



Aligning safer chemicals with patient care in BC health care facilities: research, development, and engagement

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DISCLAIMER TEXT:

This report was produced as part of the UBC Sustainability Scholars Program, a partnership between the University of British Columbia and various local governments and organisations in support of providing graduate students with opportunities to do applied research on projects that advance sustainability across the region.

This project was conducted under the mentorship of Vancouver Coastal Health staff. The opinions and recommendations in this report and any errors are those of the author and do not necessarily reflect the views of Vancouver Coastal Health or the University of British Columbia.

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List of Abbreviations

1. LMHO – Lower Mainland Health Organizations
2. FH – Fraser Health
3. PHC – Providence Healthcare
4. PHSA – Provincial Health Services Authority
5. VCH – Vancouver Coastal Health
6. EES – Energy and Environment Sustainability
7. BC PNSWC – British Columbia Provincial Skin and Wound Committee
8. CoC – Chemical of Concern
9. EPA – Environmental Protection Agency
10. ICAA – International Council of Chemical Associations
11. EU – European Union
12. REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
13. GHS – Globally Harmonized System
14. UNCED - United Nations Conference on Environment and Development
15. UN – United Nations
16. C – Carcinogenicity
17. M – Mutagenicity
18. R – Reproductive Toxicity
19. D – Developmental Toxicity
20. E – Endocrine Activity
21. AT – Acute Mammalian Toxicity
22. ST – System / Organ Toxicity
23. N – Neurotoxicity
24. SnS – Skin Sensitization
25. IrR – Respiratory tract Irritation
26. IrE – Eye Irritation
27. IrS – Skin Irritation
28. AA – Acute Aquatic Toxicity
29. CA – Chronic Aquatic Toxicity
30. P – Persistent
31. B – Bioaccumulation
32. SCIL - Safer Chemical Ingredients List
33. TSCA - Toxic Substances Control Act
34. CEPA - Canadian Environmental Protection Act
35. DSL - Domestic Substances List

1. Introduction:

Achieving energy and environmental sustainability is a priority for the Lower Mainland Health Organizations (LMHOs) which include Fraser Health (FH), Providence Healthcare (PHC), Provincial Health Services Authority (PHSA), and Vancouver Coastal Health (VCH). Lead by an environmental sustainability policy, the LMHOs are mindful of the importance of developing a [triple-bottom-line approach to sustainability](#), which balances ecological, societal, and economic imperatives, and recognizes the link between a healthy environment and a healthy population.

The Energy and Environmental Sustainability (EES) team was created in 2010 to ensure that a collaborative energy and environmental sustainability approach is taken across the LMHOs. Since then, they've partnered with many other stakeholders to integrate and enhance sustainability infrastructure and practices in a variety of programs and made health and wellness central to their work. To reduce the risks of climate change and the environmental impacts of health care construction and operations, four Green Care Focus Areas lead their work and support meaningful change:

- Smart Energy & Water
- Zero Waste & Toxicity
- Active & Clean Transportation
- Workplace Leadership

With in the Zero Waste & Toxicity focus area, EES is working on a Safer Chemicals Program which aligns with international efforts that recognize there are chemicals of concern contained in man-made products, including those used in our hospitals for construction, furnishing, maintenance, cleaning, disinfection, and patient care. Chemicals of concern refer to chemicals that, through credible evidence, have or can have adverse health effects to people or the environment, including carcinogenic and reproductive/development toxicants, and those that are persistent, bio accumulative, and toxic to the environment.

The Safer Chemicals program aims to develop a strategy across the four Lower Mainland health organizations that:

- Aligns health care sites with work undertaken by Workplace Health & Safety, Infection Control, and other clinical stakeholders in order to develop toxicity reduction targets and create a pathway towards safer chemicals
- Identifies potential chemicals of concern, including using requests for proposals to ask vendors to declare chemicals of concern in their products
- Develops a list of chemicals of concern for health care site construction and operations

In 2019 the EES team worked with a UBC Sustainability Scholar to develop a master list of chemicals of concern for health care. This list caught the attention of the Provincial Nursing Skin and Wound Committee, and they are committed to working together on a chemicals of concern list specific to skin and wound products.

