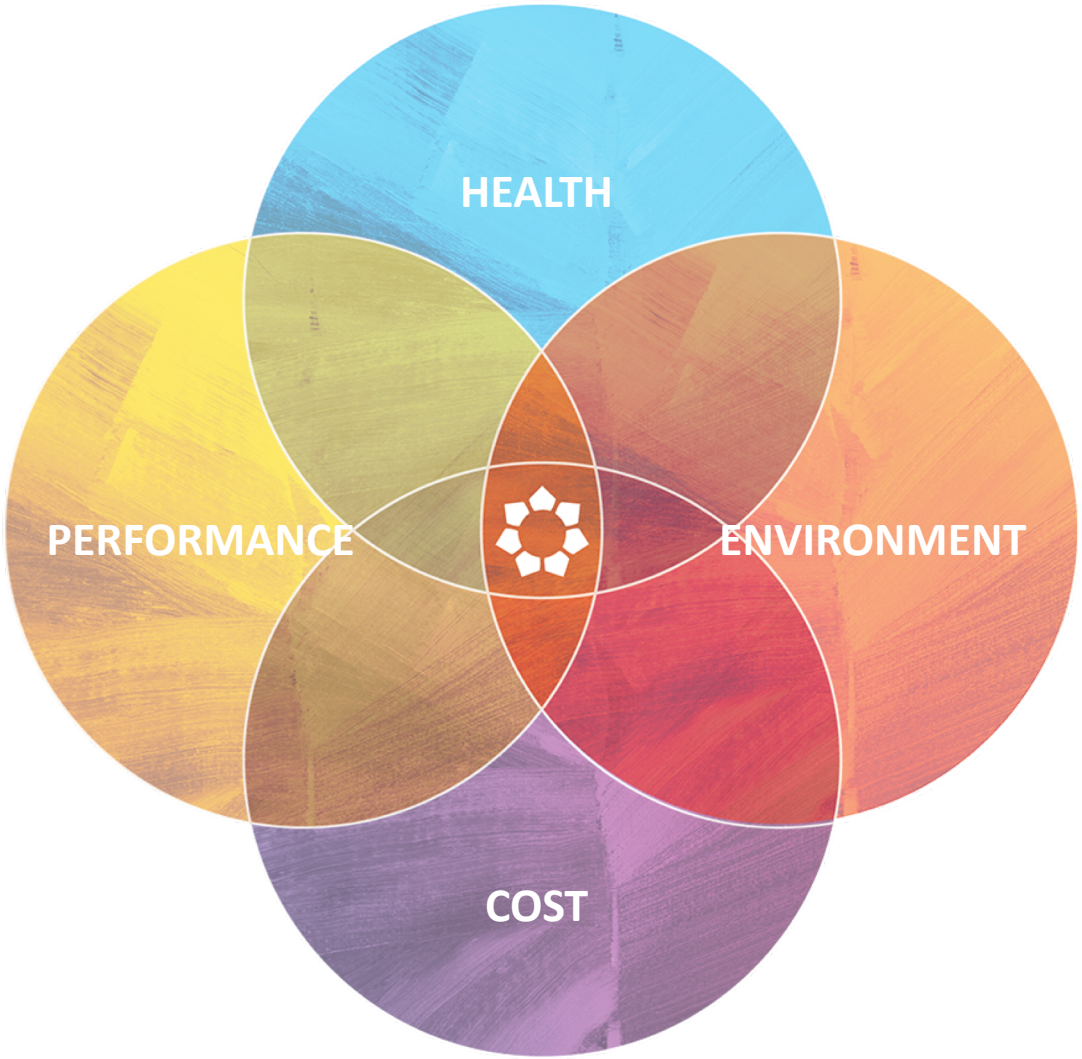
to transform the world into

A HEALTHY, SUSTAINABLE, & EQUITABLE PLACE

for the next seven generations

seventh generation

Sustainable Product Design



Products should be at the center of serving the environment and human health ***without*** compromising efficacy or an accessible price point.

Environmental Formulation Principles

USDA Biobased: 97%*

Product Attributes

- Bio-based
- Biodegradable Ingredients
- Fragrances only from essential oils and botanical extracts
- Low Aquatic Toxicity
- No Volatile Organic Compounds (VOCs)#
- No Phosphates
- No Boric Acid
- No Chlorine
- No Optical Brighteners
- Non-animal ingredients

USDA Biobased: 97%*

USDA Biobased: 95%*

*US Data; ASTM D6866 radiocarbon dating

#excluding fragrances

Human Health Formulation Principles

- **Manage Chronic Toxicity Through Tiered Risk Assessment**
  - Avoid Chronic Toxicants
    - Not Carcinogenic
    - Not Mutagenic
    - Not Neurotoxic
    - Not Reprotoxic
    - Not Endocrine Disrupting
    - No Strong Sensitizers
    - Fragrance Sensitizers disclosed on package

