

# Frequently Asked Questions - U.S.A Regulatory Version

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#### What is Suntheanine?

Suntheanine is the trade name for Taiyo's pure L-theanine (L-glutamic acid-γ-monoethylamide) produced via a method that mimics the natural process in green tea leaves resulting in a 100% pure L-isomer-theanine. It is not an extract of green tea, but rather is a patented enzymatic process using the amino acids ethylamine and L-glutamine that assures an isomerically pure L-theanine.

#### What is the mechanism of Suntheanine

- Suntheanine is absorbed in the small intestine via a sodium-coupled active transport process and crosses the blood-brain barrier where it is
  absorbed into the brain in a dose-dependent manner.
- Suntheanine may compete for absorption in the intestinal tract and brain with amino acids found in the methionine group, including isoleucine, leucine and valine. Concentrations of other amino acids are unchanged by Suntheanine.
- Suntheanine directly stimulates production of alpha brain waves (a state often achieved by meditation, one of deep relaxation and mental alertness).
- Suntheanine plays a role in the formation of the inhibitory neurotransmitter GABA and increases dopamine release through modulation of
  glycine and AMPA receptors. Suntheanine promotes a relaxation and excitatory inhibition effect without leading to drowsiness.

#### What is the regulatory status of Suntheanine?

L-theanine was approved in Japan in 1964 for unlimited use in foods. In 2000, Suntheanine was introduced in the U.S. for use in dietary supplements. Suntheanine, as produced via a patented enzymatic fermentation method, resulting in an enantiomerically pure L-theanine, was GRAS affirmed in the U.S. in 2005 for use in foods and beverages up to 250 mg/serving, with no limitation on the number of servings. In 2007 the U.S. FDA confirmed the GRAS Affirmation in its Letter of No Objection (GRN 000209).

#### What safety studies are available for Suntheanine?

Suntheanine has been shown to be safe for use as directed based on the following positive toxicology studies: 28 Day Subacute Toxicity Study, 78 Week Evaluation of Toxicity and Carcinogenicity, Acute Toxicity/LD-50 Determination and Ames Salmonella/Microsome Plate Test for Mutagenicity.

### How often should Suntheanine be taken?

There is not a set schedule for taking Suntheanine, and should be taken when levels of stress are noticed. The effects of Suntheanine are generally felt within 30 minutes, and have been shown to last up to 8 - 12 hours. Consumption of Suntheanine is not affected (positively or negatively) by the consumption of food. Suntheanine may be taken at any time.

### What is the recommended use of Suntheanine?

The intended use for Suntheanine is that of a relaxant to produce mental and physical relaxation without inducing drowsiness. Based on the results of clinical studies, it has been established that Suntheanine is effective in the range of 50 - 200 mg. It is suggested that subjects with higher levels of stress consume a minimum of 100 mg for best effects. Please note that if a person is already calm and relaxed, little to no effect will be noticed at any level of consumption.

## How should products containing Suntheanine be labeled?

Suntheanine® (L-Theanine)

# What claims can be made on Dietary Supplements containing Suntheanine?

The following is list of several recommended structure/function claims for dietary supplements containing Suntheanine:

- Reduces stress, promotes relaxation without drowsiness
- Improves quality of sleep
- Diminishes normal symptoms of PMS
- Improves mental focus, learning performance and concentration
- Reduces negative side effects of caffeine



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