

Holy Basil - Ocimum Tenuliflorum - Leaf

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HOLY BASIL - OCIMUM TENUIFLORUM - LEAF 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 - 90 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 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. Date December 18, 2018 Proper name(s), Common name(s), Source material(s) Table 1. Proper name(s), Common name(s), Source material(s) Proper name(s) Common name(s) Source material(s) Proper name(s) Part(s) Preparation Ocimum tenuiflorum Holy basil Rama tulsi Sacred basil Tulsi Ocimum tenuiflorum Leaf Dried References: Proper name: USDA 2018; McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000, API 1999; Source material: API 1999, Agrawal et al. 1996. 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 for the age category listed in this monograph for the specified route of administration are indicated in the Compendium of Monographs Guidance Document. Use(s) or Purpose(s) Traditionally used in Ayurveda (as an expectorant and/or demulcent) to help relieve cough (Kasa) and colds (Premila 2006; Paranjpe 2005; Sudarshan 2005; Mishra 2004; Williamson 2002; Kapoor 2001; Gogte 2000; API 1999; Jain 1991). Traditionally used in Ayurveda (as an expectorant) to help relieve respiratory mucus buildup (catarrh) (Premila 2006; Paranjpe 2005; Sudarshan 2005; Mishra 2004; Williamson 2002; Kapoor 2001; Gogte 2000; API 1999; Jain 1991). Traditionally used in Ayurveda as a cardi tonic (Hrdya) (Paranjpe 2005; Sudarshan 2005; Murthy 2004; Warri er 2003; Williamson 2002; Gogte 2000; API 1999). Traditionally used in Ayurveda to aid digestion (Dipani) and stimulate appetite (stomachic) (Paranjpe 2005; Murthy 2004; Warri er 2003; Kapoor 2001; Gogte 2000; API 1999; Khory 1999; Jain 1991). Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress (in case of mental and physical fatigue related to stress) (McIntyre 2011; Winston and Maim es 2007; Hoffmann 2003; Williamson 2003). Source of/Provides antioxidants (Hakim et al. 2007; Winston and Maim es 2007; Williamson 2003). The following combined use(s) or purpose(s) is/are also acceptable: Traditionally used in Ayurveda (as an expectorant and/or demulcent) to help relieve cough (Kasa) and colds and respiratory mucus buildup (catarrh) (Premila 2006; Paranjpe 2005; Sudarshan 2005; Mishra 2004; Williamson 2002; Kapoor 2001; Gogte 2000; API 1999; Jain 1991). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Methods of preparation: Dry, Powder, Non-Standardised Ethanolic Extracts (Dry extract, Tincture, Fluid extract) Antioxidant Not to exceed 3 grams of dried leaf, per day (API 1999). Ayurveda; Adaptogen 2 - 3 grams of dried leaf, per day (API 1999). Methods of preparation: Non-Standardised Aqueous Extracts (Dry extract, Decoction, Infusion) Antioxidant Not to exceed 28 grams of dried leaf, per day (Williamson 2002; Kapoor 2001). Ayurveda 7 - 28 grams of dried leaf, per day (Williamson 2002; Kapoor 2001). Adaptogen 4.2 - 28 grams of dried leaf, per day (Winston and Maim es 2007; Williamson 2002; Kapoor 2001). Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All products Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are breastfeeding, have a heart condition or diabetes (WHO 2002; Rai et al. 1997; Agrawal et al. 1996). Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking any heart or blood pressure medication (Rai et al. 1997; Agrawal et al. 1996). Relief of cough/cold/respiratory mucus buildup; Digestive aid; Adaptogen Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) Do not use this product if you are pregnant (Prakash et al. 2005; Ahmed et al. 2002; WHO 2002; Wohlmut h 2002; Kapoor 2001). 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. Storage conditions No statement required. Specifications 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. The medicinal ingredient must comply with the requirements outlined in the NHPID. References Cited Agrawal P, Rai V, Singh RB. Randomized placebo-controlled, single blind trial of holy basil leaves in patients with noninsulin-dependent diabetes mellitus. *International Journal of Clinical Pharmacology and Therapeutics* 1996;34(9):406-409. Ahmed A, Ahamed RN, Aladakatti RH, Ghosewar MG. Reversible antifertility effect of benzene extract of *Ocimum sanctum* on sperm parameters and fructose content in rats. *Journal of basic and clinical physiology and pharmacology* 2002;13:51-59. API 1999: The Ayurvedic Pharmacopoeia of India. 1st edition, Part I, Volume I. Delhi (IN): The Controller of Publications; 1999. Gogte VVM. 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Available from <http://webprod3.hc-sc.gc.ca/cnf-fce/start-debuter.do?lang=eng> Dr. Duke's Phytochemical and Ethnobotanical Databases. [Accessed 2013 February 19]. Available from <http://www.ars-grin.gov/duke/> Evans WC. Trease and Evans Pharmacognosy, 16th edition. Toronto (ON): Saunders Elsevier; 2009. Faccolia S. Cornucopia II A

