

Information Session: Improved Natural Health Products Labelling

July 27, 2022

*Natural and Non-prescription Health Products Directorate
Health Canada*

YOUR HEALTH AND SAFETY... OUR PRIORITY.



Zoom Instructions

- Please feel free to turn your camera off and mute your line until we begin the Q&A period.
- If you experience any technical difficulties, please contact nnhpd.consultation-dpsnso@hc-sc.gc.ca.

Outline

- Overview of improved natural health product (NHP) labelling elements:
 - Clearly and prominently displayed label text
 - Standardized Product Facts Table
 - Improved labelling of key allergens
 - Modernized contact information
 - Other labelling requirements (e.g., security packaging)
 - Homeopathic product labelling
- Summary of key changes since *Canada Gazette*, Part I (CGI)
- Next Steps

Key Elements of NHP Labelling

1) Clearly and prominently displayed label text

- Minimum font and contrast requirements (black on white).

2) Standardized Product Facts Table

- Enable consumers and healthcare professionals to quickly identify key product information to reduce medication errors and easily compare products.

3) Improved labelling of key allergens

- Priority food allergens, gluten, sulfites, and aspartame indications must be prominently displayed in the warnings section.

4) Modernized contact information

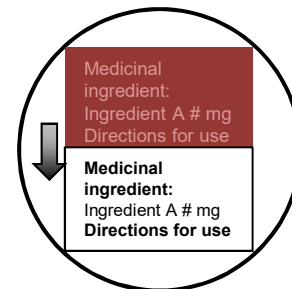
- Require the display of a telephone number, e-mail address, or website address of a contact person.

5) Other labelling requirements

- Security packaging and labelling of exempted products.

6) Homeopathic Products

- In addition to requirements above, HM statement and risk-based evidence standards.



1) Clearly and prominently displayed label text

- Labels must be clearly and prominently displayed (s.88(a)) and readily discernible (s.88(b)) to the consumer when and where they buy the product and when they use it.
- All required text must be printed with a single colour that is a visual equivalent to 100% solid black type on a white or neutral background, with a maximum 5% tint of colour (s.88(c)).
- Text must be in a standard sans serif font (s.88(d)) of at least 6 points, or 5.5 points for non-medicinal ingredients (s.88(g)).

Previous label:

CODE
 Manufactured for/Produit pour:
 Company
 Address
 City
 Customer Service Toll Free
 Number: 1-888-123-4567
 Service aux consommateurs
 sans frais
 Internet: www.name-nom.ca

