Aligning safer chemicals with patient care in BC healthcare facilities: An inventory for classifying health concerns associated with skincare ingredients

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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 organizations 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.

TERRITORY ACKNOWLEDGEMENT

The author acknowledges that the work for this project took place on the unceded ancestral lands of the xwməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), Stó:lō and Səl̓ílwətaʔ/Selilwitulh (Tsleil-Waututh) Nations.

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1. Background

Health hazards presented by chemicals can pose acute or chronic harm to human health through different exposure routes, including inhalation, dietary intake, and skin absorption [1]. Associated health effects due to the exposure include damage to the skin, eyes and other target organs, developmental and reproductive health impacts, and carcinogenic effects. In the environment, ingredients used, for example, as UV filters (e.g., benzophenone derivatives) and preservatives (e.g., parabens and triclosan) impact the environment, including aquatic ecosystem through coral bleaching or direct health impact on exposed aquatic organisms [2]. Managing health concerns requires knowledge of, for example, the chemical occurrence, concentration and exposure doses, and exposure routes, and systematic characterization of the health concerns using defined characterization criteria specific to a health hazard (the inherent ability of a chemical to cause harm) or the exposure characteristics of chemicals [3]. For skincare ingredients whose exposure occurs through the use of skincare products, managing health concerns further requires knowledge of the ingredient composition of a product, the use purpose of a product, the mixture characteristics of a chemical ingredient, *et cetera* [4]. In other words, as discussed in the current project, a holistic understanding of the (human and environmental) health concerns would require formulating ways to characterize factors contributing to the health concerns of the ingredients by justifying the classification approaches used.

Against the backdrop above, this project (titled "*Aligning safer chemicals with patient care in BC healthcare facilities*") was initiated to characterize human and environmental health concerns associated with skincare ingredients with the ultimate goal of identifying concerns and then using this information to procure the 'cleanest' product for the patients, clients and residents within the British Columbia health authorities. The project fits into the works undertaken by its collaborators/sponsors - the Energy and Environmental Sustainability (EES) team supporting Fraser Health, Providence Health Care, Provincial Health Services Authority and Vancouver Coastal Health and the Provincial Professional Practice Stream Wound Ostomy Continence's British Columbia Provincial Nursing Skin and Wound Committee (PNSWC) - which overarchingly is to improve understanding of the ingredients used within skin care products, exposures to the product ingredients, and potential harm to humans and environment due to the exposures. In order to achieve this aim, this project set to address, among others, the following questions:

- What chemical ingredients exist in potential skin care products to be used within BC healthcare facilities?
- For what purpose are the skin care product ingredients used?

- What makes the chemical ingredients a concern?
- What specific human health and environmental impacts are associated with the chemical ingredients?

According to the project's original scope, addressing these questions required developing a chemical ingredient list for products procured for BC healthcare facilities; this was done in 2012. However, as shown in Fig. 1, the project has evolved since 2012, with the first being the expansion of the list in 2016 to about 376 ingredients and later to about 450 ingredients in 2019/2020. In 2022, the 450 ingredients were curated to 389 ingredients. The curation process involved ensuring that the correct name identities of the ingredients are provided, using the ingredient identifiers (e.g., synonyms and common names) to identify ingredients with repeated identities/names and cleaning them by removing redundant names, and rearranging the final ingredients list alphabetically.

Figure 1. The timelines that show the evolution of the project

A colour coding system was developed alongside the list to classify the safety concerns of the ingredients based on several chemical characteristics like irritation potential, concentration in a product, and carcinogenicity effect (see the colour legend below-Fig.2A- for the complete coding criteria). Depending on the colour coding, different chemical safety decisions could be drawn. For example, a Dark Green colour represented safe-to-use ingredients, while at the end of the spectrum, Red colour stood for unsafe-to-use ingredients in skin care products. Although this classification system was informative and gave a good foundation to judge the safety of chemicals, several gaps still existed. For example, the necessary components required to support the classification were not included.