The British Columbia Provincial Skin and Wound Committee (BC PNSWC) works with all health authorities including Northern Health, Interior Health, Island health, Fraser Health, Vancouver Coastal Health, Provincial Health Services and First Nations Health and Providence Health Care. The BC PNSWC also works with all sectors including acute care, community care and long-term care. The chemical ingredients within the scope of this project falls into 3 groups of product line including skin cleanser, moisturizers and barriers. Goals for patient skin care contract according to PNSWC are

- Should meet clinical need
- Standardization
- Cost effectiveness
- One skin care product line
- Appropriate across lifespan
- Safe ingredients

As a part of the safer ingredient in patient skin goal, 376 chemical ingredients in 56 product lines were reviewed, and an extensive chemical ingredient list was prepared in 2017. A detailed analysis of each of these chemicals is performed as a part of this project.

2. Research Objective

This objective of this project includes:

- Creating a chemical inventory data base for the chemicals used in patient care that includes chemical and functional use description, environmental and health toxicity as well as regulatory information
- Develop a chemical screening framework to categorize chemicals by hazard and risk assessment
- Categorize chemicals based on their hazard level for internal use by the EES and BC PNSWC team

3. Research Methodology

The inventory of chemical ingredients was prepared by referring to credible resources available online that can summarize the health and environmental impact of these chemical.

To facilitate communication with stakeholders, chemicals in this inventory were screened through a process to assign them into different category based on its risk and hazard assessment.

3.1. Chemical Screening Framework:

For the ease of stakeholder engagement, Chemicals of concern (CoC) were categorized to imply the risk posed by these chemicals. A chemical screening framework was developed to take into consideration the risks and the hazard accompanying the CoC to facilitate an evidence-based decision-making process.

The chemical screening framework was developed by referring to trusted authorities and credible organizations such as the Environmental Protection Agency (EPA), International Council of Chemical Associations (ICCA) and Green Screen.

3.1.1. Resources and requirements

- Risk assessment strategy was adopted from the ICCA's Guidance on Chemical Risk Assessment [1]
- Understanding Green Screen Benchmarking process was useful in designing the chemical screening with clear definition of the benchmarking criteria as well as scores [2]
- Further, to define hazard and risk designation, EPA's Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation published in 2011 was utilized [3]

3.1.2. Other resources include

- National Institute of Health – PubChem database
- European Chemical Agency database
- United States Environmental Protection Agency
- Canadian Domestic Substances list
- International Labour organization

Steps involved in the screening process (adapted from ICCA’s global product strategy outline) [1] are shown in Fig 1:

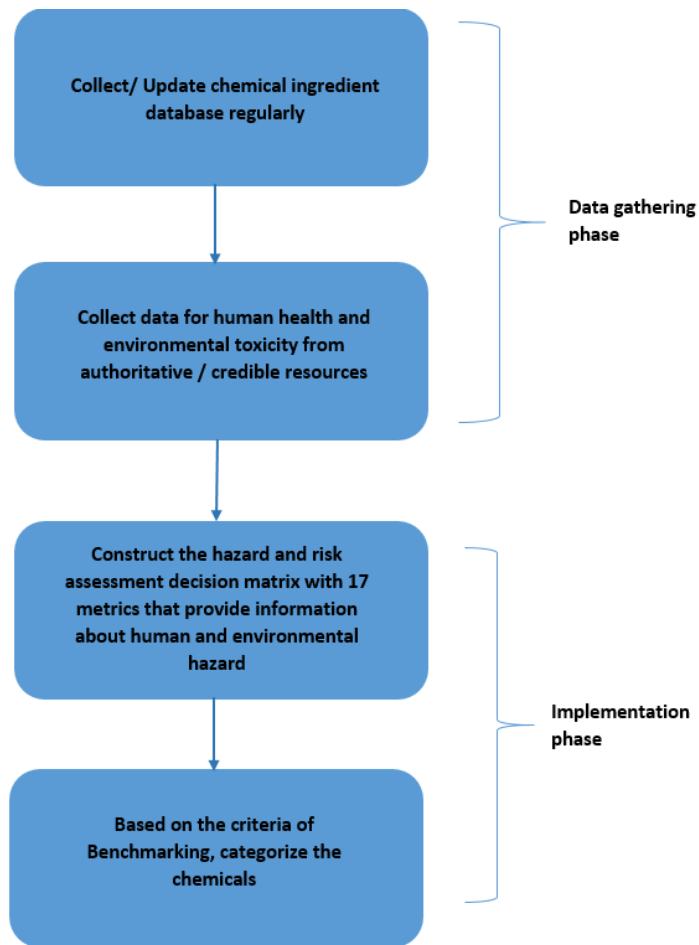


Fig 1: Chemical screening framework flowsheet

3.1.3. Data gathering phase:

In this phase, all relevant information of CoCs is collected to aid the process of risk assessment and characterization. This information includes:

- Functional utility of CoC
- Exposure type and exposure audience in the healthcare facilities
- Human health toxicity including acute and chronic effects
- Environmental Toxicity
- Properties of Concern including but not limited to Endocrine disruptors, Skin sensitizers, Persistence, Bio accumulative and Toxic properties, Carcinogens, Mutagens and developmental toxins
- Regulatory restrictions proposed by Canadian, United States, EU etc
- Exposure limitations

3.1.4. Implementation Phase:

This phase includes two steps namely:

- Defining hazard characterization and risk threshold
- Defining priority classification and allocation of substances to priorities

3.1.5. Defining hazard designation criteria:

United States EPA's Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation report [3] outlines different metric to quantify the extent of the hazard of CoCs with respect to human and environmental well-being.

Metrics that can be considered to quantify human health hazard includes:

- Acute Mammalian Toxicity
- Carcinogenicity
- Reproductive and developmental toxicity

- Mutagenicity / Geno toxicity
- Neurotoxicity
- Reproductive dose toxicity
- Respiratory and skin sensitization
- Eye and skin irritation

Metrics that can be considered to quantify environmental fate hazard includes:

- Aquatic toxicity
- Persistence
- Bioaccumulation
- Eco toxicity

3.1.6. Hazard level:

A five-level hazard classification system as shown in Fig 2 is used to evaluate hazard associated with each metric.

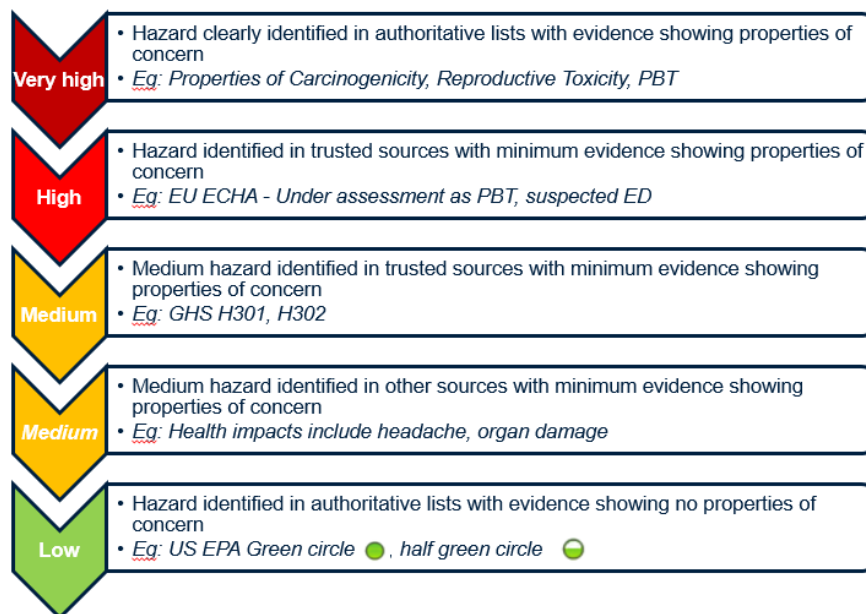


Fig 2: Five level hazard classification

3.1.7. Globally Harmonized System (GHS) classification:

To maintain consistency and for the ease of communicating hazards, Globally Harmonized System (GHS) classification is used to indicate the hazards associated with the chemicals. Effective hazard communication would ensure that employers, employees and the public are provided with adequate, practical and reliable information of the hazards of chemicals. Hence, governments, companies, workers, and public would benefit from the implementation of an effective hazard communication system [4].

Some benefits to the companies by implementing GHS include [4]:

- An increase in efficiency and reduced costs from compliance with hazard communication regulations,
- Application of expert systems resulting in maximizing expert resources and minimizing labor and costs,
- Facilitation of electronic transmission systems with international scope,
- Expanded use of training programs on health and safety,
- Reduced costs due to fewer accidents and illnesses,
- Improved corporate image and credibility

Some benefits to the workers and public include [4]:

- Improved safety for workers and others through consistent and simplified communications on chemical hazards and practices to follow for safe handling and use,
- Greater awareness of hazards, resulting in safer use of chemicals in the workplace and in the home.

