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Canada

Updates for Cosmetics

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Consumer and Hazardous Products Safety Directorate
Health Canada

Cosmetics Alliance Canada
Fall Regulatory Workshop
December 6, 2023

Outline

- Cosmetic Ingredient Hotlist
- Compliance and Enforcement
- Updates on the Regulatory Proposal for Cosmetics and Cosmetic Animal Testing Ban
- Cosmetic Notification Statistics and Improvements
- International Cooperation on Cosmetics Regulation (ICCR)
- Labelling Clarifications
- Unconscious Bias in Product Safety

Updates to the Cosmetic Ingredient Hotlist

Cosmetic Ingredient Hotlist (Hotlist)

The latest update to the Hotlist was published on August 26, 2022.

From July 13 to October 11, 2023, the Consultation on proposed updates to the Cosmetic Ingredient Hotlist was posted. Additions or changes for the following ingredients were proposed:

Prohibited list:

Proposed additions:

- Basic Green 4 (known as Malachite Green, CAS 569-64-2)
- Thioglycolic acid esters

Proposed revisions:

- Mixed cresols and derivatives
- Dialkanolamines, secondary

Restricted List:

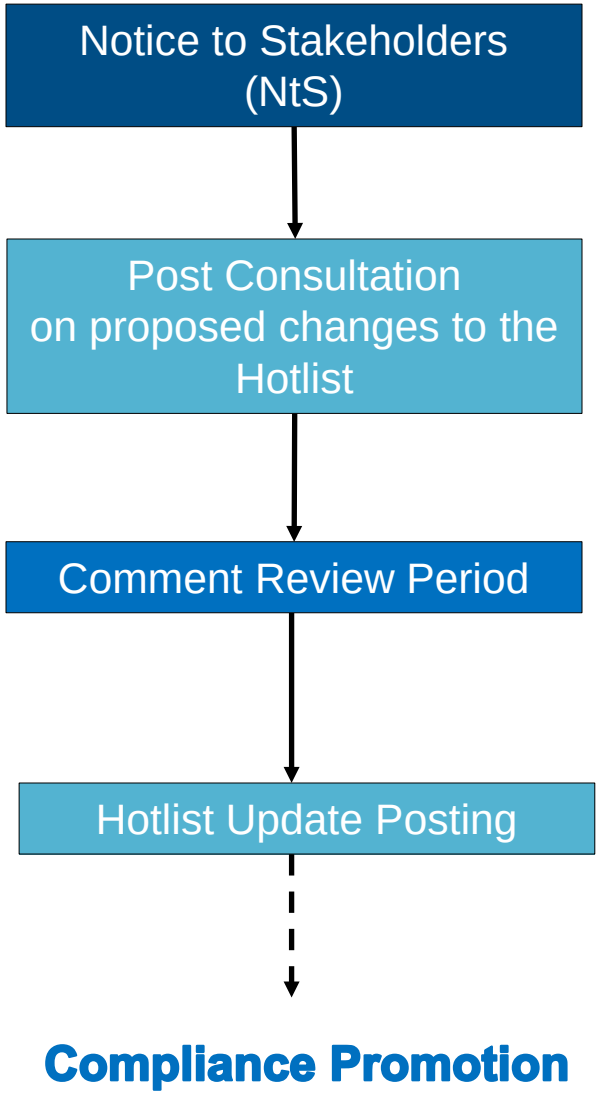
Proposed additions:

- Benzophenone
- p-Chloro-m-cresol
- Retinal
- Solvent Violet 13

Proposed revisions:

- Alpha-Hydroxy Acids
- Aluminum chlorohydrate and its associated complexes
- Peroxide and peroxide-generating compounds
- Benzoyl peroxide
- Hydroquinone
- P-Hydroxyanisole
- Retinol and its esters
- Talc

Hotlist Update 2022



November 2022 - NtS

- Notice of posting sent to Cosmetics Mailing List and email address provided by notifiers.

July 13-October 11, 2023 – Post Consultation (90 days)

- Notice of posting sent to Cosmetics Mailing List and email addresses provided by notifiers.

Winter 2023/2024 – Comment Review

- Health Canada is reviewing information provided during the consultation and will respond to comments received.

Spring 2024– Final Hotlist Update

- Anticipated Final publication; Notice of posting to be sent to Cosmetics Mailing List and email addresses provided in notifications.
- Notifiers affected by the Hotlist changes will be contacted by Health Canada.

Health Canada prioritizes compliance and enforcement in response to:

- Level of risk posed by a product; and
- Any complaints/incidents received.

Feedback on Hotlist Consultation

- Transition Times
  - Recognize this is a continued concern
  - Limited flexibility due to language of FDA
  - Long term solution - exploring option of incorporating Hotlist into CR
  - Continue to leverage the compliance promotion approach outlined in our Hotlist Update process summarized online

Feedback on Hotlist Consultation

- Need for Better Information Sharing to support consultation
  - Information Sheet Pilot

- Current Consultation
  - Categorize substances
    - Make adjustments, as necessary for certain ingredients
    - Share additional information followed by a second round of comments for others

- Longer term
  - Exploring options to improve process for the next round

- Opportunity for more detailed feedback from stakeholders

Chemicals Management Plan

Assessments have been published for the following ingredients under the Chemicals Management Plan (CMP) and may be of interest to cosmetics stakeholders.

