This is a draft Guidance Document for consultation and should be read in conjunction with the proposed regulatory changes to the *Natural Health Products Regulations* to improve the labelling of natural health product.

Guidance Document: Labelling of Natural Health Products

Table of Contents

1.0 Introduction

1.1 Purpose

The purpose of this guidance document is to help you comply with the labelling requirements for natural health products (NHPs), as outlined in Part 5 of the *Natural Health Products Regulations*. It replaces the previous Labelling Guidance Document published in 2006 and the Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products. You should also refer to the Pathway for Licensing Natural Health Products Making Modern Health Claims, Pathway for Licensing Natural Health Products used as Traditional Medicines and Evidence for Homeopathic Medicines guidance document as applicable, particularly with respect to product health claims.

This guidance document is an administrative instrument. Many of the sections of the guidance document describe requirements in the *Natural Health Products Regulations*, which have the force of law, but the Guidance document itself does not have force of law. When the Guidance document is referring to the requirements of *Natural Health Products Regulations*, or its interpretation, it will say the step is a "must" or is "required". When the guidance document refers to a best practice that does not have the force of law, it will say the step "can" or "should" be done. You are encouraged to use all practices outlined in the guidance

document, even if they are not required, so that consumers can easily understand the details about your NHP and compare it to other products, allowing them to make informed choices. Other approaches may be acceptable. You should discuss other approaches with Health Canada (see section 7.0 (Contact Information)) before you use them to make sure they comply with the *Natural Health Products Regulations*.

Health Canada reserves the right to define requirements not specifically described in this document as part of the product authorization (referred to as the terms of market authorization). Health Canada is committed to ensuring that requirements are justifiable and that decisions are clearly documented. Terms of market authorization may impose additional labelling requirements, but this guide will supersede any previously existing conflicting requirements.

1.2 Scope

This guidance document applies to NHPs as defined in the *Natural Health Products Regulations.* It includes:

- general legibility requirements (for example, contrast and font);
- format requirements, including a standardized Product Facts Table to help users find important information and compare similar products;
- information on applying available flexibilities (when applicable); and
- specific labelling instructions for certain classes of products (for example, homeopathic products).

This guidance document does not include information on product application requirements related to NHP labelling or Health Canada's review process for labels.

1.3 Definitions

Available display surface: the total surface area of a package that is physically available for labelling.

Container: a receptacle, package, wrapper or confining band in which a product is offered for sale but does not include package liners, shipping containers or any outer wrapping or box that is not ordinarily displayed to the consumer. This is based on the definition of "container" in the *Consumer Packaging and Labelling Act*. For clarity, this definition of container includes blister packs, boxes, bottles, covers, sachets, strip packs, tubes, vessels, vials and other similar articles.

Homeopathic product: a natural health product based on homeopathy. Homeopathic products must be manufactured from, or contain as medicinal ingredients, only those substances referenced in a homeopathic monograph in an approved homeopathic pharmacopoeia. They must be prepared in accordance with the methods outlined in an approved homeopathic pharmacopoeia. This is based on the definition of "homeopathic medicine" in the Evidence for Homeopathic Medicines guidance document.

Immediate container: the container that is in direct contact with the product. This is based on the definition of "immediate container" in the *Natural Health Products Regulations*.

Inner label: the label on or affixed to an immediate container of a natural health product. This is the definition of "inner label" in the *Natural Health Products Regulations*.

Innovative label: a label that acts as an extension to a product's outer label, including content that must be accessible to the consumer at point of purchase and without destroying or compromising the integrity of the label or the package.

Kit (or co-packaged product): a product would constitute a kit where:

a) the package and the natural health product are for use together as a unit;
b) each item of the kit has been approved;
c) the kit is a single treatment, a single course of treatment or needs to be used in a particular sequence; or
d) a brand name has been identified for the combination of products

Label: includes any legend, word, or mark attached to, included in, belonging to, or accompanying a natural health product. This is based on the definition of "label" in the *Food and Drugs Act*. For clarity, leaflets, inserts, innovative labels, tags attached to the natural health product and the electronic Product Facts Table are considered extensions of the label and must comply with labelling requirements.

Lowest risk product: a natural health product that is applied topically or in the mouth that has a local effect and cosmetic-like or minor health benefit. These products are used on the skin, in the oral cavity, or are smelled (for example, mouthwash, cough drops, fluoride toothpastes, aromatherapy). For additional clarity, these products do not rely on systemic absorption or ingestion to achieve their health benefit.

Outer label: the label on, or affixed to, the outside of a package of a natural health product. This is the definition of "outer label" in the *Natural Health Products Regulations*. If there is no outer label, the inner label is also the outer label.

Package: includes anything in which the product is wholly or partly contained, placed or packed that is customarily displayed to the consumer. This is based on the definition of "package" in the *Food and Drugs Act* and adapted for a natural health product context.

Point: the unit of measurement for type size that is known as a PostScript point and is equal to 0.3527777778 mm. This is the definition of "point" in the *Natural Health Products Regulations*.

Principal display panel: the part of the label that is displayed or visible under normal or customary conditions of sale. For most products, the principal display panel is found on the immediate container. However, it may be on an outer receptacle or package, if the product has one. For inner labels, the principal display panel refers to the most visible part of the label that would be presented to a consumer at the point of sale. This definition is adapted from the *Consumer Packaging and Labelling Regulations*.

Principal display surface: The principal display surface is the part of the package that is available for labelling and that is displayed or visible under normal or customary conditions of sale. This is based on the definition of "principal display surface" in the *Consumer Packaging and Labelling Regulations*. Further clarification is provided in Table 1, below.

Table 1. 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 (such as a can or bottle)	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
Bags 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

Small package: a package where the immediate container is not large enough to include an inner label that includes the required information and format by section 93 of the *Natural Health Products Regulations*. Different than "very small package."

Traditional product: a natural health product based on traditional medicine. Traditional medicine is defined as medicine based on the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. This is based on the definition of "traditional medicine" in the Pathway for Licensing Natural Health Products used as Traditional Medicines.

Very small packages: those packages for which the available surface area for the outer label is 77.5 cm² or less. If there is no outer label, the package is very small if the inner label is 77.5 cm² or less. As outlined in the *Natural Health Products Regulations.* Different than "small packages."

Table 2. Definition of available surface area

Included	Excluded
• total area of package • bottom of product if can be labelled (providing that the product will not be damaged or leak if turned upside down).	• area destroyed when opened (except single-serve containers) • area where a label cannot be physically applied • area where information cannot be legibly set out or easily viewed • Universal Product Code (UPC)

2.0 Content

You must label and package all natural health products in accordance with the *Food and Drugs Act*, the *Natural Health Products Regulations*, and any other applicable laws, regulations and guidance. All required information on the label must be in both official languages. You can use International Nomenclature of Cosmetic Ingredients (INCI) for non-medicinal ingredients.

Note: All aspects of the product label must be compliant with the *Food and Drugs Act,* including section 9 which states "No person shall label, package, treat, process, sell or advertise any drug 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."

You cannot reference the *Natural Health Products Regulations* , *Food and Drug Regulations* (in certain situations, such as for pressurized containers), or the *Food and Drugs Act* on the label unless allowed by a published Health Canada policy or guidance.

