

# **AlphaWave® L-Theanine White Paper**

**A Deeper Dive into its Stress-Reducing and Cognitive-Enhancing Benefits**

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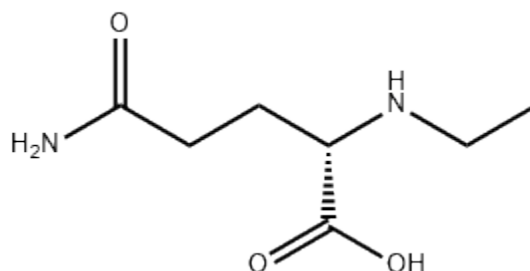
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## 1. Introduction:

AlphaWave® L-Theanine is a branded form of highly purified L-Theanine supplied by Ethical Naturals Inc. (ENI). The ingredient has garnered attention for its health benefits in promoting relaxation, focus, stress management and mental acuity. This white paper delves deeper into the unique features of this ingredient, exploring its pharmacodynamics and science-backed effects, potential applications, health benefits, and safety profile.

## 2. Abstract:

L-Theanine (L-gamma-glutamylethylamide or 5-N-ethylglutamine) is a glutamic acid analog or amino acid derivative with the following chemical structure and properties.



CAS No.	3081-61-6
Molecular Formula	C <sub>7</sub> H <sub>14</sub> N <sub>2</sub> O <sub>3</sub>
Molecular Weight	174.2
Specific Rotation	+7.7° - +8.5°
Melting Point	202-215
Solubility	Soluble in Water
Form	Solid, powder
Color	White
Odor	Odorless

L-Theanine is naturally present in tea leaves, particularly green tea. Since ancient times, it's been known that drinking green tea brings a calming, relaxing level of alertness, something that would seem in contrast to its caffeine content. In 1949, L-Theanine was first isolated and identified in green tea leaves [1]. Hundreds of studies evaluated the many health benefits of green tea, and what makes it the most consumed beverage in the world is its pleasant taste and relaxation effect. It was suggested that the neurologically-active amino acid L-Theanine is the constituent that's responsible for this calming and relaxation effect [2, 3].

Following the discovery of the beneficial effect of L-Theanine, attempts have been made to extract the purified amino acid from green the tea leaf. However, due to low yields, high cost, crop variability, and other complications, this method has remained largely unsuccessful.

AlphaWave® L-Theanine is produced by a proprietary fermentation and purification process that begins with Non-GMO corn-derived sucrose. Its special qualities include:

- **Rigorous Quality Control:** AlphaWave® is produced for ENI in a facility that has been fully audited, cGMP and ISO/FSSC-22000 certified by SGS and inspected by US-FDA. It is then tested and distributed through ENI's NSF Certified laboratory and distribution facility in Redwood City, California. This assures purity, potency, consistency, and traceability through every batch.
- **Generally Recognized as Safe (GRAS) Affirmed:** suitable for both supplement and food/beverage applications.
- **Canada Product License (NPN 80128131):** AlphaWave® L-Theanine (200mg capsule) is approved for use in Canada.
- **Australian Therapeutic Goods Administration (TGA):** AlphaWave® L-Theanine's high level of overall quality and safety has allowed it to earn TGA Approval for the Australian Market. It is now the only form of L-Theanine permitted for manufacturing use in Australia.
- **Clinical Research Backing:** Supported by three clinical studies that investigated and confirmed efficacy and safety in health benefits including relaxation, stress management, focus, recognition, and mental acuity.
- **Available in either fine powder or granular form,** ideal for either encapsulation and tableting application or food and beverage use.