- Proposed conclusions (dSARs)* published:
  - Acyclic, Monocyclic, and Bicyclic Monoterpenes Group
  - Alcohols Group
  - Monocyclic and Bicyclic Sesquiterpenes Group
  - Parabens Group
  - Salicylates Group

- Final conclusions (fSARs) published:
  - Coumarin 1
  - Other Polymers Group

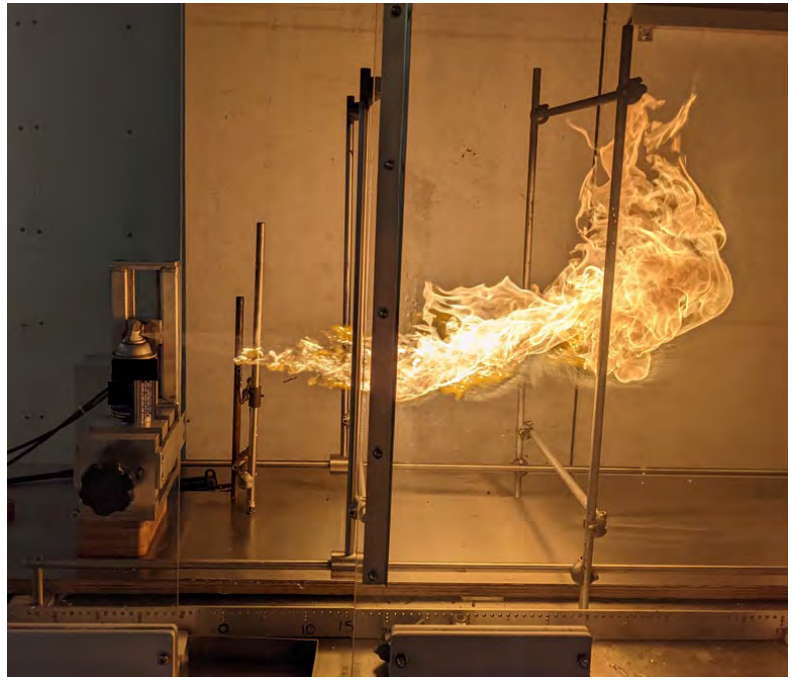
Updates on the publication of documents/consultations under the CMP.

*(may change following comment period)

Cosmetics – Compliance & Enforcement

Compliance Verification – Cosmetics in pressurized containers Project – Completed

- Objective: To verify industry compliance with the applicable requirements under the *Food and Drugs Act* (FDA) and the *Cosmetic Regulations*.
- Compliance was determined through sampling and testing of cosmetics in pressurized containers to verify if:
  - The products met the labelling requirements under sections 25, 26 and 27 of the *Cosmetic Regulations.*
- A total of 50 products were sampled.
- Results:
  - 4 recalls, 7 stop distributions, and 28 commitments were issued to address non-compliance.
- Summary report will be available online



Compliance Verification – Cyanoacrylate-based adhesives – In Progress

- Objective: To verify industry compliance to the Hotlist conditions for cyanoacrylate-based adhesives used for eyelash extensions.
- Compliance is determined through the review of labels for products available at retail (online and in person) and the review of product labels requested from establishments by Health Canada inspectors.

Updates on the Regulatory Proposal for Cosmetics and the Ban on Cosmetic Animal Testing

The proposed regulatory proposal concerning cosmetics

- The consultation in Canada Gazette, Part I, *Regulations Amending Certain Regulations Concerning the Disclosure of Cosmetic Ingredients*, ended on April 22, 2023.

- All approved comments are posted in the section “Closed consultations with published comments” of the Canada Gazette Webpage.
  - The online posting of all the comments aims to increase transparency of the regulatory process.
  - There were 66 submissions received either online or via email. Email submissions were also entered to the online platform, following receipt of consent, and are available on the Canada Gazette Webpage.

- Overall, the feedback provided was generally supportive of the overall objectives described in the proposal.

Path forward and next steps

- In August 2023, the European Commission adopted its expanded list of fragrance allergens (Annex III).
  - As a result, Health Canada conducted a targeted Cost-Benefit survey to determine if there are additional costs for industry with respect to the disclosure of the expanded list of fragrance allergens.
  - The survey results contribute to an updated Cost- Benefit Report that will be incorporated in the publication in *Canada Gazette, Part* II.

Publication in *Canada Gazette*, Part II is anticipated for Spring 2024:

- Amendments related to disclosure of fragrance allergens would come into force **two years after** the registration of the final Regulations;
- All other amendments would come into force **180 days after** the registration of the final Regulations.

Ban on Cosmetic Animal Testing – next steps

- Bill C-47 received royal assent on June 22, 2023. The amendments to the *Food and Drugs Act* relating to the animal testing of cosmetics will be coming into force on December 22, 2023.

- To support compliance by the cosmetics industry, Health Canada is developing an accompanying guidance which explains the amendments, how manufacturers, importers and sellers can comply with them, and other compliance and enforcement information.