According to the *Natural Health Products Regulations*, product labels (including both inner and outer labels) must have specific information, such as the Natural Product Number (NPN) and lot number. The regulations say where certain information must be located, for example on the principal display panel or in the Product Facts Table. They also say what formatting can be used, including specific font styles, size and contrast. In addition, labels must be legible to consumers under normal conditions of sale or use. There are flexibilities (other formatting options) for some products, including those in small packages. See section 4.0 (Flexibilities) for more information. There are also exemptions for some types of products from certain labelling requirements, see section 5.0 (Exemptions) for more information.

Marketing information on natural health product labels must be outside the Product Facts Table and must be in line with the *Food and Drugs Act*, *the Natural Health Products Regulations*, the *Competition Act*, Health Canada guidance, and any supplemental advertising pre-clearance agencies guidance.

2.1 Information required on the principal display panel of the inner and outer labels

You must include the following information on the principal display panel of both the inner and outer labels. If there is only one label, you must put the information on the principal display panel of that label. See section 4.0 (Flexibilities) for more information on other formatting options if the package cannot fit an inner label with all the required information.

- **Brand name**
  This is the name used to distinguish or identify the product. If there are multiple brand names used for the product, use only one. Note: you shall not

use a brand name that implies a recommended use that is different than the approved terms of market authorization for that product. This would be considered a violation of section 9 of the *Food and Drugs Act*.

- **Product number**
  If Health Canada authorizes your product, you will get a product number from Health Canada after submitting a product licence application. It must be clearly identified on the label by the prefix NPN for Natural Product Number, or the prefix DIN-HM for Drug Identification Numbers for homeopathic products.

- **Dosage form**
  The dosage form includes, for example, "Tablets", "Gels", etc. When the dosage form appears in the brand name of the product, the dosage form does not have to be repeated (for instance, "Vitamin C Tablets").

- **"Sterile" (if applicable)**
  Sterile products must be free from viable micro-organisms (refer to the Good Manufacturing Practices Guidance Document and the Quality of Natural Health Products Guide for the requirements for sterile products under the *Natural Health Products Regulations*).

- **Net amount in the immediate container in terms of weight, measure or number**
  The net amount is the total number of dosage units in the immediate container, by weight, measure or number. When multiple net amounts are used, each should be listed on the label. The net amount must be listed in the appropriate units:

Table 3. Net Amounts

Net Amount	Definition
Mass	For products that are solids but are not in separate dosage forms (for example, 500 g of powder)
Count	When a discrete dosage form is present (for example, 100 capsules)
Volume	For products in liquid form but not in discrete dosage forms (for example, 500 mL of syrup)

A metric symbol used for the abbreviated unit of measure is considered bilingual. Abbreviated symbols should not be followed by a period. If the complete word is being used, it must appear in both English and French. Table 4 provides more details on how to display different units of measure.

Table 4. Units of Measure

Complete Word – English	Complete Word – French	Correct Bilingual Abbreviations
Colony forming unit(s)	nombre d'unités formant colonies	CFUs
gram(s)	gramme(s)	G
kilogram(s)	kilogramme(s)	Kg
litre(s)	litre(s)	L or l
microgram(s)	microgramme(s)	Mcg
milligram(s)	milligramme(s)	Mg
millilitre(s)	millilitre(s)	mL

2.2 Information required on the outer label

You must include the following information on the outer label, or if there is no outer label, on the inner label:

- **A Product Facts Table (see details below in section 2.4)**
- **The name of the product licence holder or importer (as applicable)**
- **Recommended route of administration**
- **Lot number**
  One of the following references should come before the lot number:
  - "Lot number";
  - "Lot No.";
  - "Lot"; or
  - "(L)".
- **Expiry date**
  The expiry is the earlier of:
  - the date until which an NHP:
    - maintains its purity and physical characteristics and

  - its medicinal ingredients maintain their quantity and potency per dosage unit; or
- the date after which the manufacturer recommends that the natural health product should not be used.

The expiry date should come after a term that the general public will clearly understand, for example "Expiration", "Expiry date" or "EXP".

The expiry date should be expressed as a year and month. The year and month should be separated by a dash "-" or a slash "/". You should not use a day of expiry. If you must use a day, you should use the last day of the month and use letters for the month to avoid confusion. If you use the complete word for the month, it must appear in English and French. You should use all four numbers for the year to avoid confusion with the month or day. Table 5 shows the recommended expiry date formats. Table 6 shows the bilingual month abbreviations.

Table 5. Recommended Expiry Date Formats

Using the example of January 31, 2020 as an expiry date:

Recommended Formats	Examples	Formats Not Recommended
EXP YYYY-MM-DD	EXP 2020-JA-31 EXP 2020-01-31 (when only the last day of the corresponding month is used)	EXP JA-20 EXP 2020-01-21 (when the last day of the corresponding month is not used)
EXP DD-MM-YYYY	EXP 31-JA-2020 EXP 01-31-2020 (when only the last day of the corresponding month is used)	EXP 20-JA EXP 21-01-2020 (when the last day of the corresponding month is not used)
EXP MM-DD-YYYY	EXP JA-31-2020 EXP 31-01-2020 (when only the last day of the corresponding month is used)	EXP 01-21-2020 (when the last day of the corresponding month is not used)
EXP YYYY-MM	EXP 2020 JANUARY	

	EXP 2020-JA EXP 2020-01	
EXP MM-YYYY	EXP JANUARY 2020 EXP JA-2020 EXP 01-2020	

Table 6. Acceptable Bilingual Month Abbreviations

Abbreviation	English	French
JA	January	Janvier
FE	February	Février
MR	March	Mars
AL	April	Avril
MA	May	Mai
JN	June	Juin
JL	July	Juillet
AU	August	Août
SE	September	Septembre
OC	October	Octobre
NO	November	Novembre
DE	December	Décembre

2.3 Information required on the inner label

If the natural health product has both an inner and outer label, the following information must be on the inner label. All content requirements should align with the descriptions outlined in Table 7 (Product Facts Table Content):

- The name of the product licence holder or importer (as applicable)
- The contact information of the contact person who represents the product licence holder or importer (address, telephone number, email address or website address)
- Medicinal ingredients, quantity of each ingredient by dosage unit, and potency of each ingredient (if applicable)
- Use or purpose
- Route of administration
- Dose
- Duration of use
- Allergy alert, if applicable, including the source of the food allergen or gluten

- Contains aspartame, if applicable
- Other risk information (including those listed in sections 7.d to 7.d.10 in Table 7 and as per the terms of the product's market authorization)
- Other information (for example, recommended storage conditions)
- Lot number
- Expiry date

2.4 Information required in the Product Facts Table

You must include either:

- A bilingual Product Facts Table or
- An English Product Facts Table AND a French Product Facts Table

The Product Facts Table must be on the outer label and can be shown horizontally or vertically. If your product does not have an outer label, the information is required on the inner label. Information in the Product Facts Table does not have to be repeated elsewhere on the label.

The title, headings, and subheadings must appear in the order shown in Table 7. If a subheading is not applicable, it does not need to be included. The information in the Product Facts Table must reflect the terms of the product's market authorization and must not include promotional wording (for example "improved formulation", "fast acting", or "recommended by 4 out of 5 experts,").

