Health Canada Santé Canada

NATURAL HEALTH PRODUCT

PROBIOTICS

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

Notes

- By submitting a PLA referencing this monograph, the applicant is attesting that the product will comply fully with the recommended conditions of use and specifications section outlined in this monograph. These include species identification, strain characterization, quantification in colony forming units (CFU), and a complete assessment of virulence properties (including but not limited to: antibiotic resistance profile, virulence factor production, and toxigenic activity).
- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.
- Any non-viable form of the medicinal ingredients found in Appendix I (e.g. heat-killed, thermostabilised) is excluded from this monograph and the compendial application process.

Date March 25, 2019

Proper name(s), Common name(s), Source material(s), Strain(s)

Note

Refer to Appendix I, Table 4 for medicinal ingredients that are excluded from this monograph.

Table 1. Proper name(s), Common name(s), Source material(s), Strain(s) - BACTERIA

Proper name(s)	Common name(s)	Source material(s)	
		Part(s)	Strain(s)[1]
Bifidobacterium adolescentis	*Bifidobacterium adolescentis*	Whole cell	Strain designation
Bifidobacterium animalis subsp. *animalis*	*Bifidobacterium animalis* subsp. *animalis*	Whole cell	Strain designation
Bifidobacterium animalis subsp. *lactis*	*Bifidobacterium animalis* subsp. *lactis*	Whole cell	Strain designation
Bifidobacterium bifidum	*Bifidobacterium bifidum*	Whole cell	Strain designation
Bifidobacterium breve	*Bifidobacterium breve*	Whole cell	Strain designation
Bifidobacterium longum	*Bifidobacterium longum*	Whole cell	Strain designation

Bifidobacterium longum subsp. *infantis*	*Bifidobacterium longum* subsp. *infantis*	Whole cell	Strain designation
Bifidobacterium longum subsp. *longum*	*Bifidobacterium longum* subsp. *longum*	Whole cell	Strain designation
Bifidobacterium longum subsp. *suis*	*Bifidobacterium longum* subsp. *suis*	Whole cell	Strain designation
Lactobacillus acidophilus	*Lactobacillus acidophilus*	Whole cell	Strain designation
Lactobacillus amylolyticus	*Lactobacillus amylolyticus*	Whole cell	Strain designation
Lactobacillus amylovorus	*Lactobacillus amylovorus*	Whole cell	Strain designation
Lactobacillus brevis	*Lactobacillus brevis*	Whole cell	Strain designation
Lactobacillus buchneri	*Lactobacillus buchneri*	Whole cell	Strain designation
Lactobacillus casei	*Lactobacillus casei*	Whole cell	Strain designation
Lactobacillus coryniformis	*Lactobacillus coryniformis*	Whole cell	Strain designation
Lactobacillus crispatus[2]	*Lactobacillus crispatus*	Whole cell	Strain designation
Lactobacillus curvatus	*Lactobacillus curvatus*	Whole cell	Strain designation
Lactobacillus delbrueckii	*Lactobacillus delbrueckii*	Whole cell	Strain designation
Lactobacillus delbrueckii subsp. *bulgaricus*	*Lactobacillus delbrueckii* subsp. *bulgaricus*	Whole cell	Strain designation
Lactobacillus delbrueckii subsp. *delbrueckii*	*Lactobacillus delbrueckii* subsp. *delbrueckii*	Whole cell	Strain designation
Lactobacillus farciminis	*Lactobacillus farciminis*	Whole cell	Strain designation
Lactobacillus fermentum	*Lactobacillus fermentum*	Whole cell	Strain designation
Lactobacillus gallinarum[2]	*Lactobacillus gallinarum*	Whole cell	Strain designation
Lactobacillus gasseri	*Lactobacillus gasseri*	Whole cell	Strain designation
Lactobacillus helveticus	*Lactobacillus helveticus*	Whole cell	Strain designation
Lactobacillus hilgardii	*Lactobacillus hilgardii*	Whole cell	Strain designation
Lactobacillus johnsonii	*Lactobacillus johnsonii*	Whole cell	Strain designation
Lactobacillus kefiranofaciens	*Lactobacillus kefiranofaciens*	Whole cell	Strain designation
Lactobacillus kefiri	*Lactobacillus kefiri*	Whole cell	Strain designation
Lactobacillus mucosae	*Lactobacillus mucosae*	Whole cell	Strain designation
Lactobacillus panis	*Lactobacillus panis*	Whole cell	Strain designation
Lactobacillus paracasei	*Lactobacillus paracasei*	Whole cell	Strain designation
Lactobacillus paraplantarum	*Lactobacillus paraplantarum*	Whole cell	Strain designation
Lactobacillus plantarum	*Lactobacillus plantarum*	Whole cell	Strain designation
Lactobacillus pontis	*Lactobacillus pontis*	Whole cell	Strain designation
Lactobacillus reuteri	*Lactobacillus reuteri*	Whole cell	Strain designation
Lactobacillus rhamnosus	*Lactobacillus rhamnosus*	Whole cell	Strain designation
Lactobacillus salivarius	*Lactobacillus salivarius*	Whole cell	Strain designation
Lactobacillus sanfranciscensis	*Lactobacillus sanfranciscensis*	Whole cell	Strain designation
Lactococcus lactis	*Lactococcus lactis*	Whole cell	Strain designation