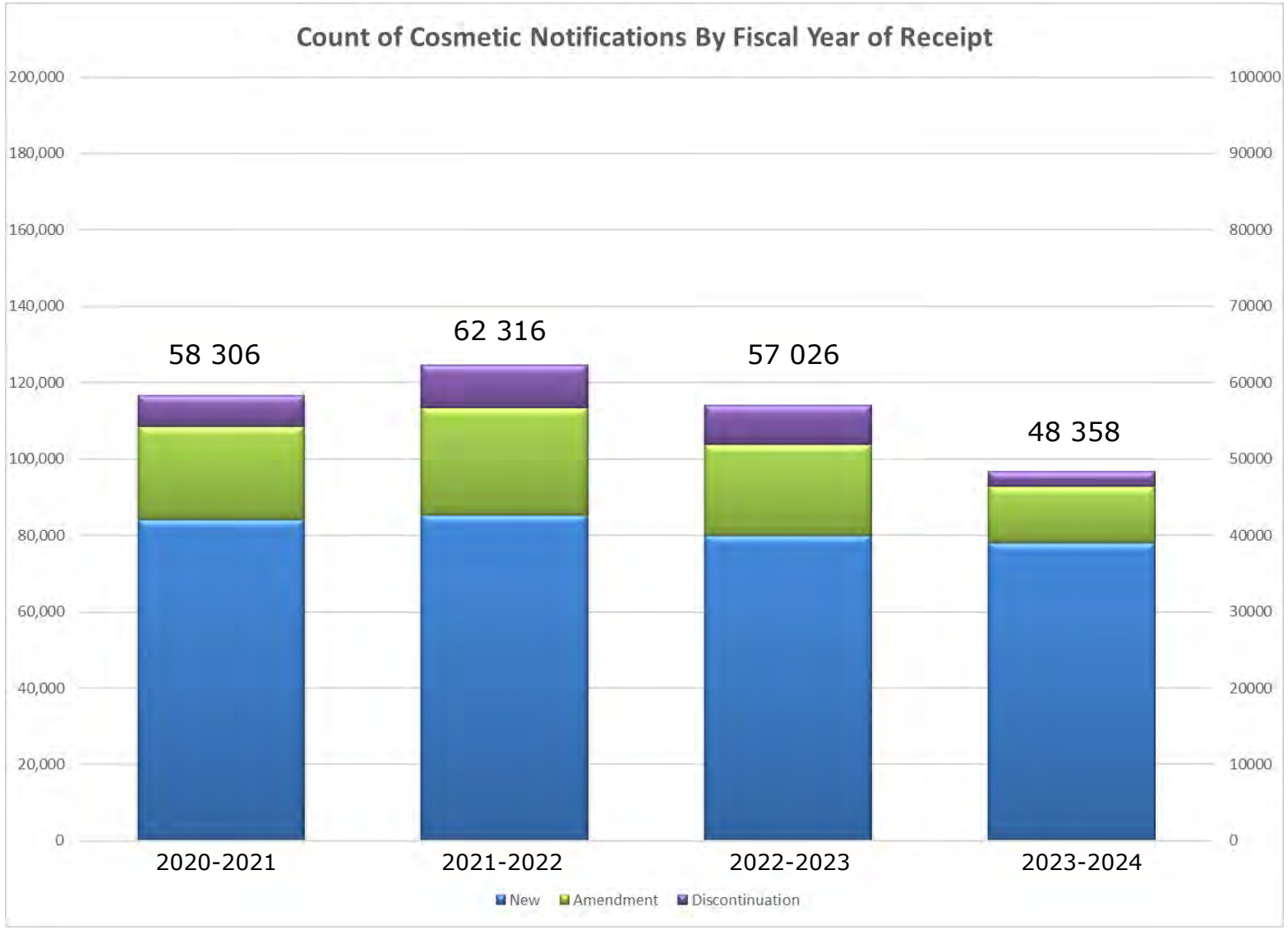
- Modifications to Health Canada's existing consumer webpages for cosmetics will also be made to inform the public about the new laws and how they can file a complaint.

- The guidance and webpage modifications will be published in December 2023.

- Health Canada continues to work on other fronts to reduce the reliance on animal testing more broadly.

Cosmetic Notification Statistics and Further Improvements to the Processing of Cosmetic Notifications

Cosmetic Notification Statistics



Automation Experience to Date

- Over 46 000 cosmetic notifications have been processed through automation since February 2022

- Along with the existing automation criteria, over 3 600 cosmetic notifications have been processed by the additional criteria for automation released in May 2023

- More than 30% of cosmetic notifications received to date meet the automation criteria

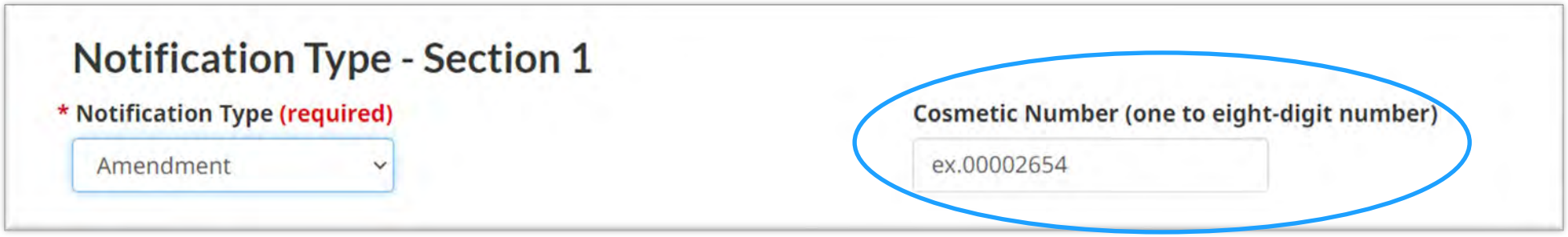
- Mitigation strategies such as the usage of business intelligence, officer’s expertise and random sampling are in place to identify potential quality and classification issues with the automated notifications.

