



Food-therapeutic good interface product assessment¹

Overview

Product name (include the ARTG # if relevant)	Cabot Health Tyrosine Pure Mood Food 125g powder
Source (consumer complaint, AFP, Customs, review, sponsor, state/territory etc)	Adverse Drug Reaction (Member of Public)
Details/background (Include copies of labels, links to advertising and any other relevant examples of presentation at Attachment 2 of this form)	According to email received, reported as a ADR, as the consumer took the medication and as a result ended up in hospital with what is suspected a reaction to this supplement. The consumer provided as much information about the reaction (D17-3524323). http://shop.cabothhealth.com.au/tyrosine-pure-mood-food-75g - Website of the goods.
Manufacturer/supplier	Health Direction Pty Ltd
Summary of lab tests (if relevant)	
Ingredients (eg as listed on label, in advertising etc)	Tyrosine

Assessment against Food-Therapeutic Goods Guidance Tool²

Question	Assessment outcome
Q1 – product solely for oral use?	Yes <input checked="" type="checkbox"/> → Go to Q2 No <input type="checkbox"/> → Go to Q6 to determine if therapeutic goods
Q2 – covered by a s7 declaration that it is therapeutic goods?	Yes <input type="checkbox"/> → Most likely a therapeutic good – provide reasoning and details below. Continue with assessment. No <input checked="" type="checkbox"/> → Go to Q3

¹ This form is designed to be used for assisting in the assessment of products at the food-therapeutic goods interface. It reflects the questions in the Guidance Tool (version May 2014). If consultation is required with other agencies (other than Customs or the AFP), use the Protocol.

² A copy of the diagram from the Guidance Tool is at Attachment 3 of this form.

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Q2 continued - Details of s7 considered and reasons why they are applicable or not	
Q3 – covered by s7AA declaration?	Yes <input type="checkbox"/> → Most likely a therapeutic good – provide reasoning and details below. Continue with assessment. No <input checked="" type="checkbox"/> → Go to Q4

Question	Assessment outcome	
Q4 - goods for which there is a standard?	Is the product “goods for which there is a standard” in the Food Standards Code? Yes <input type="checkbox"/> → Product is likely not therapeutic goods No <input checked="" type="checkbox"/> → Go to Q5	
	Provide the food standard(s) you have considered and reasons why they are/are not applicable: Maybe the goods fall into Food Standard 2.9.5. But it is not compliant with this standard as 2.9.5 – 13 requires that the nutritional information is expressed per given amount of the good. The label of the goods do not include this (apart from one metric teaspoon = 3g of pure tyrosine – But I think this is insufficient).	
Q5 - “tradition of use” as food in Australia or NZ?	Q5(a) – What kind of goods is the product? (Eg an encapsulated L-Carnitine for fat metabolism) A powder form of Tyrosine for the production of important brain chemicals that help enhance and support multiple functions.	
	Q5(b) – What is the form in which the product is presented? (eg is it a herb in dried form or encapsulated or tea in a teabag?) Powder	
	Q5(c) – Is there a use of the product as “food for humans” in Aus/NZ in that form? Yes <input type="checkbox"/> → Go to Q5(d) No <input checked="" type="checkbox"/> → Go to Q6	
	Q5(d) – Is there a “tradition” of that use in Aus or NZ? Yes <input type="checkbox"/> → Most likely a food – provide reasoning and details below. Continue with assessment. No <input checked="" type="checkbox"/> → Go to Q6	
Q6 – within para (a) of definition of “therapeutic goods” Q6(1) – determine what use <u>the product</u> appears to be for. Is the product: (If yes to (a), (b) or (c) go to	(a) Represented in any way to be for therapeutic use? (If yes, describe.)	It makes multiple claims that are therapeutic (Please see photo attachment). On the label of the goods it states: - Tyrosine is needed for the brain to make the neurotransmitters dopamine and noradrenalin. These neurotransmitters are needed for concentration, memory, satisfaction and mood control. - Tyrosine assists memory and mental performance during stressful conditions.

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	<p>Q6(2); if no to all, go to Q7)</p>		<ul style="list-style-type: none"> - Tyrosine is an amino acid (building block of protein) required by the adrenal glands to make adrenalin, which is needed for energy. - Tyrosine is used by the thyroid gland to make thyroid hormone, which controls the metabolic rate. <p>On the website it states that tyrosine may assist with the following (which indicate these goods have a therapeutic use):</p> <ul style="list-style-type: none"> - Mood disorders - Poor Memory - Poor focus and concentration - Food Cravings - Addiction - Low motivation - Low or unstable mood - Poor Thyroid Function - Inability to lose weight - Stress reduction
		<p>(b) Likely to be taken to be for therapeutic use because of the way in which it is presented? (If yes, describe.)</p>	<p>Yes – Given the statements of fact about tyrosine provided on the label of the goods, consumers are likely to take these goods as therapeutic goods due to the way in which it is presented.</p>
		<p>(c) Likely to be taken to be for therapeutic use for any other reason? (If yes, describe.)</p>	<p>No</p>
	<p>Q6(2) – determine whether that use of <u>the product</u> is “therapeutic use” ie: (If yes to (a) & (b), or (c) & (d) then it is likely therapeutic goods; otherwise, go to Q7)</p>	<p>(a) Is any disease, ailment, defect, or injury identified? (eg. Cancer, arthritis, wounds) (If yes, describe.)</p>	<p>Yes – multiple disease / ailments / defects identified (on the website). This is provided through multiple statements of fact:</p> <ul style="list-style-type: none"> - Improve mood - Increase focus and concentration - Stress reduction - Thyroid Function - Reduced Cravings - Addiction - Low motivation <p>On the website it also states that tyrosine may assist with (alleviate ailment or injury):</p> <ul style="list-style-type: none"> - Mood disorders - Poor Memory - Poor focus and concentration - Food Cravings