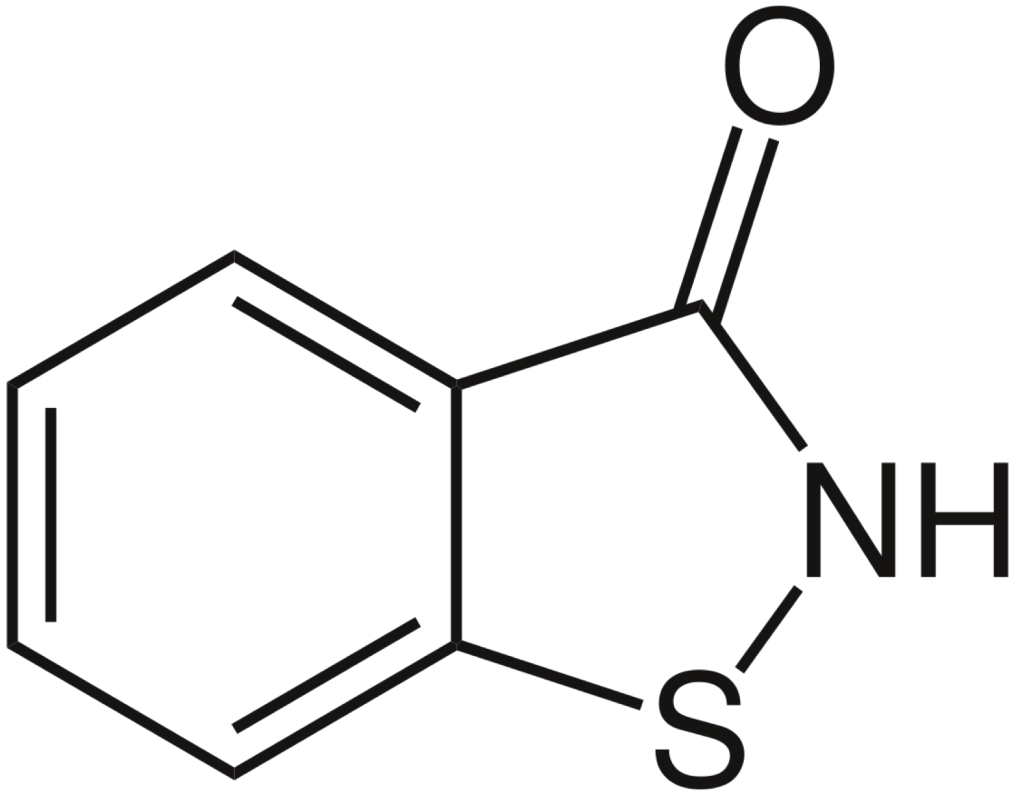
- **Manage Acute Toxicity Through Formulation**
  - Not Acutely Toxic
  - Not Irritating (dermal)
  - Not irritating (ocular)

Safer Choice

USDA CERTIFIED BIOBASED PRODUCT
93% - 100%*

Fragrance Free
SAFER CHOICE
Meets U.S. EPA Safer Product Standards
epa.gov/saferchoice

The Problem

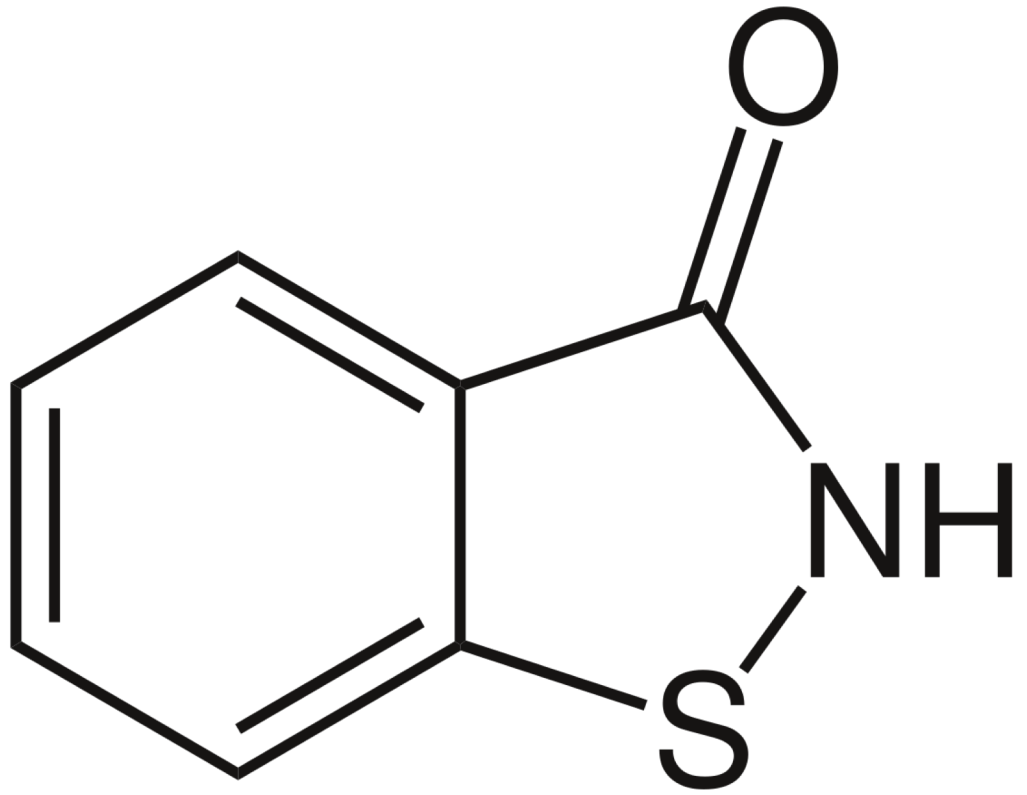


Why Antimicrobial Preservatives?

