Health Canada Santé Canada

# Guidelines for Cosmetics Manufacturers, Importers and Distributors

Canada

Our mission is to help the people of Canada
maintain and improve their health.

*Health Canada*

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importateurs et distributeurs de cosmétiques*

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# Introduction

Health Canada's Cosmetics Program works with the Canadian public to minimize the risk associated with the use of cosmetic products marketed in Canada. The Program defines requirements for:

- manufacture,
- labelling,
- distribution, and
- sale

of cosmetic products. It also evaluates compliance. The basis for the regulatory authority for the Cosmetics Program comes from the *Food and Drugs Act* (FDA) and *Cosmetic Regulations*.

It is the responsibility of the manufacturer, importer or distributor to ensure the cosmetic products they sell comply with the FDA and *Cosmetic Regulations* and other associated legislation.

The purpose of this guide is to:

- **identify** what types of products are regulated as cosmetic products
- provide **information about the legislation** in Canada that applies to cosmetic products
- **outline the roles and responsibilities** of industry and government
- **provide contact information** for further questions or requests

This document is intended to be an introduction to legislation (Acts and regulations), policies and guidelines regarding cosmetic products. It is not intended to substitute for, supersede or limit the requirements under the applicable legislation. In case of any discrepancy between this summary and the legislation, the legislation will prevail. For further information or specific questions, requests or clarification, please contact the Product Safety Office in your region (see Appendix IV – Contact Information).

# The *Food and Drugs Act* and *Cosmetic Regulations*

The authority for the Cosmetics Program is contained in the following legislation:

Cosmetics are subject to the provisions of the ***Food and Drugs Act* (FDA)**. The FDA also includes the ***Cosmetic Regulations***, which outline general safety, labelling and notification requirements.

The *Food and Drugs Act* defines a "cosmetic" as:

> "any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes."

This definition includes (but is not limited to) soap, grooming products for animals, and cosmetics used by professional esthetic services (e.g. facial masks, manicure preparations, hair dye). This also encompasses bulk products used by institutional services (e.g. handsoap in school restrooms).

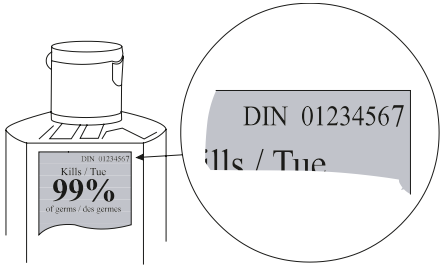
Some products that are normally thought of as cosmetics are not covered by the *Cosmetic Regulations* of the FDA. They may need to meet the requirements of other legislation and

government programs. There are four questions you can ask to help determine if a product is a cosmetic:

1. **How is the product applied?**
   Cosmetics must normally be applied to an external part of the body. An exception to this would be oral cosmetics (e.g. toothpaste, mouthwash, tooth whiteners, etc.). Cosmetics are not intentionally swallowed or inserted below the skin.

2. **Is the product a substance?**
   A substance can be defined as any distinguishable kind of organic or inorganic matter. Only substances and mixtures of substances are regulated as cosmetics. In contrast, articles or equipment which contain, dispense or apply cosmetics (e.g. hair brush, curling iron, eyeshadow brush, tanning booth, etc.) are not regulated as cosmetics.

3. **What claims are being made about the product?**
   When a product makes a therapeutic claim (e.g. to prevent or treat disease), it is classified as a drug under the *Food and Drugs Act* and therefore requires a drug identification number (DIN).



Drugs are managed by Health Canada's **Therapeutic Products Directorate** (TPD). Products containing ingredients of **natural origin** with a therapeutic function or claim are Natural Health Products (NHPs) under the authority of Health Canada's **Natural Health Products Directorate** (NHPD). Each NHP must possess a Natural Product Number (NPN).

4. **Does the substance contain one or more ingredients that primarily have a therapeutic purpose?**
   For example, toothpastes have the cosmetic purpose of cleaning teeth and freshening breath. However, if a toothpaste contains ingredients to fight against cavities and gingivitis – both therapeutic functions – it would be considered a drug or natural health product. Therapeutic ingredients prohibited or restricted in cosmetics are listed on the Cosmetic Ingredient Hotlist.

## IMPORTANT POINTS!

- The **Health Products and Food Branch Inspectorate** (HPFBI) provides compliance and enforcement services to both TPD and NHPD.
- Non-therapeutic products intended for ingestion are under the direction of Health Canada's **Food Program** and the **Canadian Food Inspection Agency** (CFIA).
- Pest repellents (e.g. insect repellent lotions) fall under the jurisdiction of the **Pesticide Management Regulatory Agency** (PMRA).
- Animal grooming products are cosmetics, but those which claim a therapeutic benefit for animals are veterinary drugs and are under the management of the **Veterinary Drugs Directorate** of Health Canada.
- Cosmetics are currently exempt from Part II of the ***Hazardous Products Act*** (HPA): the **Workplace Hazardous Materials Information System** (WHMIS).

