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# **LABELLING GUIDANCE DOCUMENT**

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## **NATURAL HEALTH PRODUCTS DIRECTORATE**

August 2006  
**Version 2.0**

“Our mission is to help the people of Canada maintain and improve their health, while respecting individual choices and circumstances.”

*Health Canada*

“Our role is to ensure that 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.”

*Natural Health Products Directorate*

Également offert en français sous le titre :  
*Document de référence concernant l'étiquetage*

This publication is also available electronically at the  
following address: [www.healthcanada.gc.ca/nhp](http://www.healthcanada.gc.ca/nhp)

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Cat. H164-24/2006E-PDF  
ISBN 0-662-44002-1

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## FOREWORD

The purpose of this guidance document is to help product licence applicants interpret the labelling and packaging requirements specified in Section 5 of the *Natural Health Products Regulations* (the Regulations) when selling a natural health product (NHP) within Canada. Included in this guidance document are labelling and packaging requirements, the labelling and packaging system, special labelling requirements and presentation of the product information on the label.

Canadian consumers have asked for labelling of all ingredients in NHPs and for warnings to be clear and understandable. With the introduction of the Regulations, Canadian consumers are now able to make more informed decisions about the NHPs they purchase. As a result, improved standardized labelling is required. Labels will need to specify the product's recommended use or purpose (health claim), dosage information, medicinal and non-medicinal ingredients and any cautions, warnings, contraindications or known adverse reactions associated with the product.

Boxes with the text of the Regulations appear in relevant locations throughout the text. A complete version of the Regulations is available on the Internet at [[http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/legislation/acts-lois/prodnatur/regs\\_cg2\\_e.html](http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/legislation/acts-lois/prodnatur/regs_cg2_e.html)].

The information in this guidance document is based on the *Natural Health Products Regulations*, which were published in the Canada Gazette, Part II, on June 18, 2003. The Regulations came into force on January 1, 2004.

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## 1.0 OVERVIEW - LABELLING AND PACKAGING REQUIREMENTS

All natural health products (NHPs) are required to be labeled and packaged according to the *Natural Health Products Regulations* (the Regulations) before sale in Canada. However, an individual can sell a NHP that does not comply with the Regulations, if the sale is restricted to a manufacturer or distributor. [*Natural Health Products Regulations*: section 86]

The inner and outer labels of a NHP must contain a list of information that helps consumers make more informed choices about products they take. Information such as the product number (natural product number - NPN, or drug identification number - DIN) and lot number (preceded by “Lot number”, “Lot No.”, “Lot” or “(L)”) are included in this list of information. [*Natural Health Products Regulations*: sections 90, 91, 93] For NHPs with only one label, all requirements for inner and outer labels outlined in the Regulations must be on that label. [*Natural Health Products Regulations*: section 89] If the immediate container of a NHP cannot accommodate an inner label that includes all information required by the Regulations, then small packaging is permitted. For small packages having minimal space for labelling, only a limited amount of information is required [*Natural Health Products Regulations*: section 94]. When a product meets the requirements for tablet disintegration, the label must indicate such information. [*Natural Health Products Regulations*: section 103]

The Regulations require security packaging for NHPs sold in packages so consumers know the product has not been opened prior to purchase. [*Natural Health Products Regulations*: section 95] NHPs in pressurized containers must have hazard symbols and cautionary statements displayed on the label to ensure consumers are adequately informed of potential safety concerns. [*Natural Health Products Regulations*: section 96] Child-resistant packaging and pertinent cautionary statements may be required on the label of NHPs that contain ingredients that may be harmful to a child. [*Natural Health Products Regulations*: section 97] When a product licence holder makes any representation on the label of a product regarding the release or availability of its medicinal ingredients to the body, then the relevant requirements for the bioavailability of this product must be met. [*Natural Health Products Regulations*: section 98]

The content and format of the NHPs’ labels must comply with requirements outlined in the Regulations. Required information on the label, such as recommended conditions of use, medicinal ingredients, non-medicinal ingredients, source material and storage conditions [*Natural Health Products Regulations*: section 87] must be displayed in both official languages. The labels of a NHP must be easily legible to the consumer under normal or customary conditions of sale or use. [*Natural Health Products Regulations*: section 88] In addition, no reference to the *Food and Drugs Regulations*, the *Natural Health Products Regulations* or the *Food and Drugs Act* may be included on the label of a NHP unless permitted by law. [*Natural Health Products Regulations*: section 92]

## 2.0 THE LABELLING AND PACKAGING SYSTEM

All NHPs sold in Canada, whether manufactured in Canada or imported from abroad, must meet the labelling requirements set out in Part 5 of the Regulations.

Part 5: LABELLING AND PACKAGING  
Section 86

- 1) No person shall sell a natural health product unless it is labelled and packaged in accordance with these Regulations.
- 2) Despite subsection (1), a person may sell a natural health product that is not labelled and packaged in accordance with these Regulations if the sale is to a manufacturer or distributor.

The Regulations require that a printed version of the proposed label text of the NHP label be submitted with the product licence application. The label text must include the regulatory information [*Natural Health Products Regulations*: part 5, sections 86-98 and 103] and must be presented on the proper panel. However, the layout of the information within a panel does not matter in the application process. Only the text of the label is required, not advertising information or graphics. The label text must be identical to the information provided in the application and any changes to the proposed label text requires the product licence holder to either notify the Natural Health Products Directorate (NHPD) or amend the product licence. The actual label of the NHP must comply with the Regulations and must contain the information that has been approved by the NHPD. Placing a new label on top of an existing label on a NHP is permitted under the Regulations.

For the purposes of this document, a label includes any legend, word, mark or tag attached to, included in, belonging to, or accompanying any NHP. A container is the blister pack, bottle, cover, sachet, strip pack, tube, vessel, vial or other similar article that covers the NHP. A package includes anything in which any NHP is wholly or partly contained, placed or packed.