### 3. Features and advantages of AlphaWave® L-Theanine:

**Table 1:** Comparison of AlphaWave® L-Theanine with generic L-Theanine

<b>Feature</b>	<b>AlphaWave® L-Theanine</b>	<b>Generic L-Theanine</b>
<b>Brand</b>	Trademark, brand protection and recognition	May not have brand recognition and protection
<b>Patent Analysis</b>	No concern for patent infringement	May have patent infringement concern
<b>GRAS status</b>	GRAS affirmed	May not have GRAS status
<b>Purity</b>	Quality is guaranteed through testing for every batch to ensure purity, potency and consistency; substantially lower heavy metal and solvent residue internal control limits.	Subject to manufacturer variations
<b>Canadian Product License</b>	AlphaWave® L-Theanine (200mg capsule) is approved for use in Canada (NPN 80128131).	May not be registered
<b>TGA Approval</b>	AlphaWave® L-Theanine is the only brand of L-Theanine that is permitted by TGA for inclusion as an ingredient in listed medicines in Australia.	Not approved by TGA
<b>Clinical Research</b>	Supported by multiple studies	Limited research on specific brands only
<b>Production readiness</b>	AlphaWave® L-Theanine is also available in denser fine granular with improved flowability (proprietary physical granulation without excipients) – suitable for encapsulation and tablet applications.	Most generic L-Theanine only available in very fine powder form; low density and low flowability. Difficult for encapsulation and tablet applications.
<b>Non-GMO compliance</b>	Non-GMO compliant	May not be GMO compliant
<b>Beverage application</b>	Neutral taste and 100% solubility in water make AlphaWave® L-Theanine ideal for beverage use.	Flavor and solubility may not be pleasant and consistent.

#### **4. The discovery of Alpha brainwaves:**

The discovery of different levels of brainwaves began in 1924 when Hans Berger, a German neurologist invented electroencephalography (EEG) [4]. This is a method of recording the electrical activity of the brain in the form of brainwaves; these are oscillating electrical voltages in the brain measuring just a few millionths of a volt. Hans Berger was the first to identify the alpha wave rhythm, and for this reason it is also sometimes referred to as the Berger wave.

Alpha brainwaves (as measured by EEG) are associated with a state of relaxed wakefulness, typically observed when a person is awake but in a relaxed state, such as during meditation [4,5]. Research has also shown that alpha brainwaves play a role in a variety of cognitive processes, including attention, memory and creativity. Higher levels of frontal region and whole scalp alpha power have also been linked to reduced anxiety and stress [5,6,7].

#### **5. Pharmacodynamics L-Theanine:**

Research on human volunteers has demonstrated that L-Theanine creates a sense of relaxation via at least two different mechanisms. First, this amino acid directly stimulates the production of alpha brain waves, creating a state of deep relaxation and mental alertness; second, L-Theanine is involved in the formation of the inhibitory neurotransmitter, gamma amino butyric acid (GABA). GABA influences the levels of two other neurotransmitters, dopamine and serotonin, producing the key relaxation effect [8]. In summary, L-Theanine promotes the production of alpha brainwaves associated with relaxation and alertness and reduces stress hormones like cortisol [8, 9, 10, 11]. Additionally, it enhances dopamine and serotonin levels, impacting mood and cognitive function [12].

Numerous studies have also investigated the effects of theanine and caffeine in combination [13, 14, 15, 16]. Evidence shows that theanine might diminish some of the less desirable physiological effects of caffeine. For example, L-theanine has been shown to blunt both caffeine's blood-pressure-increasing effects [13] and its sleep-disrupting effects [14]. Meanwhile, L-Theanine does not appear to blunt the beneficial effects of caffeine on cognitive performance. Instead, the above-described beneficial effects of theanine on some aspects of cognitive function, such as attention, have been found to be enhanced when caffeine is simultaneously ingested [15, 16, 17, 18]. Thus, most well controlled and dose-specific studies conducted recently have reported greater synergic effects when L-Theanine and Caffeine are used in combination.

AlphaWave® L-Theanine has been evaluated in 3 clinical trials. The first two studies confirmed that a single dose (200mg) of AlphaWave® L-Theanine improved the physiological indicators of acute stress in response to the MAT test compared to the placebo, including frontal region alpha power and salivary cortisol, in moderately stressed but otherwise healthy adults. The third clinical trial has evaluated safety and effectiveness of longer-term use (28 days) and in larger dose (400mg/day) in a healthy population of adults who experienced moderate stress on a regular basis. It was reported that AlphaWave® L-Theanine supplementation at larger dose for regular use was safe and significantly decreased perceived stress and light sleep, improved sleep quality and enhanced cognitive attention in the studied population [19,20].