THIS PACKAGE IS SEALED FOR SAFETY. DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING/L'ÉTiquette d'EMBALLAGE EST
 scellée POUR VOTRE sÉCURITÉ EST BRISÉ ou MANQUANT.
 DIRECTIONS/POUR L'usage: Adults: Take 1 capsule daily. Content may be sprinkled in hot water as a tea. Consult a health care
 practitioner for use beyond 1 month. Adultes: Prendre 1 capsule par jour. Le contenu peut être saupoudré dans de l'eau chaude
 comme une tisane. Consulter un praticien de la santé pour l'utilisation au-delà d'un mois.
 INDICATIONS: Traditionally used in Herbal Medicine to help maintain a healthy immune system. Used in Herbal Medicine to help
 improve physical performance in cases of physical stress. Utilisé traditionnellement en phytothérapie pour soutenir un système
 immunitaire sain. Utilisé en phytothérapie pour aider à améliorer la performance physique en cas de stress physique.
 EACH CAPSULE CONTAINS/CHACQUE CAPSULE CONTIENT:
 Asian Ginseng (4:1) Extract (Panax ginseng, Root)/Extrait de ginseng (4:1) (Panax ginseng, racine) 155 mg
 (Pharming 7 mg ginsenosides, equivalent to 420 mg raw herb/Pharming 7 mg de ginsénosides, équivalent à 420 mg d'herbe brute)
 American Ginseng (4:1) Extract (Panax quinquefolius, Root) 200 mg
 (Pharming 7 mg ginsenosides, equivalent to 420 mg raw herb/Pharming 7 mg de ginsénosides, équivalent à 420 mg d'herbe brute)
 Siberian Ginseng (12:1) (Eleutherococcus senticosus, Root) 125 mg
 (Pharming 0.044 mg eleutherosides, equivalent to 1250 mg raw herb/Pharming 0.044mg d'éléuthérosides, 1 250 mg
 équivalent à 1250 mg d'herbe brute)
 CAUTIONS/PRÉCAUTIONS: Consult a health care practitioner if symptoms persist or worsen. Consult health care practitioner prior
 to use if you have any type of acute infection, if you are taking antihypertensives, anti-psychotics, anti-thrombotics, if you have
 diabetes, or if you are taking antibiotics. Some people may experience insomnia, anxiety, or headache, in which case, discontinue use.
 Consulter un praticien de la santé si les symptômes persistent ou s'aggravent. Consulter un praticien de la santé avant l'utilisation si
 vous souffrez de tout type d'infection aiguë, si vous prenez des hypotenseurs, des antipsychotiques, des anticoagulants, si vous
 souffrez de diabète, ou si vous prenez des antibiotiques. Certaines personnes pourraient éprouver de l'insomnie, de l'anxiété ou des maux
 de tête. En cas contraire, cesser d'utiliser.
 CONTRA-INDICATIONS/CONTRE-INDICATIONS: Do not use if you are pregnant or breastfeeding, or if you have high blood pressure.
 Évitez l'usage chez les enfants. Ne pas utiliser si vous êtes enceinte ou allaitez, ou si vous souffrez d'hypertension. Gardez hors de la
 portée des enfants.
 ALSO CONTAINS/CONTIENT AUSSI: Gelatin, Vegetable Stearic Acid, Vegetable Magnesium Stearate / Glucose, Acidulic
 cellulose, Cellulose de source végétale, stéarate
 CONTAINS/CONTIENT AUSSI: No Lactose, No Wheat, No Soy, No Gluten, No Artificial Colours or Flavour, Yeast Free / Lactose,
 blé, soja, gluten, colorant ou arôme artificiel, ou levure.
 STORE IN A COOL, DRY PLACE.
 KEEP OUT OF REACH OF CHILDREN.
 GARDER DANS UN ENDROIT FRAIS ET SEC.
 HORS DE LA PORTÉE DES ENFANTS.

12345 67890

SIZE
 GROSSEUR

GINSENG
 TRIPLE
 GINSENG
 ROOT
 RACINE DE GINSENG TRIPLE
 Helps maintain a healthy immune system
 and improve physical performance
 Aide à maintenir un système immunitaire sain et améliorer la
 performance physique
 480 mg NPN 0123457
 50 CAPSULES

New label:

Product Facts / Information sur le produit
 For complete table, visit / Pour le tableau complet, visitez www.name-nom.ca

Medicinal Ingredients / Ingrédients médicinaux
 American Ginseng / Ginseng d'Amérique 4:1, 7mg ginsenosides / ginsénosides.....200 mg
 Asian Ginseng / Ginseng d'Asie 4:1, 7mg ginsenosides / ginsénosides.....155 mg
 Siberian Ginseng / Ginseng de Sibirie 12:1, 0.044mg eleutherosides / éléuthérosides.....125 mg

Warnings / Mises en garde
 Do not use if you • are pregnant or breastfeeding • have high blood pressure
 Ne pas utiliser si vous • êtes enceinte ou allaitez • souffrez d'hypertension
 Ask a healthcare practitioner before use if you • have any type of acute infection • are taking
 antihypertensives, anti-psychotics and/or blood thinners • have diabetes • are taking antibiotics
 Consultez un praticien de la santé avant l'utilisation si vous • souffrez de tout type d'infection
 aiguë • prenez des hypotenseurs, des antipsychotiques, et/ou des anticoagulants • souffrez de
 diabète • prenez des antibiotiques
 Keep out of reach of children.
 Garder hors de la portée des enfants.

Directions / Mode d'emploi
 Adults: Take 1 capsule daily. Content may be sprinkled in hot water as a tea.
 Adultes: Prendre 1 capsule par jour. Le contenu peut être saupoudré dans de l'eau chaude comme
 une tisane.

Non-medicinal ingredients / Ingrédients non-médicinaux
 Visit www.name-nom.ca for list
 Visitez www.name-nom.ca pour la liste

Questions? Call / composez le 1-888-123-4567

12345 67890

GINSENG
 TRIPLE
 GINSENG
 ROOT
 RACINE DE GINSENG TRIPLE
 Traditionally used in Herbal Medicine to help
 maintain a healthy immune system and
 improve physical performance
 Utilisé traditionnellement en phytothérapie pour aider
 à maintenir un système immunitaire sain et
 améliorer la performance physique
 90 CAPSULES 480 mg NPN 0123457
 DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING.
 NE PAS UTILISER SI LE SCEAU DE SÉCURITÉ EST BRISÉ OU MANQUANT.
 STORE IN A COOL, DRY PLACE/GARDER DANS UN ENDROIT FRAIS ET SEC.