While the NHPD recommends that new labels which meet the requirements of the Regulations be used once a product licence is issued, old labels that comply with the *Food and Drug Regulations* may be used throughout the transition period for NHPs that have drug identification numbers (DINs). All NHPs are required to meet the labelling and packaging requirements of the *Natural Health Products Regulations* by the end of the transition period for product licences, December 31, 2009. New products not on the market before January 1, 2004, must comply fully with the labelling and other requirements of the Regulations, before sale in Canada.



### 3.0 GENERAL LABELLING REQUIREMENTS

There are two main labels required for NHPs: the outer label and the inner label. An outer label means the label on or affixed to the outside of a package of a NHP. An inner label means the label on or affixed to an immediate container of a NHP. An immediate container means the container that is in direct contact with a NHP. When a proposed label text is submitted, the text corresponding to the inner and/or outer label must be clearly identified.

Leaflets or tags attached to the NHP are also considered labels and must comply with the outer labelling requirements. The outer and inner label must contain what is called a principal display panel. The principal display panel is that part of the inner or outer label that is applied to all or part of the principal display surface. This surface is the one that is displayed or visible under normal or customary conditions of sale or use. When a proposed label text is submitted, the text corresponding to the principal display panel on the inner and/or outer label must be clearly identified.

#### Principal Display Surface

Part or type of container displayed under normal conditions of sale or use	Principal display surface
Side or surface	Total area of such surface, excluding the top and bottom
Lid	Total area of the top surface of the lid
No side or surface	Any 40% of the total surface area that can be displayed, excluding the top and bottom
Bag with sides of equal dimensions	Total area of one of the sides
Bag with sides of more than one size	Total area of one of the largest sides
Wrapper or confining band too narrow to have a display surface	Total area of one side of a ticket or tag attached to the container

### 3.1 Outer Label Requirements

[*Natural Health Products Regulations*: sections 93(1) and (2)]

The following information is required on the outer label of a NHP.

On the principal display panel:

- brand name;
- product number;
- dosage form;
- the word “sterile” if the product is sterile; and
- net amount in the immediate container in terms of weight, measure or number.

On any panel:

- name and address of the product licence holder;
- name and address of the importer, when applicable;
- common name of each medicinal ingredient;
- proper name of each medicinal ingredient, if the proper name is not the chemical name;
- quantity of each medicinal ingredient per dosage unit;
- potency of each medicinal ingredient, if any;
- recommended use or purpose;
- recommended route of administration;
- recommended dose;
- recommended duration of use, if any;
- risk information (cautions, warnings, known adverse reactions and contraindications);
- recommended storage conditions, if any;
- lot number;
- expiry date;
- description of source material of each medicinal ingredient;
- non-medicinal ingredients; and
- the quantity of mercury contained in the product if it contains mercury or its salts or derivatives as a non-medicinal ingredient.

### **How to Meet the Requirements**

The proposed label text must be written either in English or French, but preferably in the same language as the majority of the submission. If label texts are provided in English and French, only one will be reviewed.

**Brand name.** This is the name used to distinguish the product. The brand name should appear on the label as the identifiable name of the product. When there are multiple brand names used for the product, each should be listed on the proposed label text label. The brand name of a NHP must not be misleading to the public (see section 9 of the *Food and Dugs Act*, below):

(a) No person shall label, package, treat, process, sell or advertise any natural health product in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

(b) A natural health product that is not labelled or packaged as required by, or is labelled or packaged contrary to, the *Natural Health Products Regulations* shall be deemed to be labelled or packaged contrary to subsection (a).

**Product number.** This is a number assigned to each NHP approved to be marketed under the Regulations as an indication of authorization by the NHPD. (e.g. NPN 8000 0001).

Part 5: LABELLING AND PACKAGING  
Product Number  
Section 91

Every product number required by these Regulations to be shown on a label of a natural health product shall

- (a) in the case of a homeopathic medicine, be preceded by the designation “DIN-HM”; and
- (b) in any other case, be preceded by the designation “NPN”.

All NHPs, except homeopathic medicines, must be identified by the prefix NPN (natural product number), followed by the product number assigned by the NHPD and granted through the product licence review process. All homeopathic medicines must be identified by the prefix DIN-HM, followed by the product number assigned by the NHPD and granted through the product licence review process.

**Dosage form.** This must be specified on the principal display panel of the label. For example, “30 Tablets” should be displayed on the label. When the dosage form appears in the brand name of the product, the dosage form does not have to be repeated, for example “Vitamin C Tablets”.

**Sterile products.** This must be specified on the principal display panel of the label, if applicable. Sterile products are free from viable micro-organisms. See the *Good Manufacturing Practices Guidance Document* for the requirements for sterile products under the Regulations.

**Net amount.** This must be specified on the principal display panel of the label. When multiple net amounts are used for the product, each should be listed on the proposed label text. The net amount is the total number of dosage units in the immediate container, by weight, measure or number. The net amount must be listed in the appropriate units:

- mass: for products that are solids but are not in discrete (i.e. separate) dosage forms (e.g. 500 g of powder);
- count: when a discrete dosage form is present (e.g. 100 capsules); or
- volume: for products in liquid form but not in discrete dosage forms (e.g. 500 ml of syrup).

The following metric symbols are considered bilingual (and should not be followed by a period):

- mg (milligrams), mcg, µg (micrograms);
- g (grams);
- kg (kilograms);
- ml, or mL (millilitres); or
- l, or L (litres).

**The name and postal code of the product licence holder or importer, when applicable.** The minimum contact information for NHP labels are as follows:

- for domestic product licence holders: name of the product licence holder and postal code;

- for foreign product licence holders: name of the product licence holder and postal code AND the name and postal code of the Canadian importer.

This information can be affixed to the product as a separate permanent sticker, or included on any other panel.