Common Issues When Submitting Cosmetic Notifications (1)

- Please review relevant Acts and regulations prior to submitting a Cosmetic Notification (CN) to the Consumer Product Safety Program.

Reminder that the submission of a Cosmetic Notification to Health Canada does not constitute approval for sale by Health Canada, or agreement that the product is in compliance with all regulatory requirements. A Cosmetic Notification for a product that does not meet the definition of a cosmetic will be referred to other areas of Health Canada.

- When submitting an Amendment, ensure the **correct** Cosmetic Number is entered into the Cosmetic Number box in Section 1.

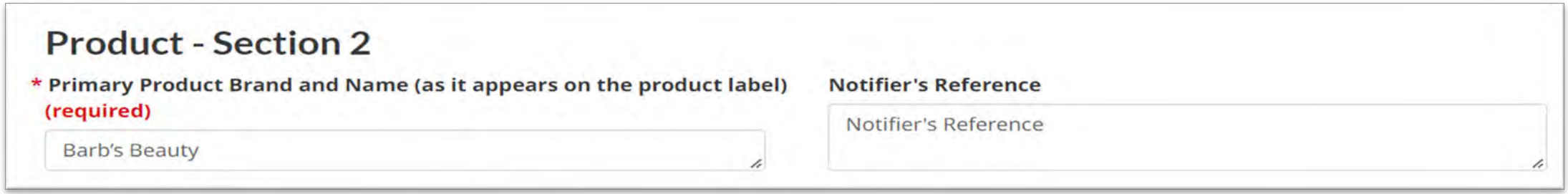


  - If the Cosmetic Number is not known, leave the box blank and it will be entered by a Health Canada Officer.

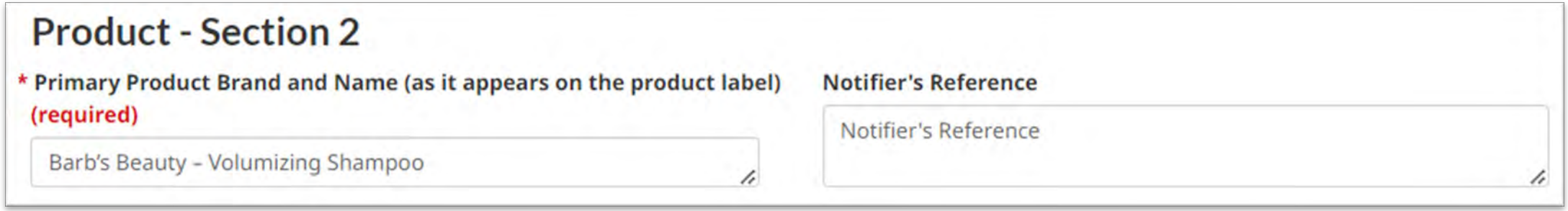
Common Issues when Submitting Cosmetic Notifications (2)

- The "Product Brand and Name" field in Section 2 should clearly identify the product :
  - Entering **only** the Company Name in this field is unacceptable.

    ☒ INCORRECT: "Barb's Beauty".



☑ **CORRECT:** "Barb's Beauty – Volumizing Shampoo";

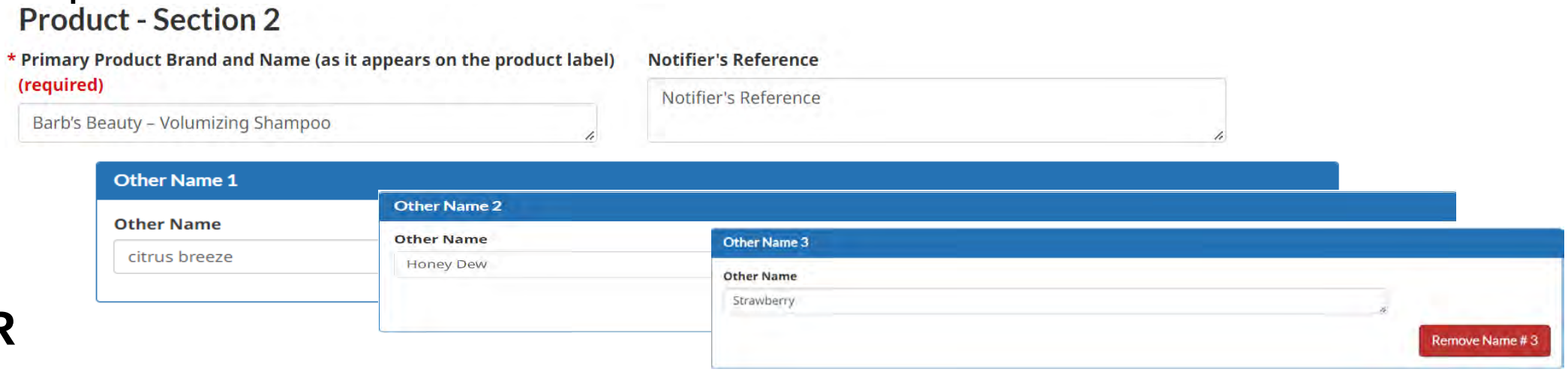


Submission of a CN with the same Product Brand and Name that has been **previously submitted by the same notifier**, will be treated as an "Amendment" and reassigned the original Cosmetic Number, thus overriding the information contained in the previous CN

Common Issues when Submitting Cosmetic Notifications (3)