For labels that are too small for a Product Facts Table, see section 4.1 (Flexibilities) for more details.

The requirement for a Product Facts Table does not apply to:

- products with very small packages,
- where the recommended duration is one day or less,
- where the immediate container includes three dosage units or less, or
- for lowest risk products.

See section 5.0 (Exemptions) for more information.

With respect to a "kit" or co-packaged products, Product Facts Tables are required on the outer label of the kit or co-packaged products. There must be a separate Product Facts Table for **each** natural health product in the kit (in other words, each product with a Natural Product Number (NPN) or Drug Identification Number – Homeopathic Products (DIN-HM)). The principal display panels and Product Facts

Tables of the natural health product(s) in the kit or co-package must be accessible at the point of sale without breaking the outer package. You should also print the Product Facts Table on the package of each natural health product, in addition to the outer package of the kit or co-packaged products, whenever possible. The outer label of the kit or co-package must also comply with the requirements for any other types of products included in the kit or co-package (for example, a medical device, non-prescription drug, or a cosmetic). Refer to the respective regulations of the other product types, such as the *Medical Devices Regulations*, the *Food and Drug Regulations*, or the *Cosmetic Regulations* for label requirements specific to those products.

Table 7. Product Facts Table Content

	Title / Heading / Subheading	Description and comments regarding content
7.a	**Product Facts** **Info-Produit** or **Drug Facts** **Info-Médicament**	If the Product Facts Table is split between different panels of the label, each additional part of the table must be titled: • 'Product Facts (continued)' or 'Info-produit (suite)'; or • 'Drug Facts (continued)' or 'Info-médicament (suite)'
7.a.1		If using an electronic Product Facts Table (e-PFT), include where to find it directly below the Product Facts title using the statement: "For full table, visit / Pour tableau complet, visitez www.websitename.ca".
7.b	**Medicinal ingredient(s)** (in each dosage unit) **Ingrédient(s) médicinal (médicinaux)** (dans chaque unité posologique) Note: The heading must include the dosage unit (for example, "in each	List the medicinal ingredients using the proper name. You can use the common name only if the proper name is the chemical name. For additional guidance on proper names and common names, refer to the Natural Health Products Ingredients Database (NHPID). Please note that the Natural Health Products Ingredient Database (NHPID) is updated biweekly. Licence holders should review the "What's New" page for updates affecting their products and revise their product labels when needed. Note: for minerals, the proper name is the medicinal ingredient in each dosage form. The salt form is considered to be its source material. Confusion around labelling of minerals is a serious safety concern. See Annex B for more information.

	tablet", "in each 5 mL", etc.).	Medicinal ingredients should be listed from highest quantity to lowest quantity or in alphabetical order. For each medicinal ingredient, you must also include: i. source material (including strain designations for live microorganisms) associated with the respective medicinal ingredient; The description of source material should be shown in parentheses following each medicinal. For example, "*Echinacea angustifolia* (Echinacea) (root)" or "Glucosamine sulfate (as potassium chloride from shellfish exoskeleton)." Note that "source material" is referred to in the Natural Health Products Ingredient Database (NHPID) as "source materials" and "source ingredients". For clarity, "strain" is not clearly captured by source material in NHPID. ii. Quantity of each ingredient per dosage unit. For topical products, specify the concentration using w/w or w/v. For extract quantities, you should list the medicinal ingredient, the quantity per dosage unit, the extract ratio and quantity dried equivalent in the format shown in the following examples: • Black cohosh (6:1 extract)....40mg (Actaea racemosa) (root) equivalent to 240mg of Black Cohosh OR • Actaea racemosa (Black cohosh) extract....40mg (6:1 equivalent to 240 mg dried root) Claims on the product label regarding the release of, or availability of, medicinal ingredients to the body

		must be properly supported by evidence and must be part of your product authorization, as per section 98 of the *Natural Health Products Regulations*. iii. potency of each ingredient (if any). You can also include method of preparation.
7.b.1		*For homeopathic products…* The following examples for homeopathic products are meant for reference and show the proper name, common name, and source material: *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 medicinal ingredients. All other labelling requirements for homeopathic medicines are applicable, see section 5.2 Labelling Requirements Specific to Homeopathic Medicines of the Evidence for Homeopathic Medicines guidance document as well as the Annex A to this guidance document. For homeopathic products, the dosage unit is not applicable. You should include dilutions here.
7.c	**Use(s)** **Usage(s)**	List the authorized recommended "Use(s)" or "Purpose(s)" (also referred to as "indications for use.") of the product. This is the intended benefit of the product when used according to the recommended conditions of use. Recommended use or purpose is different than marketing claims, which are not in the terms of market authorization but are permissible outside of the Product Facts Table (for example, new and improved formulation). You cannot have use(s) or purposes that refer to treatment, mitigation, diagnosis or cure of diseases or health-related

		conditions listed in Schedule A.1, as per section 3 of the *Food and Drugs Act*. In some cases, you can make prevention claims related to Schedule A.1 diseases or health related conditions. See the Guidance Document: Schedule A and Section 3 to the Food and Drugs Act for more information.
7.c.1		*For traditional products…* The use or purpose for traditional products must come after an approved qualifier, such as "Traditionally used…" and reflect the product's specific culture or healing paradigm as written in the terms of market authorization (for instance, "Traditionally used in Ayurvedic medicine to stimulate the digestive fire or increase agni."). If the use or purpose is based on both traditional and scientific evidence you can choose whether or not to use the wording "Traditionally used…", if consistent with the terms of the market authorization. For products with both non-traditional and traditional use claims, the medicinal ingredient(s) supporting the traditional claim should be included in the recommended use. For example, "passionflower is traditionally used in Herbal Medicine as a sleep aid" or "ashwagandha is traditionally used in Ayurveda as Rasayana (rejuvenative tonic)". If a use or purpose is supported only by scientific evidence, it must not include the words "Traditionally used…"
7.c.2		*For homeopathic products…* For homeopathic products, the qualifier "homeopathic product", "homeopathic medicine", "homeopathic remedy", or "homeopathic preparation" must come before the use or purpose.

		The qualifier must meet the size and contrast requirements outlined in section 5.2 of the *Evidence for Homeopathic Medicines* guidance document.
7.d	**Warning(s)** **Mise(s) en garde**	You should include warning statements, cautions, contraindications, and known adverse reactions in the specific order listed below. Warning statements must match the requirements of the product authorization and comply with any applicable product monographs, the *Natural Health Products Regulations*, and applicable Health Canada labelling guidance. Only the warning subheadings listed below (7.d.1 to 7.d.10) may be used. If there are no warning statements, cautions, contraindications, or known adverse reactions, you do not need to include this section of the Product Facts Table.
7.d.1	**(As applicable, examples only)** **For external use only** **Pour usage externe seulement** **For rectal use only** **Pour usage rectal seulement** **For vaginal use only** **Pour usage vaginal seulement**	Include warning statements regarding route of administration as per the product's terms of market authorization. No additional text is required. If this information is already captured under directions for use, it does not have to be repeated in the Warnings section.
7.d.2.	(As applicable) **Allergy alert** **Alerte aux allergies**	List sources of food allergens and gluten, as per subsection 1(1) of the *Food and Drug Regulations* (Part B) (B.01.010.1) which has also been included in Appendix 1 of this