Clearly and prominently displayed label text - Flexibilities

Flexibilities anyone can apply as required, if the available surface area for the label is too small to accommodate the required information:

- **Reduce the weight** of rules to 1.0 point for box frame and rules; reduce character width horizontally by 10%.
- **Remove hairlines** from the “Warnings” section.
- **Use single continuous box frame** rather than a frame around each panel used; use a bilingual Product Facts Table.
- **Leverage a condensed font**, where non-medicinal ingredients would appear as 5 points and other required information would appear as 5.5 points.
- **Begin** text immediately after headings.

Additional flexibilities if only one branding panel is used:

- **Remove** the +/- 5% size limit for character spacing; remove the 6 point font requirement for spaces between each hairline and the box frame, and permit 3 point font for bullet points.
- **Allow** hairlines and rules to be removed and for content to begin immediately after the section title. The visual separation between sections would be created by requiring each section to start on a new line and the bold font of each section title.
- **Allow** the box frame (outer border) to be removed if the label surrounding the statement is a different colour than the background of the Product Facts Table. Colour contrast would create a natural border, negating the need for a box frame.

Clearly and prominently displayed label text – Exemptions

NHPs meeting the following conditions are exempted from font and contrast requirements, but must still display all of the information contained in a standard Product Facts Table.

1. Products in **very small packages** (available surface area of 90 cm² or less) (Note: both inner labels and outer labels can independently be considered very small packages);
2. Products that contain doses for **one day's use or less**, as per the directions on the label (e.g., samples, sachets, or travel sizes); and
3. Multiple or single-dose packs providing **3 or less doses** of product (e.g., blisters, strips, push-through cards, ampoules or vials attached by a plastic strip, etc.).

Note: These products are not exempted from legibility requirements, and must be clearly and prominently displayed (s.88(a)) and readily discernible (s.88(b)) to the consumer.

2) Standardized Product Facts Table (PFT)

- A “Product Facts / Info-produit” table on the outermost label OR one PFT in English AND one French (s.93.1(1)(i)):
 - Must be on the outermost label and can be shown horizontally or vertically.
 - The PFT must not include any marketing terms or promotional wording.
- The PFT title, headings, and subheadings must appear in the following order:

Product Facts
❑ Medicinal ingredients / Ingrédients médicinaux ❑ Uses / Usages ❑ Warnings / Mises en garde ❑ Directions / Mode d'emploi ❑ Other information / Autres renseignements ❑ Non-medicinal ingredients / Ingrédients non médicinaux ❑ Questions?

Standardized Product Facts Table – Elements

- Medicinal ingredients:
 - proper name or, if the proper name is the chemical name, the common name; quantity of each ingredient per dosage unit; authorized potency; and source material.
- Uses: At least one recommended use or purpose.
- Warnings: risk information, including any cautions, warnings, contra-indications or known adverse reactions associated with the use of the natural health product.
 - Allergens: food allergen source, gluten source, and added sulphites statement and aspartame statement.
- Directions: recommended dose and recommended duration of use, if any.
- Other information: recommended storage conditions.
- Non-medicinal ingredients: qualitative list, by common name of the non-medicinal ingredients; and mercury quantity statement.
- Questions? Contains modernized contact information.

Standardized Product Facts Table – Mock-up

Product Facts
Medicinal ingredients In each xx mL Ingredient A (Ingredient A source material) X mL Ingredient B (Ingredient B source material) X mL
Uses For the relief of •xxxxxxx •xxxxxxxxxxxxxxxx •xxxxxxxxxxx
Warnings Allergens: food allergen, gluten (gluten source), sulfites Do not use if •xxxxxxx •xxxxxxxxxxxxxxxx. Ask a health care practitioner before use if •xxxxxxx •xxxxxxxxxxxxxxxx •xxxxx • if you are pregnant or breastfeeding. When using this product consult a health care practitioner if •xxxxxxxxxxxxxxxx •xxxxxxxxxxxxxxxx. Stop use and ask a health care practitioner if •xxxxx •xxxxxxxxxxx •xxxxxxx. Keep out of reach of children.
Directions Children (6 to 11 years of age): Take xx mL once per day.
Other information Store between 15-25°C. •After opening, Product XXX can be stored for xxxxxxxx. •Do not use if xxxxxx.
Non-medicinal ingredients Gluten source (gluten) List of NMLs List of NMLs List of NMLs List of NMLs List of NMLs
Questions? Call 1-8XX-XXX-XXXX

