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Labelling of Cosmetics



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Labelling of **Cosmetics**



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Foreword

This guideline is designed to assist in the preparation of labels that comply with Canadian regulatory requirements for cosmetics. The guideline contains:

- *a description of the Acts and Regulations from which the labelling requirements for cosmetics are derived,*
- *definitions of terms,*
- *current interpretations of labelling requirements by officers of the Cosmetics Program, based on legal precedents and advisory opinions established over a number of years, and*
- *sources of further information.*

Other requirements are covered only briefly in this guideline. For allowable claims for cosmetic products, please see the document ***Guidelines for Cosmetic Advertising and Labelling Claims***.

A label should convey its information in a manner that is easily read and understandable. It should be noted that certain information on a label is considered essential; information of this type is pointed out in this guideline. To ensure that all aspects of labelling are addressed, this guideline should be used in conjunction with the appropriate Acts and Regulations.

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1. Introduction

The labelling of cosmetics is governed by three Acts and their associated Regulations:

- the *Food and Drugs Act* and the *Cosmetic Regulations*,
- the *Consumer Packaging and Labelling Act* and the *Consumer Packaging and Labelling Regulations*, and
- the *Hazardous Products Act* and the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, to that Act.

Manufacturers and importers should study and understand the Acts and Regulations to ensure that they comply with all regulatory requirements. For example, every manufacturer and importer is required to submit a completed Cosmetic Notification form for each cosmetic the manufacturer intends to sell in Canada (section 30, *Cosmetic Regulations*). Submission of the form does not mean that the product is approved or that it is in compliance with the requirements of the *Food and Drugs Act* and the *Cosmetic Regulations* or the *Consumer Packaging and Labelling Act and Regulations*. It is the manufacturer's and importer's responsibility to ensure compliance with these requirements.

For information about how to obtain copies of the Acts and Regulations, see section 9, "Sources of Additional Information."

Supplementary French language labelling requirements may apply to products sold in the Province of Québec (to obtain more information, see section 9.8, "French Language Requirements").

1.1 The *Food and Drugs Act* and the *Cosmetic Regulations*

The *Food and Drugs Act* and the *Cosmetic Regulations* govern the classification and labelling of cosmetic products with regard to:

- the expression of the product's identity on its label,
- the name and address of the principal place of business of the manufacturer (see definition) indicated on the label,
- the listing of ingredients on the label, and
- the avoidable hazards presented by the cosmetic.

In addition, the Act and Regulations also address the issues of composition, safety, and advertising.

The *Cosmetic Regulations* to the *Food and Drugs Act* allow a designated Health Canada inspector to inspect:

- cosmetic products,
- locations where cosmetics are manufactured or stored, and
- any labelling or advertising material related to a cosmetic product.

The *Cosmetic Regulations* also prescribe the symbols and warning statements that are to be used on pressurized containers, as defined in the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, of the *Hazardous Products Act*.

1.2 The *Consumer Packaging and Labelling Act and Regulations*

The *Consumer Packaging and Labelling Act and Regulations* prescribe the mandatory information that must appear on the label of a prepackaged cosmetic product. That is:

- the product's identification in English and French,
- the declaration of the product's net quantity in metric units of measure in English and French, and
- the identity and principal place of business of the dealer (see definition) in English or French.

The Act and Regulations also address false or misleading representation of the product and the standardization of container size.

The *Consumer Packaging and Labelling Act and Regulations* govern only those cosmetic products sold to consumers. It does not govern cosmetics applied by cosmeticians, hairdressers, and so on, to their clients (unless such persons sell the cosmetics to their clients as prepackaged products).

1.3 Advertising Clearance

While the Regulations under the *Canadian Broadcasting Act* once specified that radio or television advertising of cosmetics must be previewed and cleared by Health Canada before it was broadcast, the Regulations under the *Canadian Broadcasting Act* have since been amended such that this is no longer a requirement. Advertising Standards Canada (ASC) is the national advertising industry selfregulatory body, and administers the *Advertising Code for Standards for Cosmetics, Toiletries and Fragrances*.

Complaints about print advertising are investigated by the Competition Bureau of Industry Canada under the authority of the *Competition Act*.

1.4 Information on Labels

This guide covers three aspects of information appearing on the labels of cosmetic products:

- the classification of cosmetic products (see section 3).
- required declarations that must appear on a label. These include:
 - a) product identity (see section 4),
 - b) net quantity (see section 5),
 - c) name and address of the manufacturer (see definition) (see section 6),
 - d) avoidable hazards and cautions (see section 7), and
 - e) ingredients (see section 8).
- sources of additional information concerning labelling requirements (see section 9).

Claims about use or effectiveness that may appear on a cosmetic products label is discussed in the *Guidelines for Cosmetic Advertising and Labelling Claims*.

2. Definitions

The following definitions may be useful.

AREA OF DISPLAY PANEL – Section 2 of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001 (*Hazardous Products Act*) – The area of the container's side or surface that contains the display panel. This area does not include the top, bottom, flanges, shoulders, or neck of the container. The area is calculated

- a) (for rectangular containers) by multiplying the height of the side that includes the display panel by the width of that side.
- b) (for cylindrical containers) by taking 40 percent of the number obtained by multiplying the container's circumference by its height.

NOTE:

- Circumference = 3.14 x diameter of container
- Circumference = 6.28 x radius of container

- c) (for an unfolded bag) by determining the area of the largest side.
- d) (for any other container) by taking 40 percent of the total surface area of the container (or the total surface area of the display panel, if the container has an obvious one).

AVOIDABLE HAZARD – Section 24(2) of the *Cosmetic Regulations (Food and Drugs Act)* – A threat of injury to the health of the user of a cosmetic that can be

- a) predicted from the cosmetic's composition, the toxicology of the ingredients, and the site of its application;
- b) reasonably anticipated during normal use; and
- c) eliminated by specified limitations on the usage of the cosmetic.

CANADIAN UNIT – Subsection 2(1) of the *Consumer Packaging and Labelling Regulations* – A unit of measurement set out in Schedule II to the *Weights and Measures Act*. For example, a metric unit.

CONTAINER – Section 2 of the *Consumer Packaging and Labelling Act* – A receptacle, package, wrapper, or confining band in which a product is offered for sale. This does not include the package liner, the shipping container, or any outer wrapping or box that is not customarily displayed to the consumer.

COSMETIC – Section 2 of the *Food and Drugs Act* – Includes any substance, or mixture of substances, that is manufactured, sold, or represented for use in cleansing, improving, or altering the complexion, skin, hair, or teeth.

This category includes deodorants, perfumes, and soaps. Products for the grooming of animals are also considered to be cosmetics.

The definitions of *drug* and *cosmetic* have certain features in common; nevertheless, it is generally understood that the requirements of the Regulations pertaining to drugs take precedence over the Regulations pertaining to cosmetics in situations where the claims for a product have both a drug and a cosmetic nature. Only a drug may make both drug and cosmetic claims; cosmetics may make only cosmetic claims. (See section 3, "Cosmetic Classification and Cosmetic Claims.")

DEALER – Paragraph 2(d) of the *Consumer Packaging and Labelling Act* – A person who is a retailer, manufacturer, processor, or producer of a

product, or a person who is engaged in the business of importing, packaging, or selling any product. (Also refer to the definition of Manufacturer.)

DRUG – Section 2 of the *Food and Drugs Act* – Includes any substance, or mixture of substances, that is manufactured, sold, or represented for use in:

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in humans or animals;
- b) restoring, correcting, or modifying organic functions in humans or animals; or
- c) disinfection in premises in which food is manufactured, prepared, or kept.

IDENTITY – As referred in Paragraph 20(b) of the *Cosmetic Regulations (Food and Drugs Act)* – The common name or generic name of a cosmetic (e.g. “face cream”), or a statement of a cosmetic’s function (e.g. “body scrub”) must be indicated on the label.