**Medicinal ingredients.** The medicinal ingredients of a NHP must be listed on the label. It is recommended that the medicinal ingredients be listed by proper name, and the corresponding common name of that ingredient should be in parentheses next to the proper name or separated by a comma. However, there is no regulatory requirement to use this format. For example, “Medicinal ingredient: *Echinacea angustifolia* (Echinacea)” or “Medicinal ingredient: *Echinacea angustifolia*, Echinacea”.

When the proper name is a chemical name, the common name must be listed on the label. For example, for the proper name of arginine, the proper name is (S)-2-amino-5-[(aminoiminomethyl)amino]pentanoic acid, the common name, arginine, needs to be listed on the label.

For the listing of homeopathic ingredients, the following examples of the common name, proper name and source material apply:

*Arsenicum album*, Arsenic trioxide  
*Apis mellifica*, Apis mellifera (whole bee)  
*Berberis vulgaris* (bark of root)  
*Chloroformum*, Chloroform

These examples are given to increase clarity in the naming of homeopathic ingredients. All other labelling requirements for homeopathic medicines are applicable. Also, these examples only cover the English labelling requirements for homeopathic medicines.

**Quantity (and potency, if any) of each medicinal ingredient per dosage unit.** For each medicinal ingredient, the quantity per dosage unit must be associated with the proper name or with the common name if the proper name is the chemical name. The authorized potency of that medicinal ingredient must also be stated, if any. For example, “Medicinal ingredient: Each tablet contains *Echinacea angustifolia* (Echinacea) (root), 1000 mg of an extract standardized to 1.2% (v/w) volatile oil”. It is also recommended that the medicinal ingredients be listed in descending order of quantity.

For expressing extract quantities, it is recommended that the medicinal ingredient, the quantity per dosage unit, the extract ratio and quantity dried equivalent be listed as following:

Black Cohosh (6:1 extract)...40 mg  
 (*Actaea racemosa*) (root) equivalent to 240 mg of Black Cohosh

**Recommended use or purpose.** All NHPs must have a health claim on their label that link the product to a disease or health-related condition (see the *Evidence for Safety and Efficacy of Finished Natural Health Products Guidance Document*). The health claim must comply with Section 3 of the *Food and Drugs Act* as they apply to NHPs:

1. No person shall advertise any NHP to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.
2. No person shall sell any NHP
  - (a) that is represented by label, or
  - (b) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.
3. Except as authorized by regulation, no person shall advertise to the general public any contraceptive product or NHP manufactured, sold or represented for use in the prevention of conception.

In other words, health claims that refer to diseases or health-related conditions listed in Schedule A are not permitted on the label. Claims for traditional use must be prefaced with qualifiers such as “traditionally used...” If the claim uses terminology specific to a particular culture or system of medicine, that culture or healing paradigm of medicine must be specified in the claim (e.g. “Traditionally used in Ayurvedic medicine to stimulate the digestive fire or increase agni.”). If both traditional and scientific evidence is available to support a proposed claim, the applicant may choose whether to use the wording “traditionally used...” If a health claim is supported only by scientific evidence, it must not include the words “traditionally used...” (refer to the *Evidence for Safety and Efficacy of Finished Natural Health Products Guidance Document*).

The three types of health claims allowed on the label are therapeutic claims, risk-reduction claims, and structure-function claims (refer to the *Evidence for Safety and Efficacy of Finished Natural Health Products Guidance Document*).

For homeopathic medicines, the qualifier “traditionally used” is not required to precede claims supported by evidence for traditional use (refer to the *Compendium of Monographs* and the *Evidence for Homeopathic Medicines Guidance Document*).

**Recommended route of administration, dose and duration of use, if any.** The recommended route of administration, the number and frequency of dosage units and the duration of use must be presented on the label. If the route of administration is not oral or dental, then the label must clearly indicate such information; otherwise, an oral or dental administration will be implied. It is recommended that the dose be divided by sub-population group when the evidence used to support the recommended conditions of use is specific to only one group. For example, “Adults: Take 1 tablet 3 times per day. Children: Take 1 tablet once per day”. For products attesting to a monograph in the Compendium, when no sub-population is specified for the recommended conditions of use, the sub-population must appear on the label as “Adult”, unless otherwise specified on the monograph.

**Risk information.** The risk information represented on the label must be identical to the information approved by the NHPD through the product licence review process.

**Recommended storage conditions, if any.** When they exist, these must be listed on one of the panels of the label, using one of the following recommended statements:

- “Under normal storage conditions” (dry, well-ventilated premises at 15–25°C);
- “Between 2 and 8°C” or “Must be refrigerated” (under refrigeration, no freezing);
- “Below 8°C” (under refrigeration);
- “Between -5 and -20°C” (in a freezer); or
- “Below -20°C” (in a deep freezer).

When applicable, the label should also say “Store away from children”.

When applicable, recommendations should also be made about the utilization period and storage conditions after opening, dilution, reconstitution of a solution (e.g. “refrigerate after opening” or “should be used within 24 hours after diluting”).

General precautionary statements, such as “avoid direct light” or “store in a dry place” may also be put on the label.

**Lot number.**

Part 5: LABELLING AND PACKAGING  
Lot Number Requirements  
Section 90

Every lot number required by these Regulations to be shown on a label of a natural health product shall be preceded by one of the following designations:

- (a) “Lot number”;
- (b) “Lot No.”;
- (c) “Lot”; or
- (d) “(L)”.

The lot number must be present on the label. It may be represented (printed or stamped) on the product package itself as long as the information is clearly displayed and is sufficiently durable to remain legible throughout the useful life of the product.

**Expiry date.** The earlier of:

- the date, expressed at minimum as a year and month, up to and including which a NHP maintains its purity and physical characteristics and its medicinal ingredients maintain their quantity per dosage unit and their potency, and
- the date, expressed at minimum as a year and month, after which the manufacturer recommends that the NHP should not be used.

Refer to the *Good Manufacturing Practices Guidance Document* for more information on expiry dates for NHPs. The expiry date must be preceded by a term that the general public will clearly understand. Examples are “Expiration”, “Expiration date” and “EXP”.