## *Product Classification:*

Here are examples of how some products are classified…

| Product Type | Cosmetic, Food, Drug or NHP? |
|---|---|
| Deodorant | *Cosmetic*, because it masks the odour of perspiration, with or without a fragrance. |
| Antiperspirant | *Drug* or *NHP*, because it suppresses the production of perspiration. |
| Face cream | *Cosmetic*, because it moisturizes skin. |
| Face cream with Sun Protection Factor (SPF) 15 | *Drug*, because it protects the skin from sun damage. |
| Chewing Gum | *Food*, because it is meant for oral consumption. |
| Tooth Whitening Gum | *Cosmetic* + *Food*, because consumption is secondary to its cosmetic cleansing property. |
| Massage Oil* | *Cosmetic*, because it lubricates and maintains the integrity of the skin<br>* provided no claims on its effects on muscles are made |
| Topical herbal remedy to speed scar healing | *NHP*, because a therapeutic function has been claimed for the natural extract used in the product. |


Cosmetic vs. Drug

## *Notification of Sale*

Notification is a mandatory requirement for the sale of cosmetics in Canada, according to section 30 of the *Cosmetic Regulations*. This entails submitting a fully completed Cosmetic Notification Form (CNF) to Health Canada **within the first 10 days** a cosmetic is available for sale. The completed CNF provides specific product information, including:

- address and contact of the company
- purpose of the cosmetic
- form of the cosmetic (e.g. gel, solid, liquid, etc.)
- ingredients of the cosmetic
- concentrations of the ingredients (ranges specified in the *Cosmetic Regulations*)

There is no fee associated with the cosmetic notification process.

The information obtained by the Cosmetics Program is considered to be confidential, and will be discussed **only** with the company (manufacturer or distributor) that submitted it. A product with an incomplete CNF will not be processed. It is possible that a notifying company may need information from a third party. If requested by the third party, this information can be kept from the notifier.

It is also necessary for companies to inform the Cosmetics Program whenever a change affecting the information on a CNF is made. Some examples of this include (but are not limited to):

- modification to the cosmetic formulation
- change of product name
- discontinuation of sale
- new company name/address, etc.

Consult the **Guide for Completing Cosmetic Notification Forms** for more details (see Appendix II – Suggested Reading). Failure to notify may result in a product being refused entry into Canada or removed from sale.

## *Safety*

The *Food and Drugs Act* (FDA) and the *Cosmetic Regulations* (CR) set safety requirements. No person shall sell any cosmetic in Canada that:

- has in or on it any substance that may cause injury to the health of the user when the cosmetic is used (section 16, FDA)
- consists in whole or in part of any filthy or decomposed substance or of any foreign matter (section 16, FDA)
- has been manufactured, prepared, preserved, packaged or stored under unsanitary conditions (section 16, FDA)
- has not been notified with Health Canada (section 30, CR)

It is the company's responsibility to ensure that a cosmetic product is safe when used as intended. Sections 22 to 28 of the *Cosmetic Regulations* detail the labelling requirements for particular products and/or containers which require cautions, warnings and instructions to protect the consumer. Section 7 of the publication ***Health Canada Guidelines: Labelling of Cosmetics*** presents these in detail (see Appendix II – Suggested Reading).

Sections 29 and 30 of the *Cosmetic Regulations* state that evidence of the safety of a cosmetic product must be provided if requested by Health Canada. As a result of the reviewed evidence, Health Canada may advise the manufacturer or distributor to take action. This action could range from re-labelling to voluntary recall of the product.

When a request to submit safety evidence is made, the information must be provided within the period of time specified by the Cosmetics Program. Once this time has lapsed, sale of the cosmetic in question is prohibited until the required data has been received, evaluated, and the safety of the product is found not to be of concern. Although not exhaustive, the Cosmetic Program's "Hotlist" (discussed below) provides many of the conditions for which additional data must be submitted.

## *The Cosmetic Ingredient Hotlist*

To help companies avoid selling products which may injure the health of the Canadian public, Health Canada has developed the Cosmetic Ingredient Hotlist—a list of substances which are prohibited or restricted in cosmetics.

The Hotlist is a science-based document which is reviewed and updated on a regular basis as new data becomes available. It keeps the cosmetic industry aware of new substances of concern.