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			<ul style="list-style-type: none"> - Addiction - Low motivation - Low or unstable mood - Poor Thyroid Function - Inability to lose weight. <p>Healthy Weight On the label of the goods:</p> <ul style="list-style-type: none"> - It states that it (tyrosine) is needed for concentration, memory, satisfaction and mood control. - Tyrosine is needed to assist memory and mental performance during stressful conditions. - Tyrosine is an amino acid (building block of protein) required by the adrenal glands to make adrenalin, which is needed for energy. - Tyrosine is used by the thyroid gland to make thyroid hormone, which controls metabolic rate.
		<p>(b) Is the product represented, presented or otherwise likely to be taken to prevent, cure or alleviate that disease, ailment, defect or injury? (If yes, describe.)</p>	<p>Yes – the label of the goods state what Tyrosine is needed for through multiple statements of fact. It is worded in such a way that it can help alleviate ailments such as:</p> <ul style="list-style-type: none"> - It states that it (tyrosine) is needed for concentration, memory, satisfaction and mood control. - Tyrosine is needed to assist memory and mental performance during stressful conditions. - Tyrosine is an amino acid (building block of protein) required by the adrenal glands to make adrenalin, which is needed for energy. <p>Tyrosine is used by the thyroid gland to make thyroid hormone, which controls metabolic rate. On the website of the goods (Website emphasizes this in italics):</p> <ul style="list-style-type: none"> - Improve mood - Increase focus and concentration - Stress reduction - Thyroid Function - Reduced Cravings - Healthy Weight <p>On the website it also states that tyrosine may assist with (alleviate ailment or injury):</p> <ul style="list-style-type: none"> - Mood disorders - Poor Memory - Poor focus and concentration - Food Cravings - Addiction - Low motivation - Low or unstable mood - Poor Thyroid Function

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			- Inability to lose weight.
		(c) Is any physiological process in a person identified? (eg. Teething, gastrointestinal systems, immunity.) (If yes, describe.)	Yes – Thyroid function, Mood disorders
		d) Is the product represented, presented or otherwise likely to be taken to influence, inhibit or modify that process? (If yes, describe.)	Not that I am aware of
Q7 - class of goods the sole/principal use of which is therapeutic use	Is the product in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use? (If yes to (a), (c) & (d) then it is likely therapeutic goods; otherwise, go to Q8)	(a) Is the product in a class of goods?	Yes <input type="checkbox"/> → Go to Q7(b) No <input checked="" type="checkbox"/> → Go to Q8
		(b) What is the class of goods? (Describe how the goods fit the class you have selected)	
		(c) Does that class of goods have a therapeutic use under the definition of the Act subparagraphs (a) and (b)? ie. to prevent, cure or alleviate a disease, ailment, defect or injury, or influence, inhibit or modify a physiological process?	Yes <input type="checkbox"/> → Go to Q7(d) No <input type="checkbox"/> → Go to Q8
		(d) Is that use the principal or ordinary use of the product?	Yes <input type="checkbox"/> → Product is therapeutic goods – end assessment No <input type="checkbox"/> → Go to Q8
Q8 – biological or medical device as defined by the Act?	Biological <input type="checkbox"/> Medical device <input type="checkbox"/> Neither biological or medical device <input checked="" type="checkbox"/>		(If biological or medical device, it is therapeutic goods; otherwise, it could be food)

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Related assessments

Are there any previous food-therapeutic goods interface assessments that are relevant to this assessment?

Yes → Provide details below
 No → Go to Other advice/information section below

Details and outcome:

Yes <input type="checkbox"/> → Provide details below No <input checked="" type="checkbox"/> → Go to Other advice/information section below

Summaries of other relevant advice/information

Source	
State/Territory agencies	
TGA Food Medicine Internal Working group	
Others	

Outcome

Likely to be therapeutic goods?

Yes No

Summary of reasons for outcome

The goods are likely to be therapeutic goods.

The goods do not fit a standard for a food. No tradition of use as a food. The ingredient is an amino acid, which is traditionally used as a supplement to increase tyrosine (in this case) levels in the body. The labels and website provide multiple statements of fact to support / reinforce what tyrosine is and does. There is however, no statement saying that taking this will increase your mood etc...

