Probiotics

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Probiotics Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 224 KB) 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 ingredient. 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 Tables 1,2 and 3 (e.g. heat-killed, thermostabilised) is excluded from this monograph and the compendial application process. All of the microorganisms found in Appendix I (Table 6) are excluded from this monograph and the compendial application process. Date January 27, 2023 Proper name(s), Common name(s), Source information, Strain(s) Note Refer to Appendix I, Table 6 for medicinal ingredients that are excluded from this monograph. Table 1. Proper name(s), Common name(s), Source information, Strain(s) - BACTERIA Proper name(s) Common name(s) Source Information 1 Part(s) Strain(s) 2 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 Companilactobacillus farciminis (Formerly Lactobacillus farciminis) Companilactobacillus farciminis (Formerly Lactobacillus farciminis) Whole cell Strain designation Fructilactobacillus sanfranciscensis (Formerly Lactobacillus sanfranciscensis) Fructilactobacillus sanfranciscensis (Formerly Lactobacillus sanfranciscensis) Whole cell Strain designation Lacticaseibacillus casei (Formerly Lactobacillus casei) Lacticaseibacillus casei (Formerly Lactobacillus casei) Whole cell Strain designation Lacticaseibacillus paracasei (Formerly Lactobacillus paracasei) Lacticaseibacillus paracasei (Formerly Lactobacillus paracasei) Whole cell Strain designation Lacticaseibacillus rhamnosus (Formerly Lactobacillus rhamnosus) Lacticaseibacillus rhamnosus (Formerly Lactobacillus rhamnosus) Whole cell Strain designation Lactiplantibacillus paraplantarum (Formerly Lactobacillus paraplantarum) Lactiplantibacillus paraplantarum (Formerly Lactobacillus paraplantarum) Whole cell Strain designation Lactiplantibacillus plantarum (Formerly Lactobacillus plantarum) Lactiplantibacillus plantarum (Formerly Lactobacillus plantarum) 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 crispatus 3 Lactobacillus crispatus 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 gallinarum 3 Lactobacillus gallinarum Whole cell Strain designation Lactobacillus gasseri Lactobacillus gasseri Whole cell Strain designation Lactobacillus helveticus Lactobacillus helveticus Whole cell Strain designation Lactobacillus johnsonii Lactobacillus johnsonii Whole cell Strain designation Lactobacillus kefiranofaciens Lactobacillus kefiranofaciens Whole cell Strain designation Lactococcus lactis Lactococcus lactis Whole cell Strain designation Latilactobacillus curvatus (Formerly Lactobacillus curvatus) Latilactobacillus curvatus (Formerly Lactobacillus curvatus) Whole cell Strain