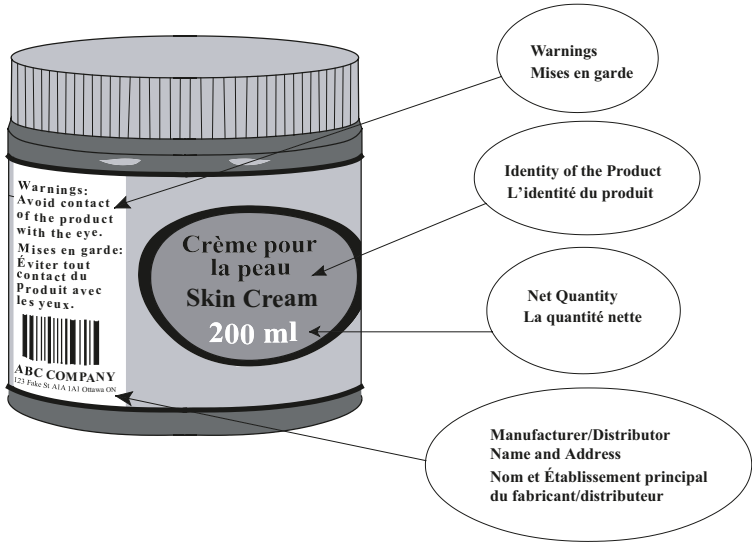
Prior to manufacturing or importing a new product, persons should review the Hotlist. If a notified cosmetic contains an ingredient which appears on the Hotlist, the manufacturer or distributor may be advised to do ***one*** (or more) of the following:

- Reduce the concentration of the ingredient to an acceptable level
- Remove the substance from the formulation
- Consider marketing the product as a drug or natural health product (requires application for a Drug Identification Number (DIN) or Natural Product Number (NPN))
- Provide evidence that the product is safe for its intended use
- Confirm that the product is labelled as required
- Confirm that the product is sold in a child-resistant package
- Remove the product from sale

The Hotlist is available both electronically and by mail (please see contact information (see Appendix II – Suggested Reading).

## *Labelling*

Labelling is regulated by the *Food and Drugs Act* (section 17), the *Cosmetic Regulations* (sections 17 through to 28), and the *Consumer Packaging and Labelling Act* (CPLA) and *Regulations*.



To comply with these requirements, cosmetic labels must supply:

- the identity of the product in English and French (if not obvious by looking at the package), using its common name (e.g. "face cream") or described in terms of its function (e.g. "body scrub", "moisturizing lotion")
- a statement of net quantity in English and French (e.g. weight, volume, number of items) in metric units of measurement
- the company name and business address
- directions, warnings or cautions in English and French where necessary for safe use of the product

In the case of aerosols and other pressurized containers, hazard symbols in specific sizes are required. In this case, the *Cosmetic Regulations* incorporates the *Consumer Chemicals and Containers Regulations* (CCCR) as they read on September 30, 2001. This document can be obtained by contacting the Cosmetics Program or by visiting our website at www.hc-sc.gc.ca/cosmetics.

Specific regulations also exist for the safe use of certain products, such as hair dyes. In addition, the *Competition Act* prohibits false and misleading representation or deceptive packaging.

Health Canada has amended the *Cosmetic Regulations* to require that cosmetic ingredients be disclosed on the product label. The safety of the Canadian public will be enhanced by making this information available to consumers and medical professionals.

The amendment requires all cosmetic products to be identified on labelling in accordance with the International Nomenclature of Cosmetic Ingredients (INCI) labelling system. This Latin-based nomenclature is known worldwide and is considered to be multi-lingual and multi-national. It is currently being used in many countries including the European Union and the United States. The new requirements will be mandatory on November 16th, 2006. For more information, please visit our website.

## *Claims*

Claims for a cosmetic – whether on a label, an advertisement, or website – must be accurate. Certain claims, such as increased attractiveness, are subject to an interpretation, but must never mislead the public.

Cosmetics can only make claims that are cosmetic in nature. A product possessing claims that are both therapeutic and cosmetic is therefore considered a drug, and must fulfill the requirements of the *Food and Drugs Act* and *Food and Drug Regulations*.


Unnacceptable (left) vs. Acceptable Claims

Consequently, the term "cosmeceutical" (used to describe a cosmetic product with pharmaceutical-like benefits) is not employed by Health Canada. Therefore, "cosmeceuticals" fall under either cosmetics or drugs, depending on the claims made and/or the composition of the product.