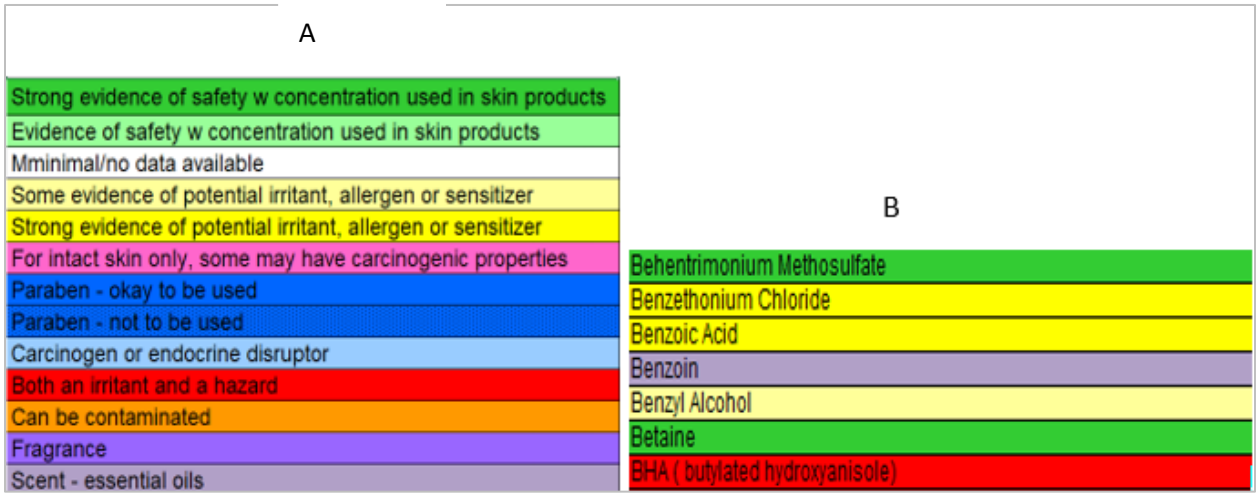


Figure 2. A-Colour legend for health concern classification and B-Example of the ingredient classification using the colour classification criteria.

2. The current project: 2022

As mentioned earlier, the list developed as of 2020 was considered simplistic and incomplete (it only contained ingredient names and colour coding classification), given that several other necessary components/details required to better characterize the safety concerns of chemicals were missing; thus, the need for a better approach to fill the gaps. The current project phase was initiated to improve the list by evaluating a wider range of available scientific evidence to determine whether a chemical ingredient has health concerns and identify different classes and categories of the concerns. This task included redevelopment, updating the existing list of ingredients using the predefined criteria and creating a process framework that guides how to keep the list up to date. In order to achieve these tasks, the current project specifically aimed to:

- Add conventional and common chemical identifiers to improve the identification and name characterization of the ingredients. This exercise will help reduce redundancy.
- Identify and review the relevant data regarding the human health hazard or risk potential of an ingredient
- Identify and review the relevant data regarding the environmental health concerns of ingredients
- Identify and document all credible sources of information supporting the human health and environmental concerns characterization approach adopted
- Define the use purpose of each ingredient and mixture composition (e.g., presence of contaminants)

- Develop a 'How-To' process document, which outlines how to:
    - Identify an ingredient from a product to evaluate
    - Collect data about the ingredient from relevant sources
    - Classify the ingredient hazard/risk potential according to predefined criteria, including the colour coding
    - Against each ingredient, add information to support the rationale behind a classification choice

3. Methodology

We followed the recommendation by the United States Occupational Safety and Health Administration (US OSHA), describing the need to have a structured approach to hazard and risk classification, data retrieval, and compilation of data to develop a chemical inventory. Accordingly, we then developed a skincare ingredient inventory (previously called 'ingredient list') consisting of all the ingredients from the previous project phases (2012-2020) and including components such as chemical classifiers (e.g., chemical name as in a product, common name, synonyms, and CAS number), health concern, etc. Table 1 shows the structural impression of the developed inventory. It shows that the inventory is structurally arranged in columns and rows, where the columns contain component descriptors (N = 20) of the chemical ingredients in the first column.