designation Lentilactobacillus buchneri (Formerly Lactobacillus buchneri) Lentilactobacillus buchneri (Formerly Lactobacillus buchneri) Whole cell Strain designation Lentilactobacillus hilgardii (Formerly Lactobacillus hilgardii) Lentilactobacillus hilgardii (Formerly Lactobacillus hilgardii) Whole cell Strain designation Lentilactobacillus kefiri (Formerly Lactobacillus kefiri) Lentilactobacillus kefiri (Formerly Lactobacillus kefiri) Whole cell Strain designation Leuconostoc citreum Leuconostoc citreum Whole cell Strain designation Leuconostoc lactis Leuconostoc lactis Whole cell Strain designation Leuconostoc mesenteroides Leuconostoc mesenteroides Whole cell Strain designation Leuconostoc pseudomesenteroides Leuconostoc pseudomesenteroides Whole cell Strain designation Levilactobacillus brevis (Formerly Lactobacillus brevis) Levilactobacillus brevis (Formerly Lactobacillus brevis) Whole cell Strain designation Ligilactobacillus salivarius (Formerly Lactobacillus salivarius) Ligilactobacillus salivarius (Formerly Lactobacillus salivarius) Whole cell Strain designation Limosilactobacillus fermentum (Formerly Lactobacillus fermentum) Limosilactobacillus fermentum (Formerly Lactobacillus fermentum) Whole cell Strain designation Limosilactobacillus mucosae (Formerly Lactobacillus mucosae) Limosilactobacillus mucosae (Formerly Lactobacillus mucosae) Whole cell Strain designation Limosilactobacillus panis (Formerly Lactobacillus panis) Limosilactobacillus panis (Formerly Lactobacillus panis) Whole cell Strain designation Limosilactobacillus pontis (Formerly Lactobacillus pontis) Limosilactobacillus pontis (Formerly Lactobacillus pontis) Whole cell Strain designation Limosilactobacillus reuteri (Formerly Lactobacillus reuteri) Limosilactobacillus reuteri (Formerly Lactobacillus reuteri) Whole cell Strain designation Loigolactobacillus coryniformis (Formerly Lactobacillus coryniformis) Loigolactobacillus coryniformis (Formerly Lactobacillus coryniformis) 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 acidipropionici Propionibacterium acidipropionici Whole cell Strain designation Propionibacterium freudenreichii Propionibacterium freudenreichii Whole cell Strain designation Propionibacterium freudenreichii subsp. shermanii Propionibacterium freudenreichii subsp. shermanii Whole cell Strain designation 1 The source material should be the same as the proper name. 2 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). 3 For "source of probiotics" claim only. References: Zheng et al. 2020, 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 information, Strain(s) - BACTERIA and FUNGI Proper name(s) Common name(s) Source information 1 Part(s) Strain(s) 2 Lacticaseibacillus rhamnosus Lacticaseibacillus rhamnosus Whole cell GG Lactobacillus johnsonii Lactobacillus johnsonii Whole cell La1 Lactobacillus johnsonii Lactobacillus johnsonii Whole cell Lj1 Lactobacillus johnsonii Lactobacillus johnsonii Whole cell NCC 533 Saccharomyces boulardii 3 Saccharomyces boulardii Whole cell Strain designation Saccharomyces cerevisiae Baker's Yeast Brewer's Yeast Brewer's yeast fungus Whole cell Strain designation 1 The source material should be the same as the proper name. 2 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). 3 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 information, Strain(s) - FUNGI Proper name(s) Common name(s) Source information 1 Part(s) Strain(s) 2 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 boulardii Saccharomyces boulardii Whole cell Strain designation Saccharomyces cerevisiae Baker's Yeast Brewer's Yeast Brewers yeast fungus 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 source material should be the same as the proper name. 2 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: Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. 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). Table 4. Medicinal ingredients from Table 2 with specific use(s) or purpose(s) Medicinal Ingredients Strains Uses or Purposes Lacticaseibacillus rhamnosus GG Helps to manage acute infectious diarrhoea Helps to manage and/or reduce the risk of antibiotic-associated diarrhoea Lactobacillus johnsonii La1 Lj1 NCC 533 An adjunct to physician-supervised antibiotic therapy in patients with Helicobacter pylori infections 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 x 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. Table 5. Medicinal ingredients from Table 2 Medicinal Ingredients Strains Uses or Purposes Doses (CFU/day) Minimum Maximum Lacticaseibacillus rhamnosus GG Management of acute infectious diarrhoea 6.0 x 10 9 1.2 x 10 10 Management/risk reduction of antibiotic-associated diarrhoea 1.0 x 10 10 2.0 x 10 10 All All other uses 1 1.0 x 10 7 N/A Lactobacillus johnsonii La1 Lj1 NCC 533 H. pylori infections 1.25 x 10 8 3.6 x 10 9 All All other uses 1 1.0 x 10 7 N/A Saccharomyces boulardii Saccharomyces cerevisiae All Risk reduction of antibiotic- associated diarrhoea 1.0 x 10 10 3.0 x 10 10 All other uses 1 1.0 x 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. Gravimetric or volumetric amounts (e.g. g, mL) are not acceptable. Direction(s) for use All medicinal ingredients found in Tables 1 and 2 except Saccharomyces cerevisiae and S. boulardii Take at least 2-3 hours before or after antibiotics (NIH 2011; APhA 2006; Biradar et al. 2005). All medicinal ingredients found in Table 3 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 Ingredients 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 conditions Liquid products 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). Non-liquid products (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. References Cited Abe S, Takayama K, Kinoshita S. Taxonomic studies on glutamic acid-producing bacteria. Journal of General and Applied Microbiology 1967;13(3):279-301. Adiloglu AK, Gönülates N, Isler M, Senol A. The effect of kefir consumption on human immune system: a cytokine study. Mikrobiyoloji Bulteni 2013;47(2):273-281. Ahmadova A, Todorov SD, Hadji-Sfaxi I, Choiset Y, Rabesona H, Messaoudi S, Kuliyev A, Franco BD, Chobert JM, Haertlé T. Antimicrobial and antifungal activities of Lactobacillus curvatus strain isolated from homemade Azerbaijani cheese. Anaerobe. 2013;20:42-49. 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International Journal of Systematic Bacteriology 1984; 34:355-357. Validation of publication of new names and new combinations previously effectively published outside the IJSB: List No. 55. International Journal of Systematic Bacteriology 1995; 45:879-880. WGO Global Guideline 2011: World Gastroenterology Organisation Global Guidelines. Practice Guideline - Probiotics and Prebiotics. [Accessed 2013 June 29]. Available from: http://www.worldgastroenterology.org/probiotics-prebiotics.html Appendix I Table 6. Excluded live microorganisms from this monograph Proper and Common Name(s) References Bacillus clausii Nielsen et al. 1995 Bacillus coagulans Skerman et al. 1980 Bacillus indicus Suresh et al. 2004 Bacillus subtilis Skerman et al. 1980 Bacillus subtilis subsp. inaquosorum Rooney et al. 2009 Clostridium butyricum Skerman et al. 1980 Enterococcus faecalis Schleifer et al. 1984 Enterococcus faecium Schleifer et al. 1984 Escherichia coli Skerman et al. 1980 Streptococcus salivarius Skerman et al. 1980 Streptococcus salivarius subsp. thermophilus Farrow and Collins 1984 Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