*International Mandate from UNCED Agenda 21,
Chapter 19*

*"A globally harmonized hazard classification
and compatible labelling system, including
material safety data sheets and easily
understandable symbols, should be available, if
feasible, by the year 2000."*

Fig 3: International Mandate from UNCED

The globally harmonized system of classification and labelling of chemicals is a system for standardizing and harmonizing classification and labelling of chemicals. GHS is not a regulation or standard by itself, rather it is a system that meet the basic requirements of hazard communication in deciding if the chemical product is hazardous. The existing systems included in this classification are:

- UN transport Recommendation
- US Requirements for workplace, consumer and pesticides
- European Union Dangerous substance and preparations directives
- Canadian Requirements for workplace, consumers and pesticides

3.1.8. GHS hazard classification and associated hazard level

Table 1 & 2 show the GHS hazard classification [5] used for categorizing CoCs and their respective hazard level adapted to suit the purpose of this project.

Human health hazard classification and hazard level:

| Number | Acronym | Explanation | Hazazrd class | Category | Hazard level |
|--------|---------|---------------------------------------------------------------------------|--------------------------|------------|--------------|
| 1 | H301 | Toxic if swallowed | AT | 3 | M |
| 2 | H302 | Harmful if swallowed | AT | 4 | M |
| 3 | H304 | May be fatal if swallowed and enters airways | Aspiration Hazard | 1 | vH |
| 4 | H311 | Toxic in contact with skin | AT | 3 | M |
| 5 | H312 | Harmful in contact with skin | AT | 4 | M |
| 6 | H314 | Causes severe skin burns and eye damage | IrS | 1A, 1B, 1C | vH |
| 7 | H315 | Causes skin irritation | IrS | 2 | H |
| 8 | H316 | Causes mild skin irritation | IrS | 3 | M |
| 9 | H317 | May cause an allergic skin reaction | SnS | 1,1A,1B | vH |
| 10 | H318 | Causes serious eye damage | IrE | 1 | vH |
| 11 | H319 | Causes serious eye irritation | IrE | 2A | H |
| 12 | H320 | Causes eye irritation | IrE | 2B | M |
| 13 | H330 | Fatal if inhaled | AT | 1,2 | vH |
| 14 | H331 | Toxic if inhaled | AT | 3 | M |
| 15 | H332 | Harmful if inhaled | AT | 4 | M |
| 16 | H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled | IrR | 1,1A,1B | vH |
| 17 | H335 | May cause respiratory irritation | ST, single exposure, IrR | 3 | M |
| 18 | H336 | May cause drowsiness or dizziness | ST, single exposure | 3 | M |
| 19 | H340 | May cause genetic defects | M | 1A,1B | vH |
| 20 | H341 | Suspected of causing genetic defects | M | 2 | H |
| 21 | H350 | May cause cancer | C | 1A,1B | vH |
| 22 | H351 | Suspected of causing cancer | C | 2 | H |
| 23 | H360 | May damage fertility or the unborn child | R | 1A,1B | vH |
| 24 | H360Df | May damage the unborn child; Suspected of damaging fertility | R | 1A,1B | vH |
| 25 | H360F | May damage fertility | R | 1A,1B | vH |
| 26 | H361 | Suspected of damaging fertility or the unborn child | R | 2 | H |
| 27 | H361f | Suspected of damaging fertility | R | 2 | H |
| 28 | H370 | Causes damage to organs | ST, single exposure | 1 | vH |
| 29 | H371 | May cause damage to organs | ST, single exposure | 2 | H |
| 30 | H372 | Causes damage to organs through prolonged or repeated exposure | ST, repeated exposure | 1 | vH |
| 31 | H373 | Causes damage to organs through prolonged or repeated exposure | ST, repeated exposure | 2 | H |

Table 1: Human health hazard classification and hazard level

Environmental hazard classification and hazard level:

| Number | Acronym | Explanation | Hazard class | Category | Hazard level |
|--------|---------|-------------------------------------------------------------------------------------|--------------------|----------|--------------|
| 1 | H400 | Very toxic to aquatic life | AA | 1 | VH |
| 2 | H401 | Toxic to aquatic life | AA | 2 | H |
| 3 | H402 | Harmful to aquatic life | AA | 3 | M |
| 4 | H410 | Very toxic to aquatic life with long lasting effects | CA | 1 | VH |
| 5 | H411 | Toxic to aquatic life with long lasting effects | CA | 2 | H |
| 6 | H412 | Harmful to aquatic life with long lasting effects | CA | 3 | M |
| 7 | H413 | May cause long lasting harmful effects to aquatic life | CA | 4 | M |
| 8 | H420 | Harms public health and the environment by destroying ozone in the upper atmosphere | Ozone layer hazard | 1 | VH |