Table 1. A representation of the inventory structure with columns containing the ingredients, their identifiers and other components deemed necessary for the health concerns classification

Ingredient	**Common name**	**Synonym**	**CAS No**	**Impurity/Stabilizing agent**	**% of the ingredient**	**Health Concern**	**Ref. Link**								
Ingredient A															
Ingredient B															
Ingredient C															

The total number of components used in the inventory development was 20. Below is an inexhaustive list of the components and their definitions.

- *Ingredient*: the chemical in a product for which evaluation is required
- *Common name*: also known as IUPAC name. It is an alternative name for a chemical that unambiguously defines the chemical but does not follow the systematic naming convention
- *Synonym*: an alternative convention name of a chemical

- *CAS number*: numeric identifier of a chemical
- *Stabilizing agent*: a chemical that is used to prevent degradation/preserve an ingredient
- *Impurity/contaminant*: a chemical that contaminates an ingredient
- *Percentage of ingredient*: percentage (by concentration) of a chemical in the ingredient mixture
- *Recommended percentage of ingredients*: standard concentration (in %) of ingredients recommended for use in specific skincare products.
- *Health concern*: human health concerns associated with an ingredient exposure
- *Chemical information source*: the website from which the information about the hazard/risk potential of a chemical is obtained
- *Reference link*: URL link to the website (in #10) where the information is obtained
- *Reference date updated*: the date (month and year) on which the information in #10 and 11 is updated
- *Product containing ingredient*: a skincare product containing the ingredient of interest
- *Additional comment*: Any other information deemed necessary to enrich understanding of the health concern of an ingredient
- *Eco-persistence*: persistence of an ingredient in wildlife or ambient environments
- *Bioaccumulation*: the ability of an ingredient to bioaccumulate in non-humans
- *Eco-toxicity*: the ability of an ingredient to pose health effects to non-humans

4. The Inventory

As discussed above, the central aim of the current exercise is to characterize human and environmental health concerns associated with skin care product ingredients. To do this, a systematic approach is required to gather and compile relevant information about the ingredients and make sense of the information by translating it to specific health concerns. In other words, characterization in the manner described in this work is specification oriented in that classifying a chemical's health concerns requires specific information unique to the target ingredient. Fig. 3 below shows an overview step-step procedure applied in developing the inventory. In so doing, however, we note that this work does not address all detailed classification requirements of chemical ingredients as might be specified, for example, in chemical SDSs (safety data sheets). Thus, one might find the conceptual breadth and depth of the inventory limiting.