The ***Guidelines for Cosmetic Advertising and Labelling Claims*** examine common acceptable and unacceptable claims for cosmetics (see Appendix II – Suggested Reading). The table below provides some examples:

| Cosmetic | Acceptable Claim | Unacceptable Claim |
|---|---|---|
| Moisturizer | Softens skin | Heals skin |
| Contour cream | Reduces the look of cellulite | Lose inches; slims/slimming |
| Acne-prone skin product | Removes Oil | Stops acne |
| Mouthwash | Helps eliminate odour-causing bacteria | Kills odour-causing germs |
| Fragrance | Soothes | Causes hormonal attraction |
| Anti-Aging/Anti-Wrinkle product | Helps prevent the look of aging | Eliminates wrinkles |

Most radio and television advertisements are previewed and cleared with organizations such as Advertising Standards Canada before they are broadcast, but printed advertisements do not require pre-clearance review. If promotional material is found to be non-compliant with the *Cosmetic Regulations*, the advertiser is asked to change or withdraw it.

## *Import and Export*

All cosmetics imported into Canada must be in compliance with sections 5 through 10 of the *Cosmetic Regulations*.

The Canada Border Services Agency (CBSA) enforces border legislation and the Customs Program. In some cases, shipments may be seized by the CBSA if notification has not been completed pursuant to section 30 of the *Cosmetic Regulations*.

# Cosmetics and the *Canadian Environmental Protection Act*

The *New Substances Notification Regulations* (NSNR) under the *Canadian Environmental Protection Act* (CEPA) requires Health Canada and Environment Canada to assess the risks posed by chemicals, polymers and biotechnology products. As per the NSNR, a cosmetic containing an ingredient that is not a part of the Domestic Substances List (i.e. it is new to Canada) may be notifiable to the New Substances Program.

A guidance document on NSN requirements for products regulated under the FDA is available on Health Canada's website at: http://www.hc-sc.gc.ca/ear-ree. For further information consult Appendix IV – Contact Information.

# Compliance and Enforcement

Regional Product Safety Inspectors are designated to monitor compliance and to enforce the relevant laws and regulations pertaining to cosmetics. The powers of inspectors are detailed in section 23 of the *Food and Drugs Act*.

For example, when a cosmetic is found to be unsafe due to a prohibited ingredient, microbiological hazard, lack of adequate labelling or unhygienic manufacturing conditions, an inspector contacts the manufacturer or distributor and discusses what action can be taken to fix the problem. Actions may include voluntary removal, recall, or seizure. Failure to comply may result in prosecution.

An inspector may examine and take samples of any cosmetic sold and/or imported into Canada. Samples of a cosmetic are taken if, for example, an inspector suspects that a particular product may be contaminated.

The size of the sample taken depends on circumstances. Some cases that might indicate a need for sampling are:

- unsatisfactory labelling
- unsanitary packaging
- damaged boxes

The procedures for taking samples are outlined in section 11 of the *Cosmetic Regulations*.

This publication outlines the basic requirements for cosmetics in Canada. While this document will be updated periodically, the information contained within is subject to change at any time. For the latest information, please visit the cosmetics section of the Health Canada website at www.hc-sc.gc.ca/cosmetics or contact your local Product Safety Regional Office (see Appendix IV – Contact Information).

# Appendix I – Glossary

**BIOTECHNOLOGY PRODUCT:** Biotechnology is the science of taking a whole, a part of or a product of a living organism and using it or changing it to produce something new. A biotechnology product is "a substance that is produced by means of biotechnology".

**CBSA – CANADA BORDER SERVICES AGENCY:** The CBSA comprises the Customs program, intelligence, interdiction and enforcement functions, and the passenger and initial import inspection services at ports of entry.

If your product is imported into Canada and has unacceptable claims or ingredients or is not notified to Health Canada, it may be held by CBSA.

**CRA – CANADA REVENUE AGENCY:** The Canada Revenue Agency (CRA) administers tax laws for the Government of Canada and for most provinces and territories, as well as the various social and economic benefit and incentive programs delivered through the tax system.

**CEPA – *CANADIAN ENVIRONMENTAL PROTECTION ACT*:** An Act respecting pollution prevention and the protection of the environment and human health in order to contribute to sustainable development. Cosmetic substances which are not the Domestic Substances List (see "DSL") are subject to the requirements of the New Substances Notification Regulations

under CEPA. Substances which are on the DSL may require review under CEPA's Existing Substances Program and/or Toxic Substances Program.

**CFIA – CANADIAN FOOD INSPECTION AGENCY:** The CFIA delivers inspection programs related to foods, plants and animals across Canada. Its role is to enforce the food safety and nutritional quality standards established by Health Canada and, for animal health and plant protection, to set standards and carry out enforcement and inspection.

