Theanine, L-

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L-THEANINE 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 - 46 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 June 3, 2019 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 ingredient(s) Source material(s) Preparation Common name(s) Proper name(s) Part(s) L-Theanine N-Ethyl-L-glutamine L-Theanine N/A Camellia sinensis Leaf Isolate L-Theanine N/A N/A Synthetic References: Proper names: NIH 2015, O'Neil et al. 2013; Common name: NIH 2015; Source materials: O'Neil et al. 2013, Zajac et al. 2003, Gennaro 2000 . 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 any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document. Use(s) or Purpose(s) Helps to temporarily promote relaxation (Nobre et al. 2008; Kimura et al. 2007; Lu et al. 2004). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 200 - 250 milligrams of L-Theanine, per day (Kimura et al. 2007; Lu et al. 2004; Song et al. 2002; Kobayashi et al. 1998). Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) No statement required. Contraindication(s) No statement required. 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. The assay must demonstrate that the percentage purity of the medicinal ingredient is no less than 98% L-theanine. The Finished Products Specifications must include testing for chemical identity and assay/ purity of the medicinal ingredient L-theanine at the raw material or finished product stage using an appropriate enantiomerically selective separation method (i.e. HPLC/APCI-MS, RP-HPLC, etc.). If testing is conducted at the raw material stage, data to demonstrate that the ingredient does not undergo racemization must be provided. References Cited Kimura K, Ozeki M, Juneja LR, Ohira H. 2007. L-Theanine reduces psychological and physiological stress responses. Biological Psychology 74(1):39-45. Kobayashi K, Nagato Y, Aoi N, Juneja LR, Kim M, Yamamoto T, Sugimoto S. 1998. The effects of L-theanine on the release of alpha-brain waves in human volunteers. Nippon Noegikagaku Kaishi 72(2)153-157. Lu K, Gray MA, Oliver C, Liley DT, Harrison BJ, Bartholomeusz CF, Phan KL, Nathan PJ. 2004. The acute effects of L-theanine in comparison with alprazolam on anticipatory anxiety in humans. Human Psychopharmacology 19(7):457-65. NIH 2015: National Institute of Health [Internet]. [Accessed 2019 May 15]. Available from: http://chem.sis.nlm.nih.gov/chemidplus/rn/1077-28-7 Nobre AC, Rao A, Owen GN. 2008. L-theanine, a natural constituent in tea, and its effect on mental state. Asia Pacific Journal of Clinical Nutrition 17(Suppl1):167-168. O'Neil MJ, Heckelman PE, Koch CB, Roman KJ, éditeurs. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals, 15th edition. Whitehouse Station (NJ): Merck & Co., Inc. 2013. Song CH, Chung KI, Song SW, Kim KS. 2002. The Effects of L-theanine on Mental Relaxation and Fatigue Perception. Journal of the Korean Academy of Family Medicine 23(5):637-645. References Reviewed Abdou AM, Higashiguchi S, Horie K, Kim M, Hatta H, Yokogoshi H. 2006. Relaxaton and immunity enhancement effects of gamma-aminobutyric acid (GABA) administration in humans. Biofactors 26(3):201-208. Haskell CF, Kennedy DO, Milne AL, Wesnes KA, Scholey AB. 2008. The effects of L-theanine, caffeine and their combination on cognition and mood. Biolgical Psychology 77(2):113-122. 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 any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

RISK INFORMATION

Caution(s) and warning(s) No statement required. Contraindication(s) No statement required. 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.The assay must demonstrate that the percentage purity of the medicinal ingredient is no less than 98% L-theanine.The Finished Products Specifications must include testing for chemical identity and assay/ purity of the medicinal ingredient L-theanine at the raw material or finished product stage using an appropriate enantiomerically selective separation method (i.e. HPLC/APCI-MS, RP-HPLC, etc.).If testing is conducted at the raw material stage, data to demonstrate that the ingredient does not undergo racemization must be provided.

REFERENCES

Route of Administration Oral

r name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Preparation	
on name(s)	Proper name(s)	Part(s)			
nineN-Ethyl-L-glutamine	L-Theanine	N/A	Camellia sinensis	Leaf	Iso
nine	N/A	N/A	Synthetic		