

Governance and Policy Instruments:
Regulatory Resources in Regulatory Strategy and Compliance:
Consumer Health Products
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The Cosmetic Ingredient Hotlist (Hotlist) is used by Health Canada to inform cosmetics manufacturers about ingredients that are prohibited or restricted to be used in their formulations and indicates the labelling requirements for cosmetics containing restricted ingredients (Government of Canada, 2020 - b). The Natural Health Products Ingredients Database (NHPID) provides information that supports the safety and efficacy of an ingredient in the form of Precleared Information (PCI) for products that contain natural health product (NHP) medicinal ingredients (Health Canada, 2022). This paper will provide an example of a prohibited and a restricted cosmetic ingredient and will elaborate on the conditions supporting the restriction using the Hotlist. In addition, the NHPID will be searched to access the PCI for a therapeutic product to demonstrate the information available to manufacturers and regulatory affairs specialists.

The Hotlist contains scientifically backed information used by Health Canada to guide cosmetic manufacturers regarding which Ingredients are prohibited or restricted (Government of Canada, 2020 - b). Prohibited Ingredients are those that must not be present in a cosmetic product and restricted ingredients are those in which conditions must be met, or a caution must be present for the cosmetic to be eligible for sale (Government of Canada, 2022 - b). If the restriction involves a maximum concentration requirement, then this number must not exceed what is specified on the Hotlist, otherwise, it does not comply with the Food and Drugs Act (FDA) (Government of Canada, 2022 - b). However, Health Canada will still enforce the FDA or the Cosmetic Regulations (CR) in cases where provisions of the Regulations or Act are not met, even if the ingredient is not listed in the Hotlist (Government of Canada, 2022 - b). In addition, the Hotlist is reviewed and amended regularly as new evidence emerges on the safety of ingredients (Government of Canada, 2022 - b).

Prohibited and restricted ingredients are each presented in separate tables on the Hotlist with ingredients listed in alphabetical order according to the International Nomenclature of Cosmetic Ingredients (INCI) name, then the Chemical Abstracts Service (CAS) number in the next column, followed by any existing synonyms or related compounds (Government of Canada, 2022 -b). If there is no INCI name then the product may be listed by another naming convention such as the common name, Latin name, the International Non-Proprietary Names (INN) set by the World Health Organization (WHO), U.S or European Pharmacopeia name, the International Union of Applied Chemistry (IUAC) name or the CAS name (Government of Canada, 2022 - b). For the restricted ingredients, the table contains additional columns related to the restrictions, indicating conditions of use by the product type, the maximum concentration permitted, and warnings and precautions that must be present on the product labelling (Government of Canada, 2022 - a).

Diethyl toluamide is an example of a prohibited ingredient in cosmetics that has the CAS number 134-62-3, and the synonym or common name is DEET (Government of Canada, 2022 - a). An example of a restricted ingredient is hydroquinone, which has 3 conditions for use (Government of Canada, 2022 - a). The first is as an oxidizing colouring agent for hair dyes where the maximum concentration permitted in the product is 0.3 % (Government of Canada, 2022 - a). The warning or cautionary statements must specify that it contains hydroquinone, that it must not be used to dye eyelashes or eyebrows, and to rinse the eyes immediately if they contact the product (Government of Canada, 2022 - a). The second condition for use is in two-component (acrylic) artificial nail systems after they are mixed for use, with a maximum concentration of 0.02% permitted (Government of Canada, 2022 - a). The third condition for use is in cyanoacrylate adhesive products at a maximum concentration of 0.1% (Government of Canada, 2022 - a). Both the second and third condition for use require a warning or cautionary statement to

avoid skin contact, and a statement advising to read the directions carefully before use (Government of Canada, 2022 - a).

The NHPID contains a search field for ingredients that lists acceptable non-medicinal ingredients and medicinal ingredients used in NHPs (Health Canada, 2022). There is also a search field for controlled vocabulary or terminology used in the NHPID that includes information on the purpose of non-medicinal ingredients present in the formulation, dosage forms, and acceptable tests for quality assurance (Health Canada, 2022). The PCI search field allows access to product monographs, as well as single ingredient monographs that have been reviewed to be acceptable by the NHPID, and according to abbreviated label standards (Health Canada, 2022). NHPs are regulated through the Natural and Non-prescription Health Products Directorate (NNHPD) and must follow the requirements for labelling, manufacturing, and product specifications stated therein (Health Canada 2022).