Leuconostoc citreum	*Leuconostoc citreum*	Whole cell	Strain designation
Leuconostoc pseudomesenteroides	*Leuconostoc pseudomesenteroides*	Whole cell	Strain designation
Leuconostoc lactis	*Leuconostoc lactis*	Whole cell	Strain designation
Leuconostoc mesenteroides	*Leuconostoc mesenteroides*	Whole cell	Strain designation
Oenococcus oeni	*Oenococcus oeni*	Whole cell	Strain designation
Pediococcus acidilactici	*Pediococcus acidilactici*	Whole cell	Strain designation
Pediococcus pentosaceus	*Pediococcus pentosaceus*	Whole cell	Strain designation
Propionibacterium freudenreichii	*Propionibacterium freudenreichii*	Whole cell	Strain designation
Propionibacterium freudenreichii subsp. *shermanii*	*Propionibacterium freudenreichii* subsp. *shermanii*	Whole Cell	Strain designation
Propionibacterium acidipropionici	*Propionibacterium acidipropionici*	Whole cell	Strain designation

[1]The PLA and label must identify the strain designation as the source material for each microorganism (e.g. Lactobacillus acidophilus ABC123 where "ABC123" is the strain designation).
[2] For “source of probiotics” claim only.
References: JCICSB 2008, Mattarelli et al. 2008, Masco et al. 2004, Roos et al. 2000, Validation List No. 68 1998, Curk et al. 1996, Wiese et al. 1996, Dicks et al. 1995, Vogel et al. 1994, Fujisawa et al. 1992, Howey et al. 1990, Collins et al. 1989, Farrow et al. 1989, Fujisawa et al. 1988, Validation List no. 20, 1985, Validation List no. 16, 1984b, Validation List no. 11, 1983, Validation List No. 8, 1982, Nakamura 1981, Johnson et al. 1980, Skerman et al. 1980, Validation List No. 4 1980, Beijerinck 1901.

Table 2. Proper name(s), Common name(s), Source material(s), Strain(s)– BACTERIA and FUNGI

Proper name(s)	Common name(s)	Source material(s)	
		Part(s)	Strain(s)[1]
Lactobacillus johnsonii	*Lactobacillus johnsonii*	Whole cell	La1
Lactobacillus johnsonii	*Lactobacillus johnsonii*	Whole cell	Lj1
Lactobacillus johnsonii	*Lactobacillus johnsonii*	Whole cell	NCC 533
Lactobacillus rhamnosus	*Lactobacillus rhamnosus*	Whole cell	GG
Saccharomyces boulardii[2]	*Saccharomyces boulardii*	Whole cell	Strain designation
Saccharomyces cerevisiae	▸ Baker's Yeast ▸ Brewer's Yeast ▸ Brewers yeast fungus	Whole cell	Strain designation