- Home care products can support microbial growth
  - Water
  - Organic matter (food)
- Microbial growth can degrade product performance and aesthetics
- Antimicrobials can:
  - Lower manufacturing costs
  - Extend shelf life
  - Counteract contamination during use

Benzisothiazolinone

- antibacterial
- antifungal
- stable above pH 7
- FIFRA registered
- Safer Choice listed
- Not “black listed”



Became unavailable due to fire at a factory manufacturing an intermediate chemical (2018).

Strategies for BIT Replacement

Short-term strategies

- Drop-in replacement
  - Safer Choice SCIL list
    - MIT
    - ~~CIT~~
    - Add OIT

Long-term strategies

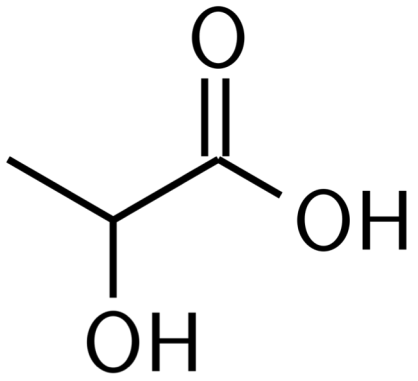
- Reformulate
  - Eliminate isothiazolinones
  - Organic acid antimicrobials
    - Citric acid
    - Lactic acid
    - Sodium benzoate
  - Important to maintain product performance!
  - Important to maintain biobased content

Level of Effort

- Tested over 200 combinations of products and antimicrobial preservatives
  - Each test take 4 weeks for a “first read”
  - Each test takes 12 weeks to complete
- BIT effective at low ppm levels
- Organic acids require 0.5-1% levels

The Problem

- For low solids products (such as window and surface cleaners) use of organic acid preservatives reduced the biobased content below our minimum acceptable level

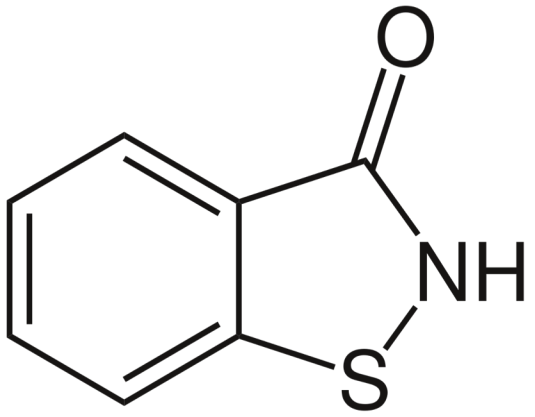


VS

USDA CERTIFIED BIOBASED PRODUCT
93% - 100%*

The Trade-off

Decision to continue to use isothiazolinone rather than reduce biobased content



and

USDA CERTIFIED BIOBASED PRODUCT
93% - 100%*

seventh generation

Questions, Discussion

Thank you!

martin.wolf@seventhgeneration.com

Case Examples of Decision Making in Alternatives Assessment

Tom Lewandowski, Ph.D., DABT, ERT, ATS

A4 Virtual Symposium •October 29, 2020

Case Example: Purely Qualitative/Narrative Comparison

	Common Chemical Name	Performance	Hazard	Availability	Comparative Exposure	Comparative Cost Per Ton	Conclusion
Compounds of Concern	Methyl isothiazolinone	Demonstrated use	Skin sensitizer, not reprotoxic, aquatic toxicity	Readily available	Existing chemicals	Existing chemicals	Compares fairly favorably with possible alternatives
Compounds of Concern	Methyl chloro isothiazolinone	Demonstrated use	Skin sensitizer, not reprotoxic, aquatic toxicity	Readily available			
Possible Alternatives	Antimicrobial 1	Used in leather process, ability to replace isothiazolones uncertain	Possible skin sensitizer, mutagenic, Prop65 repro hazard, aquatic toxicity	Readily available	Less volatile, more hydrophilic	*Less*	*Possible, Prop65 listing is a concern*
Possible Alternatives	Antimicrobial 2	Used in leather process, ability to replace isothiazolones uncertain	Possible skin sensitizer, mutagenic, Prop65 repro hazard, aquatic toxicity	Readily available	Less volatile, more hydrophilic	*Similar*	*Possible, Prop65 listing is a concern*
Possible Alternatives	Antimicrobial 3	Used in textile processing, replacing isothiazolones in some consumer products	Not sensitizing, repro at high concentrations (>300 mg/kg), lowest aquatic toxicity	Readily available	Similar volatility, more hydrophobic	*Similar*	*Explore further*
Possible Alternatives	Antimicrobial 4	Marketed for use in leather process, ability to replace isothiazolones unknown	Not sensitizing, repro at high concentrations, endocrine active, aquatic toxicity	Readily available	Less volatile, more hydrophobic	*Substantially Higher*	*Higher hazard, higher cost, probably non-viable*