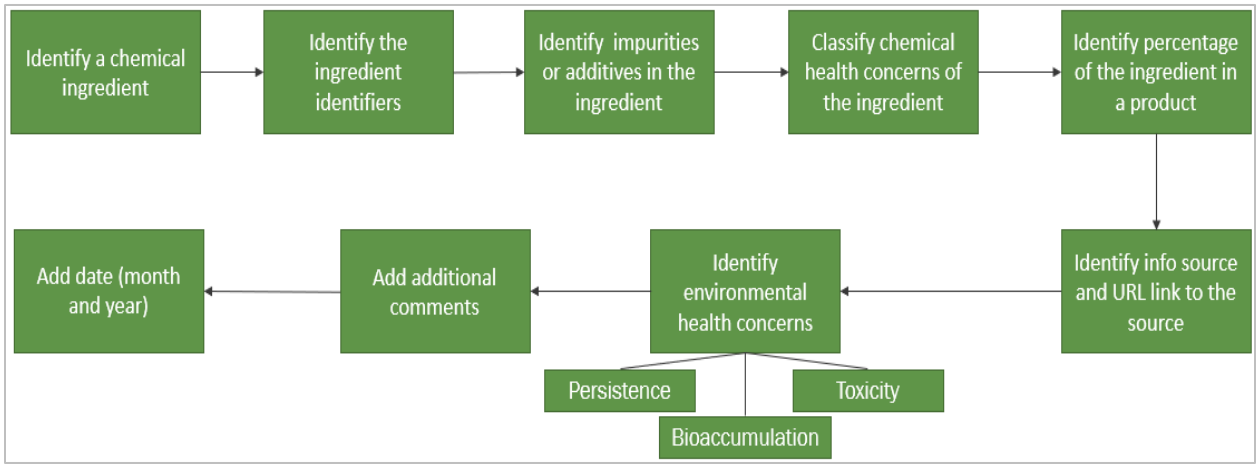


Figure 3. A summarized flow diagram of the process of adding and updating information about a chemical ingredient

4.1. Inventory development steps

The flow diagram (Fig.3) shows that the first step to adding new ingredients to the inventory is identifying the ingredient from a specific skincare product of interest. Then, the ingredient identifiers (i.e., common name, synonym, and CAS No) follow. It is necessary to include (if possible) all identifiers to diversify the understanding of different name identities of a chemical. Correct identification of ingredients in this inventory is particularly critical for retrieving accurate data about a chemical. Numerous sources, including the ones listed below, were searched for the identifiers:

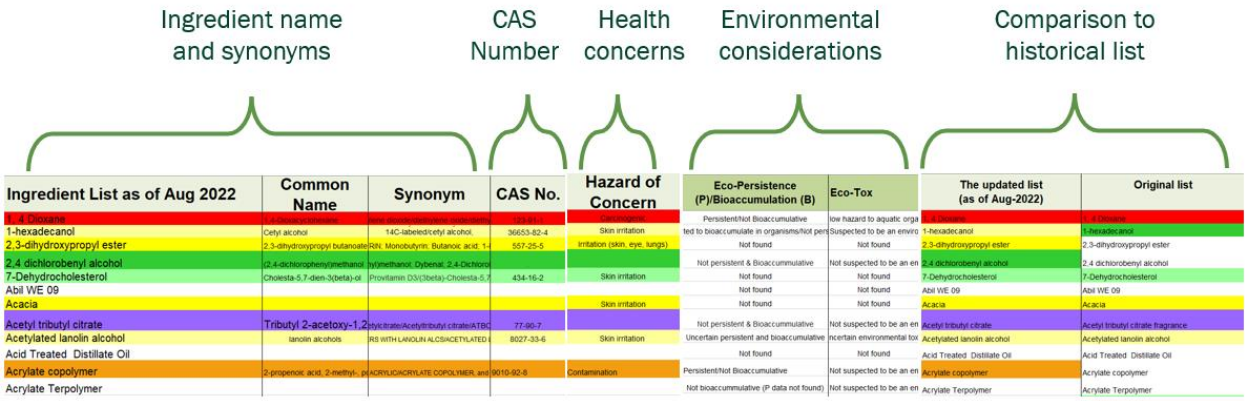
- PubChem
- EWG (environmental working group)
- Chemical material SDS
- SDSs and product safety bulletins from manufacturers or suppliers
- ChemID, etc

Once the chemical is listed and identifiers added against a specific chemical, classifying the health concerns follows. Chemical health concerns classification (in the context of this inventory) not only entails characterizing a chemical based on its potential to pose one of the following health effects: skin corrosion; irritation (eye, skin, or lungs); mutagenicity/carcinogenicity; reproductive toxicity; specific target organ toxicity, and/or allergenic effect, but also potential harm due to possible contaminant in ingredient mixture. As would be expected, listing all the possible health concern categories and relevant information to support the categorization is important in justifying the effectiveness and completeness of the classification outcome. Such relevant information can be obtained from multiple sources listed above

(e.g., EWG, Health Canada, and Cosmetic Ingredient Review websites). While including the information sources ensure easy retrieval of information on an ingredient, providing corresponding URL links to these sources makes the retrieval easier and complete; thus, any URL address should match a website where information is obtained so that a click on a link should redirect one to a corresponding relevant website.