		document. Sources of food allergens and gluten must be in bold.
	Asthma alert **Alerte à l'asthme**	The "asthma alert" is required if included in the terms of market authorization.
	Contains aspartame **Contient de l'aspartame**	The "Contains aspartame" subheading is required if the product contains aspartame. No additional text related to aspartame is required. You cannot use any other "contains" statements or "substance-free" statements (for example, dye-free, gluten-free) in the Product Facts Table. If true and verifiable, this information can appear elsewhere on the label.
7.d.3	(As applicable) **Flammability warning** **Avertissement – inflammabilité**	As per the *Consumer Chemicals and Containers Regulations*: • include flammability warnings with appropriate signal words when applicable, • include a pressurized container warning, with appropriate signal words if applicable. (See Appendix 2 of this document for more information)
7.d.4	(As applicable) **Choking Warning** **Avertissement – Étouffement**	Include any applicable choking warnings.
7.d.5	**Do not use** **Ne pas utiliser**	List all contraindications applicable to the product. You should include "consumers should not use the product unless a prior diagnosis has been made by a health care professional" when applicable or as set out in the terms of market authorization. You should also include situations when consumers should not use the product under any circumstances, even if a health care professional is consulted.

7.d.6	**Ask a health care practitioner before use (if)** **Consultez un praticien de soins de santé avant l'utilisation (si)**	List all warnings for persons with pre-existing conditions or for persons experiencing particular symptoms. List all interaction warnings, including with other natural health products, drugs, or food. Statements about use in pregnancy and while breastfeeding should be included here, when applicable. Acceptable alternatives for "health care practitioner" are: health care provider, health care professional, doctor, physician, or dentist (where appropriate). Acceptable alternatives for "praticien de soins de santé" are: fournisseur de soins de santé, professionnel de la santé, docteur, médecin, or dentiste (where appropriate).
7.d.7	**When using this product** **Lorsque vous utilisez ce produit**	List the side effects that the consumer may experience. List substances (for example, alcohol, sedatives) or activities (for example, operating machinery, driving a car) that consumers should avoid while using the product.
7.d.8	**Stop use and ask a health care practitioner (if)** **Cessez d'utiliser et consultez un praticien de soins de santé (si)**	List any signs of toxicity or other adverse reactions that would require someone to stop using the product immediately. Acceptable alternatives for "health care practitioner" are: health care provider, health care professional, doctor, physician, or dentist (where appropriate). Acceptable alternatives for "praticien de soins de santé" are: fournisseur de soins de santé, professionnel de la santé, docteur, médecin, or dentiste (where appropriate).
7.d.9	**Other warnings** **Autres avertissements**	Include other required warnings that do not fit under the warnings subheadings. State that additional information is available on other parts of the label and package insert, if applicable (as per the product authorization).

7.d.10	**Keep out of reach of children. Gardez hors de la portée des enfants.**	Include a warning about accidental overdose or ingestion, if applicable. For example, "In case of overdose/ ingestion, call a poison control centre or get medical help right away. / En cas de surdosage ou d'ingestion, appelez un centre antipoison ou obtenez immédiatement une aide médicale".
7.e	**Directions Mode d'emploi**	You must include directions for use, including dose instructions (number and frequency of dosage units) and duration, if applicable. You should also include route of administration. All information must follow the product authorization. Dose instructions for specific sub-populations must reflect supporting evidence and the terms of the market authorization. For example, "Adults (18 years and older) and adolescents (12 to 17 years): Take 1 tablet 3 times per day. Children (6 to 11 years of age): Take 1 tablet once per day." If the terms of market authorization has dosing specific to multiple sub-populations, you may choose to market the product to only one sub-population. In this case, dosage information would apply only to that sub-population. For example: "Children (6 to 11 years of age): Take 1 tablet once per day."
7.f	**Other information Autres renseignements**	This section should be limited to storage or other special instructions (for example, for disposal). If the recommended storage conditions are shown elsewhere on the same label, the heading "Other information / Autres renseignements" is not required in the Product Facts Table. If applicable, recommended storage conditions should be listed using one of the following statements: o "Under normal storage conditions" (dry, well-ventilated premises at 15-25°C); o "Between 2 and 8°C" or "Must be refrigerated" (under refrigeration, no freezing); o "Below 8°C" (under refrigeration); o "Between -5 and -20°C" (in a freezer); or

		○ "Below -20°C" (in a deep freezer). You should include information about how long the product is good for and how it should be stored after opening, dilution, or reconstitution (for example, "Refrigerate after opening" or "Should be used within 24 hours after diluting"). General precautionary statements should also be included in this section, if applicable (for example "Avoid direct light" or "Store in a dry place").
7.g	**Non-medicinal ingredient(s)** **Ingrédient(s) non médicinal (médicinaux)**	Include a list of non-medicinal ingredients by common name. Non-medicinal ingredients should be listed in alphabetical order. Non-medicinal ingredients can be listed using the International Nomenclature of Cosmetics Ingredients (INCI), regardless of the terms of market authorization. Information about preservatives that is required by regulation should appear here (for example, mercurial). This includes the quantity of mercury contained in the product if it contains mercury or its salts or derivatives as a non-medicinal ingredient. Sugar-based ingredients should be grouped together in brackets after the name "sugar(s)" in descending order by weight. This will help consumers identify all of the sources of sugar added to a natural health product and is a similar approach to food labelling.
7.h	**Questions?**	Include the contact information of the product licence holder where consumers can ask questions, report problems, or report adverse events associated with the product. Contact information may include a telephone number, an email address, postal address, or website address. It is

		encouraged, for the purposes of expedited reporting, to use a modern form of contact over a mailing address. This section may also include a symbol of a telephone or telephone receiver (☎ or ✆).

3.0 Format

The information required on the label of natural health products must be clearly and prominently displayed and accessible to the consumer when they buy the product and when they use it. For optimal contrast, all required text must be printed with a single colour that is a visual equivalent of 100% solid black type (100% screen black, dark blue, dark brown, dark green and dark purple are acceptable) on a white or neutral background with a maximum 5% tint of colour. Text must be in a standard sans serif font of at least 6 points, except for non-medicinal ingredients, which must be at least 5.5 points. If using a condensed font, text must be at least 5.5 points, except for non-medicinal ingredients, which must be at least 5 points. Characters must not come into contact with each other, or with the features of the Product Facts Table. Headings and subheadings should be left justified and in bold font.

3.1 Product Facts Table Specifications

Table 8. Format of the Standard Product Facts Table

	Design Element	Format
8.a	Panel	Two panels of the label can be used (one English panel and one French panel). If also using an e-PFT, directions on where to find it should be in the same font style as the headings and in 6 point.