**CLAIM:** A statement of something as a fact; an assertion of the properties of a product. Cosmetics can only make claims that are cosmetic in nature, or qualified in a cosmetic sense. For more information, see the *Guidelines for Cosmetic Advertising and Labelling Claims*.

**CONCENTRATION (OF A COSMETIC INGREDIENT):** The amount of a specified substance in a unit amount of a cosmetic product, e.g. 25 g of "ingredient X" in "cosmetic Y" (total weight = 1000 g), means X is present at a concentration of 2.5% in cosmetic Y.

**CPLA – *CONSUMER PACKAGING AND LABELLING ACT (AND REGULATIONS):*** An Act which addresses prepackaged non-food consumer products. This Act does not apply to any product that is a device or drug within the meaning of the *Food and Drugs Act*.

**COMPETITION BUREAU (INDUSTRY CANADA):** Administers the requirements of the *Consumer Packaging and Labelling Act*.

**COSMECEUTICAL:** A term used by some in the cosmetic industry – but not recognized by Health Canada – describing a cosmetic product with therapeutic (drug-like) benefits. Under the *Food and Drugs Act*, "cosmeceuticals" fall under either cosmetics **or** drugs, depending on the claims made and/or the composition of the product.

**COSMETIC:** "Any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes." This definition also includes soap, "professional use" (e.g. beauty salon/spa) products and grooming products for animals.

**COSMETIC INGREDIENT HOTLIST:** A list of substances which are restricted or prohibited in cosmetics in Canada. The Cosmetic Ingredient Hotlist is a document which is continually updated as new scientific information becomes available.

**CNF – COSMETIC NOTIFICATION FORM:** Section 30 of the *Cosmetic Regulations* requires a Cosmetic Notification Form (CNF) to be submitted to Health Canada within the first 10 days a cosmetic is available for sale. The Cosmetic Notification Form is a document used to submit product

information, including but not limited to: address and contact of the company, purpose of the cosmetic, form of cosmetic (e.g., gel, solid, liquid, etc.), ingredients of the cosmetic and concentration ranges of the ingredients.

**CR – *COSMETIC REGULATIONS*:** Cosmetic preparations are subject to the provisions of the *Food and Drugs Act* and its *Regulations* regarding composition, safety, labelling and advertising. The basis for the regulatory authority of the Cosmetics Program comes from the *Food and Drugs Act* and *Cosmetic Regulations*.

**DIN – DRUG IDENTIFICATION NUMBER:** The Drug Identification Number (DIN) is the number located on the label of prescription and over-the-counter drug products that have been evaluated by the Therapeutic Products Directorate (TPD) and approved for sale in Canada.

**DIN-HM – DRUG IDENTIFICATION NUMBER-HOMEOPATHIC MEDICINE:** Natural health products that have been approved under the *Natural Health Product Regulations* will either have a NPN or DIN-HM on the label (Natural Product Number or Drug Identification Number-Homeopathic Medicine). A NPN or DIN-HM lets the user know that the product has undergone and passed a review of its formulation, labelling and instructions for use.

**DSL – DOMESTIC SUBSTANCES LIST:** The Domestic Substances List (DSL) is the basis for determining whether a substance is new for the purposes of the *Canadian Environmental Protection Act* (CEPA, 1999). Substances on the DSL do not require notification unless they are proposed for a Significant New Activity (SNAc) as indicated on the DSL. Substances not appearing on the DSL are considered to be new to Canada and are subject to notification under the *New Substances Notification Regulations* (NSNR) of CEPA, 1999. Therefore, cosmetic substances not found on the DSL or proposed for SNAc must be notified to Health Canada's Environmental Assessment Unit.

**DRUG:** "Includes any substance or mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoring, correcting or modifying organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept"

**FOOD:** "Includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose "

**F&DA – *FOOD AND DRUGS ACT*:** An Act respecting food, drugs, cosmetics and therapeutic devices.

**FP – FOOD PROGRAM:** Health Canada's Food Program has the responsibility to protect and improve the health of the people of Canada through science-based policies and programs related to safe and nutritious food (see also "CFIA").

**FORM (OF A COSMETIC):** Term which describes the state of the packaged product ready for sale, e.g. aerosol, cream, granules, stick. See Appendix II of the *Guide for Completing Cosmetic Notification Forms* for the full list and definition of these terms.

**HC – HEALTH CANADA:** Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada provides national leadership to develop health policy, enforces health regulations, promotes disease prevention and enhances healthy living for all Canadians.