If the identity of a cosmetic is obvious, it does not have to be indicated. (This exception is not noted in the definition of identity that appears in Subparagraph 10(b) (ii) of the *Consumer Packaging and Labelling Act*.)

INCI NAME – Subsection 2(1) of the *Cosmetic Regulations (Food and Drugs Act)* – The INCI names refers to the International Nomenclature for Cosmetic Ingredient name assigned to an ingredient in the *International Cosmetic Ingredient (ICI) Dictionary and Handbook*, 10th edition (2004), published in Washington, D.C., U.S.A., by The Cosmetic, Toiletry and Fragrance Association Inc., as amended from time to time.

INCI is the acceptable terminology for listing ingredients on the label. The INCI names do not need to be provided on the label in both French and English as the names are considered to be multi-lingual and based on Latin.

INGREDIENT – Subsection 2(1) of the *Cosmetic Regulations (Food and Drugs Act)* – An ingredient means any substance that is one of the components of a cosmetic and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the cosmetic but that are not present in the final product as a result of the chemical process.

INNER LABEL – Subsection 2(1) of the *Cosmetic Regulations (Food and Drugs Act)* – A label on or affixed to the immediate container of a cosmetic.

LABEL – Section 2 of the *Food and Drugs Act* – Includes any legend, word, or mark attached to, included in, belonging to, or accompanying any food, drug, cosmetic, device, or package. A label is also defined as any mark, sign, device, imprint, stamp, brand, ticket, or tag (as described in Paragraph 2(f) of the *Consumer Packaging and Labelling Act*).

MANUFACTURER – Subsection 2(1) of the *Cosmetic Regulations (Food and Drugs Act)* – A person, partnership, or unincorporated association that sells, or manufactures and sells, a cosmetic under its own name or under a trademark, design, trade name or other name or mark owned or controlled by it. (Also refer to the definition of Dealer.)

METRIC UNIT – Subsection 2(1) of the *Consumer Packaging and Labelling Regulations* – A unit of measurement as set out in Schedule I to the *Weights and Measures Act*.

NAME AND ADDRESS – Paragraph 20(a) of the *Cosmetic Regulations (Food and Drugs Act)* – The identity and location of the principal place of business of the manufacturer or distributor.

Subparagraph 10(b)(i) of the *Consumer Packaging and Labelling Act* – The identity of the person (including a company) by whom or for whom the prepackaged product was manufactured or produced for resale.

In both cases above, the address must be sufficiently complete to allow postal delivery to the principal place of business.

NET QUANTITY – Subsection 4(1) of the *Consumer Packaging and Labelling Act* – The manner in which the amount of product contained in the package is expressed.

ORNAMENTAL CONTAINER – Subsection 2(1) of the *Cosmetic Regulations (Food and Drugs Act)* – A container that, except on the bottom, does not have any promotional or advertising material on it other than a trade-mark or common name, and that appears to be a decorative ornament because of a design that is on its surface or because of its shape or texture, and is sold as a decorative ornament in addition to being sold as the container of a cosmetic. An example would be a perfume bottle, which does not come in a box, that is artistically designed in such a way as to be decorative or ornamental.

OUTER LABEL – Subsection 2(1) of the *Cosmetic Regulations (Food and Drugs Act)* – A label on or affixed to the outside package of a cosmetic.

The outer label is often described as the carton label (i.e., a label on a box containing a bottle of a cosmetic).

PREPACKAGED PRODUCT – Paragraph 2(h) of the *Consumer Packaging and Labelling Act* – Any product packaged in a container that is sold to, used, or purchased by a consumer without its being repackaged.

PRINCIPAL DISPLAY PANEL – Subsection 2(2) of the *Consumer Packaging and Labelling Regulations* – The part of the label that,

- a) for containers mounted on a display card, is applied to all or part of the principal display surface of the container, or to all or part of the side of the display card that is displayed or visible under normal or customary conditions of sale or use, or to both such parts of the container and the display card;
- b) for ornamental containers, is applied to all or part of the bottom of the container, or to all or part of the principal display surface, or to all or part of a tag that is attached to the container; and
- c) for all other containers, is applied to all or part of the principal display surface.

Section 2 of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001 – The part of a container that is displayed or visible under normal or customary conditions of display or use.

PRINCIPAL DISPLAY SURFACE – Subsection 2(1) of the *Consumer Packaging and Labelling Regulations* – There are six cases:

- a) For containers that have a side or surface that is displayed or visible under customary conditions of sale or use, the principal display surface is the total area of such a side or surface, excluding the top.
- b) For containers whose lid is the part that is displayed or visible under normal or customary conditions of sale or use, the principal display surface is the total area of the top surface of the lid.
- c) For containers that do not have a particular side or surface that is displayed or visible under customary conditions of sale or use, the principal display surface is any 40 percent of the total surface area of the container, excluding the top and bottom, that can be displayed or is visible under customary conditions of sale or use.
- d) For bags with sides of equal dimensions, the principal display surface is the total area of one of the sides.
- e) For bags with sides of unequal dimensions, the principal display surface is the total area of one of the largest sides.

- f) For containers that are wrappers or confining bands so narrow in relation to the size of the product they contain that the wrapper or band is not considered to have a side or surface that is displayed or visible under customary conditions of sale or use, the principal display surface is the total area of one side of a ticket or tag that is attached to the container.

SECURITY PACKAGING – Subsection 2(1) of the *Cosmetic Regulations (Food and Drugs Act)* – A package having a security feature that provides reasonable assurance to the consumer that the package has not been opened prior to purchase.



3. Cosmetic Classification and Cosmetic Claims

The classification of a product as either a drug or a cosmetic can present a challenge. This section attempts to indicate, through examples and explanation, some current practices in classification. Cases are, however, considered on an individual basis.

3.1 Cosmetic Classification

Two factors are considered in the classification of cosmetic products:

- composition of the product, and
- the proposed use of the product.

This subsection also outlines the current status of particular products.

3.1.1 Composition

The composition of a product does not necessarily determine its classification. However, it is quite possible that an ingredient, or the concentration of an ingredient, may make the product unsuitable for classification as a cosmetic.

3.1.2 Proposed Use

According to the definitions of the terms “cosmetic” and “drug”, the key consideration for the classification of a product is its proposed use. The claims made in package inserts, in advertisements, and especially in product labels, indicate the intended use of the product.

It is also important to consider the context in which the product is marketed.

Claims that indicate that a product is a drug cannot be made for a product marketed as a cosmetic. If the manufacturer or importer chooses to remove the drug-related claim, the product may be

classified as a cosmetic. If a manufacturer or importer chooses not to remove a drug-related claim, the product may be regulated as a drug. (Information on regulatory requirements for cosmetics and drugs is available from the Cosmetics Program and from the Therapeutic Products Directorate, respectively.)

3.1.3 Examples of Classifications

Although not exhaustive, this section provides examples that may be useful in ensuring that products are properly classified. For rulings on specific items, contact the Cosmetics Program.

- Skin sunscreen lotions that have the term *SPF*, *sunscreen* or *sunblock* on the label fall under the drug category, but the same product used as a cosmetic moisturizing lotion that contains sunscreen ingredients yet does not have the above terms on the label is considered a cosmetic.
- Toothpastes (dentifrice) with fluoride are drugs since fluoride prevents caries, but toothpastes without fluoride are cosmetics since their main purpose is to freshen breath and whiten teeth.
- Antidandruff shampoos are drugs since they correct an abnormal physical state of dandruff production, while regular shampoos are cosmetics.
- Antiperspirants modify the organic function of sweat production and are therefore considered drugs. Deodorants only mask odours and are therefore cosmetics.
- A product that has only a cosmetic use, but must be swallowed to achieve the cosmetic effect (i.e., it is transported through the body to perform its cosmetic action), is regulated as a drug (e.g., preparations containing chlorophyll to deodorize breath).
- When swallowing is secondary to the cosmetic purpose, but is an integral part of the product’s use, the product is considered to be a food and not a

cosmetic (e.g., a breath mint or a lozenge sits in the mouth to deodorize breath, but as it dissolves, the components are swallowed).