Table 2: Environmental hazard classification and hazard level

3.1.9. Benchmark classification:

The benchmark used for classification of Chemicals of Concern adapted from the Green Screen benchmarking guideline [3] is shown in table [3]

| Category | Legend | Explanation | Criteria |
|-----------------------|-----------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Benchmark 1 | 1 | Avoid - Chemical of High Concern | Chemical under this category fulfils one or more of these criteria: a. High P + High B + High T (Toxicity incl. human health and ecotox) b. High P + High T (Toxicity incl. human health and ecotox) c. High B + High T (Toxicity incl. human health and ecotox) d. High T (Group I human) |
| Benchmark 2 | 2 | Use but search for safer substitute | Chemical under this category fulfils one or more of these criteria: a. Moderate P + Moderate B + Moderate T (Toxicity incl. human health and ecotox) b. High P + High B c. High P + Moderate T (Toxicity incl. human health and ecotox) d. High B + Moderate T (Toxicity incl. human health and ecotox) e. Moderate T (Group I human) f. Very high T (Toxicity incl. group II and II* human, ecotox and fate) |
| Benchmark 3 | 3 | Use but still opportunity for improvement | Chemical under this category fulfils one or more of these criteria: a. Moderate P or Moderate B b. Moderate Eco Toxicity c. Moderate T (Group II and II* human) |
| Benchmark 4 | 4 | Prefer - Safer chemical | Chemical under this category fulfils all of these criteria: Low P + Low B + Low T (Toxicity incl. human health and ecotox) |
| Not classified | NC | Search for data in the future | Not classified due to lack of data |

Table 3: Benchmark classification

4. Classified chemicals of concern:

For the purpose of classification of chemicals, 56 chemicals that were proven with considerable evidence to have shown some properties of concern were selected for risk and hazard assessment (shown in Table 4). Based on the chemical screening framework, these 56 chemicals were further classified into 4 categories: Benchmark 1, Benchmark 2, Benchmark 3 and Benchmark 4.

Chemicals classified as Benchmark 1 are chemicals that pose the highest concern and should be avoided in the patient care products. Though, chemicals classified as Benchmark 2 pose relatively low potential of hazard compared to chemicals benchmarked as class 1, a suitable substitute should be used to replace these chemicals to limit the hazard. Chemicals classified as Benchmark 3 can be used but there's still an opportunity for improvement. Chemicals classified as Benchmark 4 are safe and possess a low hazard potential. Chemicals under Benchmark 4 category are the preferred class of chemicals.