**HOTLIST (SEE "COSMETIC INGREDIENT HOTLIST")**

**INCI – INTERNATIONAL NOMENCLATURE OF COSMETIC INGREDIENTS:** A multilingual, multinational system based on Latin. Ingredient listing on cosmetic products, using the INCI system, is required by law in several countries

around the world. Created by the Cosmetic, Toiletry and Fragrance Association's (CTFA's) International Nomenclature Committee.

**ITCan – INTERNATIONAL TRADE CANADA:** ITCan supports the development of trade by providing services to exporters, developing policy and by attracting investment in the Canadian economy. ITCan may facilitate export of cosmetics into other countries by providing a list of their requirements.

**MEDICAL DEVICE:** "Any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) restoring, correcting or modifying a body function or the body structure of human beings or animals,

(c) the diagnosis of pregnancy in human beings or animals, or

(d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug"

**NATURAL HEALTH PRODUCT (NHP):** Natural Health Products are a subset of "Drug" as defined in the *Food and Drugs Act*. The NHP definition has two components: function and substance.

The function component refers to the natural health product definition capturing those substances that are manufactured, sold or represented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

(b) restoring or correcting organic functions in humans; or

(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

The substance component refers to the medicinal ingredient in a natural health product. Schedule I of the *Natural Health Products Regulations* (NHPR) outlines the medicinal ingredients that natural health products may contain. Schedule II of the NHPR specifies those substances that are not permitted in a natural health product (see "NPN","DIN-HM").

**NHPD – NATURAL HEALTH PRODUCTS DIRECTORATE:** An organization within Health Canada whose mission is to ensure that all Canadians have ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

**NPN – NATURAL PRODUCT NUMBER:** Natural health products that have been approved under the *Natural Health Product Regulations* will either have a NPN or DIN-HM on the label (Natural Product Number or Drug Identification Number-Homeopathic Medicine). A NPN or DIN-HM lets the user know that the product has undergone and passed a review of its formulation, labelling and instructions for use.

**NSNR – *NEW SUBSTANCE NOTIFICATION REGULATIONS*:** A part of *Canadian Evironmental Protection Act* (see "CEPA"), these regulations specify the information to be submitted if a substance intended for import or manufacture is not on the Domestic Substances List (DSL).

**NEW SUBSTANCES PROGRAM:** The New Substances Program is responsible for the assessment of potential risks to human and environmental health posed by new substances in Canada under the *Canadian Environmental Protection Act* (CEPA, 1999). This work is conducted jointly with Health Canada and Environment Canada. If a substance used in a product under the *Food and Drugs Act* (includes cosmetics) is

not identified on the Dometic Substances List (DSL), Health Canada's Environmental Assessment Unit must be notified.

**PEST:** "Any injurious, noxious or troublesome insect, fungus, bacterial organism, virus, weed, rodent or other plant or animal pest, and includes any injurious, noxious or troublesome organic function of a plant or animal."

**PESTICIDE / PEST CONTROL PRODUCT:**
"Any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest, and includes

(a) any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a control product to which it is added, and

(b) any active ingredient used for the manufacture of a control product"

**PMRA – PEST MANAGEMENT REGULATORY AGENCY:** All products designed to manage, destroy, attract or repel pests that are used, sold or imported into Canada are managed by Health Canada's Pest Management Regulatory Agency (PMRA). These products include chemicals, devices, and even organisms, and are referred to collectively as pest control products, or simply "pesticides."

**PURPOSE (OF A COSMETIC):** Term to describe for what reason the cosmetic is used, e.g. body makeup, deodorant, hair conditioner, lipstick, manicure preparation, skin cleanser, massage oil. See Appendix I of the *Guide for Completing the Cosmetic Notification Form* for full descriptions and codes accepted by Health Canada.

**RECALL:** An action taken by the responsible establishment/person to correct or remove from sale or consumer use a product or material that may present an unacceptable risk to health or safety of Canadians. If the recall action is not taken by an establishment or if the action taken is not effective, Health Canada may take further action to remove the product from the marketplace and/or to warn the public about the product hazard.

**THERAPEUTIC PRODUCT (SEE "DRUG")**

**TPD – THERAPEUTIC PRODUCTS DIRECTORATE:** Health Canada's Therapeutic Products Directorate is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization (see "DIN"), a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the *Food and Drugs Act* and *Regulations*.

**WHMIS – WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEM:** WHMIS is Canada's hazard communication standard. The key elements of the system are cautionary labelling of containers of WHMIS "controlled products", the provision of material safety data sheets (MSDSs) and worker education programs. Cosmetics are not considered to be WHMIS "controlled products" under the *Hazardous Products Act* and associated *Controlled Products Regulations*.