	Design Element	Format
8.b	Font Style and Weight	For all elements, you should use Helvetica Neue 55 Roman for content and should be in regular (not bold or italic) font. You should use Helvetica Neue 75 Bold for headings. Use Boldface font for the table title "Product Facts" and all headings. Subheadings should also be in bold. If Helvetica Neue is not available, the following sans serif fonts can be used: • Helvetica, Helvetica LT Standard, Helvetica Neue LT Standard • Univers, 55 Roman and 65 Bold • Frutiger, 55 Roman and 65 Bold • Arial MT Std, Regular and Bold • Arial and Arial Bold • Benton Sans, Regular and Bold Do not use: • light style of a font family (for example, Helvetica 45 or 47); or • italics (except for Latin terms or headings). Characters must not touch each other or the lines of the Product Facts Table. Character spacing must be standardized to no more than +/-5% of the standard for that font style to ensure the text is easy to read. Where needed, the character width of the type may be reduced horizontally by no more than 10% (in other words, 90% horizontal scale).
8.c	Colour (background and print)	The background colour in the Product Facts Table must be white or a uniform neutral background with a maximum 5% tint of colour. This level of tint provides only a slight colour to a background.

	Design Element	Format	
		For optimal contrast, all text and lines should be printed with a single colour that is a visual equivalent of 100% solid black type. • 100% screen black, dark blue, dark brown, dark green and dark purple are acceptable.	
8.d	Title: Product Facts or Drug Facts	Font:	• Helvetica Neue 75 Bold*
		Font Size:	• You should use 8 point
		Justification:	• Left
		Case:	• In English: First letter of each word in title is capitalized • In French: First letter of the title is capitalized • Bilingual headings may be combined with the two headings separated by a slash: "Product Facts/Info produit" or "Drug Facts/Info-médicament"
8.e	Title: Product Facts (continued) Or Drug Facts (continued)	Font:	• "Product Facts" or "Drug Facts": Helvetica Neue 75 Bold* • "(continued)" or "(suite)": Helvetica Neue 55 Roman*
		Font Size:	• You should use 7 point
		Justification:	• Left
		Case:	• In English: First letter of each word is capitalized for "Product Facts" or "Drug Facts": • Lowercase for "(continued)" (not abbreviated) • In French: First letter of the title is capitalized for "Info produit (suite)" or "Info medicament (suite)" • Bilingual headings may be combined with the two headings separated by a slash: "Product Facts (continued) /Info produit (suite)" or "Drug Facts (continued)/Info médicament (suite)"
8.f	Headings	Font:	• Helvetica Neue 75 Bold*
		Font Size:	• You should use 7 point

	Design Element	Format	
	(for example, Use(s), Warnings, Directions)	Justification:	• Left • Bilingual headings may be combined with the two headings separated by a slash (for example, "Warnings / Mises en garde"). If the table is too narrow to fit the headings on one line, they can be on separate lines. The combined headings should be left justified.
		Case:	• Only the first letter of the first word is capitalized. For example: "Medicinal ingredients"
8.g	Subheadings (for example, Do not use, Keep out of reach of children)	Font:	• Helvetica Neue 75 Bold*
		Font Size:	• 6 point
		Justification:	• Left • Bilingual subheadings may be combined with the two subheadings separated by a slash (for example, "Allergy alert / Alerte aux allergies"). If the table is too narrow to fit the subheadings on one line, they can be on separate lines. The combined subheadings must still be left justified.
		Case:	• Only the first letter of the first word is capitalized. For example: "Do not use"
8.h	Text	Font:	• Helvetica Neue 55 Roman*
		Font Size:	• 6 point
		Justification:	• Left
		Case:	• Sentence case
8.i	Bullets	You can use solid square or solid round bullets. Their size should be consistent with the Product Facts Table content.	

	Design Element	Format
8.j	Bulleted content	You can use bullets on the same line as a heading or subheading, except for the "Warnings" heading. Bulleted content can continue to the next line. For sections with multiple bullets, the end of one bullet should be separated from the beginning of the next by at least one square space the size of the letter "m". Sub-bullets may be used to organize content related to one bulleted statement. These sub-bullets can be smaller than the bullets.
8.k	Box frame, rules and hairlines	Table border: • You should use a 1.5 point weight key line or box frame to border the table • The table border should be rectangular in most cases, but can follow the shape of differently-shaped packages. • Box frames can be adjusted to go around UPCs. Rules (to separate headings, including the "Product Facts" table heading): • You should use 1.5 point weight • The rule must extend to touch each side of the box frame Hairlines (to separate subheadings within the "Warnings" section): • You should use 0.375 point weight • There should be space the width of 2 characters at 6 point font between the end of each hairline and the box frame The distance between rules or hairlines and type should be consistent.

*If Helvetica Neue is not available, an acceptable font as per "Font Style" (8b) above should be substituted.

3.2 Use of Graphics

Use graphics in the Product Facts Table only when they are trademark logos, recommended by Health Canada, or required by the *Natural Health Products Regulations* or the *Consumer Chemicals and Containers Regulations*. For example:

- a red octagon before specific warnings,
- a telephone or telephone receiver icon with the "Questions?" heading,
- graphics linked to an adverse reactions or safety signal assessment, or
- trademark logos for trademarked ingredient names.

You cannot use graphics such as pill sizes, food items or depictions of ingredients in the Product Facts Table. You can use these graphics on the same panel of label if space permits.

3.3 Packaging

Security packaging requirements, as outlined in section 95 of the *Natural Health Products Regulations*, must be followed so customers know the product has not been opened when they buy it. A security package feature can include, for example, seals, transparent wrappers, cotton inserts and lids that are sealed until opened.

You must reference the security feature on the label, unless it is evident in the product packaging. If the security feature is part of the outer package, reference to the security feature must be on the outer label.

Pressurized containers must have hazard symbols and cautionary statements on the principal display panel of the label to ensure consumers are informed of potential safety concerns (as per the *Consumer Chemicals and Containers Regulations*). Please see Appendix 2: Pressurized Containers for more information.

A statement regarding child-resistant packaging and related cautionary statements (for example, "Keep out of reach of children") are required on the label of natural health products that contain ingredients that may be harmful to children. If this information is included in the Product Facts Table, it does not have to be duplicated elsewhere on the package.

3.4 Innovative Labels

You can use innovative labels to fit required content on the label when there is not enough space on the standard label. An example of required content is the information contained in the Product Facts Table. Examples of innovative labels include peel-back, hinge, or fold-out labels. Innovative label formats must comply with applicable regulations and guidance documents. URLs or QR codes are not examples of innovative labels and cannot be used as an alternative to information being presented on the label.

General principles:

1. Innovative labels are considered extensions of the outer label. You can use the flexibilities if you have reduced to a single branding panel (see section 4.0 (Flexibilities)).
2. Consumers must be able to access the content of the innovative label at the time of product selection, before purchase and without destroying or compromising the integrity of the label or the package.
3. If you use an innovative label, you must make sure the following information is visible to the consumer at the point of selection without the customer having to manipulate the innovative label:
    - For products with a Product Facts Table, the "Product Facts" or "Drug Facts" title, the "Medicinal ingredients" and "Use(s)" sections (if the "Use(s)" section has not already been moved to the principal display panel).
        - A statement directing the consumer to the continuation of the table on the innovative label must also be visible.
    - For lowest risk products the list of "Medicinal ingredients" and "Use(s)."

4.0 Flexibilities

4.1 Flexibilities

Some products and package sizes may not have enough space to include the standard Product Facts Table format on the label. Labels may use the series of flexibilities outlined in Table 9 below if a standard Product Facts Table cannot fit on the label.