The date should be clearly displayed on the label and expressed in a manner clearly understood by the general public (for example, the year and month of expiration: 2006 APRIL). In such cases, the last day of the month is assumed to be the actual expiration date. An acceptable abbreviation is the last two digits of the year and two letters for the month (e.g. 06 AL). Common abbreviations for months of the year are JA, FE, MR, AL, MA, JN, JL, AU, SE, OC, NO and DE. The expiry date must be present on the label. It may be represented (printed or stamped) on the product package itself as long as the information is clearly displayed and is sufficiently durable to remain legible throughout the useful life of the product.

**Description of the source material of each medicinal ingredient.** This must be represented on any panel of the label. The source material must be associated with its respective medicinal ingredient. It is recommended that the description of source material be shown in parentheses and that it should follow each of the medicinal ingredients in the list. For example, if the source material is root, it should be presented as “Medicinal ingredient: *Echinacea angustifolia* (Echinacea) (root)”. If the source material is Glucosamine Sulphate 2KCl derived from shellfish exoskeleton, it may be presented in a shortened form following medicinal ingredient as “Glucosamine sulphate (2KCl, from shellfish exoskeleton)”.

In addition, the quantity of the medicinal ingredient must be associated along with the medicinal ingredient being referenced, and not with the source material to ensure the representation is not misleading. When the ingredient is derived synthetically, the word synthetic is not required to be on the label as a descriptor of the source material.

Homeopathic medicines may use an alternative method of listing source material. For detailed information, please see the *Evidence for Homeopathic Medicines* guidance document.

**Non-medicinal ingredients.** These must be presented on the outer label in a list by common name, excluding the quantity, preceded by the words “non-medicinal ingredients” (see the List of Acceptable Non-medicinal Ingredients in the *Evidence for Safety and Efficacy of Finished Natural Health Products Guidance Document* for more information on acceptable non-medicinal ingredients and their inclusion in a NHP). Non-medicinal ingredients may be shown in any order as long as they are identified as non-medicinal ingredients. Refer to the *Evidence for Homeopathic Medicines Guidance Document* to determine the acceptability of non-medicinal ingredients in homeopathic medicines.

**Mercury.** If the NHP contains mercury or its salts or derivatives as a non-medicinal ingredient or preservative, a statement that sets out the quantity of mercury contained in the product must be represented on any panel of the outer label.

**Nutritional Information.** Nutritional information is not permitted on the label as it is likely to create an erroneous impression regarding the character of the NHP. As per section 9 of the *Food and Drugs Act*, no person shall label, package, treat, process, sell or advertise any NHP in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

## 3.2 Inner Label Requirements

[*Natural Health Products Regulations*: section 93(1)]

The following information is required on the inner label of a NHP.

### On the Principal Display Panel:

- brand name;
- product number;
- dosage form;
- the word “sterile” if the product is sterile; and
- net amount in the immediate container in terms of weight, measure or number.

### On Any Panel:

- name and address of the product licence holder;
- name and address of the importer, when applicable;
- common name of each medicinal ingredient;
- proper name of each medicinal ingredient, if the proper name is not the chemical name;
- quantity of each medicinal ingredient per dosage unit;
- potency of each medicinal ingredient, if any;
- recommended use or purpose;
- recommended route of administration;
- recommended dose;
- recommended duration of use, if any;
- risk information (cautions, warnings, known adverse reactions and contraindications);
- recommended storage conditions, if any;
- lot number;
- expiry date; and
- description of source material of each medicinal ingredient.

### How to Meet the Requirements

Refer to the explanations in **chapter 3.1** for each requirement.

Part 5: LABELLING AND PACKAGING  
Exception to the Labelling Requirements  
Section 89

If a natural health product has only one label, that label shall show all the statements, information and declarations required by these Regulations to be shown on both the inner and outer labels.

When applying for a licence to sell a NHP within Canada, a proposed label text must be included as part of the licence application. The proposed label text must be written either in English or French, but preferably in the same language as the majority of the submission. If label texts are provided in both English and French, only one will be reviewed.



Refer to Figure 1 for a description of an acceptable proposed label text of a NHP with three brand names and three corresponding net amounts of a NHP that does not have an outer label (i.e. a NHP that has only one label).

**Figure 1: Example of an acceptable proposed label text of a NHP that has only one label (e.g. a NHP that has an inner label but no outer label)**

N.B.: not to be construed as the final label text copy

**Brand Name(s):** Echinacea Root/Echinacea Herbals/Corporation's Echinacea Root  
NPN# XXX  
30/60/90 Tablets

**Outer and Inner Label:**

Natural Corporation, L4K 6G1  
Imported by: Importer Corporation, M3S 5G5  
Each tablet contains *Echinacea augustifolia* (Echinacea) (root), 1000 mg  
Traditionally used to fight off colds, flus and infections  
Adult: Take 1 tablet 3x/day  
May be used up to 10-21 days

**Risk information:**

Consult a health care practitioner prior to use if you have rheumatoid arthritis  
Consult a health care practitioner prior to use if you have a progressive systemic disease such as tuberculosis, collagenosis, multiple sclerosis, AIDS, HIV infection  
Consult a health care practitioner prior to use if you have auto-immune disorders  
Consult a health care practitioner prior to use if you are taking immunosuppressants  
Consult a health care practitioner if symptoms persist  
Do not use if you are pregnant or breastfeeding  
Do not use if you have an allergy to Asteraceae / Compositae (daisy) family  
Lot.  
Exp.  
Non-medicinal ingredients: gelatin, cellulose  
Do not use if seal is broken

### 3.3 Small Packaging

A small package is an immediate container that is not large enough to accommodate an inner label that complies with the inner label requirements as described in **chapter 3.2**.

The following labelling requirements apply to small packages [*Natural Health Products Regulations*: section 94].