Simple summary statement

Gradient private client assessment, 2016

Case Example: Mostly Qualitative/Narrative Comparison

Product Group	Description	Hazard			Performance	Relative Exposure Potential	Conclusions of Preliminary AA
		Human Health	Ecological	Physical/ Chemical			
1	Priority Product (>60% DCM)	Base Case (200)	Base Case (100)	Base Case (85)	Base Case	Base Case	
2	Priority Product (<45% DCM)	Higher (265)	Similar (100)	Higher (125)	Somewhat less effective	Similar	These products would not be good substitutes for the priority product as the hazards are similar or higher, the exposure potential is similar, and the performance is somewhat reduced. Overall, not good candidates to carry over to Stage 2.
3	Acetone/Toluene/ Methanol	Lower (145)	Substantially lower (25)	Higher (150)	Clearly less effective in most cases	Similar	These products would not be good substitutes for the priority product in terms of physical hazard, although the health hazard is reduced. The exposure potential is similar, but performance is clearly inferior to priority products. Overall, not good candidates to carry over to Stage 2.
4	Dibasic esters	Substantially lower (75)	Substantially lower (45)	Substantially lower (0)	Clearly much less effective	Lower *via* air, similar to other pathways	Despite good hazard scores and reduced exposure potential for some pathways, inferior performance of these products leads to dropping this group from further considerations.
5	Benzyl alcohol	Substantially lower (20)	Substantially lower (0)	Similar (50)	Variable and difficult to reconcile results, due to test differences. Equivalent to clearly inferior performance.	Lower *via* air, similar to other pathways	Hazard scores are substantially lower than the priority product, and there is an indication of reduced exposure potential. However, performance is reported to be highly inconsistent, with some studies showing similar performance to the priority product and others showing very poor performance. Consider carrying to Stage 2 if the performance discrepancies can be resolved.
6	Caustics	Substantially lower (30)	Substantially lower (15)	Substantially lower (0)	Clearly much less effective although data are limited	Lower *via* air, potentially greater *via* water, similar for soil/sediment	Despite good hazard scores and reduced exposure potential for some pathways performance studies, leads to dropping this group from further considerations.
7	Other	Varies (110-225)	Substantially lower (0)	Varies (50-150)	No reliable data to evaluate performance	Lower *via* air, similar to other pathways	Hazard score is variable across the category, and exposure potential may be better for some products, but the absence of data to determine whether the products work leads to dropping this group from further consideration.
8	Lowell Formulation	Lower (110 or 185)	Substantially lower (10)	Higher (150)	Similar/slightly inferior performance depending on paint type for close formulation. No data on actual formulation.	Lower *via* air, similar to other pathways	There is reduced human health and ecological hazard relative to the priority product. Increased flammability could be a trade off, but this should be exploded (*e.g.*, the impacts of additives that reduce vapor pressure). Performance for similar products is nearly as good, but performance data on the current formulation are needed.

California SCP AA for DCM Paint Removers, Gradient, 2019

Case Example: Quantitative Comparison of Alternatives

- AA of alternative flame retardants for foam products
- Private business group, not done for any regulatory purpose
- Used sequential and simultaneous decision frameworks (IC2 AA Guide)
  - Sequential = sequentially screen for different modules (*e.g.*, hazard, performance) and eliminate alternatives that aren't better than current product
  - Simultaneous = evaluate all modules together, weighting according to importance
- Explored different weightings for simultaneous framework

IC2 Module Scoring

- Classified/binned current product and each alternative for the following modules
  - Performance
  - Hazard
  - Availability
  - Exposure
  - Cost
- 3 to 5 bins per module, average bin number became the module score (higher is better)
  - Some binning was arbitrary due to lack of guidance