[1]The PLA and label must identify the strain designation as the source material for each microorganism (e.g. Lactobacillus acidophilus ABC123 where "ABC123" is the strain designation).
[2]*Saccharomyces boulardii* Seguela, Bastide & Massot 1984 (Saccharomycetaceae) is not a valid proper name for a genetically distinct subtype within the species of *Saccharomyces cerevisae* (Posteraro et al. 2005). This name is still used in the scientific literature however and pending a more thorough review, will continue to be accepted as a proper name in probiotic products to prevent confusion with non-probiotic subtypes of *S. cerevisae* (McFarland 2010; NCBI 2009; Bisby et al. 2006; Malgoire et al. 2005; de Llanos et al. 2004; van

der Aa Kühle et al. 2003; McCullogh et al. 1998; Skerman et al. 1989).
References: Euzéby 2012, McFarland 2010, NCBI 2009, Bisby et al. 2006, Hawrelak et al. 2005, Malgoire et al. 2005, Pridmore et al. 2004, Gilliland 2001, Reid 1999, Sanders 1999, McCullough et al. 1998, Fujisawa et al. 1992, Collins et al. 1989, Skerman et al. 1989, Hansen 1968, Meyen ex E.C. Hansen 1883.

Table 3. Proper name(s), Common name(s), Source material(s), Strain(s) – FUNGI

Proper name(s)	Common name(s)	Source material(s)	
		Part(s)	Strain(s)[1]
Debaryomyces hansenii	*Debaryomyces hansenii*	Whole cell	Strain designation
Kluyveromyces lactis	*Kluyveromyces lactis*	Whole cell	Strain designation
Kluyveromyces marxianus	*Candida pseudotropicalis*	Whole cell	Strain designation
Saccharomyces bayanus	*Saccharomyces bayanus*	Whole cell	Strain designation
Saccharomyces cerevisiae	▸ Baker's Yeast ▸ Brewer's Yeast ▸ Brewers yeast fungus	Whole cell	Strain designation
Saccharomyces boulardii	*Saccharomyces boulardii*	Whole cell	Strain designation
Saccharomyces pastorianus	*Saccharomyces pastorianus*	Whole cell	Strain designation
Schizosaccharomyces pombe	*Schizosaccharomyces pombe*	Whole cell	Strain designation
Xanthophyllomyces dendrorhous	*Xanthophyllomyces dendrorhous*	Whole cell	Strain designation

[1]The PLA and label must identify the strain designation as the source material for each microorganism (e.g. Lactobacillus acidophilus ABC123 where "ABC123" is the strain designation).
References: Golubev 1995, van der Walt 1971, Lodder 1952, Saccardo 1895, Lindner 1893, Meyen ex E.C. Hansen 1883, Reess 1870.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms by age group:

Children 1-2 years: The acceptable pharmaceutical dosage forms are limited to emulsion/ suspension and solution/ liquid preparations(Giacoia et al. 2008; EMEA/CHMP 2006).
Children 3-5 years: The acceptable pharmaceutical dosage forms are limited to chewables, emulsion/ suspension, powders and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006).

Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:
The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Medicinal ingredients from Tables 1, 2, and 3

Source of probiotics.

Medicinal ingredients from Tables 1, 2, and 3 except Lactobacillus crispatus and Lactobacillus gallinarum

- Helps support intestinal/gastrointestinal health (Alonso and Guarner 2013; DuPont and DuPont 2011; WGOGG 2011; Rolfe 2000).
- Could promote a favorable gut flora (Bezkorovainy 2001; Morelli 2000; Collins et al. 1998).

Medicinal ingredients from Table 2 with specific use(s) or purpose(s)

Medicinal ingredients	Strains	Uses or Purposes
Lactobacillus johnsonii	La1/Lj1/ NCC 533	An adjunct to physician-supervised antibiotic therapy in patients with *Helicobacter pylori* infections
Lactobacillus rhamnosus	GG	Helps to manage acute infectious diarrhoea
		Helps to manage and/or reduce the risk of antibiotic-associated diarrhoea
Saccharomyces boulardii/ Saccharomyces cerevisiae	All	Helps to reduce the risk of antibiotic-associated diarrhoea

References: Canani et al. 2007, Bergonzelli et al. 2006, Kotowska et al. 2005, Can et al. 2006, Cruchet et al. 2003, Pantoflickova et al. 2003, Cremonini et al. 2002, Armuzzi et al. 2001, Felley et al. 2001, Guandalini et al. 2000, Vanderhoof et al. 1999, Guarino et al. 1997, McFarland et al. 1995, Surawicz et al. 1989.