## **6. Clinical studies: the science-backed effects of AlphaWave® L-Theanine:**

### **6.1 First clinical study:**

Study conducted at: The Wellington Sleep Investigation Center, University of Otago, New Zealand.

***'The Effects of AlphaWave® L-Theanine on Relaxation, Clarity and Cognitive Function: a Human Study w/20 Subjects: a randomized, double blind, placebo-controlled study'***

#### **Study design and method:**

This randomized, double blind, placebo-controlled study assessed relaxation after a 200mg dose of AlphaWave® through measurement of alpha brainwave changes by electroencephalography (EEG), and responses to stress tests. It also assessed changes in heart rate as an indication of stress level. Twenty subjects (10 male and 10 female), aged between 21 and 47 years, were tested for the effects of AlphaWave® L-Theanine or placebo.

#### **Results and conclusion:**

Consumption of 200mg of AlphaWave® L-Theanine produced significant changes over time as compared to placebo on all the variable outcomes assessed in this investigation. For example, AlphaWave® L-Theanine showed a positive effect over time on the tonic alpha power, that measures relaxed wakefulness, whereas the placebo had negative effects. Although the values for anxiety/tension were low, they decreased over time for both groups, and the decrease in AlphaWave® group was greater. The group consuming AlphaWave® also displayed reduced fatigue.

In addition, AlphaWave® L-Theanine significantly reduced the heart rate compared with placebo over the time period of the study. This was a further indication of the actual stress reduction effect of AlphaWave® L-Theanine.

The study concluded that: ' To summarize there is evidence that the Alpha Wave® L-Theanine significantly improved the tonic and phasic alpha wave activities, reduced the stress and anxiety and also lowered the heart rate with time. There was trending positive difference in the alpha wave activities and subjective scores but the heart rate reduction was highly significant at each determination.'

### **6.2 Second clinical study:**

Study conducted by: KGK Science Inc.

Published by Neurology and Health, September 2021

***'A randomized, triple-blind, placebo-controlled, crossover study to investigate the efficacy of a single 200mg dose of AlphaWave® L-Theanine on stress in a healthy adult population.'***

#### **Study design and method:**

The objective of this study, thought to be the first to investigate the effects of L-theanine in a population of healthy adults reporting moderate levels of stress, was to investigate the efficacy and safety of AlphaWave® L-Theanine both on frontal alpha power and salivary cortisol levels in healthy, moderately stressed adults. Increases in brainwave alpha power indicate greater relaxation without drowsiness, and salivary cortisol is also an objective measure of stress levels.

#### **Results and conclusion:**

The 16 subjects (cross-over design), ranging from age 16 to 60, were administered a 200mg single dose of AlphaWave® L-Theanine and the response to an acute stress model was investigated. This study was

conducted during the global SARS-CoV-2 pandemic, which has had a rapid and significant effect on both physical and mental health around the world. In the study, the single dose of AlphaWave® L-Theanine significantly increased frontal region alpha power, and significantly reduced salivary cortisol levels, compared to placebo. These changes are indicative of relaxation in the brain and demonstrate a calming response in healthy adults between 19 and 60 years of age.

The study concludes that: A single dose of AlphaWave® L-Theanine improved the physiological indicators of acute stress in response to the MAT test compared to the placebo, including frontal region alpha power and salivary cortisol, in moderately stressed but otherwise healthy adults. This is significant, as increases in brainwave alpha power is considered to reflect relaxation in the brain, suggesting a calming effect of AlphaWave® L-Theanine. The randomized, triple-blind, placebo-controlled study design is rigorous and is the gold standard for investigating the efficacy of an investigational product. Further, the crossover study design controls for confounding factors between individual participants by measuring the effects from the single dose of AlphaWave® L-Theanine and placebo in the same participant. A single dose of AlphaWave® L-Theanine was found to be efficacious, safe, and well tolerated, and should be considered as a nutraceutical supplement to manage acute stress.