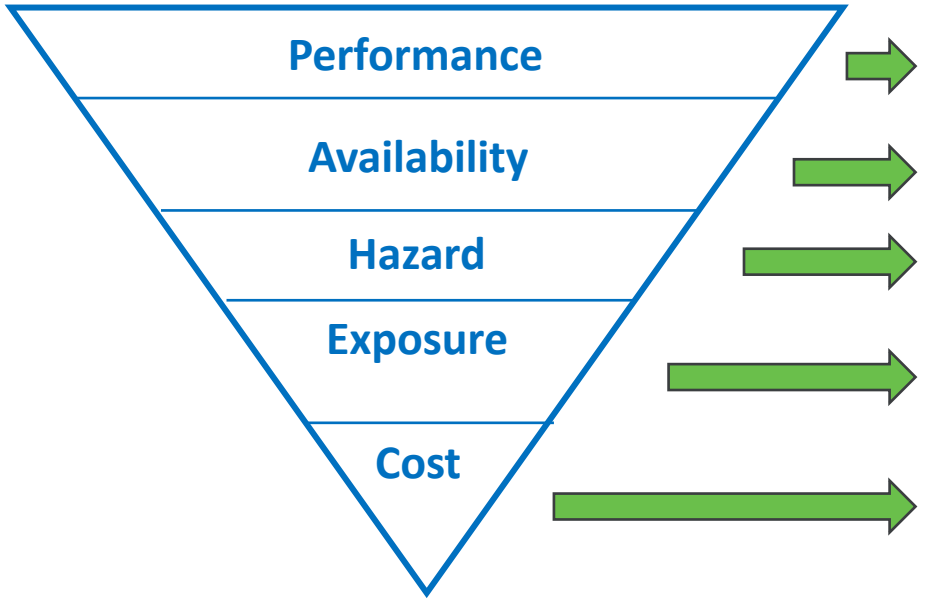
Example: Exposure Scoring

Class/Bin	Log Kow	Vapor Pressure (mm Hg at 25C)	Water Solubility (mg/L at 25C)	Env. Half-life (days)
Class 1	>5	>0.01	>10,000	>180
Class 2	0 to 5	0.01 to 10-6	100 to 10,000	60-180
Class 3	-5 to 0	10-6 to 10-10	1 to 100	16-60
Class 4	<-5	<10-10	<1	<16

	Current Chemical	Alternative 1
Log Kow	Class 2 = 2 points	Class 2 = 2 points
Vapor Pressure	Class 3 = 3	Class 3 = 3
Water Solubility	Class 2 = 2	Class 4 = 4
Env. Half-life	Class 2 = 2	Class 4 = 4
Total score	**Avg = 2.3**	**Avg = 3.3**

Decision Frameworks

- Sequential framework
  - Performance, hazard, exposure, availability, cost
  - Worse module score than current chemical = rejected
- Simultaneous framework
  - Used 4 weighting approaches

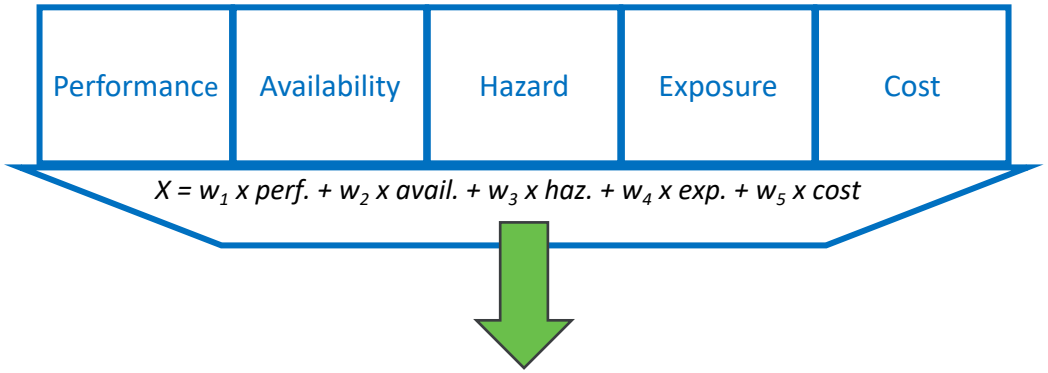


Module	Equal Weights	Weight Variant 1	Weight Variant 2	Weight Variant 3
Performance	0.2	0.15	0.15	0.4
Hazard	0.2	0.45	0.25	0.4
Exposure	0.2	0.26	0.25	NA
Cost	0.2	0.14	0.15	0.2
Availability	0.2	NA	0.2	NA

Based on Malloy et al. 2013

Add availability, slightly lower hazard wt

Only performance, hazard, and cost



Results of Sequential and Simultaneous Approaches

Alternative	Sequential Framework	Simultaneous Framework							
		Performance Score	Availability Score	Hazard Score	Exposure Score	Cost Score	Weighted Score 1	Weighted Score 2	Weighted Score 3
Current Chemical		0	4	3.2	2.3	2	2.3	2.5	
Alternative 1		0	4	3.2	3.3	2	2.6	2.7	1.7
Alternative 2					3.3	3	2.9	3.0	2.0
Alternative 3					2.5	2	2.9	2.6	2.1
Alternative 4					0.0	1	0.1	0.4	0.2
Alternative 5					0.0	1	2.0	1.2	1.9
Alternative 6		3	2	2.6	2.2	1	2.3	2.2	2.4
Alternative 7		0	4	4.2	1.7	3	2.7	2.7	2.3
Alternative 8	√	3	2				3.2	2.8	3.1
Alternative 9		0	3				2.8	2.6	1.7
Alternative 11		0	3				1.0	2.11	1.0
Alternative 12	√	5	4				3.3	3.4	3.8
Alternative 13	√	3	4	3.48	2.79	2	3.0	3.1	3.0

Sequential framework missed some alternatives that the simultaneous framework suggested may be worthwhile

Module scoring schemes didn't make much of a difference in outcome for top choices

Notes: Score 1 = Hazard × 45% + Exposure × 26% + Performance × 15% + Cost × 14%.
Score 2 = Hazard × 25% + Exposure × 25% + Performance × 15% + Availability × 25% + Cost × 15%.
Score 3 = Hazard × 40% + Performance × 40% + Cost × 20%.

