Sage - Salvia officinalis - Oral

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SAGE - SALVIA OFFICINALIS Oral 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 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 on the label. Date January 10, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Salvia officinalis Common sage Dalmatian sage Garden sage Sage Salvia officinalis Leaf Dry References: Proper name: USDA 2024; Gardner and McGuffin 2013; Common names: USDA 2024; Gardner and McGuffin 2013; Source information: Blumenthal et al. 2000; BHP 1996; Cook 1869. 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 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) Source of antioxidants/Provides antioxidants (Bradley 2006; Lima et al. 2005). Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Bradley 2006; Lima et al. 2005). (Traditionally) used in Herbal Medicine (as a carminative) to help provide relief of upset stomach and flatulence (flatulent dyspepsia) (EMA 2016; Godfrey et al. 2010; Bradley 2006; Mills and Bone 2005; BHP 1996; Culbreth 1927; Felter 1922). (Traditionally) used in Herbal Medicine (as a diaphoretic) to increase perspiration/sweating (PDR 2007; Culbreth 1927; Felter 1922; Cook 1869). (Traditionally) used in Herbal Medicine (as an antihidrotic) to reduce hyperhidrosis/excessive sweating or perspiration (EMA 2016; Bradley 2006; Mills and Bone 2005; BHP 1996; Culbreth 1927; Felter 1922). Used in Herbal Medicine to help reduce hot flushes/hot flashes/night sweats associated with menopause (Romm 2010; Bradley 2006; Mills and Bone 2000). (Traditionally) used in Herbal Medicine (as an antigalactagogue) to stop the production of breast milk (Godfrey et al. 2010; Wichtl 2004; Yarnell et al. 2003; Felter and Lloyd 1983; Culbreth 1927; Cook 1869). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to reduce excessive sweating or perspiration and to stop the production of breast milk). For multi-ingredient products: To prevent the product from being represented as a “traditional medicine”, any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiples systems of traditional medicine (e.g. Sage is traditionally used in Herbal Medicine to increase sweating). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Antioxidant Methods of preparation: Dry 1 , Non-Standardized Aqueous Extracts (Dry extract, Infusion, Infusion concentrate) Not to exceed 12 grams of dried leaf, per day (Bradley 2006; Mills et Bone 2005; Blumenthal et al. 2000; BHP 1996; Culbreth 1927). 1 Note: Dried leaf should be prepared as an infusion (see direction for use). Method of preparation: Non-Standardized Ethanolic Extracts (Dry extract, Tincture) Not to exceed 2.25 grams of dried leaf, per day (EMA 2016; Mills and Bone 2005; ESCOP 2003). Method of preparation: Fluid extract Not to exceed 6 grams of dried leaf, per day (EMA 2016; Bradley 2006; Mills and Bone 2005; ESCOP 2003; BHP 1996). Other uses Methods of preparation: Dry 1 , Non-Standardized Aqueous Extracts (Dry extract, Infusion, Infusion concentrate) 1 - 12 grams of dried leaf, per day (Mills and Bone 2005; Blumenthal et al. 2000; BHP 1996; Culbreth 1927). 1 Note: Dried leaf should be prepared as an infusion (see direction for use). Methods of preparation: Non-Standardized Ethanolic Extracts (Dry extract, Tincture) 0.3 - 2.25 grams dry leaf, per day (EMA 2016; Mills and Bone 2005; ESCOP 2003). Method of preparation: Fluid extract 1 - 6 grams of dried leaf, per day (EMA 2016; Bradley 2006; Mills and Bone 2005; ESCOP 2003; BHP

1996). Direction(s) for use Night sweats Take 1 hour before bedtime (EMA 2016). Dried leaves - All uses Pour hot boiled water on dried leaf and steep. Dried leaves - Antihidrotic (To reduce sweating,)* let infusion cool before drinking (Bradley 2006; Mills and Bone 2005; BHP 1996; Culbreth 1927; Felter 1922). Dried leaves - Diaphoretic (To increase sweating,)* drink infusion while still warm (PDR 2007; Culbreth 1927; Felter 1922; Cook 1869). *Note: Information in brackets is required on the label, when both uses to reduce and increase sweating are listed on the label. Duration(s) of Use Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks (Gardner and McGuffin 2013; Wichtl 2004; ESCOP 2003). Risk Information Caution(s) and warning(s) Carminative, Diaphoretic, Antihidrotic, Antigalactagogue Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) All products Do not use if you are pregnant or breastfeeding (Gardner and McGuffin 2013; Bradley 2006; Mills and Bone 2005). Do not use if you have a seizure disorder such as epilepsy (Gardner and McGuffin 2013; Bradley 2006; Mills and Bone 2005). 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. Sage contains thujone. For adults, the upper limit for total daily intake of thujone from health products is 6 mg. Product licence applications for oral products should include a copy of a certificate of analysis or any other equivalent document demonstrating that the thujone content of a daily dose of the product is acceptable. Because thujone content of the herbal materials can vary, the thujone content should be determined for each batch during production of the product. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited BHP 1996: British Herbal Medicine Association's Scientific Committee. British Herbal Pharmacopoeia. Bournemouth (GB): The British Herbal Medicine Association; 1996. Blumenthal M, Goldberg A, Brinckmann J. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): American Botanical Council. 2000. Bradley PR, editor. 2006: Bradley PR, editor. British Herbal Compendium Volume 2: A Handbook of Scientific Information on Widely Used Plant Drug-Companion to the British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 2006. Cook WMH. The Physio-Medical Dispensatory: A Treatise on Therapeutics, Materia Medica, and Pharmacy, in Accordance with the Principles of Physiological Medication. Cincinnati (OH): WM.H. Cook; 1869. Reprint version by Medical Herbalism and medherb.com, Boulder (CO). [Accessed 2024 March 12]. Available from: http://www.henriettesherbal.com/eclectic/cook/index.html Culbreth DMR. A Manual of Materia Medica and Pharmacology. 7 th edition Philadelphia (PA): Lea & Febiger; 1927. Abridged and alphabetized by Michael Moore, director. The Southwest School of Botanical Medicine, Bisbee (AZ). [Accessed 2024 March 12]. Available from: http://www.swsbm.com/ManualsOther/Culbreth.html ESCOP 2003: E/S/C/O/P Monographs: The Scientific Foundation for Herbal Medicinal Products. 2 nd edition. 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St. Louis (MO): Churchill Livingstone; 2010. USDA 2024: United States Department of Agriculture, Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 November 14]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch Wichtl M, editor. Herbal Drugs and