- When swallowing is incidental to the cosmetic's use, the product is a cosmetic (e.g., dentifrice or spray or drops to freshen breath).

Certain products may be classified in two categories. For example, a disposable toothbrush that contains a dentifrice may be classified as both:

- a cosmetic (subject to the *Food and Drugs Act* and the *Cosmetic Regulations*), and
- a medical device (subject to the *Medical Devices Regulations*).

The dentifrice is the cosmetic (unless the label states that it contains fluoride, in which case it would be a drug) and the toothbrush is the medical device. Such a product, as offered to the consumer, is regulated by

- the *Food and Drugs Act* and the *Cosmetic Regulations* (dentifrice),
- the *Consumer Packaging and Labelling Act and Regulations* (dentifrice), and
- the *Medical Devices Regulations* (toothbrush).

"Cosmeceutical" is a term used in the cosmetic industry for cosmetic products that have drug-like qualities. The definitions under the *Food and Drugs Act* do not allow a product to be both a cosmetic and a drug. Therefore, "cosmeceuticals" fall under either cosmetics or drugs, depending on the ingredients and claims made.

It is important to note that the rejection of a product as a cosmetic does not necessarily ensure its acceptance as a drug since safety and efficacy must be demonstrated.

3.2 Acceptable versus Unacceptable Claims

A claim can be a word, a sentence, a paragraph, or simply an implication. Examples of acceptable and unacceptable claims for cosmetic products can be found in the *Guidelines for Cosmetic Advertising and Labelling Claims* which is published by Health Canada.

4. Product Identity

For reasons such as health, safety, product comparison, and prevention of fraud, the identity of a cosmetic product must be evident when purchasing it. In the home, the product must be identifiable even after any outer packaging has been removed.

All information presented on a label must appear in such a manner that it can be easily read.

The manner in which the requirements are applied depends on the two situations described below:

- products that have both outer and inner labels (e.g., a bottle packaged in a box has two labels; the box bears the outer label, and the bottle bears the inner label), and
- products that have only an inner label (e.g., a bottle of shampoo that is not packaged in a box has only an inner label on the bottle).

4.1 Products That Have Both Outer and Inner Labels

For products that have both outer and inner labels, specific requirements apply to each type of label.

4.1.1 Outer Label Requirements

On the outer label, the declaration of product identity must appear in both English and French on the principal display panel. The declaration must clearly contrast both with the background of the label and all the other information on the label.

Official Bilingual Exemptions

Exemptions concerning official bilingual labelling may be granted in certain cases. Sections 6(3) and 6(7) of the *Consumer Packaging and Labelling Regulations* allow temporary exemptions (one year

maximum) for products undergoing bona fide test marketing and for local or specialty products.

Under these circumstances, the product may be identified in either of the two official languages.

Requests for additional information about exemptions should be directed to the Competition Bureau of Industry Canada (see section 9.1, "Further Information About the Acts").

Single Expressions

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

Additional Panels

The labels of some prepackaged products are composed of one or more additional panels of the same size and prominence as the principal display panel. The product identity may be given on the principal display panel in only one of the two official languages, provided that it is also given in the other language on one of the other panels.

Typeface

There is no restriction concerning the typeface that may be used. The information, however, must be legible.

Readability and Character Height

All information that is required to appear on a label, other than the declaration of net quantity (see "Character Height" in section 5.1.1, "Outer Label Requirements"), must be shown in a manner easily legible under normal or customary conditions of sale or use and must be in letters of not less than 1.6 mm in height. When the area of the principal

display surface is less than 10 cm², the information may be in letters of not less than 0.8 mm in height.

The minimum height of the characters corresponds to the height of an upper-case letter when only upper case is used. The minimum height corresponds to the height of the lower-case letter “o” when words appear in lower case only, or when both upper-case and lower-case letters are used.

For further details, consult sections 14, 15, and 16, of the *Consumer Packaging and Labelling Regulations*.

Numerical Count

In certain cases, when a product is normally sold by numerical count and packaged so that the content is visible and identifiable (e.g., a plastic bubble pack that contains three shades of eye shadow make up), or the label bears an accurate pictorial representation of the contents of the package, the product may be exempted from a declaration of product identity.

4.1.2 Inner Label Requirements

On the inner label, a declaration of identity must appear either in English or in French unless the identity of the product is obvious. This declaration must contrast both with the background of the label and with all the other information that appears on the label.

Obvious Identity

The identity of a product does not have to be declared if it is obvious. For instance, a clear, lightly coloured liquid that has an agreeable aroma and is packaged in a small, decorative bottle is a perfume.

Official Languages

Even though both official languages are not required on the inner label, manufacturers and importers are encouraged to declare the identity of a cosmetic product in both English and French.

4.2 Products That Have Only an Inner Label

4.2.1 Inner Label Requirements

A declaration of identity must appear in English and in French on the principal display panel. The declaration must contrast clearly with the background and all other information that appears on the label.

Single Expressions

The requirements are the same as those for the outer labels of products that have both an outer and inner label (see “Single Expressions” in section 4.1.1, “Outer Label Requirements”).

Additional Panels

The requirements are the same as those for the outer labels of products that have both an outer and inner label (see “Additional Panels” in section 4.1.1, “Outer Label Requirements”).

Typeface

The requirements are the same as those for the outer labels of products that have both an outer and inner label (see “Typeface” in section 4.1.1, “Outer Label Requirements”).

Readability and Character Height

The requirements are the same as those for the outer labels of products that have both an outer and inner label (see “Readability and Character Height” in section 4.1.1, “Outer Label Requirements”).

Obvious Identity

In certain cases the identity of a product such as a lipstick, an eyebrow pencil, an automatic mascara applicator, or a compact including powder and puff may be considered obvious. A written declaration of product identity would not be necessary. If the product is in an opaque container, the identity of the product must be expressed.



5. Net Quantity of the Product

Although the *Cosmetic Regulations* do not require a declaration of the net quantity of the product, there are several specific requirements in the *Consumer Packaging and Labelling Act and Regulations*.

In general, the packaging ought to be constructed, embellished, or presented in such a way that the consumer will not be misled about the quality or quantity of the product contained inside.

All information presented on a label must appear in such a manner that can be easily read.

The manner in which the requirements are applied depends on the two situations described below:

- products that have both outer and inner labels (e.g., a bottle packaged in a box has two labels; the box bears the outer label, and the bottle bears the inner label), and
- products that have only an inner label (e.g., a bottle of shampoo that is not packaged in a box has only an inner label on the bottle).

5.1 Products That Have Both Outer and Inner Labels

For products that have both outer and inner labels, specific requirements apply to each type of label.

5.1.1 Outer Label Requirements

On the outer label, the declaration of net quantity must appear in both English and French on the principal display panel. The declaration must contrast clearly with all the other information that appears on the label.

Units of Measure

A suitable metric symbol used for the unit of measure is considered bilingual. On the other hand, the use of a complete word normally calls for a translation. This principle is illustrated in Table 5-1.

Additional Panels

The labels of some prepackaged products are composed of one or more additional panels of the same size and prominence as the principal display panel. The net quantity may be given on the principal display panel in only one of the two official languages, provided that it is given in the other language on one of the other panels.

Table 5-1 • Units of Measure

<i>English</i>	<i>French</i>	<i>Correct Bilingual Abbreviations</i>	<i>Commonly used Incorrect Abbreviations</i>
gram	gramme	g	G, gs, g., gm
kilogram	kilogramme	kg	Kg, KG, Kgs, kg., kgm
litre	litre	L, l, ℓ*	L., Ls, l., ls
millilitre	millilitre	mL, ml, mℓ*	ML, MLS

* Although the script letters "ℓ" (for litre) and "mℓ" (for millilitre) are acceptable, the abbreviations "L" and "mL," respectively, are preferred.