4.2. Classifying human health concerns

Figure 4 shows an overview of the developed inventory and some of the 'Heath Concerns' endpoints used in the classification. Examples of the endpoints include (i) s*kin irritation,* which refers to changes or local effects at the site of first contact with the skin, regardless of whether a chemical ingredient is systemically available. Irritant ingredients are those that may cause the changes/local effects/inflammation through immediate contact with the skin, either from a single or multiple exposures [5]. (ii) *Reproductive toxicity*: It includes adverse effects of ingredients on sexual function and fertility in humans and on the development of newborns. Ingredients with reproductive effects were classified as reproductive toxicants [6]. (iii) *Carcinogenicity*: It is the ability of an ingredient to cause malignant cell growth in humans; thus, a carcinogen, in this case, includes an ingredient which can induce benign and malignant tumours in humans unless there is evidence that the tumour formation is not relevant for humans [2].



Ingredient List as of Aug 2022	Common Name	Synonym	CAS No.	Hazard of Concern	Eco-Persistence (P)/Bioaccumulation (B)	Eco-Tox	The updated list (as of Aug-2022)	Original list
1, 4 Dioxane	1,4-Dioxacyclohexane	same dioxide;diethylene oxide;diethy	123-91-1	Carcinogenic	Persistent/Not Bioaccumulative	low hazard to aquatic orga	1, 4 Dioxane	1, 4 Dioxane
1-hexadecanol	Cetyl alcohol	14C-labeled/cetyl alcohol,	36653-82-4	Skin irritation	ted to bioaccumulate in organisms/Not pers	Suspected to be an enviro	1-hexadecanol	1-hexadecanol
2,3-dihydroxypropyl ester	2,3-dihydroxypropyl butanoate	RIN, Monobutyrin, Butanoic acid, 1-	557-25-5	Irritation (skin, eye, lungs)	Not found	Not found	2,3-dihydroxypropyl ester	2,3-dihydroxypropyl ester
2,4 dichlorobenyl alcohol	(2,4-dichlorophenyl)methanol	yl)methanol, Dybenal, 2,4-Dichloro			Not persistent & Bioaccummulative	Not suspected to be an en	2,4 dichlorobenyl alcohol	2,4 dichlorobenyl alcohol
7-Dehydrocholesterol	Cholesta-5,7-dien-3(beta)-ol	Provitamin D3/(3beta)-Cholesta-5,7	434-16-2	Skin irritation	Not found	Not found	7-Dehydrocholesterol	7-Dehydrocholesterol
Abil WE 09					Not found	Not found	Abil WE 09	Abil WE 09
Acacia				Skin irritation	Not found	Not found	Acacia	Acacia
Acetyl tributyl citrate	Tributyl 2-acetoxy-1,2	ntyl citrate/Acetyltributyl citrate/ATBC	77-90-7		Not persistent & Bioaccummulative	Not suspected to be an en	Acetyl tributyl citrate	Acetyl tributyl citrate fragrance
Acetylated lanolin alcohol	lanolin alcohols	RS WITH LANOLIN ALCSACETYLATED	8027-33-6	Skin irritation	Uncertain persistent and bioaccumulative	ncertain environmental tox	Acetylated lanolin alcohol	Acetylated lanolin alcohol
Acid Treated Distillate Oil					Not found	Not found	Acid Treated Distillate Oil	Acid Treated Distillate Oil
Acrylate copolymer	2-propenoic acid, 2-methyl-, p	ACRYLIC/ACRYLATE COPOLYMER, and	9010-92-8	Contamination	Persistent/Not Bioaccumulative	Not suspected to be an en	Acrylate copolymer	Acrylate copolymer
Acrylate Terpolymer					Not bioaccummulative (P data not found)	Not suspected to be an en	Acrylate Terpolymer	Acrylate Terpolymer

Figure 4. A summary of the developed skin care product ingredient inventory

In reference to the classification criteria described in Fig. 2, the developed inventory resulted in changes in the classification of various health concerns (Fig. 5). There is a significant difference between the old and new (updated) classification. For example, the Red bar (skin irritant and carcinogenic chemicals) shows that only about 0.3% of the total ingredients (~450) were classifiable under this category in the old

list, whereas in the curated and updated classification, this number increases to about 10% of the total ingredient in the new inventory (389). This implies that the use restriction of the chemical ingredients based on their simultaneous ability to cause skin irritation and have a carcinogenicity impact on humans has increased 30fold.