A search for the chemical ingredient salicylic acid brings up the PCI for various therapies including the PCI for acne therapy that is available as the Acne Therapy Monograph and indicates what is required to receive market authorization for a topical acne product (Health Canada, 2021). A Natural Product Number (NPN) is assigned to a NHP with market authorization (Health Canada, 2021). The monograph contains two tables that divides the classification of the product based on its ingredients (Health Canada, 2021). It is classified as a NHP if it contains NHP medicinal ingredients listed in Table 1, and it does not contain the Non-Prescription Drug (NPD) medicinal ingredient listed in Table 2 (Health Canada, 2021). The product is classified as a NPD if it contains the NPD medicinal ingredient listed in Table 2 (Health Canada, 2021). Each table lists the proper names, common names, source materials and quantities in the form of percentages for the medicinal ingredients (Health Canada, 2021). In the case of acne therapy, it is considered a NPD if it contains the medicinal ingredient benzoyl peroxide within the quantity range of 2.5 - 5% (Health Canada, 2021). Salicylic acid is under common names in Table 1, with the proper name listed as 2-hydroxybenzoic acid within the quantity range of 0.5 - 2% (Health Canada, 2021). Other common name NHP medicinal ingredients listed are sulfur, resorcinol, and resorcinol monoacetate (Health Canada, 2021). The quantity requirement for sulfur is 3 - 10%, with a further specification that the appropriate dosage range must be 3 - 8% when combined with resorcinol 2% or resorcinol acetate 3% (Health Canada, 2021). In addition, the resorcinol or resorcinol acetate must be combined with sulfur and is not permitted to be used as the sole medicinal ingredient in acne therapy (Health Canada, 2021). The route of administration is topical for this product and the acceptable dosage forms listed for NPD products include ointment, cream, etcetera, and for NHPs it includes a wider range of acceptable dosage forms including soap, foam, and spray, etcetera (Health Canada, 2021). The section for use(s) or purpose(s) lists statements that may be made in the context of self care category I uses, which includes indicating that the product is for acne treatment, helps prevent acne, and helps clear acne, etcetera (Health Canada, 2022). This section includes additional statements allowed for products that contain benzoyl peroxide including “kills acne bacteria”, as well as unacceptable uses for the product in general, such as stating it “cures acne” (Health Canada, 2021). Doses are outlined for use in subpopulations that include adolescents and adults (Health Canada, 2021). For permitted combinations of sulfur with resorcinol/resorcinol monoacetate, statements cannot be made specifying that it may be used as a face wash or body cleanser (Health Canada, 2021). The directions for use that may be made for all products include specifying that new users should test if they are sensitive to the product, and if no reaction occurs then they may apply the product according to the recommended frequency of application, while the section on duration of use requires no description (Health Canada, 2021). The section for risk information includes warnings and precautions for all products with

additional statements for products that contain sulfur with or without resorcinol/resorcinol acetate, or for products that contain benzoyl peroxide (Health Canada, 2021). Contraindications for products containing sulfur with or without resorcinol/resorcinol acetate include using it on broken skin, and for products containing benzoyl peroxide this includes using it on sensitive skin (Health Canada, 2021). Adverse reactions that must be listed on all products are specified with an allergy alert required for those products containing salicylic acid or benzoyl peroxide, stating to seek medical care if manifestations of a severe allergic reaction occur (Health Canada, 2021). There is no information required under storage conditions (Health Canada, 2021). The specifications for non-medicinal ingredients states that they must be chosen from and adhere to the requirements of the NHPID and the FDR, or the Hotlist (Health Canada, 2021). The specifications also indicates that if the product contains a Table 1 NHP medicinal ingredient only, then they will be evaluated based on the specifications of the NNHPD, and the ingredient must follow the requirements of the NHPID (Health Canada, 2021). However, if the product contains NPD medicinal ingredients, then they must be evaluated based on the FDA and Regulations (Health Canada, 2021). The monograph also provides a standard drug facts table that may be found on the packaging for these products (Health Canada, 2021). This provides consumer information for active ingredients and purpose, product uses, warnings, allergy alerts, when not to use the product, when to ask a doctor or pharmacist before use, when to stop using the product and consult a doctor, a warning to keep out of the reach of children and what to do in case ingested, directions for use, list of inactive ingredients and lastly contact information for the consumer (Health Canada, 2021). The drug facts table serves as a useful template to help guide manufacturers regarding the formatting of required information on the product packaging.

In conclusion, the Hotlist provides cosmetics manufacturers with scientifically backed evidence supporting ingredient restrictions and prohibitions that products must comply with to satisfy the regulatory requirements to meet approval for legal sale, and it serves as a useful resource for regulatory affairs specialists involved in facilitating the approval process (Government of Canada, 2020 - b). The NHPID is a valuable source of information for the public and provides the requirements for non-prescription NHPs in the form of PCI that serves as a template for products seeking approval (Health Canada, 2022). Adherence with these specifications may expedite the approval for a product, where the PCI provides necessary guidance for regulatory affairs specialists involved in facilitating the approval process (Health Canada, 2022).

References:

1. Government of Canada. (2022 - a). Cosmetic Ingredient Hotlist. Retrieved October 23, 2022, from: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restricted-ingredients/hotlist.html>.
2. Government of Canada. (2022 - b). Cosmetic Ingredient Hotlist: Prohibited and restricted ingredients. Retrieved October 24, 2022, from: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restricted-ingredients.html>.
3. Health Canada. (2021). ACNE Therapy. Retrieved October 29, 2022, from: file:///C:/Users/rahil/OneDrive/Desktop/AC%20RGA/mono_acne-therapy_english.pdf
4. Health Canada. (2022). Natural Health Products Ingredients Database. Retrieved October 23, 2022, from: <http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do>.