| Chemical Name | CAS number | Property of concern (Warning mentioned in Authoritative list) | Group I Human | | | | | | | | | | Group II and III human | | | | | | | | Ecotoxicity | | | | Environ. Fate | | Benchmark | | | | |
|-------------------------------------------------|------------------------|-----------------------------------------------------------------|---------------|----|---|----|---|----|---------------------|-----------------------|---|-----|------------------------|-----|-----|----|----|---|---|--|-------------|--|--|--|---------------|--|-----------|--|--|--|----|
| | | | C | M | R | D | E | AT | ST(Single exposure) | ST(repeated exposure) | N | SnS | IR | IRs | IRe | AA | CA | P | B | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acid Treated Distillate Oil | 64742-21-8 | Carcinogenic | VH | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Petrolatum | 8009-03-8 | Carcinogenic | VH | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| 1,4 Dioxane | 123-91-1 | Suspected carcinogen | H | | | M | | | | | | | | | M | | | | | | | | | | | | | | | | 1 |
| Cocamide DEA | 68803-42-9 | Suspected carcinogen | H | | | | | | | | | | | | M | | | | | | | | | | | | | | | | 1 |
| Isobutane | 75-28-5 | Carcinogenic and mutagenic | VH | VH | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Povidone USP | 88-12-0 | Suspected carcinogen | H | | | | | | | M | M | | | | | | | | | | | | | | | | | | | | 1 |
| Ethanol | 64-17-5 | Suspected carcinogen | H | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Octoxynol-9 | 9002-99-1 | ED | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Diethyl phthalate DBP | 84-74-2 | ED, Suspected reproductive toxicity and Under assessment as PBT | | | | VH | M | VH | M | | | | | | | | | | | | | | | | | | | | | | 1 |
| Butylparaben | 94-26-8 | ED | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Nonoxonyl 9 | 26571-11-9 | ED | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| BHA (butylated hydroxyanisole) | 25013-16-5 | Under assessment as Endocrine disruptor | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Cyclotetrasiloxane D4 | 556-67-2 | PBT, Suspected ED and Reproductive toxicity | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Cyclopentasiloxane D5 | 541-02-6 | PBT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Dimethylcyclopentasiloxane | 541-02-6 | PBT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Methylparaben | 99-76-3 | Under assessment as Endocrine disruptor | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Propylparaben | 94-19-3 | Under assessment as Endocrine disruptor | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Diethyl phthalate (DEP) | 84-66-2 | Suspected developmental and reproductive toxicity | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Zinc Oxide | 1314-13-2 | Suspected reproductive toxicity | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Hexamethylcyclotrisiloxane | 107-46-0 | Under assessment as PBT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Triclosan | 3380-34-5 | Under assessment as PBT & ED | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Chlorhexidine gluconate | 18472-51-0 | May be Persistent | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Chlorphenesin | 104-20-0 | May be PBT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Decahydronaphthalene | 91-17-8 | Under assessment as PBT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Limonene | 138-86-3 | Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Sorbic Acid | 110-44-1 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Benzyl Alcohol | 100-51-6 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Cocamidopropyl Betaine | 61789-40-0 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| D-Limonene | 5989-27-5 | Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Imidazolidinyl Urea | 39236-46-9 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Iodopropanyl Butylcarbamate | 55406-53-6 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Methenamine | 100-97-0 | Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Citrus Aurantium Dulcis Peel Oil | 8028-48-6 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Isobutylparaben | 4247-02-3 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Dimethylcyclohexane PEG-7 Phosphate | 132207-31-9 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Methylchlorosiloxane zolinone | 26172-55-4 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Methylisothiazolinone | 2682-20-4 | Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Balsam tolu | 9003-64-0 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Santalum Album (sandalwood) extract | 8006-87-9 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Chamomilla recutita (matricaria) flower extract | 84082-60-0 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Hexyl Cinnamal | 101-86-0 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Linalool | 78-70-6 | Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| BHT (butylated hydroxytoluene) | 128-37-0 | Under assessment as Endocrine disruptor | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Rosmarinus officinalis (rosemary) leaf extract | 84604-14-8 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| D&G Green #6 | 128-80-3 | May be PBT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Hexyldecanol | 2425-77-6 | Under assessment as PBT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Octylododecanol | 5333-42-6 | Under assessment as PBT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Quaternium 15 | 4080-31-9 | May be Skin sensitizing and Persistent | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Methyl Glucose Dioleate | 86893-19-8 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | NC |
| Vanilla Planifolia Fruit Extract (fragrance) | 8024-06-4 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | NC |
| Lavender Essential Oil | 8000-28-0 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | NC |
| Clove Oil | 8000-34-8 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | NC |
| Citrus Grandis Peel Oil | 90045-43-5 / 8016-20-4 | May be Skin sensitizing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | NC |

Table 4: Chemicals of concern classified list

5. Government Regulatory Framework:

The chemical inventory list contains various government regulations in addition to human health and environment hazard warnings. Some of the recurring government regulatory framework in the inventory includes:

- Domestic Substances List (DSL) by Government of Canada
- Canadian Environmental Protection Act (CEPA)
- Cosmetics ingredients hotlist by Government of Canada
- US EPA Safer Chemical Ingredients List (SCIL)
- Toxic Substances Control Act (TSCA) Chemical Substances Control Inventory by US EPA
- European Union Cosmetics Products legislation

Domestic Substances List (DSL):

The DSL was published by Environment and Climate Change Canada on May 4, 1994. This list is an inventory of 23,000 substances that are manufactured, imported or used in Canada on a commercial scale [6]. Chemical substances have been screened since 1994 before permitting their use. However, chemicals introduced prior to 1994 had not been examined for their potential risks by the government. But the CEPA 1999 requires that these substances be sorted by the Government of Canada. In September 2006, Canada completed the scientific evaluation of these 23,000 chemicals by using information from industry, academic research and other countries [7].

The Canadian Environmental Protection Act (CEPA, 1999):

CEPA is one of the most important environmental laws governing the assessment and management of chemical substances in Canada [8]. This act's purpose is to protect the environment, and the health and wellbeing of Canadians and a major part of this act is focused on pollution prevention and addressing the potential risks posed by chemical substances.

Definition of "toxic" substances according to CEPA 1999 are those that enter or may enter the environment at levels or conditions that [8]:

- Have or may have a harmful effect on the environment
- Are or could be dangerous to the environment that life depends on
- Are or could be dangerous to human life or health.

