

NATURAL HEALTH PRODUCT

GARLIC – *ALLIUM SATIVUM*

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 March 31, 2023

Proper name(s), Common name(s), Source information

Garlic dried bulb

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)
<i>Allium sativum</i>	Garlic	<i>Allium sativum</i>	Bulb	Dry

References: Proper name: USDA 2018; Common name: McGuffin et al. 2000; Source information: ESCOP 2003, Bradley 1992.

Garlic essential oil

Table 2. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
<i>Allium sativum</i>	Garlic essential oil	<i>Allium sativum</i>	Bulb

References: Proper name: USDA 2018; Source information: ESCOP 2003, Bradley 1992.

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 2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giaccoia et al. 2008; EMEA/CHMP 2006).

Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giaccoia 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 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)

- ▶ Traditionally used in Herbal Medicine to help relieve the symptoms associated with upper respiratory tract infections and catarrhal conditions (such as nasal congestion/buildup of excess mucuous) (Mills and Bone 2005; ESCOP 2003; Bradley 1992; Felter and Lloyd 1983).
- ▶ Used in Herbal Medicine to help reduce elevated blood lipid levels (hyperlipidemia) in adults (Kojuri et al. 2007; Macan et al. 2006; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Blumenthal et al. 2000; Bradley 1992).
- ▶ Used in Herbal Medicine to help maintain cardiovascular health in adults (Kojuri et al. 2007; Macan et al. 2006; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Blumenthal et al. 2000; Bradley 1992).

The following combined use(s) or purpose(s) is/are also acceptable:

- ▶ Used in Herbal Medicine to help reduce elevated blood lipid levels (hyperlipidemia) and maintain cardiovascular health in adults (Kojuri et al. 2007; Macan et al. 2006; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Blumenthal et al. 2000; Bradley 1992).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Table 3. Dose information for garlic bulb presented as dose per day

Subpopulation(s) ^{1,2}		Garlic bulb (g/day)	
		Minimum	Maximum
Children	2-4 years	0.08	2
	5-9 years	0.1	3
	10-11 years	0.2	6
Adolescents	12-14 years	0.2	6
	15-17 years	0.5	12
Adults	18 years and older	0.5	12

¹ Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of garlic in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997.

² Adult dose supported by the following references: Kojuri et al. 2007; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Blumenthal et al. 2000; Bradley 1992.

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Table 4. Dose information for allicin and alliin presented as dose per day. Extracts should be standardized to allicin and/or alliin.

Subpopulation(s) ^{1,2}		Minimum (mg/day)		Maximum (mg/day)	
		Allicin	Alliin	Allicin	Alliin
Children	2-4 years	0.17	0.3	2	4.5
	5-9 years	0.25	0.5	3	7
	10-11 years	0.5	1	6	14
Adolescents	12-14 years	0.5	1	6	14
	15-17 years	1	2	12	27
Adults	18 years and older	1	2	12	27

¹ Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of garlic in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997.



² Adult dose for allicin supported by the following references: Kojuri et al. 2007; Mills and Bone 2005; ESCOP 2003; Kannar et al. 2001; Bradley 1992. Adult dose for alliin calculated based on the conversion ratio of 0.45 mg allicin: 1 mg alliin (ESCOP 2003).

Method of preparation: Oil, Essential (water steam distillation)

Table 5. Dose information for garlic essential oil presented as dose per day

Subpopulation(s)		Garlic essential oil (mg/day)	
		Minimum	Maximum
Adults ¹	18 years and older	2	5

¹Adult dose supported by the following reference: Bradley 1992.

Direction(s) for use

No statement required.

Combination rule

No permitted combinations between ingredients from Table 1 and 2. This monograph only supports single ingredient products for compendial applications.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Relief of upper respiratory tract infections and catarrhal (nasal congestion) conditions

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

All uses

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners or protease inhibitors (Brinker 2018; Mills and Bone 2005).



- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant (Brinker 2018; Mills and Bone 2005).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have diabetes (Brinker 2018; Mills and Bone 2005).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Brinker 2018; Mills and Bone 2005).

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* (NHPR).

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

Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications.

Bove M. 2001. An Encyclopedia of Natural Healing for Children & Infants, 2nd edition. Toronto (ON): McGraw-Hill.



Bradley PR, editor. 1992. *British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1*. Bournemouth (UK): British Herbal Medicine Association.

Brinker F. 2018. *Online Updates and Additions to Herb Contraindications and Drug Interactions, 4th edition*. Sandy (OR): Eclectic Medical Publications. [Accessed 2018 June 1]. Available from: <https://www.eclecticherb.com/herb-contraindications-drug-interactions/>

EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. [Accessed 2018 June 1]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003782.pdf

ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme.