Standardized Product Facts Table – Flexibilities

Flexibilities anyone can apply as required, if the available surface area for the label is too small to accommodate a standard PFT:

- **Move** source information for medicinal ingredients/non-medicinal ingredients elsewhere in the label.
- **Move** source information for medicinal ingredients/non-medicinal ingredients to a leaflet, or in a Product Facts Table (PFT) on a package insert or website.
- **Move** “Use(s)” section to the principal display panel.
- **Move** “Other information” section from the PFT to the elsewhere on the label and remove heading from PFT.
- **Remove** the “Product Facts (continued)” and “Info-produit (suite)” titles and point the consumer to continued information (for example, by using an arrow) if PFT spans over two panels.

Additional flexibilities if only one branding panel is used:

- **Move** point-of-use warnings to an insert or leaflet.
 - **Move**, for lowest-risk products only, point-of-use warnings to a website.
- **Allow** medicinal ingredients to continue onto the inside of an innovative label if the “Use(s)” has been moved to the principal display panel.
- **Allow** for the abbreviation of Latin binomial names where appropriate (e.g., herbal ingredients, prebiotics and probiotics).

Flexibilities for products with four or more medicinal ingredients:

- **Display** medicinal ingredients quantity per dosage unit and potency on the same line, separated by bullets; or 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.
- **Allow** the use of additional subheadings: vitamins, probiotics, minerals, herbs, other medicinal ingredients.

Standardized Product Facts Table – Flexibilities

Before – CGI Proposal

Full EN & FR PFT with no flexibilities used:

Products Facts	Info-produit
Medicinal ingredients Each drop contains (20 drops correspond to 1 mL). Angelica (Angelica archangelica root (1.2.5-3.5)) 5 µL. Caraway (Carum carvi fruit (1.2.5-3.5)) 5 µL. Celandine (Chelidonium majus herb (1.2.5-3.5)) 5 µL. Licorice (Glycyrrhiza glabra root (1.2.5-3.5)) 5 µL. Bitter candytuft (Iberis amara plant (1.1.5-2.5)) 7.5 µL. Chamomile (Matricaria chamomilla flower (1.2.0-4.0)) 10 µL. Lemon balm (Melissa officinalis leaves (1.2.5-3.5)) 5 µL. Peppermint (Mentha x piperita leaves (1.2.5-3.5)) 2.5 µL. Mary's thistle (Silybum marianum fruit (1.2.5-3.5)) 5 µL.	Ingrédients médicinaux Contenu d'une goutte (20 gouttes correspondent à 1 mL). Angélique (racines d'Angelica archangelica [1.2.5-3.5]) 5 µL. Cumin des prés (fruits de Carum carvi [1.2.5-3.5]) 5 µL. Chélidoine (Chelidonium majus [1.2.5-3.5]) 5 µL. Régliasse (racines de Glycyrrhiza glabra [1.2.5-3.5]) 5 µL. Ibérède blanche (Iberis amara [1.1.5-2.5]) 7,5 µL. Camomille (fleurs de Matricaria chamomilla [1.2.0-4.0]) 10 µL. Mélisse (feuilles de Melissa officinalis [1.2.5-3.5]) 5 µL. Menthe poivrée (feuilles de Mentha x piperita [1.2.5-3.5]) 2,5 µL. Chardon-Marie (fruits de Silybum marianum [1.2.5-3.5]) 5 µL.
Uses For the relief of symptoms associated with functional and motility conditioned gastro-intestinal disturbances e.g. functional dyspepsia and irritable bowel syndrome. •For symptomatic relief of irritable bowel syndrome and functional dyspepsia •Nausea •vomiting •bloating/gas •abdominal cramps •early satiety/feeling of fullness •abdominal/stomach pain.	Usages Pour le soulagement des symptômes associés aux troubles gastro-intestinaux fonctionnels et liés à la motilité, par exemple la dyspepsie fonctionnelle et le syndrome du côlon irritable. •Pour le soulagement des symptômes du syndrome du côlon irritable et de la dyspepsie fonctionnelle •nausées •vomissements •ballonnements/flatulences •crampes abdominales •sensation de plénitude •douleurs abdominales/à l'estomac.
Warnings Do not use if pregnant or breast feeding unless advised by a health care practitioner. Product X® contains 31% alcohol. Patients with illness related to alcohol should avoid Product X®. Ask a health care practitioner before use if you have •a peptic ulcer •liver disorder •epilepsy •if abdominal pain occurs in children under 6. When using this product consult a health care practitioner if •symptoms persist •expected relief is not achieved within 7 days •for use beyond 4 consecutive weeks. Stop use and ask a health care practitioner if signs of liver injury (e.g. jaundice, dark urine or uncoloured stool) or hypersensitivity (e.g. allergy, skin reactions) occur. •Cases of liver injury and hypersensitivity have been reported. Keep out of reach of children.	Mises en garde Ne pas utiliser pendant la grossesse ou l'allaitement, sauf avis contraire d'un professionnel de la santé. Product X® contient 31 % d'alcool. Product X® est à proscrire chez les patients qui présentent une maladie liée à l'alcool. Consultez un professionnel de la santé avant l'utilisation en présence d'un ulcère gastro-duodénal •d'un trouble hépatique •d'épilepsie •de douleurs abdominales chez un enfant de moins de 6 ans. Lorsque vous utilisez ce produit , consultez un professionnel de la santé •si les symptômes persistent •si le soulagement escompté n'est pas obtenu après 7 jours •pour la prise de Product X® pendant plus de 4 semaines de suite. Cessez d'utiliser et consultez un professionnel de la santé en cas de signes de lésions hépatiques (p. ex. jaunisse, urine foncée ou selles décolorées) ou d'hypersensibilité (p. ex. allergie et réactions cutanées). •Des cas de lésions hépatiques et d'hypersensibilité ont été signalés. Garder hors de la portée des enfants.
Directions Shake well before use •Take 3 times a day in some liquid before or with meals according to the following: •Adult (12 years and over): 20 drops •6 to 12 years: 15 drops •3 to 6 years: 10 drops	Mode d'emploi Bien agiter avant l'emploi. •Ajouter le nombre de gouttes voulu (voir ci-dessous) à un peu de liquide et prendre la solution obtenue 3 fois par jour avant ou avec les repas. •Adultes (12 ans et plus) : 20 gouttes •De 6 à 12 ans : 15 gouttes •De 3 à 6 ans : 10 gouttes.
Other information Store between 15-25°C. •After opening, Product X® can be stored for at least 8 weeks. •Do not use if seal around base of screw top is detached or missing.	Autres renseignements Conservé entre 15 et 25 °C. •Une fois ouvert, le flacon se conserve pendant au moins 8 semaines. •N'utiliser que si la bague de sécurité à la base du bouchon à vis est intacte.
Non-medicinal ingredients Ethanol	Ingrédient non médicinal Éthanol
Questions? 1-8XX-XXX-XXXX	Questions? 1-8XX-XXX-XXXX

MADE IN CANADA

MADE IN CANADA

PFT with flexibilities used:

Products Facts/Info-produit
Medicinal ingredients/Ingrédients médicinaux Each drop contains (20 drops correspond to 1 mL). Angelica 5 µL. •Caraway 5 µL. Celandine 5 µL. •Licorice 5 µL. •Bitter candytuft 7.5 µL. Chamomile 10 µL. •Lemon balm 5 µL. •Peppermint 2.5 µL. •Mary's thistle 5 µL. For additional information on medicinal ingredient source and potency see: www.website.com. Chaque goutte contient (20 gouttes correspondent à 1 mL). •Angélique 5 µL. •Cumin des prés 5 µL. •Chélidoine 5 µL. •Régliasse 5 µL. •Ibérède blanche 7,5 µL. •Camomille 10 µL. •Mélisse 5 µL. •Menthe poivrée 2,5 µL. •Chardon-Marie 5 µL. Pour de plus amples informations sur source et l'activité des ingrédients médicinaux, voir : www.website.com.
Warnings/Mises en garde Do not use if pregnant or breast feeding unless advised by a health care practitioner. Ne pas utiliser pendant la grossesse ou l'allaitement, sauf avis contraire d'un professionnel de la santé. Product X® contains 31% alcohol. Patients with illness related to alcohol should avoid Product X®/Product X® contient 31 % d'alcool. Product X® est à proscrire chez les patients qui présentent une maladie liée à l'alcool. Ask a health care practitioner before use if you have •a peptic ulcer •liver disorder •epilepsy •if abdominal pain occurs in children under 6. Consultez un professionnel de la santé avant l'utilisation en présence d'un ulcère gastro-duodénal •d'un trouble hépatique •d'épilepsie •de douleurs abdominales chez un enfant de moins de 6 ans. When using this product consult a health care practitioner if •symptoms persist •expected relief is not achieved within 7 days •for use beyond 4 consecutive weeks. Lorsque vous utilisez ce produit , consultez un professionnel de la santé •si les symptômes persistent •si le soulagement escompté n'est pas obtenu après 7 jours •pour la prise de Product X® pendant plus de 4 semaines de suite. Stop use and ask a health care practitioner if signs of liver injury (e.g. jaundice, dark urine or uncoloured stool) or hypersensitivity (e.g. allergy, skin reactions) occur. •Cases of liver injury and hypersensitivity have been reported. Cessez d'utiliser et consultez un professionnel de la santé en cas de signes de lésions hépatiques (p. ex. jaunisse, urine foncée ou selles décolorées) ou d'hypersensibilité (p. ex. allergie et réactions cutanées). •Des cas de lésions hépatiques et d'hypersensibilité ont été signalés. Keep out of reach of children. Garder hors de la portée des enfants.
Directions/Mode d'emploi Shake well before use •Take 3 times a day in some liquid before or with meals according to the following: •Adult (12 years and over): 20 drops •6 to 12 years: 15 drops •3 to 6 years: 10 drops. Bien agiter avant l'emploi. •Ajouter le nombre de gouttes voulu (voir ci-dessous) à un peu de liquide et prendre la solution obtenue 3 fois par jour avant ou avec les repas. •Adultes (12 ans et plus) : 20 gouttes •De 6 à 12 ans : 15 gouttes •De 3 à 6 ans : 10 gouttes.
Non-medicinal ingredients/Ingrédient non médicinal Ethanol/Ethanol
Questions? 1-8XX-XXX-XXXX

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After – CGI publication

Leveraging all flexibilities available:

Products Facts/Info-produit
For information on medicinal ingredient source, potency, and non-medicinal ingredients see : www.website.com./Pour des informations sur la source et la puissance des ingrédients médicinaux et les ingrédients non médicinaux, voir : www.website.com. Medicinal ingredients/Ingrédients médicinaux Each drop contains (20 drops correspond to 1 mL). Angelica 5 µL. •Caraway 5 µL. Celandine 5 µL. •Licorice 5 µL. •Bitter candytuft 7.5 µL. Chamomile 10 µL. •Lemon balm 5 µL. •Peppermint 2.5 µL. •Mary's thistle 5 µL. Chaque goutte contient (20 gouttes correspondent à 1 mL). •Angélique 5 µL. •Cumin des prés 5 µL. •Chélidoine 5 µL. •Régliasse 5 µL. •Ibérède blanche 7,5 µL. •Camomille 10 µL. •Mélisse 5 µL. •Menthe poivrée 2,5 µL. •Chardon-Marie 5 µL.
Warnings/Mises en garde Do not use if pregnant or breast feeding unless advised by a health care practitioner. Ne pas utiliser pendant la grossesse ou l'allaitement, sauf avis contraire d'un professionnel de la santé. Product X® contains 31% alcohol. Patients with illness related to alcohol should avoid Product X®/Product X® contient 31 % d'alcool. Product X® est à proscrire chez les patients qui présentent une maladie liée à l'alcool. Ask a health care practitioner before use if you have •a peptic ulcer •liver disorder •epilepsy •if abdominal pain occurs in children under 6. Consultez un professionnel de la santé avant l'utilisation en présence d'un ulcère gastro-duodénal •d'un trouble hépatique •d'épilepsie •de douleurs abdominales chez un enfant de moins de 6 ans. Keep out of reach of children. Garder hors de la portée des enfants.
Directions/Mode d'emploi Shake well before use •Take 3 times a day in some liquid before or with meals according to the following: •Adult (12 years and over): 20 drops •6 to 12 years: 15 drops •3 to 6 years: 10 drops. Bien agiter avant l'emploi. •Ajouter le nombre de gouttes voulu (voir ci-dessous) à un peu de liquide et prendre la solution obtenue 3 fois par jour avant ou avec les repas. •Adultes (12 ans et plus) : 20 gouttes •De 6 à 12 ans : 15 gouttes •De 3 à 6 ans : 10 gouttes.
Questions? 1-8XX-XXX-XXXX

MADE IN CANADA

Standardized Product Facts Table – Exemptions

NHPs meeting the following conditions are not required to display the product facts in a PFT format, but must still display all of the information contained in a standard PFT.