Typeface

The numerical part of the net quantity declaration must appear in boldface type. No restrictions regarding typeface apply to any other information included in the net quantity declaration (e.g., the units of measure, symbols, abbreviations). However, the declaration must be legible.

Other Net Quantity Declarations

Certain requirements for net quantity declarations are applied to the specific situations described below:

a) When a product is declared by count and this count is less than two, the net quantity may be considered already declared by the product identity declaration. Where this option is exercised, it is advisable to display the product identity using the type height specified for the declaration of net quantity (see "Numerical Count" in section 4.1.1, and "Character Height," in this section above).

b) The net quantity of a kit for a single use or application may be expressed by giving its identity (see "Official Bilingual Exemptions," "Single Expressions," and "Additional Panels" in section 4.1.1) and an indication in English and in French that the contents are sufficient for a single use or application. Home permanents and colouring shampoos fall into this category.

c) The net quantity of a kit for multiple uses or applications may be expressed as illustrated by the following examples:

- "This kit contains 10 artificial nails, 5 mL of adhesive, and 7 mL of cleaner."
- "This make up kit contains 50 mL of white base cream, 10 g of loose powder, and 4 jars of cream (red, green, black, and yellow) of 5 mL each."
- "This epilatory kit contains enough material to epilate two legs."

Prepackaged Products

As required by sections 22, 23, and 36 of the *Consumer Packaging and Labelling Regulations*, the declaration of the net quantity of a prepackaged product must be expressed

- by volume, when the product is a liquid, gas, or viscous substance; or
- by weight, when the product is a solid.

Supplementary, Non-metric Declarations

A non-metric declaration of net quantity may be provided. However, this information is considered supplementary to the main declaration. The non-metric declaration must not be false or misleading to the consumer.

Table 5-2 • **Character Heights Corresponding to the Area of the Principal Display Surface**

Area of Principal Display Surface	Minimum Character Height
Not more than 32 cm ² (5 sq. in.)	1.6 mm (1/16 in.)
More than 32 cm ² (5 sq. in.) but not more than 258 cm ² (40 sq. in.)	3.2 mm (1/8 in.)
More than 258 cm ² (40 sq. in.) but not more than 645 cm ² (100 sq. in.)	6.4 mm (1/4 in.)
More than 645 cm ² (100 sq. in.) but not more than 25.8 dm ² (400 sq. in.)	9.5 mm (3/8 in.)
More than 25.8 dm ² (400 sq. in.)	12.7 mm (1/2 in.)

For example, supplementary declarations using American gallons, which are slightly smaller than Canadian gallons, can be misleading. The label must note that American gallons are being used (e.g., 3.79 L (1 gallon U.S.)).

The use of U.S. fluid ounces, which are slightly larger than Canadian fluid ounces, can be confusing. It is recommended that the U.S. units be noted if both millilitres and U.S. fluid ounces are being used (e.g., 591 mL, 20 fl. oz. U.S.).

Separation of Numerals from Units

A single space must be used to separate the numerical part of the declaration from the unit of measure. For example:

- "500 mL" is correct, and
- "500mL" is incorrect.

Using the Word "Net"

It is not necessary to use expressions such as "net," "net weight," "net contents," or "net quantity" in the declaration of net quantity.

Precision of Declared Quantity

Quantity must be expressed to three figures in the decimal system. However, it is not necessary to indicate zeros to the right of a decimal point. Three exceptions to these requirements are permitted:

- a) If the quantity is less than 100 grams or millilitres, it may be shown to two figures. Zeros to the right of the decimal point need not be shown. For example:
- 85 g is correct,
 - 85.2 g is permissible, and
 - 85.15 g is incorrect.

- b) If the quantity is less than one, it may be expressed
- in the decimal system with a single zero to the left of the decimal point, or
 - in words.

c) A specific variation of (b) permits 500 grams and 500 millilitres to be shown, respectively, as "one-half kilogram" or "one-half litre." These declarations may be expressed in decimal figures or in words.

For 500 grams, the following expressions are acceptable:

- 500 g
- 0.5 kg
- one-half kilogram (un demi-kilogramme)
- one-half kg (un demi kg)

For 500 millilitres, the following expressions are acceptable:

- 500 mL
- 0.5 L
- one-half litre (un demi-litre)
- one-half L (un demi L)

When it is necessary to round the metric declaration to the specified three (or two) figures, the rounding is performed in one of the following three ways:

a) When the digit to be discarded is less than five, the last digit retained should not be changed. For example, when 984.3 is rounded to three figures, (discarding the figure to the right of the decimal point) it becomes 984.

The same rationale applies to numbers below 100. For example, rounding 68.4 (discarding the figure to the right of the decimal point) to two figures yields 68.

b) When the digit to be discarded is exactly five and is followed only by zeros, the last digit retained should be rounded up if it is an odd number but should be left unchanged if it is even. For example:

- 984.50 becomes 984
- 985.50 becomes 986
- 68.50 becomes 68
- 7.450 becomes 7.4
- 7.550 becomes 7.6

c) When the digit to be discarded is greater than five, or is a five followed by at least one digit other than zero, the last digit to be retained should be increased by one. For example:

- 984.7 becomes 985
- 984.51 becomes 985

Average Quantity

The actual amount of product contained in the package must correspond to the amount declared within the tolerance prescribed (refer to tolerance tables in Schedule I of the *Consumer Packaging and Labelling Regulations*).

Aerosol Products

All aerosol products should comply with section 22.1 of the Consumer Packaging and Labelling Regulations. The net quantity of aerosol products must be declared by weight (propellant plus ingredients).

5.1.2 Inner Label Requirements

A declaration of net quantity is not required on the inner label. If the manufacturer chooses to include such a declaration on the inner label, it must not be false or misleading to the consumer.

5.2 Products That Have Only an Inner Label

Products that have only an inner label must meet the same labelling requirements as those for the outer label of products that have both an outer and inner label (see section 5.1.1, “Outer Label Requirements”).

The declaration of net quantity must appear in both English and French on the principal display panel. The declaration must contrast clearly with all the other information that appears on the label. In this way, the consumer will know the net quantity of the product purchased.

6. Name and Address of Manufacturer

Sometimes it is necessary for the public, associations, medical practitioners, government agencies, or other interest groups to know the identity of the party that is responsible for a product (e.g., in order to communicate with the responsible party). This party is often known as the *manufacturer or dealer*.

It is important that the name and address on the label appearing in section 2(a) of the Cosmetic Notification Form for the product that is submitted to the Cosmetics Program correspond to the name and address on the label.

The manner in which the requirements are applied depends on the two situations described below:

- products that have both outer and inner labels (e.g., a bottle packaged in a box has two labels; the box bears the outer label, and the bottle bears the inner label), and
- products that have only an inner label (e.g., a bottle of shampoo that is not packaged in a box has only an inner label on the bottle).

6.1 Products Having Both Outer and Inner Labels

6.1.1 Outer Label Requirements

On the outer label the name and address of the manufacturer or dealer must appear on the outside surface of the package (anywhere except the bottom but conforming to the requirements discussed in “Imported Products,” below) in such a manner that can be easily read.

Official Languages

The name and address may appear in English, in French, or in both official languages.

Typeface

There is no restriction on the typeface to be used, except that the information must be easily read.

Character Height

When only upper-case letters are used, the character height must be at least 1.6 mm. When both upper-case and lower-case letters are used, the height corresponding to the lower-case “o”-in the appropriate style of print-must be at least 1.6 mm.