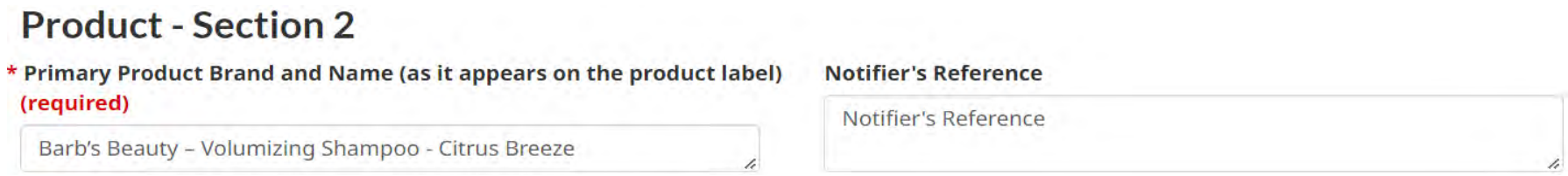
You may submit multiple products in one CN, **IF** the product base remains unchanged in composition, except for slight variation in color, fragrance or flavouring. When submitting one CN for multiple products, either:

a. capture the variations in the “Other Product Names” field of Section 2 of the Form.



OR

b. Submit one CN per product variation



Ingredient concentrations for mixed or diluted products

- Products intended for dilution where the diluent is not supplied, e.g.bath bombs
  - CNF should reflect the final concentrations of the ingredients in the product as sold to the consumer (i.e. prior to dilution).
- For products where all components of the final product are supplied together and mixed prior to application, e.g. at-home hair dye kits or DIY nail polish or lip balm kits
  - CNF should reflect the composition of the final product as it would be applied to the body.
  - See the definition of a kit in the Guide to complete a Cosmetic Notification form
- Products supplied together but used separately (e.g. gift basket) or sequentially (e.g. treatment solution and neutralization solution)
  - not considered “kits” for the purpose of the form
  - each product should be notified separately.
- Products where components intended for mixing may be sold separately (e.g. developers sold separately from dye solutions for hair salon use)
  - concentrations should generally reflect concentration as supplied
  - additional context may be provided in the Product Description in Section 2 of the CNF or as an Additional Document in Section 6.

Where additional information is required, for example to determine if a Hotlist condition is met, Health Canada may contact the notifier.

International Cooperation of Cosmetics Regulation

International Cooperation on Cosmetics Regulation (1)

- **Taiwan Food and Drug Administration (TFDA) is the Chair for ICCR-18:**
  - Steering Committee is composed of cosmetic regulatory authorities from Brazil, Canada, Chinese Taipei, European Union, Israel, Japan, Republic of Korea and United States.
  - Observer countries : Argentina, Chile, Cape Verde, Egypt, People's Republic of China, Saudi Arabia, Thailand, and the United Kingdom.

- **The Annual Meeting will be held from July 9- 11, 2024 in Taipei City**
  - To review Previous meeting outcomes.

International Cooperation on Cosmetics Regulation (2)

Topics to be discussed during the ICCR-18 Annual Meeting include:

1) **Consumer Communications JWG:**

   The topic proposed is “Navigating Cosmetic Pseudoscience”.

2) **Integrated Strategies for Safety Assessment of Cosmetic Ingredients JWG II:**

   The draft best practices report with updated safety assessment workflow will be finalized during this cycle.

3) **Per- and Polyfluoroalkyl Substances (PFAS)**

   Regulators and observer regulators filled out a survey about regulating PFAS

   Survey was shared with ITAs to solicit information about PFAS usage in cosmetics

Labelling Clarifications

Planned updates to Industry Guide for the labelling of cosmetics

1. Section 4.1 includes unclear messaging regarding bilingual labelling of product identity on the inner label. It will be revised to reflect the following:

   From the CPLR:

   - Subsection 6(2) requires that all mandatory label information be shown in **English and French** except the dealer's name and address which can appear in either language.
   - Paragraph 12 (b) requires that the **identity** of the product, in terms of its common or generic name or in terms of its function, be present on the **principal display panel.**

   From the CR:

   - Section 18 requires that **all** mandatory label information, other than the INCI name, be presented in **both English and French**.
   - Paragraph 20 (b) requires the product **identity** to be on the **inner label.**

   Certain expressions are considered officially bilingual in themselves, such as "parfum," "eau de toilette," or "cologne".

2. We will also be removing the reference to the Marking of Imported Goods Order as it does not apply to cosmetics.

Unconscious Bias in Product Safety

Project Background

- **Consumer Product Safety Program Mandate**:
  - To help protect the health and safety of Canadians by identifying, assessing, managing, and communicating health and safety risks from consumer products and cosmetics.
- **Trigger**:
  - **2021**: Clerk of the Privy Council issued a "*Call to Action on Anti-Racism, Equity, and Inclusion in the Federal Public Service*"
  - **2022**: "*HECSB Equity, Diversity and Inclusion (EDI) and Anti-Racism Action Plan*"
  - **2023**: CHPSD identified where unconscious bias and systemic racism may exist in our program areas and activities, including in cosmetic product safety testing
- **Cosmetic Product Safety Program - Areas of Unconscious Bias**:
  - Use of the Fitzpatrick Skin Type Scale (FSTS) in clinical studies
  - Representation in clinical skin irritation studies (age, sex or gender, skin types)
  - If skin irritation is being assessed and measured in an objective and unbiased way, notably on those with darker skin tones.
- **Result**: Anti-racism in Science (**ARiS**) project initiated in 2023

Project Context

Adequate representation in Alpha Hydroxy Acid clinical safety studies is critical to assess cosmetic safety for all consumers

- Industry submits AHA clinical irritation studies to satisfy Hotlist requirements; assumed participants generally representative of the intended users
- Without labelling restrictions on who can / cannot use these products, how can CHPSD be sure that consumers outside of the target market will also be safe, if these products are applied?
- While the participants included may be representative of the intended users, are they representative of the Canadian population? If not, who is missing from an EDI perspective?
- How do we determine if study participants are adequately representative of the Canadian population if one of our units of measure for inclusion purposes (the FSTS) is not objective, inclusive, or representative?