**Link to full study:** <https://link.springer.com/article/10.1007/s40120-021-00284-x>

### **6.3 Third clinical study:**

Study conducted by: KGK Science Inc

Published in Neurology and Health, May 2024

***Safety and Efficacy of AlphaWave® L-Theanine Supplementation for 28 Days in Healthy Adults with Moderate Stress: A Randomized, Double-Blind, Placebo-Controlled Trial*** (Marc Moulin, David C. Crowley, Lora Xiong, Najla Guthrie, Erin D. Lewis *Neurol Therapy*).

**Study design and method:** The latest study was designed to further examine the safety and efficacy of AlphaWave® over a longer period of time than previous research.

For this study thirty healthy adults (18–65 years) with moderate stress were randomized to AlphaWave® L-Theanine (400 mg L-theanine/day) or placebo ( $n = 15/\text{group}$ ) for 28 days. Stress was assessed by salivary cortisol, Perceived Stress Scale (PSS) and Depression, Anxiety and Stress Scale-21; sleep was assessed by the Healthy People Sleep Quality Index and actigraphy device; cognition was assessed by Computerized Mental Performance Assessment System; mood was assessed by Profile of Mood States. All outcomes were measured at baseline, Days 14 and 28. Safety included vital signs, clinical chemistry, haematology and adverse events (AEs).

### **Results and conclusion:**

The study evaluated the safety and effectiveness of longer-term use (28 days) and in larger dose (400mg/day) in a healthy population of adults who experienced moderate stress on a regular basis. It was reported that AlphaWave® L-Theanine supplementation at larger dose for longer term regular use (28 days; 400mg/day) was safe and significantly decreased perceived stress (measured by PSS scores, a validated measure of self-reported stress) and light sleep, improved sleep quality and enhanced cognitive attention in the studied population. A decrease in stress is important for this population as an inverse association between stress and quality of life has been reported previously suggesting AlphaWave® L-Theanine supplementation may represent a strategy to improve quality of life.

**Link to full study:** <https://link.springer.com/article/10.1007/s40120-024-00624-7>



## **7. Stability of AlphaWave® L-Theanine for supplement and beverage use:**

7.1 Bulk Powder: No degradation was found after 9-month accelerated (AC) stability test and 3-year long-term (LT) stability tests. It is suggested that AlphaWave® L-Theanine is stable in solid powder form and in its original package (double inner virgin polyethylene bags, and in transportation drum) for not less than 3 years (Appendix I).

7.2 Hard-shell Capsules: No degradation was found after 9-month accelerated (AC) stability test and 3-year long-term (LT) stability tests. It is suggested that AlphaWave® L-Theanine is stable when it is in hard capsule form and packed in white HDPE bottle with screw cap for not less than 3 years. If desired, about 5% overage is suggested to cover potential test variation or individual capsule weight variation.

7.3 Gummies: Minor degradation was noticed in 6-month AC stability test in a single L-Theanine gummy formulas. A 20% overage is suggested to cover potential degradation to claim 2-year shelf life.

7.4 Beverage: Short-term stability of AlphaWave® L-Theanine in liquid solution at different temperature and pH conditions are reported as basic and reference information for beverage application (Appendix II).

Disclaimer: The above stability data was conducted by ENI with single active ingredient and commonly used excipients. It is solely used as reference information for R&D work of finished goods (FGs). The FG manufacturer shall be responsible for conducting your own stability test on your specific FG to determine the shelf life of a specific FG.

## 8. Typical application of AlphaWave® L-Theanine in a capsule form

Supplement Facts:

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Serving Size: 1 vegetarian capsule

	Amount per serving	% Daily Value
L-Theanine (AlphaWave®)	200mg	†

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Other Ingredients: Microcrystalline Cellulose, Hypromellose (vegetarian capsule), Silicon Dioxide

## 9. Specification of AlphaWave® L-Theanine

Refer to Appendix III and IV.