With the statements of fact provided, it fall under the definition of therapeutic use. Thus, it would be likely that these goods are therapeutic goods.

Assessor

██████████

Date

08/01/2018

Comments/action items (eg Refer to ECT for action; proposal to remove from ARTG; contact state/territory/FSANZ etc)

Refer to ECT for action.

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Attachment 1 - Relevant definitions

Term	Source ³	Definition
		<as add required>

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³ Common sources of definitions are likely to include legislation, legislative instruments and dictionaries

Attachment 2 - Examples of presentations/representations

Use this page to provide copies of labels, advertising and any other relevant examples of presentation.

2.1 Website of the goods (Pages 3 – 4 are unrelated):

180218 Tyrosine Pure Mood Food 75g
CABOT HEALTH <http://shop.cabothealth.com.au>
 Your health is your greatest asset

Search...

Home <http://shop.cabothealth.com.au/> / Stress and Nerves/stressandnerves/ / Tyrosine Pure Mood Food 75g/Tyrosinepuremoodfood75g

TYROSINE PURE MOOD FOOD 75G
 Free from any additives or fillers

TYROSINE PURE MOOD FOOD 75g
 Free from any additives or fillers

TYROSINE PURE MOOD FOOD 75g

\$25.50

IN STOCK

1

<http://shop.cabothealth.com.au/tyrosine-pure-mood-food-75g>

180218 Tyrosine Pure Mood Food 75g

CALCULATE SHIPPING

Qty: 1

Country: **Australia**

Post Code:

DESCRIPTION REVIEWS 0 0 0 0 0

TYROSINE PURE MOOD FOOD

Tyrosine is an amino acid that is required for the production of important brain chemicals (neurotransmitters) that help to support and enhance mood, concentration, memory and learning. The amino acid is critical for the production of thyroid hormones and the synthesis of proteins, enzymes and muscle tissues in the body. Our Tyrosine Pure Mood Food contains a highly potent amino acid form tyrosine that is free from any additives or fillers.

The benefits of Tyrosine:

- Improved mood:** Tyrosine is required for the production of neurotransmitters – dopamine, adrenaline and noradrenaline. Studies have shown that deficiencies of these brain chemicals are correlated with increased incidence of depression and other mood disorders. Tyrosine may act as a mood elevator, helping to stabilize mood and improve feelings of happiness and satisfaction.
- Increased focus and concentration:** Due to tyrosine's involvement in neurotransmitter production, it may help to improve focus, motivation and concentration. Tyrosine could serve as a useful amino acid prior to exercise or work, to help improve mental performance.
- Stress reduction:** In times of stress, additional tyrosine may be needed, as stress depletes noradrenaline in the body. Tyrosine may assist in the management of stress and improve the adaptive effects of the brain chemicals.
- Thyroid function:** Tyrosine plays a critical role in the production of thyroid hormones T3 and T4. The thyroid gland is responsible for regulating metabolism, growth and development, body temperature, and heart rate.
- Reduced cravings:** Low dopamine levels have been associated with increased food cravings and excessive hunger. As dopamine works on the reward centre of the brain, maintaining healthy dopamine levels may assist in the management of addiction. Tyrosine may be helpful for those with food or alcohol addiction.
- Healthy weight:** Due to tyrosine's involvement in producing thyroid hormones, it may assist in the maintenance of a healthy weight range. The thyroid is responsible for regulating metabolism and controlling the metabolic rate for fat burning. As this amino acid may also help to control hunger and cravings, it could serve as a useful supplement as part of a weight loss regime.

Tyrosine may assist with:

- Mood disorders
- Poor memory
- Poor focus and concentration
- Food cravings
- Addiction
- Low motivation
- Low or unstable mood
- Poor thyroid function
- Inability to lose weight

Dosage:

- Adults:** 1-2 teaspoons, 2-3 times daily in a glass of water or juice, 30 minutes before meals or as directed by your healthcare professional.
- Children:** 1 teaspoon, 2-3 times daily in a glass of water or juice, 30 minutes before meals or as directed by your healthcare professional.

Cautions and contraindications:

Tyrosine supplements should not be taken by people using monoamine oxidase inhibitor antidepressant drugs (eg. Nardil) and L-dopa. Tyrosine may cause a severe raise in blood pressure (especially taking these medications). Tyrosine should not be taken at the same time as the Parkinson's/MS/Alz medication, Levodopa (L-dopa). If symptoms persist, customers should consult their healthcare practitioner.

Each level 5mL metric teaspoon contains:
 Pure Tyrosine 15 + 1.8 g

<http://shop.cabothealth.com.au/tyrosine-pure-mood-food-75g>

2.2 Label of the goods:



2.3 Advertisement from an Australian website (<https://www.vitaminking.com.au/tyrosine-mood-food-125g-by-cabot-health-sandra-cabot/>):

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Attachment 3 – Flow chart

GUIDANCE TOOL DIAGRAM – IS THE PRODUCT A “THERAPEUTIC GOOD”?