# Appendix II – Suggested Reading

Please note that the following URLs are subject to change.

Bacteriological Analytical Manual Online
(United States Food and Drug Administration)
http://www.cfsan.fda.gov/~ebam/bam-toc.html

Business: Information and Services
(Importing, Exporting, Duties, Taxes, etc.)
http://www.ccra-adrc.gc.ca/customs/business/menu-e.html

*Canadian Environmental Protection Act* and Related Regulations
http://www.ec.gc.ca/substances/nsb/eng/reg_e.htm

*Competition Act*
http://laws.justice.gc.ca/en/C-34/

*Consumer Packaging and Labelling Act and Regulations*
http://laws.justice.gc.ca/en/C-38/

Cosmetic Ingredient Hotlist
http://www.hc-sc.gc.ca/hecs-sesc/cosmetics/hotlist_intro.htm

Customs: General Information and Services
http://www.cbsa-asfc.gc.ca/general/menu-e.html

*Exports and Imports Permits Act*
http://laws.justice.gc.ca/en/E-19/

*Exports Permits Regulations*
http://laws.justice.gc.ca/en/E-19/SOR-97-204/

Guide for Completing Cosmetic Notification Forms
http://www.hc-sc.gc.ca/hecs-sesc/cosmetics/notification.htm

Guidelines for Cosmetic Advertising and Labelling Claims
http://www.adstandards.com/en/clearance/cosmeticGuidelines.asp

Health Canada Guidelines: Labelling of Cosmetics
http://www.hc-sc.gc.ca/hecs-sesc/cosmetics/publication/labelling_cosmetics/toc.htm

International Business Development
http://www.dfait-maeci.gc.ca/trade/intl_bus_dev-en.asp

Labelling Assessment Tool: Consumer Packaging and Labelling
http://cb-bc.gc.ca/epic/internet/incb-bc.nsf/vwGeneratedInterE/cp01035e.html

*New Substances Notification Regulations*
http://laws.justice.gc.ca/en/C-15.31/SOR-94-260/

# Appendix III – Helpful Resources

## Government Organizations

### *Canada:*

Canadian Food Inspection Agency
www.inspection.gc.ca/

Canada Revenue Agency (CRA)
www.cra-arc.gc.ca/

Environment Canada – New Substances Program
www.ec.gc.ca/substances/nsb/eng/index_e.htm

Food Program
www.hc-sc.gc.ca/food-aliment/

Industry Canada – Competition Bureau
www.cb-bc.gc.ca

Industry Canada –Strategis: Canada's Business and Consumer Site
http://strategis.ic.gc.ca/

International Trade Canada (ITCan)
http://www.itcan-cican.gc.ca

Natural Health Products Directorate
http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/

Pest Management Regulatory Agency
http://www.pmra-arla.gc.ca/

Therapeutic Products Directorate
www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/

Veterinary Drugs Directorate
www.hc-sc.gc.ca/vetdrugs-medsvet/

***United States:***

Food and Drug Administration, Center for Food Safety and Applied Nutrition, Cosmetics and Colors
http://www.cfsan.fda.gov/~dms/cos-toc.html

***Europe:***

European Union – European Commission's Enterprise Directorate General
http://pharmacos.eudra.org/F3/home.html

## Industry Links

CCTFA – Canadian Cosmetics, Toiletries and Fragrances Association
www.cctfa.ca

CTFA – Cosmetics, Toiletries and Fragrances Association (U.S. )
www.ctfa.org

COLIPA – The European Cosmetic, Toiletry and Perfumery Association
www.colipa.com

Direct Sellers Association of Canada (DSA of Canada)
www.dsa.ca

Society of Cosmetic Chemists (SCC)
www.scc.org

# Appendix IV – Contact Information

Please contact your local Product Safety Office for cosmetic enquiries. For enquiries from the United States, please consult the responsibility list at the end of this Appendix.

***British Columbia and Yukon***

Regional Product Safety Office
Health Canada
#210-3625 Lougheed Highway
Vancouver, British Columbia
V5M 2A6

Tel: (604) 666-5003
Fax: (604) 666-5988
e-mail: Bby_Prodsafe@hc-sc.gc.ca

***Alberta and Northwest Territories***

Regional Product Safety Office
Health Canada
Canada Place, Room 839
9700 Jasper Avenue
Edmonton, Alberta
T5J 4C3

Tel: (780) 495-2626
Fax: (780) 495-2624
e-mail: Edm_Prodsafe@hc-sc.gc.ca
(use this for Northwest Territories)

Regional Product Safety Office
Health Canada
Harry Hays Building, Room 282
220-4th Avenue South East
Calgary, Alberta
T2G 4X3