Fitzpatrick Skin Type Scale

- Used in dermatology to investigate the association between the level of epidermal melanin, UV light exposure, and risk of skin damage for phototherapy treatments.
- Skin type classification is based on a self-assessment, then totaling the score from each question.

Physical traits:

Genetic (physical traits)

	Score				
Characteristics	**0**	**1**	**2**	**3**	**4**
What are the colour of your eyes?	Light blue or green, grey	Blue, green, grey	Dark blue or green, light brown (hazel)	Dark brown	Brownish black
What is the colour of your hair (naturally and before aging)?	Red	Blonde	Chestnut or dark blonde	Dark brown	Black
What is the colour of your skin (unexposed areas)?	Pink	Very pale	Light brown or olive	Brown	Dark brown
Do you have freckles on unexposed areas?	Many	Several	Few	Rare	None

Sun sensitivity:

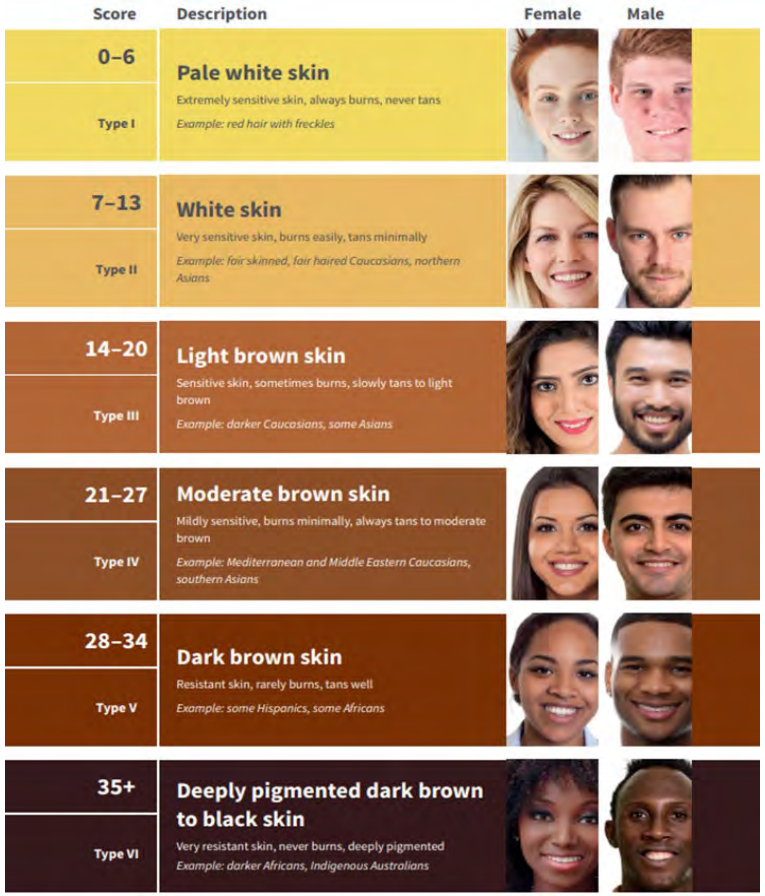
Sensitivity (reaction to sun exposure)

	Score				
Exposure	**0**	**1**	**2**	**3**	**4**
What happens to you skin if you stay in the sun for an extended period?	Severe burns, blistering, peeling	Moderate burns, blistering, peeling	Burns sometimes followed by peeling	Rare burns	No burns
Do you turn brown after sun exposure?	Never	Rarely	Sometimes	Often	Always
How brown do you get?	Hardly or not at all	Light tan	Medium tan	Dark tan	Very dark tan
Is your face sensitive to the sun?	Very sensitive	Sensitive	Mildly sensitive	Resistant	Very resistant

Tanning behaviours:

Intentional exposure (tanning habits)

	Score				
Exposure	**0**	**1**	**2**	**3**	**4**
How often to you tan?	Never	Rarely	Sometimes	Often	Always
When did you last expose your skin to the sun or artificial tanning sources (tanning beds)?	More than three months ago	In the last 2–3 months	In the last 1–2 months	In the last week	In the last day



Challenging the Fitzpatrick Skin Type Scale

- The scale was developed in 1975 to categorize individuals for use in phototherapy research, based on their self-reported physical traits, sun sensitivity, and tanning behaviours. *It was **not** developed for use to screen participants into studies assessing chemical irritation to the skin.*

- The scale is based on **self-reported, non-objective questions that are open to personal interpretation and unconscious biases**. Some suggested responses are vague and undefined (*rarely, sometimes, frequent, often; many, several, few; sensitive, mildly sensitive, very sensitive*).

- The scale is limited to only **six** representative skin types, has been demonstrated to overrepresent those with lighter skin tones, underrepresent those with darker skin tones, and is not sufficiently representative of a diverse population basis, such as in Canada.