Top alternatives

Using the C2C Certified Material Health Assessment Methodology to evaluate tradeoffs in hazard profiles and exposure routes: TiO_2 case study

Matteo Kausch, PhD
Cradle to Cradle Products Innovation Institute

INSTITUTE AND PROGRAM HISTORY

2002

Book publication: Cradle to Cradle: Remaking the Way We Make Things

2005

MBDC created certification programme
Version 1.0

2009

Version 2.1

2010

Institute founded in San Francisco, California

2012

Institute becomes Cradle to Cradle Certified™ administrator and certification body

Institute opens European office in The Netherlands

2013

Version 3.0

2015

Version 3.1
Material Health Certificate introduced

2019

1st Draft Version 4.0
Developed in multi-stakeholder process

1st Public Comment Period

2020

2nd Draft Version 4.0
2nd Public Comment Period

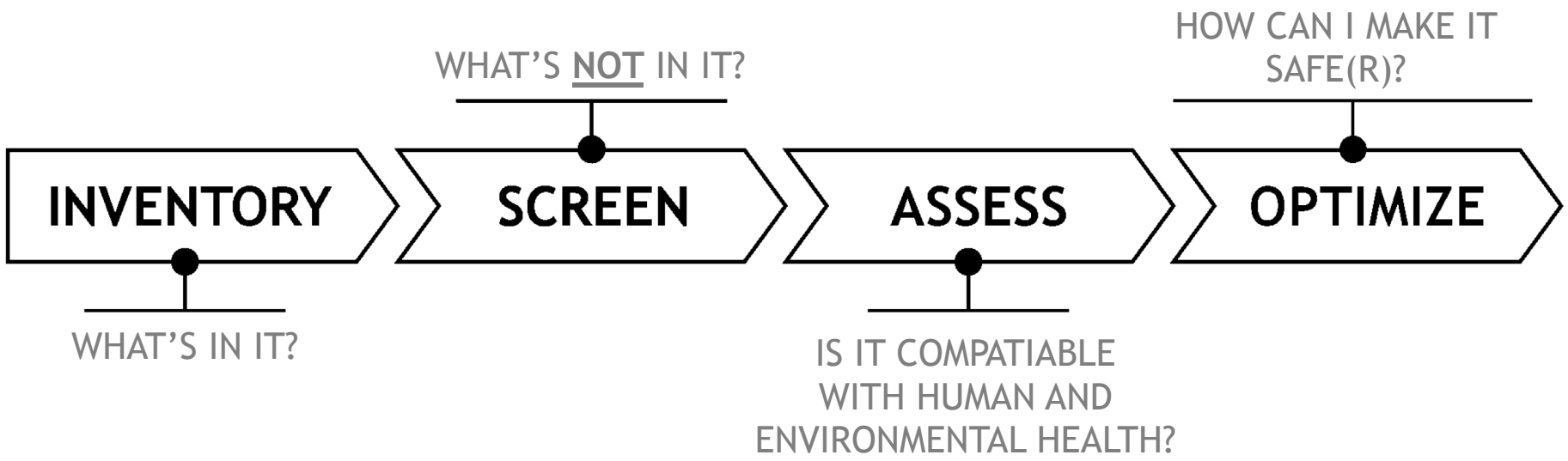
CRADLE TO CRADLE CERTIFIED™

Ensure materials are safe for humans and the environment

MATERIAL HEALTH

Chemicals and materials used in the product are selected to prioritize the protection of human health and the environment, generating a positive impact on the quality of materials available for future use and cycling.

MATERIAL HEALTH FOCUS AREAS



MATERIAL HEALTH ASSESSMENT METHODOLOGY OVERVIEW

Goal: Assign an **A - ideal**, **B - preferred**, **C - acceptable**, **X- significant risks** or **GREY - insufficient data** rating to each **homogeneous material** subject to review in the product using the following **3 steps**:

1) Conduct chemical hazard assessment

2) Conduct exposure assessment & assign chemical risk ratings

3) Assign material assessment rating

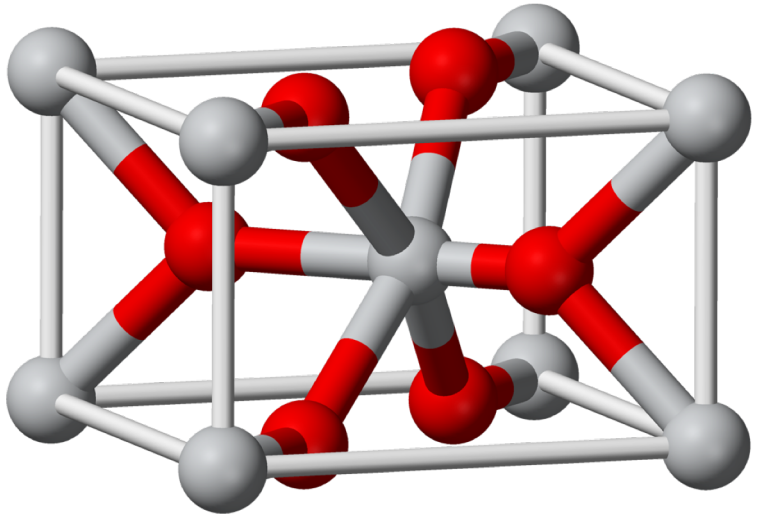
BACKGROUND

- Carbon black, TiO_2, and crystalline silica are substances used in a large variety of articles and formulated products
- Commonly recognized as hazardous and listed on numerous authoritative lists; however, hazards are specific to the route of inhalation and may thus not be relevant in many applications
- HPDC was looking to develop special conditions for these three initially and potentially additional substances meeting the same requirements in the future
- **Goal: Establish under which conditions TiO_2, carbon black, and crystalline silica are considered 'acceptable' according to the C2C Certified MHAM (in support of special condition).**

Titanium Dioxide

CAS #: 13463-67-7

- Most common, naturally occurring form of titanium
- Very common pigment (estimated to be 2/3 of all pigments)
- Applications include: paint, sunscreen, and food coloring
- Crystalline (rutile structure most common): continuous network of tetragonal unit cells with each Ti^{4+} surrounded by 6 O^{2-} (and each O^{2-} by 3 Ti^{4+})
- Suspected Carcinogen (EU Cat. 2)



HAZARD ASSESSMENT

RED (significant hazard), YELLOW (borderline hazard), GREEN (no hazard), or GREY (data gap) - hazard rating assigned to each endpoint

Human Health

Carcinogenicity	Mutagenicity
Reproductive & Developmental Toxicity	Skin, Eye, and Respiratory Corrosion/Irritation
Neurotoxicity	Endocrine Disruption
Oral Toxicity	Dermal Toxicity
Inhalation Toxicity	Sensitization of Skin and Airways
Other	

Environmental Health

Fish Toxicity	Daphnia Toxicity
Algae Toxicity	Bioaccumulation
Persistence	Terrestrial Toxicity
Climatic Relevance	Other

Chemical Class

Organohalogens	Toxic Metals

HAZARD ASSESSMENT

RED (significant hazard), YELLOW (borderline hazard), GREEN (no hazard), or GREY (data gap) - hazard rating assigned to each endpoint

Human Health

Carcinogenicity	Mutagenicity
Reproductiv Developmer	
Neurotoxicit	
Oral Toxicity	
Inhalation T	Airways
Other	

Strategy 1: Comparative evaluation matrices -- used in every C2C Certified assessment.

Environmental Health

Fish Toxicity	Daphnia Toxicity
	n
	city

Chemical Class

Organohalogens	Toxic Metals

Titanium Dioxide

CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI	R	G	G	Y	G	G	Y	-	G	G

Environmental

Inv	Fish	Alg	P	B	C	T
G	G	-		G	G	-

Other

OX	TMe	O
G	G	G

Titanium Dioxide

CAS #: 13463-67-7

Split mammalian toxicity by exposure route, aquatic toxicity by taxon.

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI	R	G	G	Y	G	G	Y	-	G	G

Environmental

Inv	Fish	Alg	P	B	C	T
G	G	-		G	G	-

Other

OX	TMe	O
G	G	G

Titanium Dioxide

CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI						G	Y	-	G	G

Strategy 2: Rule-based evaluation of data gaps.

Environmental

Inv	Fish	Alg	P	B	C	T
G	G	-		G	G	-

Other

OX	TMe	O
G	G	G

Titanium Dioxide

CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI					G	G	Y	-	G	G

Endpoints for which data gaps are acceptable according to MHAM.

Envi

Inv	Fish	Alg	P	B	C	T
G	G	-		G	G	-

Other

OX	TMe	O
G	G	G

Titanium Dioxide

CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI	R	G	G	Y	G	G	Y	✓	G	G

Environmental

Inv	Fish	Alg	P	B	C	T
G	G	-		G	G	✓

Other

OX	TMe	O
G	G	G

Titanium Dioxide

CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI	R	G	G						G	G

Environmental

Inv	Fish	Alg	P	TMe	O
G	G	-		G	G

Typically aquatic toxicity data is required for all three organism types. However, if solubility is below 0.001 mg/l, data gaps are allowed.

Titanium Dioxide CAS #: 13463-67-7

Human Health

ODI

Environm

P, B, and aquatic toxicity (AT) endpoints are rolled into a ‘combined AT risk flag’ according to the MHAM. Unless there are red hazards or data gaps in at least one other endpoint of the group, P rating is irrelevant.

Inv	Fish	Alg	P	B	C	T
G	G	✓		G	G	✓

OX	TMe	O
G	G	G

Titanium Dioxide

CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI	R	G	G	Y	G	G	Y	✓	G	G

Environmental

Inv	Fish	Alg	P	B	C	T
G	G	✓	n/a	G	G	✓

Other

OX	TMe	O
G	G	G

Titanium Dioxide

CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI	R	G	G	Y	G	G	Y	✓	G	G

Strategy 3: Exposure considerations.