Using flexibilities does not change the order of the information in the Product Facts Table. This means that some products would have a full table on a label, whereas others may have a partial table on a label and a full table on a tag or leaflet attached to the immediate container, a package insert and/or a URL directing consumers to an electronic Product Facts Table (e-PFT). In all cases, information necessary for the safe selection of the product must appear on the outer label of the physical product.

When moving information outside the Product Facts Table, a note directing the consumer to its location must appear below the Product Facts title, in the font style consistent with the headings. For example, "For full table, visit / Pour tableau complet, visitez www.websitename.ca."

If you are using an e-PFT, you must follow the technical standards for the Canadian Drug Facts Table outlined in the Guidance Document: Electronic Canadian Drug Facts Table Technical Standards. **Note: Using an e-PFT does not replace the use of a Product Facts Table on the physical product label.**

Table 9. Flexibilities available for the Product Facts Table

	Heading / Design element	Flexibility
9.a	**Recommended changes:** Make these changes to fit more information in the available space. They are not required before you can use Level 1, 2, or 3 flexibilities.	
9.a.1	Product Facts	If your Product Facts Table is on more than one panel, you can remove the "Product Facts (continued)" and "Info-produit (suite)" titles or the "Drug Facts (continued)" and "Info-médicament (suite)" titles and point the consumer to continued information (for example, by using an arrow).
9.a.2	Headings	In the "Warnings" and/or "Non-medicinal ingredients" and/or "Use(s)" and/or "Other information" sections, you can begin the text immediately following the heading.
9.a.3	Box frame, rules and hairlines (solid black lines	You can remove the hairlines from "Warnings" section.
		You can reduce the weight of rules to 1.0 point.

	separating headings)	Where multiple panels are sequential, use a single, continuous box frame rather than a frame around each individual panel being used. When applying a continuous box frame, all panels of the Product Facts Table should maintain a consistent orientation. Text should not be within 3.175mm of a fold line.
9.a.4	Font style	You can choose a condensed font. Helvetica Neue 57 Condensed and Helvetica Neue 77 Bold Condensed are approved. If Helvetica Neue is not available, the following condensed fonts are considered acceptable: • Helvetica, Condensed and Bold Condensed • Helvetica LT, Condensed and Bold Condensed • Helvetica Neue LT, Condensed and Bold Condensed • Univers, 57 Condensed and 67 Bold Condensed • Frutiger, 57 Condensed and 67 Bold Condensed • Arial MT Std, Condensed and Bold Condensed • Arial Narrow and Arial Bold Narrow • Benton Sans Condensed, Regular and Medium You can also reduce the character width horizontally by up to 10% (in other words, 90% horizontal scale).
9.a.5	Use(s)	You can move "Use(s)" content to the principal display panel. "Uses" must be consistent with the terms of the product authorization and cannot be combined with promotional statements.
9.a.6	Other information	You can place "Other information" content (for example, storage instructions) elsewhere on the label and remove the heading from the Product Facts Table.
9.b Level 1 Flexibilities You can use Level 1 flexibilities even if you have not used all recommended changes outlined above.		
9.b.1	Bilingual Product Facts Table	Use a bilingual Product Facts Table instead of separate English and French Product Facts Tables.

9.b.2	Condensed font	You can use a 5 point font (when condensed), for the "Non-medicinal ingredients" section and a 5.5 point font (when condensed) for all other Product Facts Table sections.
9.b.3	Non-medicinal ingredients	You can move "Non-medicinal ingredients" outside of the Product Facts Table and place elsewhere on the label. The heading must remain in the Product Facts Table and include directions to where the information is located (for example, "See bottom of carton for list").
9.c Level 2 Flexibilities: You can use Level 2 flexibilities even if you have not used all recommended changes outlined above.		
9.c.1	Non-medicinal ingredients	You may move any "Non-medicinal ingredients" that are not implicated as an allergen from the label to a tag or leaflet attached to the immediate container of the product, a package insert or an electronic Product Facts Table. The heading must be maintained in the Product Facts Table with a note directing the consumer to where the information is located. For example: "See www.websitename.com for further information on Non-medicinal ingredients / Voir www.websitename.com pour plus d'informations sur les Ingrédients non-médicinaux "
9.d Level 3 Flexibilities: You can use Level 3 flexibilities even if you have not used all recommended changes outlined above.		
9.d.1	Medicinal ingredients	You can move the source information for medicinal ingredients from the label to a tag or leaflet attached to the immediate container of the product, a package insert or an e-PFT. The heading must be maintained in the Product Facts Table with a note directing the consumer to where the information is located. The tag, leaflet, package insert, or e-PFT must meet the requirements of the Product Facts Table. Note: strain designations for live microorganisms should not be removed.

		You must include in this section a quantitative list of the medicinal ingredients by their proper name. You may use a common name only if the proper name is the chemical name. It is important to note that in certain cases, the claim could be false and misleading without the use of both the proper and the common name. In those cases, this flexibility would not be appropriate. Potency information may also be moved to an e-PFT, package insert or tag affixed to the product.
9.d.2	Warnings	Point-of-selection warnings (see Table 9) are required on the label, without exception. These include warnings related to route of administration, drowsiness or excitability and should be in bold. Point-of-use warnings (see Table 10) for Category I products may be removed from the Product Facts Table and placed on a package insert or tag affixed to a label. Examples include: "When using this product / Lorsque vous utilisez ce produit" and/or "Stop use and ask a health care practitioner if / Cessez d'utiliser et consultez un professionnel de la santé si". The subheadings of the moved warnings must be replaced with the following text: "Read package insert before use for complete warnings. / Lire la notice d'accompagnement avant l'utilisation."

Table 10. Warnings needed at point-of-selection and point-of-use

Point-of-selection Point-of-selection warnings are needed to make an informed purchasing decision.	**Point-of-use** Point-of-use warnings are needed to safely use the product.
For external/rectal/vaginal use only	
Allergy alert / Asthma alert	
Flammability warning	
Choking warning	
Do not use	
Ask a health care practitioner before use if	Stop use and ask health care practitioner if
Keep out of reach of children	
When using this product (related to drowsiness or excitability)	When using this product (unrelated to drowsiness or excitability)
Other warnings may be needed at point of selection or point of use depending on the nature of the warning, including those identified in Table 7 (7.d to 7.d.10). Please contact Health Canada at the address provided in section 7.0 of this document if further clarification is required.	

4.2 Labelling of Products with Six or More Medicinal Ingredients

If the product has six or more medicinal ingredients, you can display the "Medicinal ingredients" section within the Product Facts Table with the medicinal ingredients, quantity per dosage unit, and potency (if applicable) in one of these ways:

- presented on the same line, separated by bullets; or
- put into columns to show text in both official languages on the same line; or
- left justified text used for one official language and right justified for the second.

You can also use the following subheadings in the "Medicinal ingredients" section:

- vitamins
- probiotics
- minerals
- herbs
- other ingredients

5.0 Exemptions

5.1 Exemptions from the Product Facts Table and other labelling requirements

Products meeting one or more of the following criteria are exempt from the content requirements outlined in sections 2.2 (Information required on the outer label), 2.3 (Information required on the inner label), 2.4 (Information required in the Product Facts Table), 3.1 (Product Facts Table specifications) and 4.1 (Flexibilities):

- products in very small packages (as defined in section 1.3 of this document);
- products where the recommended duration of use is one day or less;
- multiple or single-dose packs providing 3 or less doses of product such as blisters, strips, push-through cards, ampoules or vials attached by a plastic strip, etc.; and
- lowest risk products (as defined in section 1.3 of this document).