All of the microorganisms found in Appendix I (Table 6) are excluded from this monograph and the compendial application process.

DOSAGE FORM(S)

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:Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

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 Ingredients Database (NHPID) and must meet the limitations outlined in the database. NoteCryoprotectants: 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 conditions Liquid products Store in refrigerator in a tightly closed, light-resistant container. NoteThis 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). Non-liquid products (optional) Store in refrigerator in a tightly closed container (Liu 2009; Juarez Thomas 2004; Shillinger 1999).

STORAGE CONDITION(S)

Liquid products Store in refrigerator in a tightly closed, light-resistant container. NoteThis 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). Non-liquid products (optional) Store in refrigerator in a tightly closed container (Liu 2009; Juarez Thomas 2004; Shillinger 1999).

SPECIFICATIONS

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 Tables 1,2 and 3 (e.g. heat-killed, thermostabilised) is excluded from this monograph and the compendial application process. All of the microorganisms found in Appendix I (Table 6) are excluded from this monograph and the compendial application process.

REFERENCES

Table 2. Proper name(s), Common name(s), Source information, Strain(s) - BACTERIA and FUNGIProper name(s)Common name(s)Source information1Part(s)Strain(s)2Lacticaseibacillus rhamnosusLacticaseibacillus rhamnosusWhole cellGGLactobacillus johnsoniiLactobacillus johnsoniiWhole cellLa1Lactobacillus johnsoniiLactobacillus johnsoniiWhole cellLj1Lactobacillus johnsoniiLactobacillus johnsoniiWhole cellNCC 533Saccharomyces boulardii3Saccharomyces boulardiiWhole cellStrain designationSaccharomyces cerevisiaeBaker's YeastBrewer's YeastBrewer's yeast fungusWhole cellStrain designation 1The source material should be the same as the proper name. 2The 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). 3Saccharomyces boulardiiSeguela, Bastide & Massot 1984 (Saccharomycetaceae) is not a valid proper name for a genetically distinct subtype within the species ofSaccharomyces 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 ofS. 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 information, Strain(s) - FUNGIProper name(s)Common name(s)Source information1Part(s)Strain(s)2Debaryomyces hanseniiDebaryomyces hanseniiWhole cellStrain designationKluyveromyces lactisKluyveromyces lactisWhole cellStrain designationKluyveromyces marxianusCandida pseudotropicalisWhole cellStrain designationSaccharomyces bayanusSaccharomyces bayanusWhole cellStrain designationSaccharomyces boulardiiSaccharomyces boulardiiWhole cellStrain designationSaccharomyces cerevisiaeBaker's YeastBrewer's YeastBrewers yeast fungusWhole cellStrain designationSaccharomyces pastorianusSaccharomyces pastorianusWhole cellStrain designationSchizosaccharomyces pombeSchizosaccharomyces pombeWhole cellStrain designationXanthophyllomyces dendrorhousXanthophyllomyces dendrorhousWhole cellStrain designation 1The source material should be the same as the proper name. 2The 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