Some important sections within the CEPA 1999 that was used in the risk assessment of chemicals database in this project are:

Section 73, criteria 1 under Categorization of substances on Domestic Substances List [9]:

According to this criteria, the Ministers shall, within seven years from the giving of Royal Assent to this Act, categorize the substances that are on the Domestic Substances List by virtue of section 66, for the purpose of identifying the substances on the List that, in their opinion and on the basis of available information,

- **(a)** may present, to individuals in Canada, the greatest potential for exposure; or
- **(b)** are persistent or bio accumulative in accordance with the regulations, and inherently toxic to human beings or to non-human organisms, as determined by laboratory or other studies.

According to section 64 of CEPA 1999, substances are considered harmful if they are entering or could enter the environment in quantities or concentrations or under conditions that [10]:

- have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- constitute or may constitute a danger to the environment on which life depends; or
- constitute or may constitute a danger to human life or health in Canada.

Cosmetics Ingredient Hotlist by Government of Canada:

Cosmetics Ingredient Hotlist is a science-based document that health Canada uses to communicate that certain chemical substances may be prohibited or restricted for use in cosmetics. The cosmetics products must meet the requirements of the Food and Drugs Act (FDA) and the Cosmetics Regulations (CR). In addition to legislative provisions, entries on the hitlist can be linked to the following legislations [11]:

- Section 16 of the FDA (the general prohibition)
- Section 2 of the FDA (definitions for the purpose of product classification)
- Section 24 of the CR (avoidable hazard labelling)
- Specific individual prohibitions and restrictions for substances outlined in the CR

Cosmetics ingredient hotlist consists of two distinct tables that includes the prohibited list and restricted ingredients list. Prohibited ingredients should not be present in cosmetic products sold in Canada.

Restricted ingredients should meet the conditions of use and/or cautionary statements as outlined to be present in cosmetic products sold in Canada.

US EPA Safer Chemical Ingredients List (SCIL):


The SCIL is a list of chemical ingredients that has been evaluated by Safer Choice Program and has determined to be safer than traditional chemical ingredients. The criteria for safer chemical ingredients address a broad range of potential toxicological effects including [12]:


- carcinogens, mutagens, reproductive or developmental toxicants;
- persistent, bio accumulative and toxic chemicals;
- systemic or internal organ toxicants;
- asthmagens;
- sensitizers; and
- chemicals on authoritative lists of chemicals of concern.


Additionally:

- Chemicals that exhibit endocrine activity are closely evaluated. Those associated with toxicological hazards are not allowed.
- Impurities can be present in chemicals that are used in Safer Choice products. Safer Choice limits impurities that do not meet its criteria to not more than 0.01 percent in the final product. The safer chemicals list does not include impurities.

Safer chemical choice labels are as follows:

 **Green circle** - The chemical has been verified to be of low concern based on experimental and modeled data.

 **Green half-circle** - The chemical is expected to be of low concern based on experimental and modeled data. Additional data would strengthen our confidence in the chemical's safer status.

 **Yellow triangle** - The chemical has met Safer Choice Criteria for its functional ingredient-class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints.

■ **Grey square** - This chemical will not be acceptable for use in products that are candidates for the

TSCA Chemical Substances Control Inventory:

TSCA inventory plays a central role in the regulation of most industrial chemicals in the United States. Section 8(b) of the TSCA requires EPA to compile, keep current and publish a list of each chemical substance that is manufactured, processed or imported to the United States [13]. EPA evaluates the potential risks from new and existing chemical and acts to address the risks chemicals may have on human health and the environment.

European Union Cosmetic products regulation:

[Regulation \(EC\) N° 1223/2009](#) on cosmetic products is the main regulatory framework for finished cosmetic products when placed on the EU market. It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector. It provides a robust, internationally recognised regime, which reinforces product safety while taking into consideration the latest technological developments, including the possible use of nanomaterials.

6. Recommended chemical ingredient screening workflow:

The suggested workflow to utilize the chemical ingredient inventory database and the categorized properties of concern chemical list is as follows:

- Initially, a search is carried out for the chemical ingredient under investigation in the categorized properties of concern chemical list that contains 56 categorized chemicals that have been proven to have inherent hazard associated with it,
- If the search returns successful, then the information about the chemical and its hazard can be used for further analysis,
- If the search return unsuccessful, then proceed to search the chemical ingredient inventory database that contains information about 300+ chemicals used in patient care in BC facilities,
- If the search returns successful, then the information about the chemical and its hazard can be used for further analysis,
- If the search returns unsuccessful, then the “new” chemical ingredient is added to the existing chemical ingredient inventory database
- Further, data about the “new” chemical ingredient is collected and is subject to the chemical screening framework to be categorized according to its hazard properties.