1. Products in **very small packages** (available surface area of 90 cm² or less)
(Note: both inner labels and outer labels can independently be considered very small packages);
2. Products that contain doses for one day's use or less, as per the directions on the label (e.g., samples, sachets, or travel sizes);
3. Multiple or single-dose packs providing 3 or less doses of product (e.g., blisters, strips, push-through cards, ampoules or vials attached by a plastic strip, etc.); and

Note: If a NHP meets one of the above three conditions, it is exempt from font, format, contrast and PFT requirements. Label information must still be clearly and prominently displayed and readily discernible to the consumer.

4. Lowest-risk products

- NHPs that have a localized or cosmetic-like effect and are either applied on the skin or in the mouth, or are recommended for aromatherapy or organotherapy (e.g., lozenges, fluoride toothpastes); topical nasal decongestant or cough drops.
- **Additions since CGI: aromatherapy, organotherapy, flower essences, and topical nasal decongestants and counterirritants.**

3) Improved labelling of key allergens

- Products containing a food allergen, gluten or added sulphites (+10 ppm) must display the sub-heading “**Allergens / Allergènes**” in bold type under “**Warnings**” (s.93.1(11)) and list sources of allergens, the word “gluten”, followed by its gluten source in brackets, and sources of sulfites (s.91.2 – s.91.4).
- Food allergens (s.1(1)) are:
 - (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) molluscs;
 - (j) fish; or
 - (k) mustard seeds
- Products containing aspartame must display the statement “Contains aspartame / Contient de l’aspartame” in bold type under “Warnings” (s.93.1(12)).

4) Modernized contact information

- You must display the name of the product licence holder or importer on the outermost label (s.93.1(b)).
- You must display the telephone number, email address or website address of a contact person who represents the product licence holder under the heading “Questions?” in the Product Facts Table (PFT), or elsewhere on the label if the NHP does not require a PFT (s.93.1(18)).

Product Facts (continued)	
Directions Do not chew tablets. Children (6 to 11 years of age): Take x tablet once per day.	
Other information Store between 15-25°C. •After opening, Product XXX can be stored for xxxxxxxxxx •Do not use if xxxxxxxx.	
Non-medicinal ingredients Gluten source (gluten) List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs	
Questions?	Call 1-8XX-XXX-XXXX

5) Other Labelling Requirements

Labelling requirements for products exempted from having to display a PFT and other labelling requirements for products that are not exempted:

Principal display panel of the inner and outer labels	Outer Label	Inner Label
❑ Brand name. ❑ Product number. ❑ Dosage form (e.g., tablets and gels). ❑ “Sterile” (if applicable). ❑ Net amount in the immediate container in terms of weight, measure or number.	❑ Product Facts table (if applicable). ❑ The name of the product licence holder or importer. ❑ Recommended route of administration. ❑ Lot number. ❑ Expiry date.	❑ The name of the product licence holder or importer. ❑ Contact information. ❑ Medicinal ingredients. ❑ At least one use or purpose. ❑ Recommended route of administration. ❑ Dose and duration of use. ❑ “Allergens” statement and sources statement. ❑ Aspartame statement. ❑ Risk information. ❑ Storage information, lot number, and expiry date.

If the product only has one label, it is considered an inner label.

Other Labelling Requirements

1) Security Packaging

- is only required for NHPs that are intended for human use and are:
 - a mouthwash;
 - to be inhaled, ingested or inserted into the body; or,
 - for ophthalmic use (s.95(1)).
- Removal of security packaging requirements for topical NHPs to align with non-prescription drug requirements, effective immediately.
- Security package features include seals, transparent wrappers, cotton inserts, and lids that are sealed until opened.
- Addresses Canada's commitment to amending security packaging requirements and to align with Canada-United States-Mexico Agreement (CUSMA).