Tel: (403) 292-4677
Fax: (403) 292-4644
e-mail: Cal_Prodsafe@hc-sc.gc.ca

### *Manitoba and Saskatchewan*

Regional Product Safety Office
Health Canada
510 Lagimodiere Boulevard
Winnipeg, Manitoba
R2J 3Y1

Tel: (204) 983-5490
Fax: (204) 984-0461
e-mail: Mb_Prodsafe@hc-sc.gc.ca

Regional Product Safety Office
Health Canada
Room 412, Federal Building
101-22nd Street East
Saskatoon, Saskatchewan
S7K 0E1

Tel: (306) 975-4502
Fax: (306) 975-6040
e-mail: Sk_Prodsafe@hc-sc.gc.ca

### *Ontario and Nunavut*

Regional Product Safety Office
Health Canada
2301 Midland Avenue
Toronto, Ontario
M1P 4R7

Tel: (416) 973-4705
Fax: (416) 973-1746
e-mail: Tor_Prodsafe@hc-sc.gc.ca
(Use this for Nunavut)

Regional Product Safety Office
Health Canada
55 Bay St. N., 9th Floor
Hamilton, Ontario
L8R 3P7

Tel: (905) 572-2845
Fax: (905) 572-4581
e-mail: Tor_Prodsafe@hc-sc.gc.ca

### *Québec*

Regional Product Safety Office
Health Canada
1001 rue St-Laurent ouest
Longueuil, Quebec
J4K 1C7

Tel: (450) 646-1353
Fax: (450) 928-4066
e-mail: Quebec_Prod@hc-sc.gc.ca

Regional Product Safety Office
Health Canada
Montreal

Tel: (514) 283-5488

Regional Product Safety Office
Health Canada
901 Cap Diamant, Suite 266-1
Québec City, Québec
G1K 4K1

Tel: (418) 648-4327, 1-800-561-3350
Fax: (418) 649-6536
e-mail: Quebec_Prod@hc-sc.gc.ca

### *Atlantic*

New Brunswick and
Prince Edward Island
Regional Product Safety Office
Health Canada
10 High Field Street, 1st Floor
Moncton, New Brunswick
E1C 9V5

Tel: (506) 851-6638
Fax: (506) 851-3197
e-mail: Atlantic_ProdSafe@
hc-sc.gc.ca

### *Nova Scotia*

Regional Product Safety Office
Health Canada
1505 Barrington Street,
Suite 1625
Halifax, Nova Scotia
B2Y 3Z7

Tel: (902) 426-8300
Fax: (902) 426-6676
e-mail: Atlantic_ProdSafe@hc-sc.gc.ca

### *Newfoundland*

Regional Product Safety Office
Health Canada
The John Cabot Building,
3rd Floor
10 Barter's Hill
Post Office Box 1949
St. John's, Newfoundland
A1C 5R4

Tel: (709) 772-4050
Fax: (709) 772-5945
e-mail: Atlantic_ProdSafe@hc-sc.gc.ca

### *National Program:*

Cosmetics Division
Consumer Product Safety Bureau
Product Safety Programme
Health Canada
MacDonald Bldg, A.L. 3504D
123 Slater Street
Ottawa, ON
K1A 0K9

Tel: (613) 946-6452
Fax: (613) 952-3039
email: cosmetics@hc-sc.gc.ca
Website: www.hc-sc.gc.ca/cosmetics

## *U.S. responsibility list for Product Safety regions in Canada:*

**BC & Yukon**
Alaska
California
Hawaii
Nevada
Oregon
Washington

**Alberta & NWT**
Arizona
Colorado
Idaho
Montana
New Mexico
Utah
Wyoming

**Manitoba & Saskatchewan**
Arkansas
Iowa
Kansas
Louisiana
Minnesota
Missouri
Nebraska

**Manitoba & Saskatchewan** *(cont'd)*
North Dakota
OklahomaSouth
Dakota
Texas
Wisconsin

**Ontario**
Illinois
Indiana
Michigan
New York
North Carolina

**Quebec**
Connecticut
Maine
Massachusetts
New Hampshire
New Jersey
Ohio
Pennsylvania
Rhode Island
Vermont

**Atlantic**
Alabama
Delaware
District of Columbia
Florida
Georgia
Kentucky
Maryland
Mississippi
Puerto Rico
South Carolina
Tennessee
Virginia
West Virginia

## Health Canada – Environmental Assessment Unit

***Environmental assessment submission enquiries:***

(613) 941-7365.

***General enquires:***

1-888-492-1104 or 613-941-8322

http://www.hc-sc.gc.ca/ear-ree/