Imported Products

When a prepackaged product is wholly manufactured or produced in a country other than Canada, the identification of the manufacturer or dealer may be expressed in the following ways: (a) showing the identity and principal place of business of the manufacturer outside Canada, or (b) showing the identity and principal place of business of the Canadian dealer, preceded by the words “imported by” (“importé par”) or “imported for” (“importé pour”), or (c) showing a statement of the geographic origin of the product immediately adjacent to identity and principal place of business of the Canadian dealer.

Bulk Products Packaged in Canada

Where a product is wholly produced in a country other than Canada, imported into Canada in bulk, packaged (at other than the retail level) in Canada, and then labelled, it must be labelled in the same manner as previously described in (b) and (c) of “Imported Products” in Section 6.1.1, “Outer Label Requirements,” above. For further information, contact Industry Canada (see section 9.1, “Further Information About the Acts”).

Responsibility for Packaging

When reference is made on the label directly or indirectly to the place where the packaging was made or where the label was printed (not where the product was made), the reference must be accompanied by a supplementary declaration indicating that the place of manufacture refers only to the package or the label.

6.1.2 Inner Label Requirements

On the inner label, the name and address of the manufacturer or dealer must be displayed so that it can be easily read. The name and address may be located anywhere except the bottom of the container (this does not apply to ornamental containers).

Official Languages and Typeface

See “Official Languages” and “Typeface” in section 6.1.1, “Outer Label Requirements,” above.

6.2 Products With an Inner Label Only

When the product is presented in packaging that includes only a single label, the regulations require the declaration of the name and address of the manufacturer or dealer to be presented as described in the subsections that follow.

6.2.1 Readability

The name and address of the manufacturer or dealer must be displayed so that it can be easily read. The information must not be displayed on the bottom of the container.

6.2.2 Other Requirements

All other requirements for the declaration of name and address are the same as those for outer labels of products that have both an outer label and an inner label. Refer to section 6.1.1, “Outer Label Requirements,” above.



7. Avoidable Hazards and Cautions

The *Food and Drugs Act* (section 16) and the *Cosmetic Regulations* (section 24) comprehensively prohibit the sale of products that present a hazard to the health of the user. When an avoidable hazard is associated with the use of a product, the product may be sold on condition that a warning describes how to use, or when not to use, the product in order to eliminate the risk. This requirement can be satisfied through a combination of instructions for use, cautions, and symbols, in both English and French.

In some cases, the manner in which the requirements are applied depends on the two situations described below:

- products that have both outer and inner labels (e.g., an aerosol can packaged in a box has two labels; the box bears the outer label, and the can bears the inner label), and
- products that have only an inner label (e.g., an aerosol can that is not packaged in a box has only an inner label on the bottle).

A sample or facsimile of the labels and inserts used with a product of this type must be submitted with the Cosmetic Notification (as described in Subsection 30(1) (b) of the *Cosmetic Regulations*).

7.1 Prescribed Cautions for Hair Dyes, Mercury-containing Products, and Genital Deodorants in Pressurized Containers

For certain products, such as hair dyes and products that contain mercury, the manner of eliminating hazards is prescribed by the *Cosmetic Regulations*.

7.1.1 Hair Dyes

Hair dyes that contain para-phenylenediamine or other coal tar dye bases or coal tar dye intermediates, must bear the following warning, as prescribed in section 22 of the *Cosmetic Regulations*, on its outer and inner labels:

- **“CAUTION:** This product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so may cause blindness.”
- **“MISE EN GARDE:** Ce produit contient des ingrédients qui peuvent causer de l’irritation cutanée chez certaines personnes; il faut donc d’abord effectuer une épreuve préliminaire selon les directives ci-jointes. Ce produit ne doit pas servir à teindre les sourcils ni les cils; en ce faisant, on pourrait provoquer la cécité.”

Preliminary Tests

Each package of this type of hair dye must be accompanied by an instruction stating that the product may cause serious inflammation of the skin in some persons, and that a preliminary test should always be carried out to determine if the user has a special sensitivity to the product. This instruction must appear in both official languages.

Instructions similar to the following should describe, in English and French, how to conduct a preliminary test:

- 1) Using either soap and water or alcohol, clean a small area of skin behind the ear or on the inner surface of the forearm.

2) Apply a small quantity of the hair dye, as prepared for use, to the area and allow it to dry.

3) After 24 hours, gently wash the area with soap and water.

4) If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test, however, should be carried out before each application.

5) The hair dye should never be used for dyeing eyebrows or eyelashes, because inflammation of the eye or even blindness may result.

7.1.2 Mercury-containing Products

Cosmetics that contain mercury or its salts or derivatives as a preservative must possess a declaration on the outer label that indicates the name of the preservative and its concentration in the cosmetic. (Refer to sections 15.1 and 22.1 of the *Cosmetic Regulations*.)

7.1.3 Genital Deodorants in Pressurized Containers

A deodorant for use in the genital area that is sold in a pressurized container must carry the following information on its outer and inner labels as prescribed in section 23 of the *Cosmetic Regulations*.

- "Directions: For external use only. Use sparingly and not more than once daily. Spray external skin surface while holding nozzle at least 8 inches from the skin."
- "Mode d'emploi: Pour usage externe seulement. Employer modérément pas plus d'une fois par jour. Vaporiser sur la surface externe de la peau en tenant le bec à une distance d'au moins 8 pouces."

- "Caution: Do not apply internally or to broken, irritated or itching skin. Do not use when wearing a sanitary napkin. Discontinue use immediately if a rash or irritation develops. Consult a physician if the rash or irritation persists or if there is any unusual odour or discharge at any time."
- "Mise en garde: Ne pas appliquer sur une surface interne ou sur une surface éraflée, irritée ou en proie à la démangeaison. Ne pas utiliser avec des serviettes hygiéniques. Cesser immédiatement l'emploi en cas d'éruption ou d'irritation. Consulter un médecin si l'éruption ou l'irritation persiste ou en cas d'odeur ou de sécrétion inhabituelle."

7.2 Prescribed Cautions for Pressurized Metal Containers

Pressurized metal containers have the characteristics listed below:

- the container is metal and not reusable,
- the contents of the container are under pressure, and
- a manually operated valve in the container is used to release the contents.

7.2.1 Products That Have Only an Inner Label

If the packaging of a pressurized metal container only has an inner label, the following items must be provided:

- a) The symbol shown in Figure 7.1 must appear on the display panel of the label.

Figure 7.1:
The "Explosive" symbol superimposed on the "Caution" symbol.



To determine the smallest size of symbol that may be used, follow this procedure:

- i) calculate the area that is four percent of the area of the display panel.

$$\text{SURFACE} = (0.04) \times (\text{area of display panel})$$

- ii) calculate the diameter of a circle whose area is that determined in i).

$$\text{DIAMETER} = \sqrt{(1.27) \times (\text{SURFACE})}$$

If the diameter obtained is less than 6.4 mm, 6.4 mm should be used as the diameter in the following step. However, if the diameter obtained is less than 6.4 mm and the net quantity declared is less than 30 mL or 30 g, 6.0 mm may be used as the diameter?

- iii) draw a circle having the diameter obtained from (ii).
- iv) draw the symbol entirely within the circle. All of its "points" (three in this case) should just touch the circle. (Note that the length of one side of the triangle is 0.83 times the diameter of the circle.)

b) The words "CAUTION" and "ATTENTION" must appear on the display panel of the label.

These signal words must appear immediately below the symbol and they must be printed in boldface type (sans serif capitals). The height of the characters used for these words must be not less than one quarter of the diameter calculated for the size of the symbol (see item (a), above). The signal words do not have to appear side by side.

c) The message "CONTAINER MAY EXPLODE IF HEATED" and "CE CONTENANT PEUT EXPLOSER S'IL EST CHAUFFÉ" must appear on the display panel of the label.

These statements (which describe the nature of the primary hazard) must appear immediately below the signal word (see item (b), above) in boldface or medium face type (sans serif capitals).