Dose(s)

Subpopulation(s)

Children 1 to 11 years, Adolescents 12 to 17 years and Adults 18 years and older (Gill and Prasad 2008; Lenoir-Wijnkoop et al. 2007; Hawrelak 2006; Picard et al. 2005; Reid et al. 2003).

Quantity(ies)

Method of preparation: Live

Medicinal ingredients from Tables 1 and 3

1.0×10^7 total Colony Forming Units (CFU) or more, per day (Gill and Prasad 2008; Lenoir-Wijnkoop et al. 2007; Hawrelak 2006; Picard et al. 2005; Reid et al. 2003).

Note
The minimum daily dose is the total CFU count per day provided from all live microorganisms present in the product formulation; it is not to be interpreted as a minimum quantity for individual microorganisms.

Medicinal ingredients from Table 2

Medicinal ingredients	Strains	Uses or Purposes	Doses (CFU/day)	
			Minimum	Maximum
Lactobacillus johnsonii	La1/Lj1/ NCC 533	*H. pylori* infections	1.25×10^8	3.6×10^9
	All	All other uses[1]	1.0×10^7	N/A
Lactobacillus rhamnosus	GG	Management of acute infectious diarrhoea	6.0×10^9	1.2×10^{10}
		Management/risk reduction of antibiotic-associated diarrhoea	1.0×10^{10}	2.0×10^{10}
	All	All other uses[1]	1.0×10^7	N/A
Saccharomyces boulardii/ Saccharomyces cerevisiae	All	Risk reduction of antibiotic-associated diarrhoea	1.0×10^{10}	3.0×10^{10}
		All other uses[1]	1.0×10^7	N/A

[1]For 'All other uses', the total recommended daily CFU count must meet the minimum of 10^7 either as a single ingredient or in combination.

References: Gill and Prasad 2008, Canani et al. 2007, Lenoir-Wijnkoop et al. 2007, Bergonzelli et al. 2006, Hawrelak 2006, Can et al. 2006, Picard et al. 2005, Pantoflickova et al. 2003, Reid et al. 2003, Cremonini et al. 2002, Armuzzi et al. 2001, Felley et al. 2001, Vanderhoof 1999, Guarino et al. 1997, McFarland et al. 1995.

Notes

- All individual strain quantities of live microorganisms must be indicated on the PLA form, label and finished product specifications in Colony Forming Units (CFU) per dosage unit.

- Multiple microorganisms cultured together with only one combined microorganism count (i.e., blends) are not included in this monograph.
- Volumetric amounts (e.g. g, mL) are not acceptable.

Direction(s) for use

All acceptable medicinal ingredients found in Tables 1 and 2 except Saccharomyces cerevisiae/S. boulardii

Take at least 2-3 hours before or after antibiotics (NIH 2011; APhA 2006; Biradar et al. 2005).

All acceptable medicinal ingredients found in Table 3 and Saccharomyces cerevisiae/S. boulardii

Take at least 2-3 hours before or after taking antifungal medications (NIH 2011; APhA 2006; Biradar et al. 2005).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you have fever, vomiting, bloody diarrhoea or severe abdominal pain (APhA 2006; WHO 2005; CPhA 2002).
- Stop use and consult a health care practitioner/health care provider/health care professional/ doctor/physician if symptoms of digestive upset (e.g. diarrhea) occur, worsen and/or persists beyond 3 days (APhA 2006; WHO 2005).

Contraindication(s)

Do not use this product if you have an immune-compromised condition (e.g. AIDS, lymphoma, patients undergoing long-term corticosteroid treatment) (APhA 2006; Cukovic-Cavka et al. 2006; Ledoux et al. 2006; Riquelme et al. 2003; Lherm et al. 2002).

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredient Database (NHPID) and must meet the limitations outlined in the database.

Note
Cryoprotectants: All ingredients that are intentionally added during the manufacturing process of a live microorganism to preserve its stability/viability need to be disclosed as non-medicinal ingredients.