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Day C, Flatt PR, Gould BJ, Bailey CJ. Diabetes Research 1989;10(2):69-73. Tildesley NTJ, Kennedy DO, Perry EK, Ballard CG, Savelev S, Wesnes KA, Scholey AB. Salvia lavandulaefolia (Spanish Sage) enhances memory in healthy young volunteers. Pharmacology, Biochemistry and Behavior 2003;75:669-674. Tildesley NTJ, Kennedy DO, Perry EK, Ballard CG, Wesnes KA, Scholey AB. Positive modulation of mood and cognitive performance following administration of acute doses of Salvia lavandulaefolia essential oil to healthy young volunteers. Physiology & Behavior 2005;83:699-709. Umezu T. Evaluation of the effects of plant-derived essential oils on central nervous system function using discrete shuttle-type conditioned avoidance response in mice. Phytotherapy Research 2012;26(6):884-891. Wake G, Court J, Pickering A, Lewis R, Wilkins R, Perry E. CNS acetylcholine receptor activity in European medicinal plants traditionally used to improve failing memory. Journal of Ethnopharmacology 2000; 69:105-114. Walch SG, Kuballa T, Stühlinger W, Lachenmeier DW. Determination of the biologically active flavour substances thujone and camphor in foods and medicines containing sage (Salvia officinalis L.). Chemistry Central Journal 2011;5:44. Weiss RF. Fintelmann VF. Herbal Medicine. 2 nd edition, revised and expanded. Stuggart (NY): Thieme; 2000. World Health Organization. International Programme on Chemical Safety. Toxicological Evaluation of Certain Food Additives: WHO Food Additives Series 16. Geneva (CH): World Health Organization; 1981. [Accessed 2024 March 12]. Available from: http://www.inchem.org/documents/jecfa/jecmono/v16je01.htm World Health Organization. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Thujone. [Accessed 2024 March 12]. Available from: http://www.inchem.org/documents/jecfa/jeceval/jec_2273.htm World Health Organization. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Isothujone. [Accessed 2024 March 12]. Available from: http://www.inchem.org/documents/jecfa/jeceval/jec_2273.htm Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

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.

DOSE(S)

Umezu T. Evaluation of the effects of plant-derived essential oils on central nervous system function using discrete shuttle-type conditioned avoidance response in mice. Phytotherapy Research 2012;26(6):884-891. Wake G, Court J, Pickering A, Lewis R, Wilkins R, Perry E. CNS acetylcholine receptor activity in European medicinal plants traditionally used to improve failing memory. Journal of Ethnopharmacology 2000; 69:105-114. Walch SG, Kuballa T, Stühlinger W, Lachenmeier DW. Determination of the biologically active flavour substances thujone and camphor in foods and medicines containing sage (Salvia officinalis L.). Chemistry Central Journal 2011;5:44. Weiss RF. Fintelmann VF. Herbal Medicine. 2ndedition, revised and expanded. Stuggart (NY): Thieme; 2000. World Health Organization. International Programme on Chemical Safety. Toxicological Evaluation of Certain Food Additives: WHO Food Additives Series 16. Geneva (CH): World Health Organization; 1981. [Accessed 2024 March 12]. Available from: http://www.inchem.org/documents/jecfa/jecmono/v16je01.htm World Health Organization. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Thujone. [Accessed 2024 March 12]. Available from: http://www.inchem.org/documents/jecfa/jeceval/jec_2273.htm World Health Organization. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Isothujone. [Accessed 2024 March 12]. Available from: http://www.inchem.org/documents/jecfa/jeceval/jec_2273.htm

RISK INFORMATION

Caution(s) and warning(s) Carminative, Diaphoretic, Antihidrotic, Antigalactagogue Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) All products Do not use if you are pregnant or breastfeeding (Gardner and McGuffin 2013; Bradley 2006; Mills and Bone 2005).Do not use if you have a seizure disorder such as epilepsy (Gardner and McGuffin 2013; Bradley 2006; Mills and Bone 2005). 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 CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

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.Sage contains thujone. For adults, the upper limit for total daily intake of thujone from health products is 6 mg. Product licence applications for oral products should include a copy of a certificate of analysis or any other equivalent document demonstrating that the thujone content of a daily dose of the product is acceptable. Because thujone content of the herbal materials can vary, the thujone content should be determined for each batch during production of the product.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Salvia officinalis	Common sageDalmatian sageGarden sageSage	Salvia officinalis	Leaf	Dry