The height of the characters used for these messages must be:

- at least 1.5 mm when the area of the display panel is 100 cm² or less,
- at least 3.0 mm when the area of the display panel is more than 100 but not more than 330 cm²,
- at least 6.0 mm when the area of the display panel is more than 330 but not more than 650 cm²,
- at least 9.0 mm when the area of the display panel is more than 650 but not more than 2600 cm², and
- at least 12 mm when the area of the display panel is more than 2600 cm².

d) The following statements must appear on any one panel of the label, except the bottom of the container:

"Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store at temperatures over 50°C."

and

"Contenu sous pression. Ne pas placer dans l'eau chaude ni près des radiateurs, poeles ou autres sources de chaleur. Ne pas percer le contenant ni le jeter au feu, ni le conserver à des temperatures dépassant 50°C."

These statements of precaution may be shown entirely in upper case, or in upper and lower case, and must be printed in sans serif type. The statements "FIRST AID TREATMENT" and "PREMIERS SOINS" must be printed in boldface capital letters. Capital letters should have a height of:

- at least 1.5 mm when the area of the display panel is 170 cm² or less,
- at least 3.0 mm when the area of the display panel is more than 170 but not more than 330 cm²,
- at least 4.5 mm when the area of the display panel is more than 330 but not more than 650 cm², and
- at least 6.0 mm when the area of the display panel is greater than 650 cm².

7.2.2 Products That Have Both Outer and Inner Labels

If a product in a pressurized metal container has both an outer label and an inner label, refer to Table 7-1 for the requirements that must appear on both types of label.

7.3 Prescribed Cautions for Flammable Products in Pressurized Metal Containers

In addition to the requirements described in section 7.2, “Prescribed Cautions for Pressurized Metal Containers” specific labelling requirements apply to flammable products in pressurized metal containers.

Flammable products in pressurized metal containers have the characteristics listed below:

- the container is metal and not reusable,
- the contents of the container are under pressure,
- a manually operated valve in the container is used to release the contents, and
- the spray can be ignited.

(Refer to section 26 of the *Cosmetic Regulations* and official method DO-30: Determination of Flame Projection)

7.3.1 Products That Have Only an Inner Label

If the packaging of a flammable product in a pressurized metal container only has an inner label, certain items must be provided on the label. This section breaks down the requirements into:

- products with a flame projection of less than 15 cm
- products with a flame projection of 15 cm or more but less than 45 cm and
- products with a flame projection of 45 cm or more or a flashback to the container.

Table 7-1 • Requirements for Pressurized Metal Containers That Have Both Outer and Inner Labels

<i>Net Quantity of Product</i>		<i>Refer to Item in section 7.2.1</i>
More than 120 mL/120 g	outer label	(a), (b), (c), (d)
	inner label	(a), (b), (c), (d)
120 mL/120 g or less but more than 60 mL/60 g	outer label	(a), (b), (c), (d)
	inner label	(a), (b), (c)*
60 mL/60 g or less	outer label	(a), (b), (c), (d)
	inner label	(a), (b)*

* Items that are not mentioned for a label type are optional.

Flame Projection Less Than 15 Centimetres

Products with a flame projection of less than 15 centimetres must contain the following items on the inner label:

- a) The symbol shown in Figure 7.2, on the display panel of the label.

Figure 7.2:

The "Flammable" symbol superimposed on the "Caution" symbol.



The size of this symbol can be determined using the procedure in section 7.2.1, item (a).

- b) The words "CAUTION" and "ATTENTION" on the display panel of the label. (Because the requirements for pressurized metal containers are also applied (see section 7.2.1, item (b)) these signal words should already be present.)

- c) The words "FLAMMABLE" and "INFLAMMABLE" on the display panel of the label.

The location, style of appearance, and size of the characters is described in section 7.2.1, item (c).

- d) The statements "*Do not use in presence of open flame or spark*" and "*Ne pas utiliser en présence d'une flamme nue ou d'étincelles*" must be present on any one panel of the label except the bottom of the container.

The height of the characters used in such a message is described in section 7.2.1, item (d).

These statements may be combined with those in section 7.2.1, item (d), if desired.

Flame Projection 15 Centimetres or More but Less Than 45 Centimetres

Products with a flame projection of between 15 cm or more but less than 45 cm must contain the following items on the inner label:

- a) The symbol shown in Figure 7.3, on the display panel of the label.

Figure 7.3:

The "Flammable" symbol superimposed on the "Warning" symbol.



The minimum size of this symbol can be determined using the procedure in section 7.2.1, item (a). The symbol's "points" (four in this case) must just touch the circle.

- b) The words "WARNING" and "AVERTISSEMENT" on the display panel of the label.

The location, style of appearance, and size of the characters used for such signal words is described in section 7.2.1, item (b). The signal words "CAUTION" and "ATTENTION" may be omitted in this case because "WARNING" and "AVERTISSEMENT" indicate a higher degree of hazard.

c) The words “FLAMMABLE” and “INFLAMMABLE” on the display panel of the label.

The location, style of appearance, and size of the characters is described in section 7.2.1, item (c).

d) The statements *“Do not use in presence of open flame or spark”* and *“Ne pas utiliser en présence d’une flamme nue ou d’étincelles”* must be present on any one panel of the label except the bottom of the container.

The height of the characters used in such a message is described in section 7.2.1, item (d).

These statements may be combined with those in section 7.2.1, item (d), if desired.

Flame Projection 45 Centimetres or More or Flashback to the Container

Products with a flame projection of 45 centimetres or more, or if there is a flashback to the container, must contain the following items on the inner label:

a) The symbol shown in Figure 7.4, on the display panel of the label.

Figure 7.4:
The “Flammable” symbol superimposed over the “Danger” symbol.



The size of this symbol can be determined using the procedure in section 7.2.1, item (a). The symbol’s points (eight in this case) must just touch the circle.

b) The words “DANGER” on the display panel of the label.

The location, style of appearance, and size of the characters used for such a signal word is described in section 7.2.1, item (b). The signal words “CAUTION” and “ATTENTION” may be omitted because “DANGER” indicates a higher degree of hazard.

c) The words “EXTREMELY FLAMMABLE” and “EXTREMELY INFLAMMABLE” on the display panel of the label.

The location, style of appearance, and size of the characters is described in section 7.2.1, item (c).

d) The statements *“Do not use in presence of open flame or spark”* and *“Ne pas utiliser en présence de flamme nue ou d’étincelles”* must be present on any one panel of the label except the bottom of the container.

The height of the characters used in such a message is described in section 7.2.1, item (d).

These statements may be combined with those in section 7.2.1, item (d), if desired.

7.3.2 Products That Have Both Outer and Inner Labels

If the packaging of a flammable product in a pressurized metal container has both an outer label and an inner label, the labelling requirements must appear in the manner described in this section.

The information is divided into the net quantities of the products in the containers:

- net quantity more than 120 mL/120 g,
- net quantity is 120 mL/120 g or less but more than 60 mL/60 g, and
- net quantity is 60 mL/60 g or less.

Refer to Table 7-2 for the requirements that apply.

7.4 Prescribed Cautions for Mouthwashes

Mouthwashes must be packaged in security packaging. The label must carry a statement or an illustration that draws attention to the security feature if the feature is not self-evident and not an integral part of the product's immediate container.

7.5 Non-prescribed Cautions

For other hazards the manner of elimination is not explicitly prescribed in the *Cosmetic Regulations*. It is the manufacturer's and importer's responsibility to recognize an avoidable hazard and to eliminate it by providing specific limits on the use of the cosmetic. The following comments may be of some assistance in this regard.