Guest Editorial

The Use and Misuse of Fitzpatrick's Skin Types

Journal of Cutaneous Medicine & Surgery
2022, Vol. 26(1) 15–16
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DOI: 10.1177/12034754211061074
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Harvey Lui, Tashmeet

Measuring Skin Cancer Risk in African Americans: Is the Fitzpatrick Skin Type Classification Scale Culturally Sensitive?

Latrice C. Pichon, PhD, MPH; Hope Landrine, PhD; Irma Corral, PhD, MPH; Yongping Hao, PhD; Joni A. Mayer, PhD; Katherine D. Hoerster, MS, MPH

Objective: Fitzpatrick's Skin Type Classification Scale often is used to assess sun sensitivity and skin cancer risk. Because the scale was developed with Whites, its utility and validity with Blacks may be limited by its reliance on the European-cultural terms suntan and sunburn. We tested the hypothesis that most Blacks would be unable to classify their skin into the four Fitzpatrick skin types.

Design, setting, statewide sample adults were admin their skin into th and/or margina inspired intens publication

Introduction

Skin type, defined as an individual's propensity to tan or sunburn, is a ...dictor of both non-melanoma and ... There are ethnic groups.[4–7] For example, these self-reported skin-type categories do not correlate well with sun reactivity among ethnic groups such as Koreans,[4] other Asians,[5] Arabs,[6] and African Americans.[7] The reason may be that the skin types rely on the words tan (ie, the skin ...regulation. Specifically

Canadian Dermatology Association

DOI: 10.1111/bjd

DHS SCIENCE AND TECHNOLOGY

Revisiting the Fitzpatrick Scale and Face Photo-based Estimates of Skin Phenotypes

October 29, 2020

John Howard, Yevgeniy Sirotin, & Jerry Tipton
The Maryland Test Facility

Self-reported pigmentary phenotypes and race are significant but incomplete predictors of Fitzpatrick skin phototype in an ethnically diverse population

Steven Y. He, BS,[a] Charles E. McCulloch, PhD,[b] W. John Boscardin, PhD,[b,c] Mary-Margaret Chren, MD,[a] Eleni Linos, MD, DrPH,[a] and Sarah T. Arron, MD, PhD[a]
San Francisco, California

Received: 18 February 2021 | Revised: 27 March 2021 | Accepted: 19 April 2021
DOI: 10.1002/ski2.40

REVIEW ARTICLE

SKIN HEALTH AND DISEASE

Skin cancers in skin types IV–VI: Does the Fitzpatrick scale give a false sense of security?

PERSPECTIVES

Equity in skin typing: why it is time to replace the Fitzpatrick scale

British Journal of Dermatology
BJD

SKIN OF COLOR
IN COLLABORATION WITH THE SKIN OF COLOR SOCIETY

Racial Limitations of Fitzpatrick Skin Type

Olivia R. Ware, BA; Jessica E. Dawson, BS; Michi M. Shinohara, MD; Susan C. Taylor, MD

NEWS

Check for updates

The BMJ
Cite this as: *BMJ* 2022;377:o1175
http://dx.doi.org/10.1136/bmj.o1175
Published: 10 May 2022

Researchers propose new evidence based scale for describing skin colour

Gareth Iacobucci

Doctors and researchers have been urged to adopt a new scale for describing the range of human skin colours that aims to tackle the lack of a standard approach in current medical practice and academia.

...is used as intended, ...are inconsistencies with its accuracy; for example, self-reported FSTs have correlated poorly with sunburn