Proper name(s)	Common name(s)	Source Information1	
Part(s)	Strain(s)2		
Bifidobacterium adolescentis	Bifidobacterium adolescentis	Whole cell	Strain designation
Bifidobacterium animalissubsp.animalis	Bifidobacterium animalissubsp.animalis	Whole cell	Strain designation
Bifidobacterium animalissubsp.lactis	Bifidobacterium animalissubsp.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 longumsubsp.infantis	Bifidobacterium longumsubsp.infantis	Whole cell	Strain designation
Bifidobacterium longumsubsp.longum	Bifidobacterium longumsubsp.longum	Whole cell	Strain designation
Bifidobacterium longumsubsp.suis	Bifidobacterium longumsubsp.suis	Whole cell	Strain designation
Companilactobacillus farciminis(FormerlyLactobacillus farciminis)	Companilactobacillus farciminis(FormerlyLactobacillus farciminis)	Whole cell	Strain designation
Fructilactobacillus sanfranciscensis(FormerlyLactobacillus sanfranciscensis)	Fructilactobacillus sanfranciscensis(FormerlyLactobacillus sanfranciscensis)	Whole cell	Strain designation
Lacticaseibacillus casei(FormerlyLactobacillus casei)	Lacticaseibacillus casei(FormerlyLactobacillus casei)	Whole cell	Strain designation
Lacticaseibacillus paracasei(FormerlyLactobacillus paracasei)	Lacticaseibacillus paracasei(FormerlyLactobacillus paracasei)	Whole cell	Strain designation
Lacticaseibacillus rhamnosus(FormerlyLactobacillus rhamnosus)	Lacticaseibacillus rhamnosus(FormerlyLactobacillus rhamnosus)	Whole cell	Strain designation
Lactiplantibacillus paraplantarum(FormerlyLactobacillus paraplantarum)	Lactiplantibacillus paraplantarum(FormerlyLactobacillus paraplantarum)	Whole cell	Strain designation
Lactiplantibacillus plantarum(FormerlyLactobacillus plantarum)	Lactiplantibacillus plantarum(FormerlyLactobacillus plantarum)	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 crispatus3	Lactobacillus crispatus	Whole cell	Strain designation
Lactobacillus delbrueckii	Lactobacillus delbrueckii	Whole cell	Strain designation
Lactobacillus delbrueckiisubsp.bulgaricus	Lactobacillus delbrueckiisubsp.bulgaricus	Whole cell	Strain designation
Lactobacillus delbrueckiisubsp.delbrueckii	Lactobacillus delbrueckiisubsp.delbrueckii	Whole cell	Strain designation
Lactobacillus gallinarum3	Lactobacillus gallinarum	Whole cell	Strain designation
Lactobacillus gasseri	Lactobacillus gasseri	Whole cell	Strain designation
Lactobacillus helveticus	Lactobacillus helveticus	Whole cell	Strain designation
Lactobacillus johnsonii	Lactobacillus johnsonii	Whole cell	Strain designation
Lactobacillus kefiranofaciens	Lactobacillus kefiranofaciens	Whole cell	Strain designation
Lactococcus lactis	Lactococcus lactis	Whole cell	Strain designation
Latilactobacillus curvatus(FormerlyLactobacillus curvatus)	Latilactobacillus curvatus(FormerlyLactobacillus curvatus)	Whole cell	Strain designation
Lentilactobacillus buchneri(FormerlyLactobacillus buchneri)	Lentilactobacillus buchneri(FormerlyLactobacillus buchneri)	Whole cell	Strain designation
Lentilactobacillus hilgardii(FormerlyLactobacillus hilgardii)	Lentilactobacillus hilgardii(FormerlyLactobacillus hilgardii)	Whole cell	Strain designation
Lentilactobacillus kefiri(FormerlyLactobacillus kefiri)	Lentilactobacillus kefiri(FormerlyLactobacillus kefiri)	Whole cell	Strain designation
Leuconostoc citreum	Leuconostoc citreum	Whole cell	Strain designation
Leuconostoc lactis	Leuconostoc lactis	Whole cell	Strain designation
Leuconostoc mesenteroides	Leuconostoc mesenteroides	Whole cell	Strain designation
Leuconostoc pseudomesenteroides	Leuconostoc pseudomesenteroides	Whole cell	Strain designation
Levilactobacillus brevis(FormerlyLactobacillus brevis)	Levilactobacillus brevis(FormerlyLactobacillus brevis)	Whole cell	Strain designation
Ligilactobacillus salivarius(FormerlyLactobacillus salivarius)	Ligilactobacillus salivarius(FormerlyLactobacillus salivarius)	Whole cell	Strain designation
Limosilactobacillus fermentum(FormerlyLactobacillus fermentum)	Limosilactobacillus fermentum(FormerlyLactobacillus fermentum)	Whole cell	Strain designation
Limosilactobacillus mucosae(FormerlyLactobacillus mucosae)	Limosilactobacillus mucosae(FormerlyLactobacillus mucosae)	Whole cell	Strain designation
Limosilactobacillus panis(FormerlyLactobacillus panis)	Limosilactobacillus panis(FormerlyLactobacillus panis)	Whole cell	Strain designation
Limosilactobacillus pontis(FormerlyLactobacillus pontis)	Limosilactobacillus pontis(FormerlyLactobacillus pontis)	Whole cell	Strain designation
Limosilactobacillus reuteri(FormerlyLactobacillus reuteri)	Limosilactobacillus reuteri(FormerlyLactobacillus reuteri)	Whole cell	Strain designation

