

Complaint to TGA: Hydroxycut Hardcore Elite

Publications:

- <https://www.nutritionwarehouse.com.au/hydroxycut-hardcore-elite-pro-series-by-muscletech.html>
- <https://www.supplementwarehouse.com.au/muscletech-hydroxycut-hardcore-elite.html>
- <https://www.evelynfaye.com.au/hydroxycut-hardcore-elite.html>
- <https://www.australiansportsnutrition.com.au/hydroxycut-hardcore-elite.html>
- <https://www.elitesupps.com.au/products/hydroxycut-hardcore-elite>
- <https://www.chemistwarehouse.com.au/buy/87988/hydroxycut-hardcore-elite-110-capsules>
- <https://www.vfsupplements.com.au/muscletech-hydroxycut-hardcore-elite.html>
- Etc.

Date/Edition: 20/09/2018

Product: Hydroxycut Hardcore Elite (ARTG: 303324) attached. N.B. **ARTG Start Date 22/05/2018**

Permitted indications: Enhance/promote energy levels in adults only. Helps enhance/promote calorie burning in adults only

Indication Requirements: Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Sponsor: Export Corporation Australia Pty Ltd, PO Box 3150, BROADWAY NEDLANDS, WA, 6009

Claims:

- “A well formulated supplement suitable for athletes and anyone that is looking to increase their energy levels, improve athletic performance and reduce fat mass”.
- The supplement is a great combination of power producing, fat melting and energy promoting agents.”
- “Some studies show that a combination of coffee and exercise can bring about significant reduction in fat cells than just coffee or exercise alone.”
- “Green coffee is also shown to improve mood and cognitive performance in some research studies”
- “Green coffee is rich in chlorogenic acid which is a potent antioxidant that eliminates free radicals and also inhibits fat absorption, which also makes it an effective weight loss ingredient”
- “Coleus forskhlii: It is an ancient herb that is used in treating respiratory disorders and heart problems. This herb is also found to be effective in preventing weight gain and also help in stimulating fat loss. Studies have shown that the enzyme present in this herb helps in preventing the fat deposit in the body and the herb is also safe for consumption”
- Capsicum annum (cayenne): Cayenne pepper is known to increase metabolism by burning the fat. It is a perfect weight loss tool as it curbs appetite. Many studies have shown that the bio-active compound called capsaicinoids aid in rapid weight loss by boosting the fat-burning rate in the body”.
- “This product can be called a "Power Generator" due its caffeine and theobromine content which increases strength and power as well as energy levels”.
- “It improves performance considerably since the first dose. It is an ideal supplement for weight loss with its green coffee extract which is scientifically to be a component with high thermogenic and lipolytic capacity, even if you do not follow a low-calorie diet.”

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Directions:

“To assess your tolerance, for the first day, take one (1) capsule. On days two and three take two (2) caps once daily. On day four and beyond, take two (2) capsules twice daily. 30 to 60 minutes before your two largest meals. Do not snack between meals. Do not take within five hours of sleep. Do not exceed four (4) capsules in a 24-hour period. Do not use for more than eight weeks”.

Warning:

“**Contains caffeine (152.5 mg per capsule)** The product is not intended for use by persons under 18. This product should not be consumed by individuals with heart problems, sleep or anxiety disorders. Do not combine with other sources of caffeine such as coffee, energy drinks or other caffeinated beverages”.

Research:

The advertisements for this product contain claims not found in the ARTG permitted indications and lacks the indication requirement.