On the inner label:

- brand name;
- a qualitative list by proper name, or by common name when the proper name is the chemical name, that in descending order of quantity per dosage unit, sets out all medicinal ingredients that the product contains (i.e. the list should be in order of quantity, but the quantity itself is not required);
- recommended dose;

- recommended duration of use, if any;
- lot number;
- expiry date;
- product number;
- the word “sterile” if the product is sterile;
- the net amount in the immediate container in terms of weight, measure or number;
- recommended use or purpose; and
- when the package does not have an outer label, a statement that refers the purchaser or consumer to a leaflet that displays the statements, information and declarations required to be shown on the outer label.

On the outer label, if any:

- must be labelled as required in **chapter 3.1**.

### How to Meet the Requirements

Refer to the explanations in **chapter 3.1** for each requirement.

When a leaflet is required because the small package does not have an outer label, then all information required to be on the outer label must be included in that leaflet. The leaflet must be affixed or attached to the immediate container. When a proposed label text is submitted, the text corresponding information present on the leaflet must be clearly identified.

When submitting a proposed label text specifically for a small package, clearly indicate the information as small package requirements.

## 3.4 Security Packaging

A security package means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase. Examples of security packaging are seals, transparent wrappers, cotton swab inserts and lids that are sealed until opened. Security packaging is a requirement for NHPs under the Regulations. Unless it is self-evident in the product packaging, a reference to the security feature must be identified on the proposed label.

Part 5: LABELLING AND PACKAGING  
Security Package Requirements  
Section 95

- 1) Subject to subsection (2), no person shall sell or import a natural health product that is packaged unless the natural health product is contained in a security package.
- 2) Subsection (1) does not apply to lozenges.
- 3) Subject to subsection (4), a statement or illustration that draws attention to the security feature of the security package referred to in subsection (1) shall be shown
  - a) on the inner label; and

- b) if the security feature is part of the outer package, on the outer label.
- 4) Subsection (3) does not apply if the security feature of a security package is self-evident and is an integral part of the immediate container.

## 4.0 HOMEOPATHIC MEDICINES LABELLING

	Homeopathic Medicines with a Non-Specific Recommended Use or Purpose*	Homeopathic Medicines with a Specific Recommended Use or Purpose*
<b>Identification of Medicine Type</b>	One of the following must appear on the label: “homeopathic medicine”, “homeopathic remedy”, “homeopathic drug”, “homeopathic preparation”.	
<b>Statement of Recommended Use or Purpose</b>	No recommended use or purpose, whether explicit or implicit, is permitted on the label.	Label must state the recommended use or purpose in specific, current, unambiguous terms.
<b>Statement of Risk Information</b>	Label must make a statement to the effect of : a) “Consult a health care practitioner if symptoms persist or worsen.” OR b) “To be used on the advice of a homeopathic practitioner, health care practitioner or physician.”	Risk information must be appropriate to the proposed claim. In the absence of other risk statements, the label must include a statement to the effect of “Consult a health care practitioner if symptoms persist or worsen.”

\*Please see the *Evidence for Homeopathic Medicines* guidance document, chapter 7.4.1, for a definition of this category.

### 4.1 Labelling of Nasal, Ophthalmic and Otic Homeopathic Medicines

The labelling of homeopathic medicines for nasal or ophthalmic use must follow the specifications outlined in the most current edition of *Homeopathic Pharmacopeia of the United States* (HPUS) or the *European Pharmacopoeia*.

HPUS ophthalmic solution specifications include:

- a label stating the preservatives used, if applicable; and
- for multiple-dose containers, a warning stating that the preparation should not be used more than 30 days after the seal has broken (these multiple-dose containers should not exceed 15 mL).

HPUS nasal solution specifications include:

- a label stating all preservatives, isotonicity, viscosity and stabilization agents.

Homeopathic medicine ear drops must be labeled with a statement to the effect of “Consult a health care practitioner if you have a fever, ear pain, changes in hearing and/or discharge from the ear.”

## 5.0 SPECIAL LABELLING REQUIREMENTS

### 5.1 Pressurized Containers

A pressurized container is a disposable metal container designed to release pressurized contents by use of a manually operated valve that forms an integral part of the container. Examples of pressurized containers are aerosol containers and metallic pumps or sprays.

Part 5: LABELLING AND PACKAGING  
Pressurized Containers  
Section 96

Sections A.01.061 to A.01.063 of the Food and Drug Regulations apply in respect of natural health products.

Subject to exceptions listed below, the following are labelling requirements for pressurized containers under the *Food and Drug Regulations*.

Principal Display Panel of Inner Label and Outer Label:

- the following hazard symbol:



accompanied by the signal word “CAUTION/ATTENTION”; and

- the primary hazard statement “CONTAINER MAY EXPLODE IF HEATED./ CE CONTENANT PEUT EXPLOSER S’IL EST CHAUFFÉ”.

AND





One Panel of Either the Inner or Outer Label:

- the statement “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”.

The above requirements do not apply, where in relation to a NHP, the design of the container, the materials used in its construction, or the incorporation of a safety device eliminate the potential hazard therein.

Subject to the exceptions listed below, when a NHP is packaged in a pressurized container and has a flame projection of a length set out in column I for items 1 to 3 of Table 1 or a flashback, as set out in column I of item 4 of Table 1, as determined by official method DO-30 (Determination of Flame Projection, dated October 15, 1981), then the requirements for flame projection and flashback containers are as follows:

**Table 1: Hazard Information Required for Flame Projection and Flashback Containers**

Item	Column I Flame Projection Length or Flashback	Column II Hazard Symbol	Column III Signal Word	Column IV Primary Hazard Statement
1.	Less than 15 cm		Caution	Flammable
2.	15 cm or more, but less than 45 cm		Warning	Flammable
3.	45 cm or more		Danger	Extremely Flammable
4.	Flashback		Danger	Extremely Flammable

(From Section A.01.062 of the *Food and Drug Regulations*)

The following are labelling requirements for flame projection and flashback containers.