For information on labelling requirements for these products, see section 5.2 below. Although you do not have to use a Product Facts Table to show this information, Health Canada encourages you to do so whenever possible.

5.2 Labelling of Exempted Products

This section outlines the labelling requirements that apply to the exempted products listed above in section 5.1.

All content must align with the descriptions outlined in Table 7.

Both the inner and outer labels must show:

- The name of the product licence holder or importer.
- The contact information of the contact person who represents the product licence holder or importer (address, telephone number, email address or website address)
- Medicinal ingredients, quantity of each ingredient by dosage unit, and potency of each ingredient (if applicable)
- Use or purpose
- Route of administration
- Dose

- Duration of use
- Allergy alert, if applicable, including the source of the food allergen or gluten (in bold)
- Contains aspartame, if applicable (in bold)
- Other risk information (including those listed in sections 7.d to 7.d.10 in Table 7)
- Other information (for example, recommended storage conditions)
- Lot number
- Expiry date

The outermost label must show:

- Non-medicinal ingredients
- The quantity of mercury contained in the product if it contains mercury or its salts or derivatives as a non-medicinal ingredient.
- A description of the source material of the medicinal ingredients

For products in very small packages, products where the recommended duration of use is one day or less and products packaged with 3 doses or less, if the required information does not fit on the label, non-medicinal ingredients can be moved from the label to:

- a tag or leaflet attached to the immediate container of the product,
- a package insert, or
- a website.

Non-medicinal ingredients may also be moved to a tag, leaflet, package insert, or website for lowest risk products if, after using 5 point condensed font for non-medicinal ingredients and 5.5 condensed font for all other required information, the required information does not fit on the label.

If there is still not enough space on the label for all the required information, the description of the source material of each medicinal ingredient can be moved to:

- a tag or leaflet attached to the immediate container of the product,
- a package insert, or
- a website.

Lowest-risk products may also remove any point-of-use warnings to a tag or leaflet, package insert, or a website.

Please note: all lowest risk products are still required to meet the font and contrast requirements outlined in section 3.0 (Formatting)

In all cases, if you move information off the label, you must indicate on the label where to find the information.

For multiple or single dose packs, the required label information should be unaffected by the removal of dosage units. You can do this by printing in a repetitive manner (for instance, blister packages should be printed so that the information can be read for individual units after destruction of part of the package).

5.3 Labelling of Products in Small Packages

If the immediate container and its available display surface is not large enough to accommodate the labelling requirements outlined in this guidance document, the labelling requirements in this guidance document can be shown in a leaflet that is attached to the immediate container. However, for these small packages, the inner label must include the following information (and in alignment with Table 7):

- Brand name;
- Medicinal ingredients
- Recommended dose
- Recommended duration of use (if any);
- Lot number;
- Expiry date;
- Product number;
- "Sterile" and “Stérile” if the product is sterile;
- Net amount in the immediate container in terms of weight, measure or number; and
- Recommended use(s) or purpose(s).

6.0 Implementation

From the date that the regulations are signed, there will be a three-year coming into force period for all products, with an additional three-year transition period (for a total of six years) for licenced products. Compliance and enforcement will occur at the manufacturing level. For improved clarity for consumers, Health Canada encourages the implementation of the improved labelling requirements as early as possible.

7.0 Contact Information

For questions about natural health product labelling, contact Health Canada's Natural and Non-prescription Health Products Directorate at hc.nnhpd-dpsnso.sc@canada.ca

ANNEX A: HOMEOPATHIC PRODUCT LABELLING

1.0 Scope

This Annex applies to Health Canada-authorized homeopathic products. These products have product numbers with the prefix "DIN-HM". These labelling requirements are to be applied in addition to the labelling requirements set out in this guidance document, the labelling requirements outlined in the Evidence for Homeopathic Medicines guidance document, and in the applicable monographs. Homeopathic products must meet all applicable requirements in the *Natural Health Products Regulations*.

2.0 Labelling requirements for homeopathic products

2.1 General Labelling Requirements

This section replaces the information on homeopathic labelling outlined in the 2006 NHP Labelling Guidance Document. It also replaces changes that were introduced to homeopathic cough, cold and flu products for children 12 years and under in 2015.

Table A.1 outlines labelling requirements for homeopathic products with specific claims and non-specific claims.

Table A.1. Labelling requirements for homeopathic products

	Homeopathic Products with a Non-Specific Claim	Homeopathic Products with a Specific Claim
Identification of Product Type	One of the following statements is to appear on the label: "Homeopathic Product", "Homeopathic Remedy", "Homeopathic Medicine", or "Homeopathic Preparation" in a minimum font size of 6 on the principal display panel with appropriate contrast.	
Statement of Recommended Use or Purpose	Do not put a recommended use or purpose on the label.	You must put the recommended use(s) or purpose(s) on the label in specific, current, unambiguous terms, or, when

	Homeopathic Products with a Non-Specific Claim	Homeopathic Products with a Specific Claim
		applicable, in accordance with the monograph.
Statement of Risk Information	Label must state: "Consult a health care practitioner/ health care provider/ health care professional/ doctor/ physician if symptoms persist or worsen" AND "Consult a health care practitioner/ health care provider/ health care professional/ doctor/ physician prior to use if you are pregnant or breastfeeding" (unless evidence is provided which specifically supports the safety of the medicinal ingredients in these subpopulations).	Risk information must be consistent with the terms of market authorization. In the absence of other risk statements, the label must include statements to the effect of: "Consult a health care practitioner/ health care provider/ health care professional/ doctor/ physician if symptoms persist or worsen" AND "Consult a health care practitioner/ health care provider/ health care professional/ doctor/ physician prior to use if you are pregnant or breastfeeding" (unless evidence is provided which specifically supports the safety of the medicinal ingredients in these subpopulations).

2.2 Front-of-Package Disclaimer

All homeopathic products that do not submit modern scientific evidence to support their health claims as part of their product licence application are required to include the following statement on the front of the package "This claim is based on traditional homeopathic references and not scientific evidence."

The format requirements for the statement can be found below:

- Use bold text in a sans serif font with a minimum size of 12 points.

- For optimal contrast, use a single colour that is a visual equivalent of 100% solid black type for the statement text. 100% screen black, dark blue, dark brown, dark green and dark purple are acceptable.
- Use white or a uniform neutral background with a maximum 5% tint of colour for the background of the statement. This level of tint provides only a slight colour to a background.
- If the label surrounding the statement is the same color as the background behind the statement, include a rectangular border around the statement to increase its visibility. The border can be in any colour with sufficient contrast to be visible. The text of the statement must not touch the border. (Note: if the contrast between the colour of the label and the background of the statement creates a natural border, it is not necessary to add an additional border to the statement).

Example:

This claim is based on traditional homeopathic references and not scientific evidence.