Storage condition(s)

All liquid preparations

Store in refrigerator in a tightly closed, light-resistant container.

Note
This requirement does not apply to shelf-stable liquid dosage form preparations (i.e. oil suspensions and emulsions indicated in the Compendium of Monographs Guidance Document).

All non-liquid preparations (optional)

Store in refrigerator in a tightly closed container (Liu 2009; Juarez Thomas 2004; Shillinger 1999).

Specifications

- The medicinal ingredients must comply with the requirements outlined in the NHPID and the following requirements are expected to be met by each live microorganism attesting to this monograph:
  - The species Latin binomial identification must be up to date and validated.
  - Survivability of the microorganisms in the human gut must be demonstrated. In-vitro gastric acid and bile resistance testing is considered acceptable.
  - The microorganism must be identified by phenotype and genotype:
    - Phenotyping must be assessed based on characteristics routinely used to distinguish the species from others. This includes a series of testing for sufficient confirmation of observable traits of the species.
    - Genotyping must be assessed as follows:
      - Species identification by comparison of genome sequence homology in percentage, to both “identical” and “closely related” type strains – obtained from an internationally recognized culture collection;

      AND
      - Strain characterization through an up to date complete/whole genome sequencing method.

- Absence of virulence of each live microorganism must be established through the following:
  - Comparison of antibiotic/antifungal resistance profile to typical species resistance – as published by an internationally recognized panel;

  AND
  - Explanation of the genetic basis of each atypical antibiotic/antifungal resistance to the species OR demonstration of the absence of all known genetic mechanisms of resistance;

  AND
  - Demonstration of lack of horizontal antibiotic/antifungal resistance transfer ability;

  AND
  - Demonstration of susceptibility to therapeutic concentrations of at least two commercially available antimicrobial/antifungal agents;

  AND
  - Demonstration of the absence of genetic elements responsible for the production of virulence factors characteristic to the genus;

  AND
  - Demonstration of lack of toxigenic activity (i.e. production of toxins) known to the genus.

- Regarding risk information:
  - If any bacterial/fungal strain in the product has come into contact with a priority allergen or derivative (e.g. soy, gluten, milk, fish via the culture media) (list available at: http://www.hc- sc.gc.ca/fn-an/securit/allerg/fa-aa/index-eng.php) that is not listed as a medicinal or non- medicinal ingredient, one of the following risk statements must be included on the product label:
    - Do not use this product if you have a XXX allergy (CG 2011; HC 2009);

    OR
    - (May) contain(s) XXX (HC 2012a; HC 2012b; CG 2011; HC2009; HC 2003).
  - If any bacterial/fungal strain in the product possesses unexplained atypical resistance to any antibiotic/antifungal agent (Mathur and Singh 2005), the name(s) of the antibiotic(s)/ antifungal(s) agent(s) must be indicated as a contraindication on the PLA form and label as follows:
    - Do not use this product if you are taking XXX (e.g. Do not use this product if you are taking ampicillin).

    Note: The above risk statement is not applicable to Class I (compendial) and Class II applications. If applicable to the strain attesting to this monograph, additional evidence must be provided and reviewed under the Class III stream.

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. In the case of live microorganisms, this includes the following:
  - Stability/viability measures put into place must ensure that a minimum of 80% of the quantity declared on the product label is present at the end of shelf life.
  - In the case where the live microorganism can interfere with microbial impurity testing, a detailed rationale on how the final product complies is required. Such rationale should

include measures for live microorganism distinguishing at the finished product stage, along with a detailed explanation on how quality assurance measures are put into place to ensure microbial purity.

Note

Information on the manufacturing process, including but not limited to the above, must be maintained by the applicant or the manufacturer and provided to Health Canada upon request.

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Appendix I

Table 4. Excluded live microorganisms from this monograph

Proper and Common name(s)	References
Escherichia coli	Skerman et al. 1980
Bacillus coagulans	Skerman et al. 1980
Bacillus subtilis	Skerman et al. 1980
Clostridium butyricum	Skerman et al. 1980
Enterococcus faecium	Schleifer et al. 1984
Streptococcus salivarius	Skerman et al. 1980