Principal display panel of inner label and outer label:

- the hazard symbol set out in column II of the same item in Table 1
- the signal word set out in column III of the same item in Table 1 in both official languages;  
and
- the primary hazard statement set out in column IV of the same item in Table 1 in both official languages.

AND

One panel of either the inner label or outer label:

- the statement “Do not use in presence of open flame or spark. / Ne pas utiliser en présence d’étincelles”.

## Exceptions to Flame Projection and Flashback Container Requirements

Condition of Pressurized or Flame Projection/Flashback Container	Exception
Net contents are less than 60 ml or 60 g	Inner label may show only item a) from the pressurized container requirements, above, or items a) and b) from the flame projection and flashback container requirements, above.
Net contents are more than 60 ml or 60 g, but less than 120 ml or 120 g	Inner label may show only items a) and b) from the pressurized container requirements, above, or items a), b) and c) from the flame projection and flashback container requirements, above.
Net quantity is less than 30 ml or 30 g	Hazard symbol must be of a size that can be circumscribed by a circle with a diameter of at least 6 mm.
Net contents are either less than 60 ml or more than 60 ml, but less than 120 ml and are sold in a package	Outer label may show item c) from the pressurized container requirements, above, or item d) from the flame projection and flashback container requirements, above.

## 5.2 Cautionary Statements and Child-Resistant Packages

Cautionary statements are used on labels to set out warnings for the use of certain NHP ingredients in children. When the quantity of certain medicinal ingredients in a NHP exceeds a specified level, child-resistant packaging is required.

<p style="text-align: center;">Part 5: LABELLING AND PACKAGING Cautionary Statements and Child Resistant Packages Section 97</p> <p>Subsections C.01.001(2) to (4) and C.01.028(1), paragraphs C.01.028(2)(b) and (c), section C.01.029, subsection C.01.031(1), paragraphs C.01.031.2(1)(a) and (c) to (g), subsection C.01.031.2(2), and paragraphs C.01.031.2(3)(a) and (c) of the Food and Drug Regulations apply in respect of natural health products.</p>
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A child-resistant package is defined as the following as per subsections C.01.001(2) to (4) of the *Food and Drug Regulations*:

- (2) A child resistant package is a package that
  - (a) when tested in accordance with an acceptable method,
    - (i) in the case of a test group comprising children, cannot be opened
      - (A) by at least 85 per cent of those children prior to a demonstration to them of the proper means of opening the package, and
      - (B) by at least 80 per cent of those children after the demonstration, and
    - (ii) in the case of a test group comprising adults

- (A) can be opened by at least 90 per cent of those adults, and
- (B) where the package is designed so that, once opened and re-closed, it continues to meet the requirements of subparagraph
  - (i), can be so re-closed by at least 90 per cent of those adults; or
- (b) complies with the requirements of one of the following standards, namely,
  - (i) Canadian Standards Association Standard CAN/CSA-Z76.1-M90, entitled *Reclosable Child-Resistant Packages*, published January 1990, as amended from time to time,
  - (ii) European Standard EN 28317:1992, entitled *Child-resistant packaging- Requirements and testing procedures for reclosable packages*, as adopted by the European Committee for Standardization on October 30, 1992, recognized by the British Standards Institution, and effective February 15, 1993 and by the Association française de normalization, and effective December 20, 1992, and which reiterates fully the international standard ISO 8317:1989, as amended from time to time, and
  - (iii) Code of Federal Regulations (United States), Title 16, Section 1700.15, entitled *Poison prevention packaging standards*, as amended from time to time.
- (3) For the purpose of this section, “test group” means
  - (a) in relation to children, a group of at least 200 children who
    - (i) are healthy and have no obvious physical or mental disability,
    - (ii) are between 42 and 51 months of age, and
    - (iii) represent evenly, within plus or minus 10 per cent, each monthly age between 42 and 51 months calculated to the nearest month; and
  - (b) in relation to adults, a group of at least 100 adults who
    - (i) are healthy and have no obvious physical or mental disability,
    - (ii) are between 18 and 45 years of age, and
    - (iii) represent evenly, within plus or minus 10 per cent, each yearly age between 18 and 45 years calculated to the nearest year.
- (4) For the purpose of this section, an amendment from time to time to a standard referred to in paragraph (2)(b) becomes effective 18 months after the date designated by the competent authority and the effective date for the amendment.

The following are labelling requirements for child-resistant packages and cautionary statements as they relate to specific ingredients.



## **Ingredient Requirements (A)**

[*Natural Health Products Regulations*: section 97]

<b>Natural Health Product Ingredient</b>	<b>Inner Label and Outer Label Requirements</b>
Acetylsalicylic acid or its salts or derivatives, salicylic acid or a salt thereof, or salicylamide	When recommended for children, a cautionary statement to the effect that the NHP should not be administered to a child younger than two years of age, except on the advice of a physician
Boric acid or sodium borate as a medicinal ingredient	A cautionary statement to the effect that the NHP should not be administered to a child younger than three years of age
Hyoscine (scopolamine) or a salt thereof	A cautionary statement to the effect that the NHP should not be used by persons suffering from glaucoma or when it causes blurring of the vision or pressure pain within the eye
Phenacetin, either singly or in combination with other NHPs	The following cautionary statement: "CAUTION: May be injurious if taken in large doses or for a long time. Do not exceed the recommended dose without consulting a physician".
Acetylsalicylic acid for internal use	A cautionary statement to the effect that the NHP should not be administered to or used by children or teenagers who have chicken pox or flu symptoms before a physician or pharmacist is consulted about Reye's syndrome. This statement must also refer to the fact that Reye's syndrome is a rare and serious illness.

## **Ingredient Requirements (B)**

[*Natural Health Products Regulations*: section 97]

When a NHP contains:

- salicylic acid, a salt thereof or salicylamide;
- acetylsalicylic acid, or any of its salts or derivatives;
- acetaminophen; or
- more than 5% alkyl salicylates

OR

is in a package that contains:

- more than the equivalent of 250 mg of elemental iron; or
- more than the equivalent of 120 mg of fluoride ion, unless the NHP is intended solely for use in dentists' offices

THEN

- the inner and outer label must carry a cautionary statement to the effect that the NHP should be kept out of the reach of children.