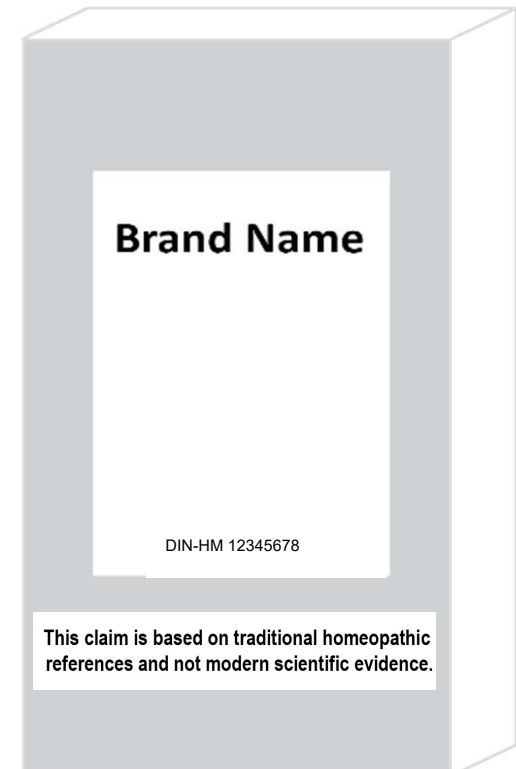
2) Additional administrative amendments to clarify existing rules and minor clarifications to the regulations, which will not impact industry.

6) Homeopathic Product Statement

- Commercially available homeopathic products (HMs) not supported by modern scientific evidence require the following statement on the front of package:
 - **“This/These claim(s) or *This product is/are based on traditional homeopathic references and not modern scientific evidence”**
 - *option for HMs without claims
- Formatting requirements: black, bold, 12 pt text in a sans serif-font on a white background.

Small HM packages – Flexibilities

- If the statement does not fit on the outer label, the font can be reduced to 50% of the largest brand name.
- A minimum 5.5 point font is recommended when 50% of the font size of the largest brand name is very small or when the statement will not fit otherwise.
- There are no flexibilities or exemptions for nosode-specific labelling.



Homeopathic Evidence Standards

- For claims referencing higher-risk claims (i.e., non-self resolving conditions with potential harm to health if product efficacy is underperforming), **modern scientific evidence will be required.**

Claims that would not require scientific evidence Examples:	Claims that would require scientific evidence Examples:
Earache “Symptomatic relief of minor earache”	Ear infection “Temporary relief from inflammation or infection of the ear”
Flu “Symptomatic relief of flu symptoms, including cough”	Fever “Relief of fever”
Minor skin conditions “Temporary relief of minor skin irritation and itching”	Serious skin conditions including psoriasis and eczema “Relief of symptoms associated with eczema eruptions”
Oral Canker Sores “Symptomatic relief of canker sores”	Ulcers other than canker sores “Temporary relief of ulcerative pain”

Note: As is currently required, HM claims always need to include the homeopathic medicine prefix, and must be for symptomatic relief. The examples above show partial claims in order to emphasize differences between lower- and higher-risk claims.

Summary of key changes since *Canada Gazette*, Part I

1) Font and contrast

- Clarification that regulatory information moved to innovative labels, leaflets, package inserts and websites must meet font and contrast requirements.

2) Product Facts Table (PFT) requirements

- Clarification that package inserts and websites must now display standardized PFTs if leveraging flexibilities.
- Exemptions: expansion of the exemption from 77.5 cm² to 90 cm² or less for “very small package.”

3) Allergens

- New requirement of the labelling of “added sulfites”; replacement of “Allergy Alert” with “Allergens.”

4) Modernized contact information

- Mandatory requirement of modernized contact information.

5) Security packaging

- New exemptions to align security packaging exemptions with non-prescription drugs.

6) Introduction of flexibilities for the statement appearing on homeopathic products.

Next Steps: Coming Into Force

- **July 6, 2022:**
 - Amendments to the *Natural Health Products Regulations* to implement improved NHP labelling changes were published in CGI and came into force.
 - Security packaging and administrative amendments came into force immediately, while other provisions have a transition period.
 - Updated guidance documents published on Health Canada's website.
- **July 6, 2025:**
 - Coming into force of new labelling regulations and homeopathic statement for new products (i.e., products licensed on or after July 6, 2022).
- **July 6, 2028:**
 - Coming into force of labelling regulations and homeopathic statement for all products (i.e., products licensed before July 6, 2022).

Questions



Natural and Non-Prescription Health
Products Directorate (NNHPD)

Contact us directly at:

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