Table 7-2 • Requirements for Flammable Products in Pressurized Metal Containers That Have Both Outer and Inner Labels

<i>Net Quantity of Product</i>		<i>Refer to Item in subsections of 7.3.1 (depending on flashback or type of flame projection)</i>
More than 120 mL/120 g	outer label	(a), (b), (c), (d)
	inner label	(a), (b), (c), (d)
120 mL/120 g or less but more than 60 mL/60 g	outer label	(a), (b), (c), (d)
	inner label	(a), (b), (c)*
60 mL/60 g or less	outer label	(a), (b), (c), (d)
	inner label	(a), (b)*

* Items that are not mentioned for a label type are optional.

7.5.1 Non-metallic Containers

Although requirements are prescribed for products (flammable or otherwise) that are sold in pressurized metal containers, the manufacturer should consider providing the consumer with equivalent information when the container is non-metallic. For more information, refer to sections 7.2 and 7.3 of this guide.

7.5.2 Patch Tests

If a caution of the type “make a patch test” (“effectuer un test épicutané”) appears on the label, the necessity for doing the test is implied. Therefore, instructions for carrying out the patch test should be provided.

A reference to the location of the instructions on the label may be provided with the caution message, or the instructions themselves may be provided with the caution message.

If this type of caution is not necessary, the caution message, and the instructions for following it, should not appear.

7.5.3 Caustic Depilatories

Caustic depilatories should carry instructions for hazard-free use, and should also point out the risk of chemical burns.

7.5.4 Melted Epilatories

Epilatories that must be liquified by melting through the application of heat before use should carry instructions for hazard-free use, and should also point out the risk of burns.



8. Ingredients

On December 1, 2004, Health Canada published amendments to the *Cosmetic Regulations* in Part II of the *Canada Gazette*. The Regulations now require mandatory ingredient labelling on all cosmetic products sold in Canada. The requirements come into force on November 16, 2006, at which time they become law. This means that persons selling cosmetic products in Canada will have to be in compliance with all the new requirements by that time.

8.1 International Nomenclature for Cosmetic Ingredients (INCI) System

INCI stands for the International Nomenclature for Cosmetic Ingredients. It is a system for naming cosmetic ingredients that is multilingual, multinational and based on Latin. The INCI labelling system was designed in 1973 and developed over a period of more than 30 years. It was created by the American Cosmetic, Toiletry and Fragrance Association's International Nomenclature Committee and the INCI system forms the basis of the *International Cosmetic Ingredient (ICI) Dictionary and Handbook* (currently in its tenth edition). The Dictionary and Handbook presents, in detail, the bulk of INCI names juxtaposed with their corresponding empirical chemical formulas, technical/trade names, Chemical Abstracts System numbers (CAS No.), or alternate numbers. This allows for the unambiguous identification of ingredients. Health Canada, along with other government and industry representatives, is a participant of the International Nomenclature Committee, which determines the INCI name assigned to each cosmetic ingredient. INCI is the mandatory nomenclature in the United States, the European Union, and now Canada.

8.2 Ingredient Nomenclature

The *Cosmetic Regulations* require that all cosmetic products sold in Canada must list the ingredients on the label using the International Nomenclature for Cosmetic Ingredients (INCI) labelling system as found in the most recent edition of the *International Cosmetic Ingredient (ICI) Dictionary and Handbook*. The list of ingredients must appear on the outer label of a cosmetic, or if the cosmetic has only one label, on that label. Extra descriptive or marketing terminology is not acceptable in the ingredient list, although it is permissible elsewhere on the label. For certain ingredients and products, such as botanicals and ornamental containers, the manner for listing these is prescribed by the *Cosmetic Regulations*.

8.2.1 Botanicals

Botanicals are ingredients that are directly derived from a plant and that have not been chemically modified before being used in the preparation of a cosmetic. In the INCI Dictionary, botanicals are listed using their genus, species, common name, plant part and extraction method. Therefore, the INCI name for orange peel extract would be *Citrus aurantium dulcis (orange) peel extract*. In Canada, botanicals must be listed using at least the genus and species portions of the INCI name.

e.g. INCI name: *Citrus aurantium dulcis (orange) peel extract*

The label must show at least "Citrus aurantium dulcis".

It is also acceptable to show the complete INCI name, however, it is not required at this time. Please refer to section 21.2(3) of the *Cosmetic Regulations*.

8.2.2 Ingredients Listed in the Schedule

An ingredient that is included in the schedule to the *Cosmetic Regulations* may be listed one of two ways: either by its EU trivial name set out in column 1 of the schedule or by the appropriate English and French equivalents set out in columns 2 and 3 (as described in section 21.2(4)). It is also acceptable for all three terms to be used together. Please note that it is not permissible to use the English equivalent without the French equivalent or vice versa.

For persons choosing to use the English and French equivalents, the *Cosmetic Regulations* do not prescribe a specific method for writing the English and French equivalents. While some persons find it convenient to use a slash "/" in between the two terms, other persons may prefer to use a different method. The requirement is that both terms need to appear on the label in such a way that it is clearly understood they are equivalent.

Please note that the ingredients listed in the schedule are the only ones which may need to appear in both French and English.

8.2.3 Ingredients Without INCI Names

Most cosmetic ingredients do have INCI names, so it is important to look through the INCI Dictionary carefully. However, if there truly is no INCI name, the ingredient must be listed by its chemical name from a recognized source. Such sources include:

British Medical Association and Royal Pharmaceutical Society of Great Britain Joint Formulary Committee. *British National Formulary 47 (BNF 47)*. Oxon, UK: Pharmaceutical Press, 2004. Source: www.bnf.org

British Pharmacopoeia Commission. *British Pharmacopoeia*. 2004 ed. United Kingdom: British Pharmacopoeia Commission, 2004. Source: www.pharmacopoeia.org.uk

Committee on Food Chemicals Codex. *Food Chemicals Codex*. 5th ed. USA: Committee on Food Chemicals, 2003. Source: www.iom.edu/report.asp?id=15730

European Pharmacopoeia Commission. *European Pharmacopoeia*. 5th ed. Strasbourg: Directorate for the Quality of Medicines, 2004. Source: www.pheur.org

Society of Japanese Pharmacopoeia. *Japanese Pharmacopoeia*. 14th ed. (JPXIV). Japan: Yakuji Nippo Ltd, 2001. Source: www.yakuji.co.jp/yakuji/publications200101.html

United States Pharmacopoeia. *USP 28-NF*. USA: The United States Pharmacopoeia Convention Inc., 2004. Source: www.usp.org

United States Adopted Names Council. *2004 Published USAN*. USA: American Medical Association, 2004. Source: www.ama-assn.org/ama/pub/category/12409.html

8.3 How to List Ingredients on the Label

All information required by the *Cosmetic Regulations* must be clearly legible and remain so throughout the useful life of the cosmetic. While there is no prescribed font size or type face for the ingredient lists, the list must be clearly legible to the consumer under normal conditions of sale and use.

8.3.1 Descending Order of Predominance

Ingredients must be listed on the label in descending order of predominance, in their concentration by weight (as described in section 21.4(1) of the *Cosmetic Regulations*). This means that the ingredients at the beginning of the list are present in the product in a greater amount than those at the end of the list. Please see sections 8.3.2 through 8.3.5 of these guidelines for exceptions to this rule.

8.3.2 Ingredients with Concentrations of 1% or Less

Ingredients that are present at a concentration of 1% or less may be listed in random order after the ingredients present at a concentration of more than 1% (as described in section 21.4(2) of the *Cosmetic Regulations*). While it is acceptable to continue to list ingredients present at such small amounts in descending order of predominance, it is not necessary, as long as they are present in the ingredient list.

8.3.3 Colouring Agents

All colouring agents, regardless of their concentration, may be listed in random order after the ingredients that are present at a concentration of more than 1% (as described in section 21.4(2) of the *Cosmetic Regulations*). It is also acceptable to list colouring agents in descending order of predominance.