### **Ingredient Requirements (C)**

[*Natural Health Products Regulations*: section 97]

If a NHP package contains:

- more than 1.5 g salicylic acid or the equivalent quantity of any of its salts or salicylamide;
- more than 2 g of acetylsalicylic acid or the equivalent quantity of any of its salts or derivatives;
- more the 3.2 g of acetaminophen;
- more than the equivalent of 250 mg of elemental iron; or
- more than the equivalent of 120 mg of fluoride ion, unless the NHP is intended solely for use in dentists' offices

THEN

- the inner label and outer label must carry a cautionary statement to the effect that there is enough of that ingredient in the package to seriously harm a child.

The inner label and outer label must carry a cautionary statement to the effect that there is enough of that ingredient in the package to seriously harm a child.

The cautionary statements required under Ingredient Requirements (A), (B) and (C), above, must be preceded by a prominently displayed symbol octagonal in shape, conspicuous in colour and on a background of contrasting colour.

#### **(A) Exceptions to Ingredient Requirements**

[*Natural Health Products Regulations*: section 97]

Subject to the (B) Exceptions to Ingredient Requirements, below:

No person may sell a natural health product described in Ingredient Requirements (B) unless:

- when the natural health product is recommended solely for children, it is packaged in a child resistant package,

**OR**

- when the natural health product is not recommended solely for children, at least one of the sizes of packages available for sale is packaged in a child resistant package;

**AND**

When a natural health product described in subsection Ingredient Requirements (B) is packaged in a package that is not a child resistant package, the outer label must carry a statement that the natural health product is available in a child resistant package.

The information under (A) Exceptions to Ingredient Requirements does not apply to a NHP that is:

- sold only in containers that have roll-on or spray applicators or permanently installed wick applicators; and
- intended solely for use in dentists' offices, or packaged for hospital use only.

**(B) Exceptions to Ingredient Requirements**

[*Natural Health Products Regulations*: section 97]

The above ingredient requirements do not apply to a natural health product that is:

- required by the *Food and Drug Regulations* or the *Narcotic Control Regulations* to be sold by prescription;
- in effervescent or powder form;
- in suppository form;
- intended for topical use, unless it is a liquid preparation containing more than 5% alkyl salicylates;
- packaged in a non-reclosable package containing not more than two adult standard dosage units per package;
- in toothpaste form; or
- repackaged by a pharmacist or practitioner at the time of sale.

It should be noted, however, that drug-NHP combinations are always regulated as drugs under the *Food and Drugs Act* and *Food and Drug Regulations*.

### 5.3 Standards and Grades

When a standard or grade (e.g. USP standard) is given for a NHP and is given a name or designation, no person may represent that name or designation on the label of or any advertisement for that NHP unless that NHP conforms to the standard or grade.

A NHP with a prescribed standard will be exempt from the standard of any NHP contained in any publication in Schedule B to the Act in that such a NHP will differ from that standard with respect to colour, flavour, shape and size, if such a difference does not interfere with any method of assay prescribed in any such publication.

Where a manufacturer's standard is used for a NHP, the manufacturer shall make available to the Director, on request, information on that standard and on the method of analysis for the NHP acceptable to the Director.

No person may use a manufacturer's standard for a NHP that provides:

- a lesser degree of purity than the highest degree of purity; or
- a greater variation in potency than the least variation in potency, for that NHP in any publication mentioned in Schedule B to the Act.

### 5.4 Tablet Disintegration

Part 5: LABELLING AND PACKAGING  
Tablet Disintegration Times  
Section 103

Subsection C.01.015(1) and paragraphs C.01.015(2)(d) to (f) of the *Food and Drug Regulations* apply in respect of natural health products.

When a product meets the requirements for enteric coated tablets under Chapter 1 of the *Evidence for Quality of Finished Natural Health Products Guidance Document*, then the label must indicate that the tablet carries an enteric coating or a coating designed to serve a purpose similar to that of an enteric coating (refer to the *Evidence for Quality of Natural Health Products Guidance Document* for the requirements).

Part 5: LABELLING AND PACKAGING  
Medicinal Ingredient Representations  
Section 98

Subsection C.01.012 of the *Food and Drug Regulations* applies in respect of natural health products.

When a product licence holder makes any representation on the label of a product with regards to the release or availability of its medicinal ingredients to the body, then the relevant requirements for the bioavailability of this product must be met (refer to the *Evidence for Quality of Natural Health Products Guidance Document* for the requirements).

## 5.5 Organic Products

“Organic” is a labelling and advertising term that denotes a plant or a plant material, a fungus or a non-human animal material certified to have been produced in accordance with the production, processing, packaging, storage and distribution provisions of the National Standard of Canada for Organic Agriculture. Certification according to other organic standards is also acceptable. Products not within the scope of agricultural standards (e.g. aquatic non-human animal material, algae, cyanobacteria, (“blue-green algae”)) must be certified to have been produced in accordance with an aquacultural or other applicable organic standard.

Organic labeling is voluntary if a NHP is labelled as “organic” or contains organic ingredients. However, it is recommended that the following conditions be met. Products that are certified organic or contain certified organic ingredients may display the following terms and symbols on the label:

- organic;
- organically grown;
- organically raised;
- organically produced;
- biological or biodynamic; and
- symbols for, alternative spellings of, word sets of and phonetic renderings of these words.

Each of the above terms may be preceded by the term *certified*.

## 5.6 Irradiated Products

An irradiated product is a product processed with ionizing radiation in accordance with the *Food and Drugs Regulations*. Irradiation can improve the quality, safety and variety of the product for the consumer.