Felter HW, Lloyd JU. 1983. *King's American Dispensatory, Volume 1, 18th edition*. Sandy (OR): Eclectic Medical Publications [Reprint of 1898 original].

Giacoia GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. *Clinical Therapeutics* 2008; 30(11):2097-2101.

JC 2008: Justice Canada. Food and Drug Regulations C.01.021. [online]. Ottawa (ON): Justice Canada. [Accessed 2018 June 1]. Available from: http://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-110.html#h-156

Kannar D, Wattanapenpaiboon N, Savige G, Wahlqvist M. 2001. Hypocholesterolemic effect of an enteric-coated garlic supplement. *Journal of the American College of Nutrition* 20(3):225-231.

Kojuri J, Vosoughi A, Akrami M. 2007. Effects of anethum graveolens and garlic on lipid profile in hyperlipidemic patients. *Lipids in Health and Disease* 6(5):1476-1511.

Macan H, Uykingpang R, Alconel M, Takasu J, Razon R, Amagase H, Niihara Y. 2006. Significance of garlic and its constituents in cancer and cardiovascular disease: aged garlic extract may be safe for patients on warfarin therapy. *Journal of Nutrition* 136:793S-795S.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. 2000. *Herbs of Commerce, 2nd edition*. Silver Spring (MD): American Herbal Products Association.

McIntyre A. 2005. *Herbal Treatment of Children - Western and Ayurvedic Perspectives*. Toronto (ON): Elsevier Limited.

Mills S, Bone K. 2005. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone.

Schilcher H. 1997. *Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists*. Stuttgart (D): Medpharm Scientific Publishers.

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. *Allium sativum* L. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2018 June 1]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

References reviewed

BHP 1996: *British Herbal Pharmacopoeia*. Bournemouth (UK): British Herbal Medicine Association.

BHP 1983: *British Herbal Pharmacopoeia*. Cowling (UK): British Herbal Medical Association.

Budoff M. 2006. Aged garlic extract retards progression of coronary artery calcification. *The Journal of Nutrition* 136(3 Suppl):741S-744S.

CDC 2007: Centers for Disease Control and Prevention. Update: International Outbreak of Restaurant-Associated Botulism -- Vancouver, British Columbia, Canada [online]. *Morbidity and Mortality Weekly Report (MMWR)* October 18, 1985 / 34(41):643. Atlanta (GA): Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services. [Accessed 2008 May 9]. Available from: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000627.htm>

Gardner CD, Lawson LD, Block E, Chatterjee LM, Kiazand A, Balise RR, Kraemer HC. 2007. Effect of raw garlic vs commercial garlic supplements on plasma lipid concentrations in adults with moderate hypercholesterolemia. *Archives of Internal Medicine* 167(4):346-353.

HC 2007: Health Canada. *Natural Health Products Directorate Guidance Document for the Evidence for Quality of Finished Natural Health Products, Version 2.0* [online]. Ottawa (ON): Her Majesty the Queen in Right of Canada, represented by the Minister of Health. [Accessed 2008 May 9]. Available from: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq_e.html

HC 2006. Health Canada. *Health Products and Food Branch (HPFB) Standards and Guidelines for Microbiological Safety of Food - An Interpretive Summary* [online]. Ottawa (ON): Food Directorate Evaluation Division, Bureau of Microbial Hazards, Health Canada. [Accessed 2008



May 9]. Available from: http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/volume1/intsum-somexp_e.html

Lund B. 1993. Quantification of factors affecting the probability of development of pathogenic bacteria, in particular *Clostridium botulinum*, in foods. *Journal of Industrial Microbiology* 12(35):144-155.

Mills S, Bone K. 2000. *Principles and Practice of Phytotherapy*. Toronto (ON): Churchill Livingstone.

NIH 2008a: National Institutes of Health. ChemIDplus advanced [online]. Alliin; RN: 556-27-4. Bethesda (MD): Specialized Information Services, National Library of Medicine, National Institutes of Health, US Department of Health & Human Services. [Accessed 2008 May 9]. Available from: <http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp>

NIH 2008b: National Institutes of Health. ChemIDplus advanced [online]. Allicin; RN: 539-866. Bethesda (MD): Specialized Information Services, National Library of Medicine, National Institutes of Health, US Department of Health & Human Services. [Accessed 2008 May 9]. Available from: <http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp>

NIH 2008c: National Institutes of Health. ChemIDplus advanced [online]. S-allylcysteine; RN: 21593-77-1. Bethesda (MD): Specialized Information Services, National Library of Medicine, National Institutes of Health, US Department of Health & Human Services. [Accessed 2008 May 9]. Available from: <http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp>

Ziaei S, Hantoshzadeh P, Rezasoltani P, Lamyian M. 2001. The effect of garlic tablet on plasma lipids and platelet aggregation in nulliparous pregnant at high risk of preeclampsia. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 99(2):201-206.