## 10. Generally Recognized as Safe GRAS affirmation summary

The Life Sciences Research Organization, Inc. (LSRO) has conducted GRAS assessment for the above product through scientific analyses. It is concluded that AlphaWave® L-Theanine conforms to the criteria required by FDA for GRAS affirmation for its intended use at appropriate dosage as follow:

AlphaWave® L-Theanine is intended to fortify both solid foods (e.g., hard candy, chewing gum, food bars, and others) and beverages (e.g., fruit juice, drinking water, tea drinks, yogurt, milk, and others). The proposed daily recommended intake for beverage is 50 to 250 mg of L-Theanine per serving (8 fl oz beverage). The maximum recommended daily intake is 250 mg of AlphaWave® L-Theanine per serving.

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## PRODUCT SPECIFICATION

<b>Product :</b> AlphaWave® L-Theanine	<b>Version Number :</b> N05
<b>Ingredient :</b> Pure L-Theanine (purity >98%) powder	<b>Issued On :</b> 01/17/24
<b>Part No. :</b> E-TS9-03	<b>Issued By :</b> Solomon Y.
<b>Special Note :</b> Kosher certified; no excipients or carriers used; ETO-free and non-irradiated.	<b>Approved By :</b> Lora X.

PHYSICAL-CHEMICAL TESTS	SPECIFICATION	METHODS
<b>IDENTIFICATION</b> Appearance Odor/Taste Fingerprint	White fine or crystalline powder Characteristic Corresponds to reference chromatogram	Organoleptic Organoleptic NIR/HPLC
<b>ASSAY</b> L-Theanine	≥ 98%	HPLC
<b>TESTS</b> Residue of Solvents (Ethanol) <b>HEAVY METALS</b> Arsenic Cadmium Lead Mercury <b>MICROBIOLOGICAL</b> Total Plate Count Yeast & Mold Total Coliforms Escherichia coli Salmonella	Complies with USP standard (≤ 0.5%) ≤ 1.0 ppm ≤ 0.5 ppm ≤ 1.0 ppm ≤ 0.1 ppm ≤ 10,000 cfu/g ≤ 1,000 cfu/g Negative (< 10 cfu/g) Absence in 10 g Absence in 10 g	USP (467) USP USP USP USP USP/AOAC USP/AOAC USP/AOAC USP/AOAC USP/AOAC

### REMARKS:

- (1) Control points verified at ENI Internal Quality Control Lab and/or an FDA Registered lab in accordance with ENI product approval and testing protocol (ENI.SOP.H.1).
- (2) Actual results may vary ± 10% to the specifications due to laboratory test variability.

### SHELF LIFE AND STORAGE:

3 years in sealed container(s) under a controlled room or cool temperature; low humidity environment; away from light.



## PRODUCT SPECIFICATION

**Product :** AlphaWave® L-Theanine Granular  
**Ingredient :** Pure L-Theanine (purity >98%) granular powder  
**Part No. :** E-TG1-08  
**Special Note :** No excipients or carriers used;  
ETO-free and non-irradiated.

**Version Number :** N05  
**Issued On :** 11/06/23  
**Issued By :** Solomon Y.  
**Approved By :** Lora X.

PHYSICAL-CHEMICAL TESTS	SPECIFICATION	METHODS
<b>IDENTIFICATION</b> Appearance Odor/Taste Fingerprint	White fine granular powder Characteristic Corresponds to reference chromatogram	Organoleptic Organoleptic NIR/HPLC
<b>ASSAY</b> L-Theanine	≥ 98%	HPLC
<b>TESTS</b> Tap Density Mesh Size <b>HEAVY METALS</b> Arsenic Cadmium Lead Mercury <b>MICROBIOLOGICAL</b> Total Plate Count Yeast & Mold Total Coliforms Escherichia coli Salmonella	0.55 – 0.85 g/ml 92~100% through 20 mesh ≤ 1.0 ppm ≤ 0.5 ppm ≤ 1.0 ppm < 0.1 ppm ≤ 10,000 cfu/g ≤ 1,000 cfu/g Negative (< 10 cfu/g) Absence in 10 g Absence in 10 g	USP USP USP USP USP USP USP/AOAC USP/AOAC USP/AOAC USP/AOAC USP/AOAC

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