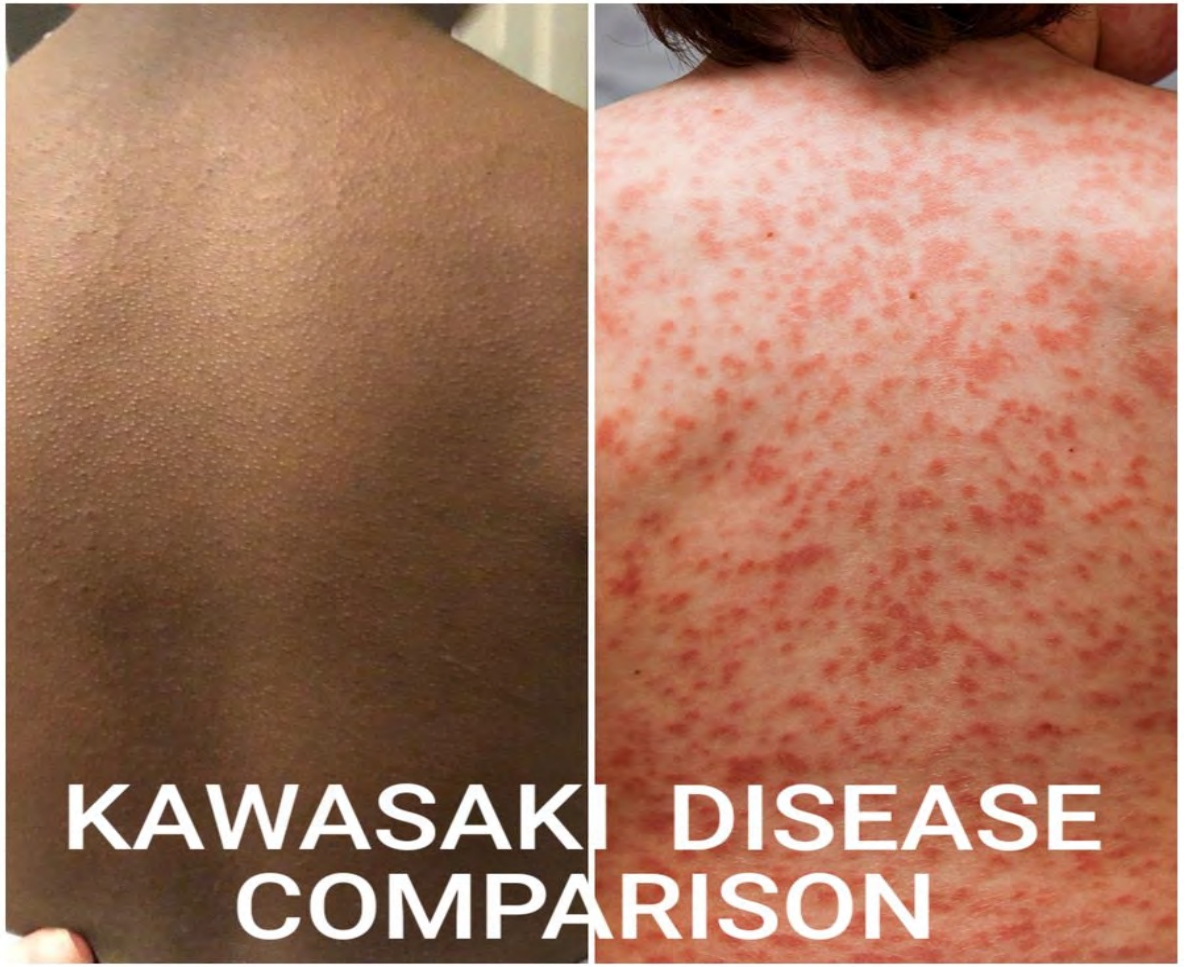
ARiS Reflection Questions

For AHA clinical safety studies submitted by Industry:

- Do we have the **disaggregated data** necessary to determine baseline diversity and representation (who is being tested regarding age, sex or gender, Fitzpatrick skin type)?
- Are there disparities in the reporting of irritation levels among those of different skin tones, potentially resulting in underreporting or overreporting (bias)?
- Since the FSTS is not an appropriate tool for cosmetic evidence of safety use, what other alternative, more inclusive scales are available?
- Can we identify best practices in clinical study design and methodology that are appropriate to the CHPSD cosmetic product safety program?
- Are irritation assessments being made consistently and objectively **across all skin tones**, ensuring uniformity in both methodology and the identification of irritation?

Assessing Erythema on Darker Skin Tones

- Erythema can present differently on darker versus lighter skin tones.
- More subtle signs of erythema, often found in AHA product safety studies, will be harder to detect.
- **Who** (professional judgement) and **how** irritation is identified and measured (visual assessment *vs*. instrumentation) is important.



From: https://twitter.com/brwnskinmatters/status/1171514403453145088

ARiS Research

Retrospective analysis of in-house AHA clinical studies:

- If disaggregated data is being provided
- Who is being screened in from an EDI perspective (age, sex or gender, Fitzpatrick skin type)
- Are participants representative of the diverse Canadian population
- Participant trends in irritation
- Summary of assessment protocols, average number of study participants, who is assessing the studies, what rating scales are most commonly used and their appropriateness

Literature search on:

- How age, sex or gender, and skin type or race influence skin irritation potential
- Identifying the most commonly used skin measurement devices
- Identifying the most common human skin irritation assessment protocols and scales used in regulatory jurisdictions and by medical professionals
- Review recently updated guidance for Good Clinical Practice, Research Ethics for human study participants

Continued...

Consultations:

- External experts in colourism and anti-racism (Dr. Ellis Monk, Harvard University)
- Canadian Dermatology Association (Skin Health Program) on their industry requirements, minimum number of participants, inclusion criteria
- Health Canada partners on the skin irritation studies they receive, number and diversity of clinical trial participants, if they have published guidance for industry on preferred study protocols
- Industry & Clinical Study Laboratories on the challenges they have conducting clinical studies for evidence of cosmetic safety purposes

Regulatory Environmental Scan:

- What EDI requirements do other Health Canada partners have in place for clinical studies conducted on humans?
- Do they have regulatory requirements for providing disaggregated data?
- What other skin scales are commonly used in regulatory jurisdictions, medical studies, academia?

Sephora Canada

- Forbes Canada's Best Employers for Diversity 2023 (#24)
- Commitment for 25% of their brands to be BIPOC owned by 2026
- DE&I Progress Report 2022
- Colour iQ technology to measure depth, undertone and saturation to find the perfect foundation
- Racial Bias in Retail Study

Fenty Beauty

- Shade Finder – Using AI Technology to find perfect foundation shade
- Fenty Beauty's Diverse Foundation shade range sets an industry standard

LUSH

- Summer 2022 Diversity Report that provides employee data demographics in the North American markets – US & Canada

L'Oréal Paris

- Skin Color Chart – with use of the Chromasphere to provide insights on the aging process

Kiehl's

- Skin assessment tool – Derma-Reader

Contact us

cosmetics@hc-sc.gc.ca

Contact your designated Regional Product Safety Office:

https://www.canada.ca/en/health-canada/corporate/contact-us/regional-product-safety-offices.html

or

via telephone 1-866-662-0666

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