A search of PubMed found no good evidence from clinical trials that coffee or chlorogenic acid (green coffee) is an effective weight loss ingredient. See also, “Dr. Oz and Green Coffee Beans – More Weight Loss Pseudoscience”.¹

A small double blind, placebo-controlled, randomized clinical trial conducted at Victoria University, Melbourne tested *C. forskohlii* (n=15) against a placebo (n=15) in overweight or obese individuals in conjunction with a hypocaloric diet. No significant weight loss difference (or any other anthropometric measures) was found with *C. forskohlii* compared to the placebo group.² Similar results were found in another small double blind, placebo-controlled, randomized clinical trial (n=23).³

A review of the role of capsaicinoids in weight management concluded that long-term randomised trials are needed.⁴ The Natural Medicines Database agreed that more evidence is needed to rate capsicum for weight loss.⁵

There are five previous upheld complaints about this product on the CRP database and one more referred to the TGA (better dealt with by another authority (TGA)).^{6,7}

Conclusion:

I allege this advertisement breaches the Therapeutic Goods Act 1989, s.22(5) and the Therapeutic Goods Advertising Code 2015, s.4(1)(a), 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 6(3)(c)(d) and 7(3).

¹ <https://sciencebasedmedicine.org/dr-oz-and-green-coffee-beans-more-weight-loss-pseudoscience/>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4663611/>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2129145/>

⁴ <https://www.ncbi.nlm.nih.gov/pubmed/24246368>

⁵ <https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements/professional.aspx?productid=945>

⁶ http://www.tgacrp.com.au/complaint-register/?_search=%20Hydroxycut

⁷ http://www.tgacrp.com.au/withdrawn-complaints/?_search=Hydroxycut

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20 September 2018

Acknowledgment

This advertisement was selected by a Monash BMS3052 student team for their WAM assignment.

Screen shots follow:

The screenshot shows the Nutrition Warehouse website interface. At the top, there is a navigation bar with the logo 'NUTRITION WAREHOUSE BIG BRANDS WAREHOUSE PRICES', a search bar with 'Search Products...' and a 'SEARCH' button, and a shopping cart icon showing '\$0.00 (0)' and a 'CHECKOUT' button. Below the navigation bar is a red menu bar with categories: CATEGORIES, BRANDS, SPECIALS, NEW, CLEARANCE, FIND A STORE, ARTICLES, and HELP. The main content area features a product page for 'HYDROXYCUT HARDCORE ELITE PRO SERIES BY MUSCLETECH'. On the left is an image of the product bottle, which is black with red and white text. The bottle label includes 'MUSCLETECH PERFORMANCE SERIES', 'HYDROXYCUT HARDCORE ELITE', and '110 CAPSULES'. To the right of the image, the product title is displayed in red and black. Below the title, there is a star rating of five stars and the text 'Be the first to review this product'. The price is shown as 'FROM: \$58.95' with a crossed-out 'RRP: \$74.95' and 'SAVE \$16.00'. Below the price, there is a green button that says 'NOTIFY ME!'. To the right of the product information, there is a Muscletech logo and a list of promotional offers: 'NEED HELP? Call 1300 837 785 or Email us', 'FREE SHIPPING OR GIFT on orders over \$150', '30 DAY GUARANTEE Don't Like It for any reason? Let us know', and 'OVER 60 STORES Australia Wide'. At the bottom of the page, there is a URL: <https://www.nutritionwarehouse.com.au/hydroxycut-hardcore-elite-pro-series-by-muscletech.html>

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Hardcore HydroxyCut Elite Pro Series was created by the award winning team at Muscletech and is a well formulated supplement for athletes and anyone that is looking to increase their energy levels, improve athletic performance and reduce fat mass. It is a great combination of power producing, fat melting and energy promoting agents.



Ingredients

Coffea arabica (coffee): Coffee contains caffeine which works by stimulating the brain, heart, and muscles. As a combination in a supplement, coffee works together to improve focus, awareness and mental performance. Coffee beans are high in biologically active substances such as nicotinic acid, trigonelline, caffeine, tannic acid and quinolinic acid. Some studies show that a combination of coffee and exercise can bring about significant reduction in fat cells than just coffee or exercise alone. This is because caffeine stimulates the breakdown of fat in the body and exercise accelerates the process.