8.3.4 Fragrance

In the case of fragrances, the word “parfum” may be used to indicate that ingredients have been added to the cosmetic to produce or mask a particular odour. The term “parfum” may either be inserted at the end of the list of ingredients or

inserted at the appropriate point in descending order of predominance. If persons do not choose to use the term “parfum” to indicate the presence of fragrance ingredients, they must list each fragrance ingredient individually.

8.3.5 Flavour

In the case of flavours, the word “aroma” may be used to indicate that ingredients have been added to the cosmetic to produce or mask a particular flavour. The term “aroma” may either be inserted at the end of the list of ingredients or inserted at the appropriate point in descending order of predominance. If persons do not choose to use the term “aroma” to indicate the presence of flavour ingredients, they must list each flavour ingredient individually.

8.3.6 Make-up, Nail Polish and Nail Enamel

For make-up products (e.g. lipstick, blush, eyeshadow), nail polish and nail enamel, which are sold in a range of colour shades, all colouring agents used in the range may be listed if they are preceded by the symbol “+/-” or “±” or the phrase “may contain/peut contenir” (as described in section 21.2(2) of the *Cosmetic Regulations*). It is unacceptable to use this notation for other cosmetic products, such as hair dyes.

8.3.7 Cosmetics in Small Packages or Containers

It is of paramount importance that the information required to be shown on the label of a cosmetic be clearly legible. However, some cosmetics are so small that requiring the ingredient list to appear on the label would make it difficult to see the information. Therefore, for cosmetics whose immediate container or outside package is so small

that the information would not be clearly legible, the list of ingredients may appear on a tag, tape or card affixed to the container.

8.3.8 Cosmetics in Ornamental Containers

In the case of a cosmetic in an ornamental container that has no outside package (i.e. a perfume bottle without a box), the list of ingredients may appear on a tag, tape or card affixed to the container.

8.3.9 Oddly-Shaped Cosmetics

In the case of a cosmetic that has no outside package and whose size, shape or texture, or that of its immediate container, makes it impractical for a tag, tape or card to be affixed to the container (e.g. bath beads), the list of ingredients may instead appear in a leaflet that must accompany the cosmetic at the point of sale.

8.4 Products Exempted from Mandatory Ingredient Labelling

Some products can have a dual purpose and, as a result, will fall under more than one piece of legislation simultaneously. An example of such a product would be a chewing gum that claims to whiten the teeth. Under the *Food and Drugs Act*, a chewing gum is a food, but it must also adhere to the requirements of the *Cosmetic Regulations* because it also makes cosmetic claims (to whiten teeth). Because many of these dually-classified products already require ingredient listing under other Regulations, the decision was made to exempt them from the provision to list the ingredients using the INCI system. Therefore, the requirements to list the ingredients under the *Cosmetic Regulations* do not apply to any product whose ingredient labelling is regulated under the *Food and Drug Regulations* or the *Natural Health Product Regulations*.



9. Sources on Additional Information

9.1 Further Information About the Acts

To obtain information regarding the *Food and Drugs Act* (as it relates to cosmetics), the *Cosmetic Regulations*, and the *Consumer Chemical Container Regulations* as they read on September 30, 2001 contact:

Cosmetics Program
Health Canada
MacDonald Building, A.L. 3504D
123 Slater Street
Ottawa, Ontario
K1A 0K9
Telephone: (613) 946-6452
Website: www.healthcanada.gc.ca/cosmetics

To obtain information regarding the *Food and Drugs Act* as it relates to drugs, contact:

Submission and Information Policy Division
Therapeutic Products Directorate
Health Canada
Finance Building
Tunney's Pasture
Ottawa, Ontario
K1A 0L2
Telephone: (613) 941-0839
Website: www.hc-sc.gc.ca/dhp-mps/index_e.html

To obtain information about non-cosmetic products with respect to the *Consumer Packaging and Labelling Act and Regulations*, contact:

Competition Bureau
Industry Canada
Place du Portage, Phase I
50 Victoria St.
Hull, Quebec
K1A 0C9
Toll free in Canada: 1-800-348-5358

Outside of Canada: (819) 997-4282
TTD (hearing impaired): 1-800-642-3844
FAX: (819) 997-0324
Website: www.competitionbureau.gc.ca

9.2 Obtaining Government Documents

9.2.1 Canadian Government Publishing Centre

The publications listed below may be obtained from:

Canadian Government Publishing
Ottawa, Canada
K1A 0S9
Telephone: (819) 956-4802
Website: publications.gc.ca

These documents are also available on-line at the Government of Canada Justice site at canada.justice.gc.ca, or through links at Health Canada's Cosmetics Program website www.healthcanada.gc.ca/cosmetics.

9.2.2 Documents

Government documents related to cosmetics include:

- *Food and Drugs Act*, the *Cosmetic Regulations*, and their amendments.
- *Consumer Packaging and Labelling Act and Regulations*, and their amendments.
- *Competition Act and Regulations*, and their amendments.
- *Hazardous Products Act* and its amendments.
- *Weights and Measures Act and Regulations*, and their amendments.
- Marking of Imported Goods Order.

9.3 Flame Projection Information

In order to obtain a copy of Official Method DO-30, Determination of Flame Projection contact:

Cosmetics Program

Health Canada

MacDonald Building, A.L. 3504D

123 Slater Street

Ottawa, Ontario

K1A 0K9

Telephone: (613) 946-6449

Website: www.healthcanada.gc.ca/cosmetics

9.4 Canadian Metric Practice Guide

The Canadian Metric Practice Guide may be obtained from:

Canadian Standards Association (CSA)

178 Rexdale Boulevard

Etobicoke, Ontario

M9W 1R3

Telephone: (416) 747-4044

Toll free: 1-800-463-6727

Website: www.csa.ca

9.5 Canadian Border Services Agency

Issues dealing with the Canadian customs relative to cosmetics may be clarified by contacting:

Canadian Border Services Agency

Automated Customs Information Service (ACIS) line

From within Canada: 1 800 461-9999 (toll free)

From outside Canada: (204) 983-3500 or

(506) 636-5064 (long-distance charges apply)

Website: www.cbsa.gc.ca

9.6 Advertising Standards Canada (ASC)

Advertising Standards Canada, formerly the Canadian Advertising Foundation, provides is the national advertising industry self-regulatory body, and administers the *Advertising Code for Standards for Cosmetics, Toiletries and Fragrances*. The latest version is obtainable at the following address:

Advertising Standards Canada

175 Bloor Street East, Suite 1801

Toronto, Ontario

M4W 1H5

Telephone: (416) 961-6311

Facsimile: (416) 961-7904

Website: www.adstandards.com

9.7 Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA)

The Canadian Cosmetic, Toiletry, and Fragrance Association is composed of manufacturers and marketers of cosmetics, toiletries, and fragrances, and those who supply materials and services to the cosmetic, toiletry, and fragrance industry. Further information may be obtained by contacting:

Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA)

420 Britannia Road East, Suite 102

Mississauga, Ontario

L4Z 3L5

Telephone: (905) 890-5161

Website: www.cctfa.ca

9.8 French Language Requirements

To obtain details on the labelling of products for the Québec market, contact:

French Language Office
Government of Québec
Tour de la Bourse
800 Victoria Place
Montréal, Québec
H4Z 1G8
Telephone: (514) 873-6565
Website: www.olf.gouv.qc.ca

9.9 International Cosmetic Ingredient Dictionary and Handbook

The Dictionary can be obtained from:

The Cosmetic, Toiletry and Fragrance Association (CTFA)
1101 17th Street, NW, Suite 300
Washington, D.C. 20036-4702
Telephone: (202) 331-1770
Fax: at (202) 331-1969.
Website: www.ctfa.org

It can also be obtained through the Canadian distributor at:

Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA)
420 Britannia Road East
Suite 102
Mississauga, Ontario
L4Z 3L5
Telephone: (905) 890-5161
Fax: (905) 890-2607
E-mail: cctfa@cctfa.ca