Graduated flexibilities for products in small packages:

Some products and package sizes may not have sufficient space to include the front-of-package statement with the formatting outlined above. These products can access the following graduated flexibilities if the statement does not fit. Use the first flexibility before using the second, use the second before using the third:

1. Use a condensed font and reduce the character width horizontally by up to 10% (in other words, 90% horizontal scale).
2. For products in small packages where the label surrounding the statement is white, you can remove the statement border if a natural box or outline is created by the contrast of the package to highlight the information related to the statement. For products in packages for which the available surface area for the outer label is 77.5 cm^2 or less, if the disclaimer does not fit, the font may be reduced so it is equal to 120% of the smallest font used elsewhere on the label. For instance, if the largest font on the label is 6

points, then the disclaimer must be a minimum of 7.2 points. Contrast requirements still apply.

3.0 ADDITIONAL GUIDANCE FOR SPECIFIC TYPES OF PRODUCTS

3.1 Labelling of Nasal, Ophthalmic and Otic Homeopathic Products

The labelling of homeopathic products for nasal or ophthalmic use must follow the specifications outlined in the latest edition of Homeopathic Pharmacopeia of the United States or the European Pharmacopoeia.

Homeopathic Pharmacopeia of the United States 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 (multiple-dose containers should not exceed 15 mL).

Homeopathic Pharmacopeia of the United States nasal solution specifications include a label stating all preservatives, isotonicity, viscosity and stabilization agents.

Homeopathic otic (ear) drops are to be labelled with a statement to the effect of "Ask a doctor if you have a fever, ear pain, changes in hearing and/or discharge from the ear."

3.2 Labelling specific to Nosodes

In addition to the labelling requirements outlined in the rest of this guidance document, nosodes linked to vaccine-preventable infectious disease are to contain the following label statements on the principal display panel in sans serif font with a minimum size of 12 points:

- “This product is neither a vaccine nor an alternative to vaccination.”
- “This product has not been proven to prevent infection. Health Canada does not recommend its use in children and advises that your child receive all routine vaccinations.”

Nosodes linked to infectious diseases are to contain the following label statements on the principal display panel in sans serif font with a minimum size of 12 points:

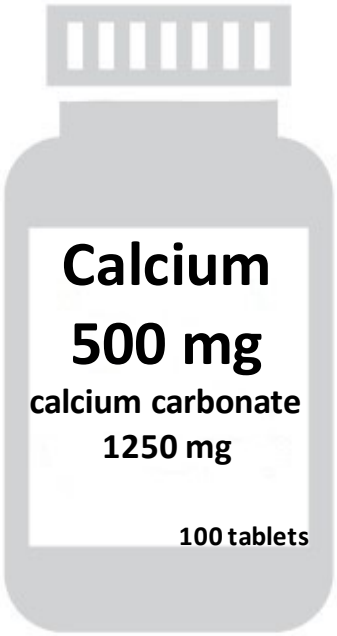
- "This product has not been proven to prevent infection."

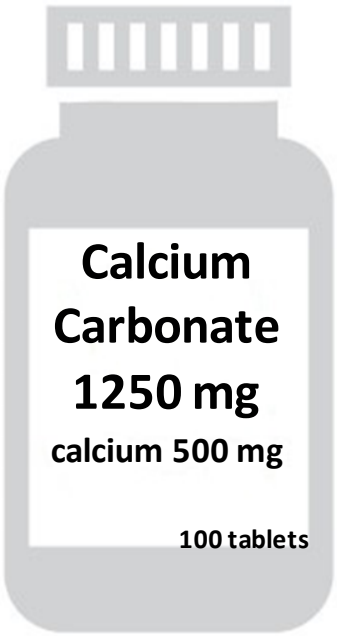
Annex B: Single-entity Mineral Supplements

With regard to single-entity mineral supplements, potencies and content of the active component can differ significantly among various salt forms. The salt form may affect not only the elemental strength, but also absorption characteristics (for example, for iron and calcium products). When examining a product, consumers and health care professionals may find it difficult to distinguish between the dose of an active ingredient's salt form and the dose of the active moiety itself. Confusion between the active moiety or elemental content, and salt content of the mineral as displayed on the label, has led to medication errors including dosing errors.

For mineral supplements in the form of a salt, the following labelling best practices are recommended to support safe use:

- Both the element and the salt with their corresponding strengths should be identified on the principal display panel (PDP) to ensure correspondence with the range of instructions from health care professionals to consumers.
- The strengths should be located in close proximity to the corresponding name (that is, strength of salt near salt name, strength of element near element name). Placing the strength of the elemental content near the salt name, without clearly identifying it as the strength of the element, should be avoided as it may lead to misinterpretation and dosing errors.
- If space is an issue and the principal display panel cannot accommodate both the salt name/strength and the element name/strength, the strength that appears on the principal display panel must correspond to the description of the ingredient, and be placed in close proximity to that name (either the source material or the medicinal ingredient). In other words, if the brand name is the salt name, then the strength must correspond to that of the salt.
- If both the element and salt are listed on the side panel, the strength of both should be specified and clearly associated with the corresponding name, (that is, Elemental calcium 500 mg (calcium carbonate 1250 mg)).
- These labelling best practices are applicable to single-entity mineral salts that may be recommended to consumers by health care professionals in conventional practice settings (that is, iron salts, zinc salts, magnesium salts, and calcium salts with or without vitamin D).
- Examples of acceptable descriptions of a calcium product:





If both the element and its salt with their corresponding strengths cannot be accommodated on the principal display panel, one of the following formats is acceptable:

- Calcium 500 mg
- Calcium Carbonate 1250 mg
- Calcium Carbonate (*along with* '500 mg elemental calcium' *spaced away from the name)*
- Calcium 500 mg (derived from calcium carbonate)

Annex C: Food-like Natural Health Products

For natural health products that are in a food format, nutrition information can be included on the label, along with any other marketing information, as long as it is not false and misleading under the *Food and Drugs Act*. Food products must also follow the requirements outlined in the Food and Drug Regulations and the applicable food and nutrition labelling guidance documents.

Appendix 1: Allergens and Aspartame

This list of food allergens and sources has been included from the *Food and Drug Regulations* (Part B) (B.01.010). It is included in this guidance document for ease of reference, further to requirements for allergen labelling in section 2.4 of this document. If there are any discrepancies between this list and the *Food and Drug Regulations*, follow the *Food and Drugs Regulations*.

Food allergen means any protein from any of the following foods, or any modified protein, including any protein fraction, that is or is derived from any of the following ingredients:

(a) almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts;
(b) peanuts;
(c) sesame seeds;
(d) wheat or triticale;
(e) eggs;
(f) milk;
(g) soybeans;
(h) crustaceans;
(i) shellfish;
(j) fish; or
(k) mustard seeds

Gluten means

(a) any gluten protein from the grain of any of the following cereals or from the grain of a hybridized strain that is created from at least one of the following cereals:

(i) barley,
(ii) oats,
(iii) rye,
(iv) triticale,
(v) wheat; or

(b) any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of the cereals referred to in

paragraph (a) or from the grain of a hybridized strain referred to in that paragraph.

Sulphites means one or more of the following food additives that are present in a prepackaged product: potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium dithionite, sodium metabisulphite, sodium sulphite, sulphur dioxide and sulphurous acid

Aspartame means an artificial sweetener that is a derivative of aspartic acid and phenylalanine. This definition is derived from the Health Canada website.