Coffea canephora (Green coffee): Green coffee is known to be a powerful antioxidant that can reduce the free radical damage that can occur during intense workout. Green coffee is also shown to improve mood and cognitive performance in some research studies. Green coffee is rich in chlorogenic acid which is a potent antioxidant that eliminates free radicals and also inhibits fat absorption, which also makes it an effective weight loss ingredient.

<https://www.nutritionwarehouse.com.au/hydroxycut-hardcore-elite-pro-series-by-muscletech.html>

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Caffeine anhydrous: Studies show that caffeine increases energy expenditure from fat without using protein and glycogen. This is very important as it spares the muscles, prevents their breakdown for energy during an intense work out.

Coleus forskhlii: It is an ancient herb that is used in treating respiratory disorders and heart problems. This herb is also found to be effective in preventing weight gain and also help in stimulating fat loss. Studies have shown that the enzyme present in this herb helps preventing the fat deposit in the body and the herb is also safe for consumption.

Capsicum annuum (cayenne): Cayenne pepper is known to increase metabolism by burning the fat. It is a perfect weight loss tool that curbs appetite. Many studies have shown that the bio-active compound called capsaicinoids aid in rapid weight loss by boosting the burning rate in the body.

DAY 1 & DAY 2	DAY 3 & DAY 4	DAY 5 & DAY 6	DAY 7 & BEYOND
1 capsule, 1x daily	2 capsules, 1x daily	2 capsules prior to meal 1, 1 capsule prior to meal 2	2 capsules, 2x daily

This supplement is not made from inadequate mixtures, is free of fillers and contains no prohibited substances. This product can be called "Power Generator" due its caffeine and theobromine content which increases strength and power as well as energy levels.

It improves performance considerably since the first dose. It is an ideal supplement for weight loss with its green coffee extract which is scientifically proven to be a component with high thermogenic and lipolytic capacity, even if you do not follow a low-calorie diet.

<https://www.nutritionwarehouse.com.au/hydroxycut-hardcore-elite-pro-series-by-muscletech.html>

Why use Hydroxycut Hardcore Elite?

The ultra lean body you've always dreamed of can be a reality with MuscleTech **Hydroxycut Hardcore Elite!** You can be the envy of your friends, the head-turner, the picture of fit perfection that other women secretly want to be. Whether your desire is to tighten up for a two-piece, or to prepare to step onstage for a competition, **Hydroxycut Hardcore Elite!** is the ultimate in weight-loss support you've been looking for. To help you achieve your best shape possible, look no further than the product that was designed to deliver results other products just can't touch.

Hydroxycut Max Quite simply the world's most extreme women's fat burner!

In one 6-week clinical study, subjects using the key ingredient in **Hydroxycut Hardcore Elite!** (Cissus quadrangularis) lost an average of 10.56 lbs., while the placebo group actually gained an average of 2.64 lbs.

Max Dose

Hydroxycut Max! contains a unique blend of 25 different ingredients to make it the world's most extreme female fat burner. The key ingredients in **Hydroxycut Hardcore Elite!** radically amplify natural hormones – women's key fat-burning hormone. Plus, **Hydroxycut Hardcore Elite!** includes the clinically studied amounts of those key ingredients, not just a few dashes like some other companies' products might.

Max Potency

The revolutionary **Hydroxycut Hardcore Elite!** formula – featuring the Max! Weight-Loss Matrix and Max! Liqui-Burn – is suspended in a liquid matrix, and encased in Rapid-Release Liquid-Caps that dissolve up to 5 times faster than regular tablets. The instant after your very first dose, you'll know that **Hydroxycut Hardcore Elite!** isn't like anything else you've ever tried!

Max Science

Formulated by a medical doctor-led team of researchers, **Hydroxycut Hardcore Elite!** relies on a multi-level system of metabolic interactions, which operate in sequence to literally crank the female metabolic rate into overdrive. This unrelenting metabolic boost causes a surge of lipolytic catalysis and thermogenic combustion – which is what scientists call fat burning and heat production. **Hydroxycut Hardcore Elite!** is without question the most extreme women's fat burner on earth! See how the key ingredients in **Hydroxycut Hardcore Elite!** go to work at burning fat and calories in your body.