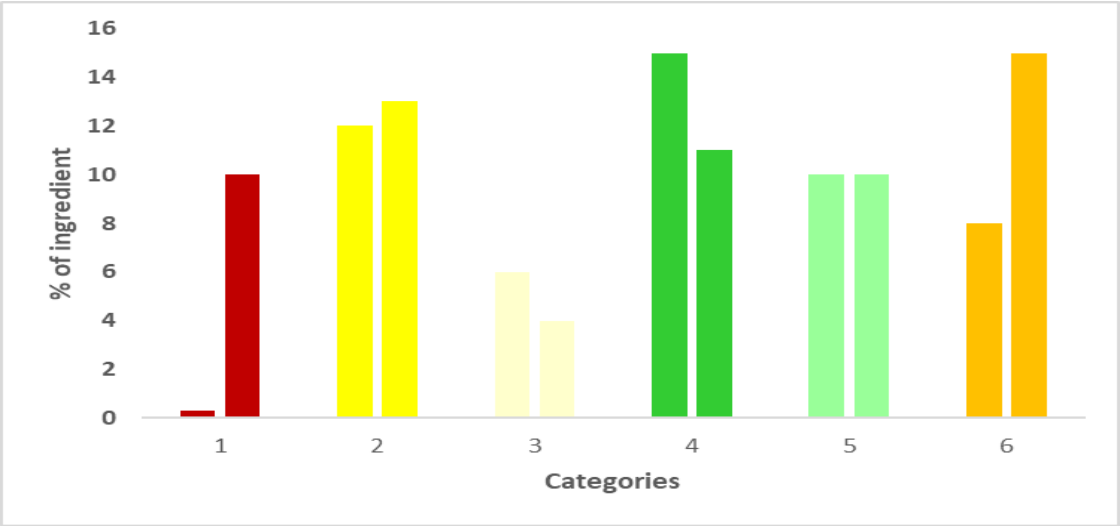


Figure 5. The old (bars on the left) and new-updated (bars on the right) classification summary for some of the ingredients in the inventory, based on the categorization criteria described in Fig. 2A.

Overall, the changes in the number of ingredients classified under specific categories are attributed to the additional data gathered in the new inventory, suggesting a better understanding of the health concerns associated with the ingredients. This improvement was further attributed to the use of all available information, especially where there was conflicting information from different sources, pooling evidence that increased the strength of a conclusion about a health concern and using diverse yet potentially adequate available information.

4.3. Classifying environmental concerns

The contribution of skincare ingredients used in the making, for example, surfactants (e.g., body wash, shampoo, and hand cleanser), to environmental pollution is well recognized through the discharges into aquatic and terrestrial environments [7]. Persistent, bioaccumulative, and toxic (PBT) are the categorization criteria used by several regulatory authorities, including Health Canada and Environment and Climate Change Canada, to classify and regulate chemicals in consideration of such pollution conditions [8]. The environmental persistence of a chemical in, for example, water, soil, sediment, or air refers to the ability of a chemical to resist degradation under natural environmental conditions, while chemical bioaccumulation is the potential of a chemical to accumulate in an organism, usually, if the

uptake rate exceeds elimination rate. On the other hand, (eco)toxicity refers to the ability of a chemical to cause harm to biological systems [8].