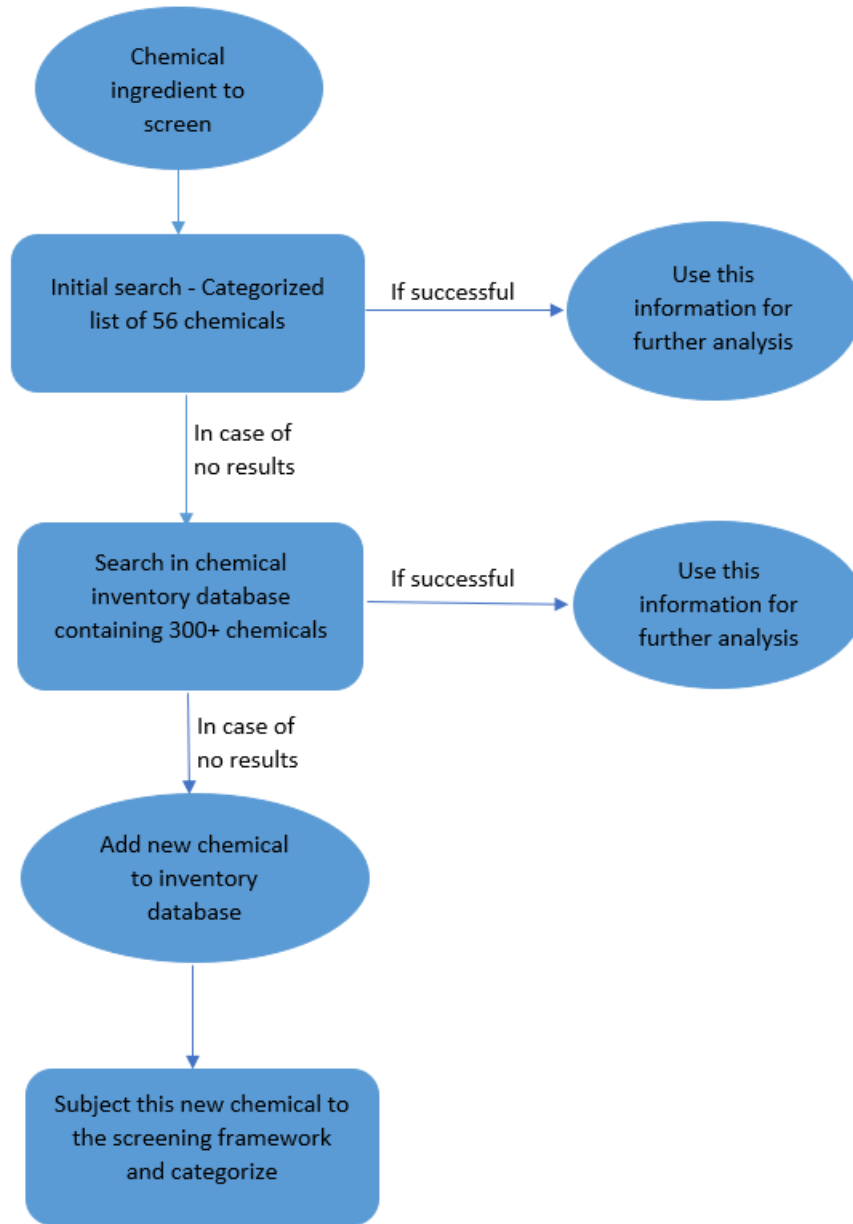


Fig 4: Recommended chemical ingredient screening workflow

7. Recommendations:

- The chemicals benchmarked as category 1 should be avoided and suitable alternatives for chemicals in category 2 should be researched

- There is considerable data gap for certain chemicals, hence authoritative (ie, government approved) lists should be frequently checked for any new information / update regarding the hazards of the chemicals
- As new information about the chemicals are found out, the chemicals of concern inventory list should be frequently updated, and the chemicals must be categorized accordingly
- Due to the time constraint of this project, priority was given for the chemicals that have been recorded by the authoritative lists to show properties of concern to human and environment. Thus, in the future, other chemicals in the list should also be screened and categorized based on the above-mentioned framework

8. References:

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14. European Union Cosmetics legislation https://ec.europa.eu/growth/sectors/cosmetics/legislation_en