source book of edible plants. Vista (CA): Kampong Publications; 1998. Grover JK, Yadav S, Vats V. Medicinal plants of India with anti-diabetic potential. *Journal of Ethnopharmacology* 2002;82(1):81-100. Holy Basil (*Ocimum sanctum* L.) Natural Standard Professional Monograph [Internet]. Natural Standard Inc; 2012 [Accessed 2012 February 06]. Available from <http://naturalstandard.com/databases/herbssupplements/holybasil.asp> Kapoor S. *Ocimum sanctum*: A therapeutic role in diabetes and the metabolic syndrome. *Hormone and Metabolic Research* 2008;40:296. Liu JP, Zhang M, Wang M, Grimsgaard S. Chinese herbal medicines for type 2 diabetes mellitus (Review). *Cochrane Database of Systemic Reviews* 2002, Issue 3. Art. No.: CD003642. DOI: 10.1002/14651858.CD003642.pub2. McGuffin, M., Hobbs, C., Upton, R., Goldberg, A. *American Herbal Products Association's Botanical Safety Handbook*. Boca Raton, Florida: CRC Press LLC. 1997. Miller R, Miller S. *Tulsi Queen of Herbs: India's Holy Basil*. The Green Isle Enterprise: Salt Spring Island (BC); 2003. Mills S, Bone K. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Mondal S, Varma S, Bamola VD, Naik SN, Mirdha BR, Padhi MM, Mehta N, Mahapatra SC. Double-blinded randomized controlled trial for immunomodulatory effects of Tulsi (*Ocimum sanctum* Linn.) leaf extract on healthy volunteers. *Journal of Ethnopharmacology* 2011; 136 (3): 452-456. Mondal S, Mirdha BR, Mahapatra SC. The science behind sacredness of Tulsi (*Ocimum sanctum* Linn). *Indian Journal of Physiology and Pharmacology* 2009;53(4):291-306. Rosenbaum CC, O'Mathúna DP, Chavez M, Shields K. Antioxidants and anti-inflammatory dietary supplements for osteoarthritis and rheumatoid arthritis. *Alternative Therapies in Health and Medicine* 2010;16(2):32-40. Shekelle PG, Hardy M, Morton SC, Coulter I, Venuturupalli S, Favreau J, Hilton LK. Are Ayurvedic herbs for diabetes effective? *The Journal of Family Practice* 2005;54(10):876-886. Singh N. A new concept on the possible therapy of stress diseases with "adaptogen" (anti-stress drugs) of indigenous plant origin. *Current Medical Practice* 1981;25:1-50. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Eugenol. [Internet]. [Updated 31 January 2006; Accessed 2012 February 7]. Available from http://www.inchem.org/documents/jecfa/jecval/jec_841.htm Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Beta-Caryophyllene. [Internet]. [Updated 28 January 2006; Accessed 2012 February 7]. Available from http://www.inchem.org/documents/jecfa/jecval/jec_389.htm Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Eugenyl Methyl Ether. [Internet]. [Updated 12 November 2001; Accessed 2012 February 7]. Available from http://www.inchem.org/documents/jecfa/jecval/jec_846.htm Ulbricht C, Basch E, Weissner W, Hackman D. An evidence-based systematic review of herbs and supplement interactions by the Natural Standard Research Collaboration. *Expert Opinion on Drug Safety* 2006;5(5):719-728. Yeh GY, Eisenberg DM, Kaptchuk TJ, Phillips RS. Systematic review of herbs and dietary supplements for glycemic control in diabetes. *Diabetes Care* 2003;26(4):1277-1294. Zamin M. *Ocimum sanctum* may overcome fatigue stress. *Pakistan Journal of Biological Sciences*. 2011; 14 (21), 1000-1001. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions No statement required.

DOSAGE FORM(S)

Acceptable dosage forms for the age category listed in this monograph for the specified route of administration are indicated in the Compendium of Monographs Guidance Document.

RISK INFORMATION

Caution(s) and warning(s) All products Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are breastfeeding, have a heart condition or diabetes (WHO

2002; Rai et al. 1997; Agrawal et al. 1996).Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are taking any heart or blood pressure medication (Rai et al. 1997; Agrawal et al. 1996). Relief of cough/cold/respiratory mucus buildup; Digestive aid; Adaptogen Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) Do not use this product if you are pregnant (Prakash et al. 2005; Ahmed et al. 2002; WHO 2002; Wohlmuth 2002; Kapoor 2001). 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. Storage conditions No statement required.

STORAGE CONDITION(S)

No statement required.

SPECIFICATIONS

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.The medicinal ingredient must comply with the requirements outlined in the NHPID.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation		
Ocimum tenuiflorum	Holy basilRama tulsiSacred basilTulsi	Ocimum tenuiflorum	Leaf	Dried