Burn Calories and Bodyfat Like Never Before with Hydroxycut Max

You'll truly understand what kind of power the science behind **Hydroxycut Hardcore Elite!** provides you with. Your senses heighten and your mental focus intensifies. You feel your energy rise and at that instant, you'll fully understand what kind of energizing power you've got. But you can only feel and see the weight-loss power of **Hydroxycut Hardcore Elite!** if you get it working for you in your diet and exercise program.

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<https://www.supplementwarehouse.com.au/muscletech-hydroxycut-hardcore-elite.html>

N.B this appears to be a different formulation

DESCRIPTION	NUTRITIONAL INFORMATION
<p>New HYDROXYCUT® HARDCORE ELITE from our #1 selling Hardcore Supplement Brand.</p>	
<p>All new HYDROXYCUT® HARDCORE ELITE was built from the ground up with one purpose in mind: to help provide you with an incredible experience. With Coleusforskohlii, theobroma, green coffee extract and caffeine, this formula delivers a one-of-a-kind experience. HYDROXYCUT® HARDCORE ELITE also contains an ingredient (caffeine) to help give you a serious boost of extreme energy support after just one dose!</p>	
<p>Two Scientific Studies: Subjects Saw Significant Weight Loss Support Data analysis of the results from both studies on the key ingredient (green coffee extract) shows significant statistics in supporting weight loss and fat loss. HYDROXYCUT® HARDCORE ELITE also contains the popular ingredient, Coleusforskohlii.</p>	
<p>If you demand an effective edge and want a support formula that works as hard as you do – look no further than HYDROXYCUT® HARDCORE ELITE.</p>	
<p>Directions: Adults Only: To assess your tolerance, for the first day, take 1 capsule once daily. On days 2 and 3, take 2 capsules once daily. On day 4 and beyond, take 2 capsules twice daily, 30 to 60 minutes before your two largest meals (e.g., breakfast and lunch). Do not snack between meals. For best results, use for 60 days combined with diet and training. Do not take within 5 hours of bedtime. Do not exceed 4 capsules in a 24-hour period. Do not use for more than 8 weeks. Drink 10 glasses of water daily for general good health. Read the entire label before use and follow directions provided.</p>	
<p>This product must be used with a calorie controlled eating plan and an appropriate exercise plan.</p>	

<https://www.evelynfaye.com.au/hydroxycut-hardcore-elite.html>



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	303324	Hydroxycut Hardcore Elite
ARTG entry for	Medicine Listed	
Sponsor	Export Corporation Australia Pty Ltd	
Postal Address	PO Box 3150, BROADWAY NEDLANDS, WA, 6009 Australia	
ARTG Start Date	22/05/2018	
Product category	Medicine	
Status	Active	
Approval area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1. Hydroxycut Hardcore Elite

Product Type	Single Medicine Product	Effective date	22/05/2018
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Permitted Indications

- Enhance/promote energy levels in adults only
- Helps enhance/promote calorie burning in adults only

Indication Requirements

- Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- Product presentation must not imply or refer to imply chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

Warnings

- Adults only (or words to that effect).
- Contains caffeine [state quantity per dosage unit or per mL or per gram of product] [must be clear and legible].

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
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Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Components

1. Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Caffeine	25 mg
Capsicum annuum	500 microgram
Equivalent: Capsicum annuum (Dry)	3 mg
Coffea canephora	100 mg
Equivalent: Coffea canephora (Dry)	800 mg
Coffea canephora	73.98 mg
Equivalent: Coffea canephora (Dry)	3.699 g
Plectranthus barbatus	12.5 mg
Equivalent: Plectranthus barbatus (Dry)	850 mg
Theobroma cacao	50 mg

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Public Summary