Loigolactobacillus coryniformis(FormerlyLactobacillus coryniformis)	Loigolactobacillus coryniformis(FormerlyLactobacillus coryniformis)	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 acidipropionici	Propionibacterium acidipropionici	Whole cell	Strain designation
Propionibacterium freudenreichii	Propionibacterium freudenreichii	Whole cell	Strain designation
Propionibacterium freudenreichiisubsp.shermanii	Propionibacterium freudenreichiisubsp.shermanii	Whole cell	Strain designation

Proper name(s)	Common name(s)	Source information1	
Part(s)	Strain(s)2		
Lacticaseibacillus rhamnosus	Lacticaseibacillus rhamnosus	Whole cell	GG
Lactobacillus johnsonii	Lactobacillus johnsonii	Whole cell	La1
Lactobacillus johnsonii	Lactobacillus johnsonii	Whole cell	Lj1
Lactobacillus johnsonii	Lactobacillus johnsonii	Whole cell	NCC 533
Saccharomyces boulardii3	Saccharomyces boulardii	Whole cell	Strain designation
Saccharomyces cerevisiae	Baker's YeastBrewer's YeastBrewer's yeast fungus	Whole cell	Strain designation

Proper name(s)	Common name(s)	Source information1	
Part(s)	Strain(s)2		
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 boulardii	Saccharomyces boulardii	Whole cell	Strain designation
Saccharomyces cerevisiae	Baker's YeastBrewer's YeastBrewers yeast fungus	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

Medicinal Ingredients	Strains	Uses or Purposes
Lacticaseibacillus rhamnosus	GG	Helps to manage acute infectious diarrhoea
Helps to manage and/or reduce the risk of antibiotic-associated diarrhoea		
Lactobacillus johnsonii	La1Lj1NCC 533	An adjunct to physician-supervised antibiotic therapy in patients
Saccharomyces boulardiiSaccharomyces cerevisiae		Helps to reduce the risk of antibiotic-associated diarrhoea

edicinal Ingredients	Strains	Uses or Purposes	Doses (CFU/day)	

himum	Maximum			
cticaseibacillus rhamnosus	GG	Management of acute infectious diarrhoea	6.0 x 109	1.2 x 1010
nagement/risk reduction of antibiotic-associated diarrhoea	1.0 x 1010	2.0 x 1010		
	All other uses1	1.0 x 107	N/A	
ctobacillus johnsonii	La1Lj1NCC 533	H. pyloriinfections	1.25 x 108	3.6 x 109
	All other uses1	1.0 x 107	N/A	
ccharomyces boulardiiSaccharomyces cerevisiae	All	Risk reduction of antibiotic- associated diarrhoea	1.0 x 1010	3.0 x 1010
other uses1	1.0 x 107	N/A		

Proper and Common Name(s)	References
Bacillus clausii	Nielsen et al. 1995
Bacillus coagulans	Skerman et al. 1980
Bacillus indicus	Suresh et al. 2004
Bacillus subtilis	Skerman et al. 1980
Bacillus subtilis subsp. inaquosorum	Rooney et al. 2009
Clostridium butyricum	Skerman et al. 1980
Enterococcus faecalis	Schleifer et al. 1984
Enterococcus faecium	Schleifer et al. 1984
Escherichia coli	Skerman et al. 1980
Streptococcus salivarius	Skerman et al. 1980
Streptococcus salivarius subsp. thermophilus	Farrow and Collins 1984