					C	T
G	G	✓	n/a	G	G	✓

Other

OX	TMe	O
G	G	G

Titanium Dioxide CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI	R	G	G	Y	G	G	Y	✓	G	G

Other

OX	TMe	O
G	G	G

Look at exposure route sub-endpoints: only hazards related to inhalation of dust form, 'yellow' risk if in bulk form/ embedded in matrix (C2C Certified Exposure Methodology).

Titanium Dioxide

CAS #: 13463-67-7

Human Health

	C	M	R&D	E	O	D	I	N	S	C/Irr
ODI	R	G	G	Y	G	G	Y	✓	G	G

Environmental

Inv	Fish	Alg	P	B	C	T
G	G	✓	n/a	G	G	✓

Other

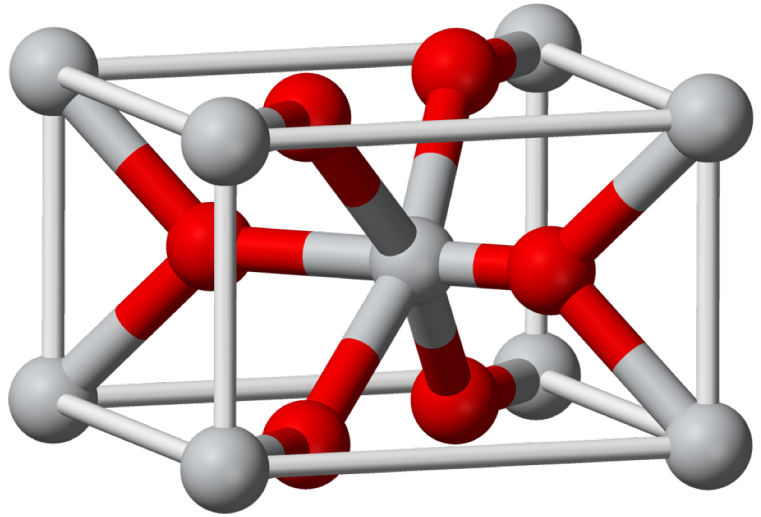
OX	TMe	O
G	G	✓

Titanium Dioxide

CAS #: 13463-67-7

Conclusion:

- Based on hazard profile and following the C2C Certified MHAM, and Exposure Methodology, this substance is ‘c’ assessed (i.e. ‘acceptable’) when embedded in a material matrix (i.e. non-inhalable). It is ‘x’ assessed (i.e. ‘problematic’) in inhalable form.



LESSONS FOR PRACTITIONERS

- Endpoint specific considerations (physical parameters, etc.) around data availability can improve treatment of data gaps (what data is reasonable to require?)
- Looking at hazards by exposure route and taxon (for aquatic toxicity) will lead to more representative conclusions (are we ignoring data gaps because they do not fall under a traditional endpoint?)
- Exposure considerations can fundamentally change chemical prioritization for specific product applications (are identified hazards relevant given the product/material context?)
- The C2C Certified Material Health Assessment Methodology offers a structured framework for considering these tradeoff and making informed decisions.

THANK YOU!

c2ccertified.org

Closing Thoughts

ASSOCIATION FOR THE ADVANCEMENT OF ALTERNATIVES ASSESSMENT

Organized by The Lowell Center for Sustainable Production at University of Massachusetts Lowell

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Welcome to the Association for the Advancement of Alternatives Assessment (A4)

Join Now

Advancing the science, practice, and policy of alternatives assessment and informed substitution

A4 welcomes you to this week's International Symposium!

Watch this short video and help us celebrate the faces, places and events that have shaped A4's growing community.

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Thank you to our A4 Program Committee













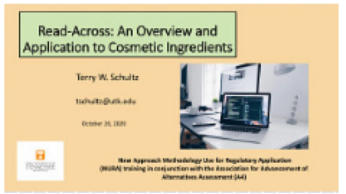



Friday: NURA Short Course

New Approach Methodology Use for Regulatory Application (NURA) – Part 2

P1.01. Ouédraogo - New Insight in Read Across.pdf

P1.02. Lester - Similarity Consideration in Analog Selection.pdf



P1.03. Schultz - Overview and Application to Cosmetic Ingredients.pdf

To register for Friday's Part 2 session, please visit:
http://saferalternatives.org/2020-virtual-symposium/short-course-nura

To access presentations for Parts 1 and 2, please visit:
https://pcrm.widencollective.com/portals/nteaew1t/NURAA4

ASSOCIATION FOR THE ADVANCEMENT OF ALTERNATIVES ASSESSMENT

“One of the most essential, and powerful steps to change is understanding that there are alternatives”

-Mary O’Brien 2000

Join Us!

- A4 is dedicated to advancing the science, practice, and policy of alternatives assessment and informed substitution.
  - The **vision** of A4 is that every essential function performed by a chemical, material, process, or product is achieved with safe and sustainable solutions
  - The **mission** of A4 is to enhance the science of alternatives assessment, advance informed substitution, and support a vibrant, effective community of practitioners
- Learn from state of the science webinars, Network with the world’s leading AA practitioners
- Join the A4 at: https://www.saferalternatives.org/membership/