Labelling of irradiated products is voluntary. However, if a NHP is labelled as irradiated, it is recommended that one of the following statements be used: “Treated with irradiation,” “Treated by irradiation” or “Irradiated”.

## **5.7 Hybrid Products**

Hybrid NHPs are products that contain, in addition to the NHP, a medical device a drug, a food, or a cosmetic. A hybrid product may be subject to one or more of the *Natural Health Products Regulations*, *Medical Devices Regulations*, *Food and Drug Regulations*, or *Cosmetics Regulations*, depending on the ingredients, representation for use (primary purpose) and health claims of that product.

## **5.8 Eucalyptus and Camphor Products**

While eucalyptus and camphor products are safe when used according to the label directions, there is, however, a potential health risk if these products (not authorized for oral use) are accidentally swallowed, specifically by children. As such, the NHPD has resolved to implement appropriate risk mitigation measures to reduce the risk of accidental ingestion of eucalyptus and camphor products. The NHPD is requesting that manufacturers of eucalyptus oil and camphor products voluntarily label and package these products in the following manner:

### **Labelling**

All NHPs containing more than 25% eucalyptus oil and/or 2.5% camphor must have a label warning (KEEP OUT OF REACH OF CHILDREN, NOT TO BE TAKEN ORALLY), and directions to contact the Poison Control Centre if accidentally ingested.

### **Security Packaging**

- All NHPs containing, in solid or semi-solid form, more than 25% eucalyptus oil, must be contained in a child-resistant package.
- All NHPs containing, in liquid form, more than 25% eucalyptus oil, must be contained in a child-resistant package, unless the container has a nominal capacity of 15ml or less.
- All NHPs containing, in solid or semi-solid form, more than 12.5% camphor, must be contained in a child-resistant package.
- All NHPs containing, in liquid form, more than 2.5% camphor, must be contained in a child-resistant package, unless the container has a nominal capacity of 15 ml or less.

## 6.0 PRESENTATION OF INFORMATION ON THE LABEL

### 6.1 Content

The following information will explain what requirements on the label must be presented in both English and French.

Part 5: LABELLING AND PACKAGING  
Language Requirements  
Section 87

(1) Subject to subsection (2), when required by these Regulations to be shown on the label, the following information respecting a natural health product shall be in both English and French:

- a) any of the information referred to in paragraphs (a) to (f) of the definition “recommended conditions of use”  
[i.e. its recommended use or purpose, its dosage form, its recommended route of administration, its recommended dose, its recommended duration of use, if any, and its risk information, including any cautions, warnings, contra-indications or known adverse reactions];
- b) the common name and proper name of each medicinal ingredient and each non-medicinal ingredient that it contains;
- c) a description of the source material of a medicinal ingredient; and
- d) its storage conditions.

(2) The common name or proper name of a medicinal ingredient or non-medicinal ingredient shall be shown in any other language if the name does not have an English or French equivalent.

Any other language can be used on the label in addition to the above language requirements, unless otherwise indicated. Bilingual information may be affixed on a separate panel or sticker.

Part 5: LABELLING AND PACKAGING  
Reference to Regulations  
Section 92

No reference, direct or indirect, to the *Food and Drugs Act*, the *Food and Drug Regulations* or to these Regulations shall be made on any label of or in any advertisement for a natural health product unless the reference is specifically required by law.

## 6.2 Format

Part 5: LABELLING AND PACKAGING  
Presentation of Information  
Section 88

The statements, information and declarations required by these Regulations to be shown on a label of a natural health product shall be

- a) clearly and prominently displayed; and
- b) readily discernible to the purchaser or consumer of the natural health product under the customary conditions of purchase and use.

A person with normal vision should be able to read the information on the label of a NHP without straining. The information on the label should be set out in a manner that is sufficiently durable to remain legible throughout the useful life of the product or, in the case of a refillable container, the useful life of the container, under normal conditions of transportation, storage, sale and use. Information that the Regulations require to be shown on a label must be shown in a manner easily legible to the consumer under normal or customary conditions of sale or use.

## 6.3 Colour Contrast

The colour contrast must be sufficient to make the required information on the label conspicuous and easy to read, as required in Section 88 of the Regulations. In other words, the colour contrast between the information on the label and the background may be equivalent to at least a 70% screen of black and white. It is recommended that the colours red and green not be used together to avoid problems for consumers who are colour blind.

## **APPENDIX 1: LABELLING TEMPLATE**

### **Label Text Requirements**

#### **Inner Label and Outer Label**

Front Panel (principal display panel):

- brand name;
- product number;
- dosage form;
- “sterile”, if it is sterile; and
- net amount in the immediate container.

Side Panel:

- name and address of the product licence holder;
- name and address of the importer, if any;
- medicinal ingredients;
  - proper name (common name) (source), quantity, potency, extract ratio and quantity dried equivalent (as applicable)
  - proper name (common name) (source), quantity, potency, extract ratio and quantity dried equivalent (as applicable)
  - etc...
- recommended use or purpose;
- recommended route of administration, recommended dose, recommended duration of use, if any;
- risk information: cautions, warnings, contraindications, known adverse reactions;
- recommended storage conditions, if any;
- expiry date; and
- lot number.

#### **Outer Label Only:**

- non-medicinal ingredients; and
  - common name
  - common name
  - etc...
- quantity of mercury.

#### **Bilingual Text:**

- recommended use or purpose;
- dosage form;
- recommended route of administration, recommended dose, recommended duration of use, if any;
- risk information: cautions, warnings, contraindications, known adverse reactions;
- medicinal ingredients;



- proper name (common name) (source), quantity, potency, extract ratio and quantity dried equivalent (as applicable)
- proper name (common name) (source), quantity, potency, extract ratio and quantity dried equivalent (as applicable)
- etc...
- non-medicinal ingredients; and
  - common name
  - common name
  - etc...
- storage conditions, if any.

**Pressurized Container:**

- signal word, primary hazard statement; and
- additional cautions.

**Cautionary statements:** as required.