The PBT criteria were used to characterize the ingredients' non-human/environmental health concerns according to the information from the websites listed earlier. 53 (14%) of the ingredients were found to be persistent (e.g. Hydrogenated Polydecene), 160 (42%) not persistent (e.g., Imidazolidinyl Urea), while information on the persistence of 176 (42%) ingredients was not found (e.g., Hydroxylated Lanolin). 178 (46%) of the ingredients were bioaccumulative in the environment (e.g., dimethyl siloxane), 177 (45%) were not bioaccumulative (e.g., dimethyl phthalate), while information on the bioaccumulative potential of the rest (34; 9%) was not found (e.g., dimethicone PEG-7 phosphate). 113 (29%) were toxic (e.g., D-limonene), 166 (43%) non-toxic (e.g., dipropylene glycol), and toxicity information on the rest (110; 28%) was not found (e.g., ethylhexylglycerine). 50 (13%) of the ingredients (e.g., aminomethyl propanol) met all the PBT criteria. According to regulatory authorities like Health Canada (section 64 of CEPA 1999) [9], the 50 ingredients meet the PBT criteria of chemicals of high concern; thus, their use in skin care products should be prohibited.

5. Next steps for the inventory

As mentioned earlier, the purpose of the inventory system is to ensure that the health concerns of the chemical ingredients in skincare products procured by BC health facilities are classified and that information concerning the health concerns is communicated in an understandable way for the health authorities. We align with the US OSHA recommendation that, besides the classification components in the inventory, it is necessary to develop a numerical ranking system for health concerns to guide the prioritization of action against the potential risk of the chemicals. Thus, we recommend that the next step of this project is to develop a tiered scheme for ranking the ingredients based on the different endpoints, such as skin/eye irritation and specific target organ toxicity. As with the human health concerns, we also recommend future efforts to determine a coding system for the environmental health concerns of the ingredients based on the persistence, bioaccumulation and toxicity criteria.

Exposure dose to ingredients in a product depends on the ingredients' concentration in the product. It is important, therefore, to determine the ingredients' concentration to accurately determine the ingredients' dose effect for endpoints such as skin/eye irritation and specific target organ toxicity. The ingredients' concentration should be determined and compared with the standard recommended percentage for each ingredient to improve the classification system in the developed inventory.

Down the road, it will also be important to assess how factors such as climate change exacerbate health issues related to the chemical ingredients but also sustainable strategies to eliminate the harmful ingredients from skin care products in BC healthcare facilities.

6. Recommended decision logic and Conclusion

Figure 6 shows a conceptual decision logic that considers decision pathways for human and environmental health concerns. As explained earlier, human health concern assessment of the ingredients starts with identifying an ingredient from a skin care product. Several other steps follow after that. This includes gathering relevant data such as skin irritation and allergenic effect of ingredients from credible and relevant sources (e.g., Environmental Working Group Health Canada websites). Depending on the availability of health concern data, it might be necessary to collate data from different sources to ensure sufficient data to draw a conclusion or ensure the strength of the weight of evidence about a health concern in question. Additionally, where possible, different classes of health concerns may be combined to guide the final colour decision about a potential human health impact of an ingredient. For example, skin irritation combined with carcinogenic effects will lead to a Red Colour code, representing an ingredient of high human health concern; thus, a product containing a Red Colour would not be considered for procurement within BC Health Authorities.

As a good practice, the EES team and PNSWC may follow chemical regulatory tools provided by Health Canada (HC) or Environment and Climate Change Canada (ECCC) to decide whether to completely abolish a product containing specific ingredients or make other recommendations based on toxicity potential of an ingredient (Environment and Climate Change Canada, 2010). HC and the ECCC, under the Canadian Environmental Protection Act (CEPA 1999), categorize a chemical as 'toxic' based on its likelihood and magnitude of harm it may cause to human health or the environment. According to CEPA 1999 Schedule 1 (Section 64) [9], a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under other conditions that:

- 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
- constitute or may constitute a danger in Canada to human life or health

As specified under CEPA 1999, a substance that has been declared 'toxic' should be subjected to virtual elimination (CEPA defines virtual elimination as the ultimate reduction of the quantity or concentration of a substance in the release below a level of quantification specified by HC or ECCC) to reduce exposure.

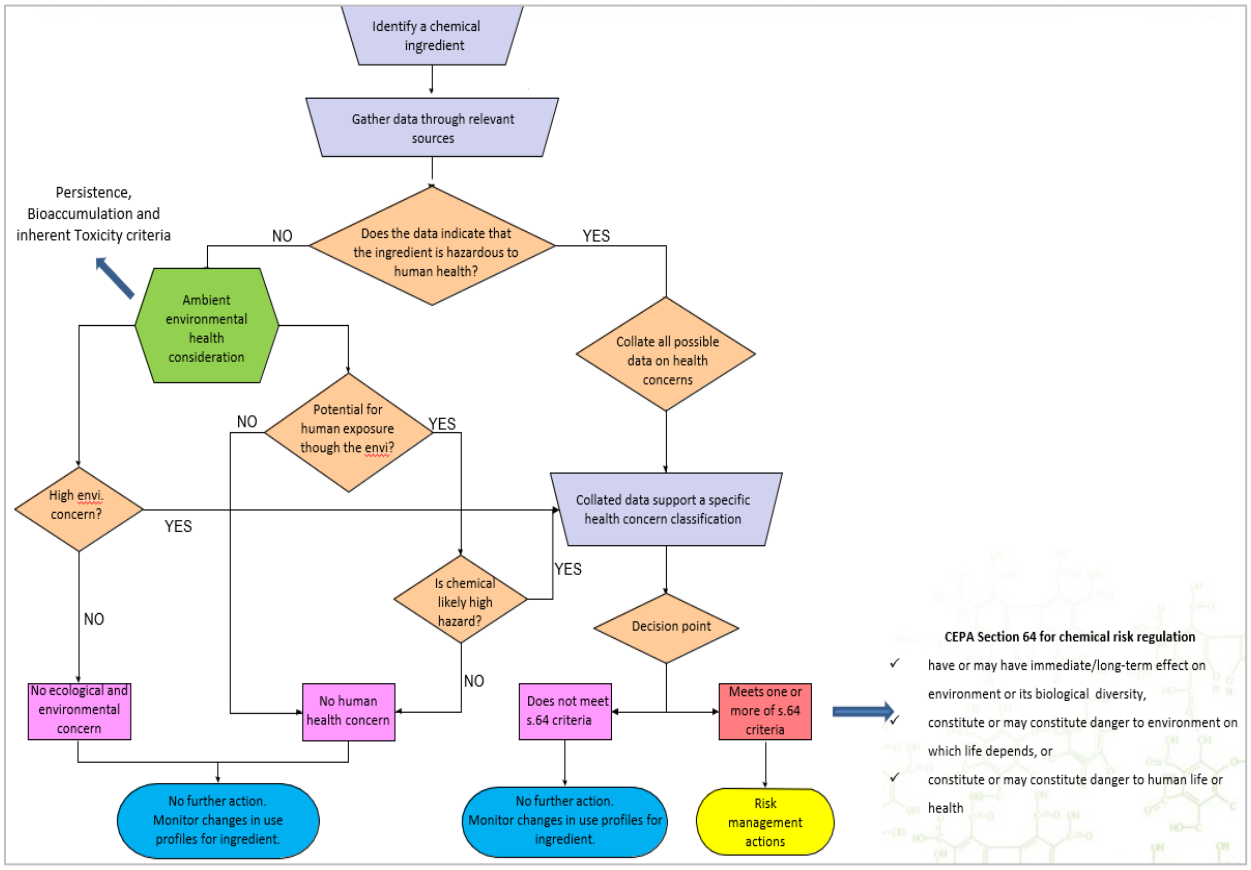


Figure 6. A decision logic summarizing the human and environmental health concern classification and applicable health concern management framework

On the other hand, based on the weight of evidence on human health, an ingredient may be considered non-hazardous to human health but still has the potential to cause harm to the ambient environment through the lens of the PBT criteria. If this is the case, then the CEPA 1999 (Section 64) is applicable. Human exposure to chemical ingredients could also be considered through the environment, where if there is substantial exposure (e.g., via drinking water), then the human health assessment logic described earlier can be applied. Otherwise, no action may be required at this point.

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