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Dietary Supplements and Operation Supplement Safety

Dietary Supplements and Operation Supplement Safety





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Slides are not to be renurnosed



Continuing Education

This webinar has been approved to offer continuing education credit. Please stay tuned for more information!

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Today's Presenter



Andrea T. Lindsey, MS

Director of Operation Supplement Safety & Senior Nutrition Scientist

In support of The Consortium for Health and Military Performance Department of Military and Emergency Medicine, F. Edward Hébert School of Medicine Uniformed Services University of the Health Sciences Contractor, Henry M. Jackson Foundation for the Advancement of Military Medicine





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Disclosure Information

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The authors have no financial interests or relationships to disclose.

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Objectives

At the end of this presentation and activity, participants will be able to:

- Describe how dietary supplements (DS) are regulated.
- Discuss key topics related to dietary supplements and Performance Enhancing Substances (PES).
- Explain how Operation Supplement Safety (OPSS) is educating Service Members, healthcare providers, and allied health professionals.
 - Review DoDI 6130.06: *Use of Dietary Supplements in the DoD and* substances on the *DoD Prohibited Dietary Supplement Ingredients List*

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Selected Regulations for Dietary Supplements

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What is a Dietary Supplement?

- Defined by the Dietary Supplement Health and Education Act of 1994 (DSHEA):
- Intended to supplement the diet
- Must be taken by mouth
- In the form of a tablet, capsule, powder, softgel, gummy, gelcap, liquid, or bar
- Contains one or more of the following dietary ingredients:
 - Vitamin
 - Mineral
 - Herb or other botanical
 - Amino acid
 - A dietary substance to supplement and increase total dietary intake
 - A concentrate, metabolite, constituent, extract, or combination of the above
- Must be labeled as a dietary supplement and have a Supplement Facts label

Dietary Supplement Regulations

Common Misconceptions/Myths:

- "Supplements are unregulated"
- "There's no FDA oversight on supplements"

Facts: Dietary supplements <u>are</u> regulated by Food and Drug Administration (FDA), but...

- FDA does NOT approve supplements before they are marketed
- Manufacturer is responsible for ensuring products are properly labeled and safe
- If a product has already been introduced to the market the FDA can take action if the product is NOT safe or is misbranded

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Federal Trade Commission (FTC) Responsibilities

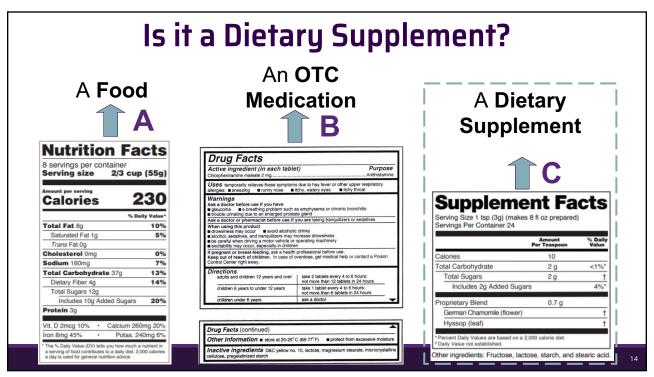
Broad mandate: stop deceptive and unfair practices in commerce (including false and unsubstantiated marketing claims)

- -Ads must be truthful and not misleading
- -Objective claims must be substantiated before they are made



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Labeling



What You May NOT Know...

Food

Generally recognized as safe (GRAS)



OTC Medication

Proven evidence of efficacy and known safety

Active ingredient (in each table Chlorpheniramine maleate 2 mg	
Uses temporarily relieves these symptoms allergies: ■ sneezing ■ runny nose ■ it	due to hay fever or other upper respiratory tchy, watery eyes itchy throat
 trouble urinating due to an enlarged prostat 	
Ask a doctor or pharmacist before use if y	rou are taking tranquilizers or sedatives
When using this product ■ drowsiness may occur ■ avoid alcoholic	drinks
■ alcohol, sedatives, and tranquilizers may in ■ be careful when driving a motor vehicle or o ■ excitability may occur, especially in children	crease drowsiness operating machinery
 be careful when driving a motor vehicle or of excitability may occur, especially in children of pregnant or breast-feeding, ask a health 	crease drowsiness operating machinery
 be careful when driving a motor vehicle or of excitability may occur, especially in childrer if pregnant or breast-feeding, ask a health Keep out of reach of children. In case of or 	crease drowsiness pperating machinery 1 professional before use.
■ be careful when driving a motor vehicle or excitability may occur, especially in childrer if pregnant or breast-feeding, ask a health Keep out of reach of children. In case of or Control Center right away. Directions	crease drowsiness operating machinery professional before use. verdose, get medical help or contact a Poison take 2 tablets every 4 to 6 hours;

Drug Facts (continued)	
Other information ■ store at 20-25°C (68-77°F)	■ protect from excessive moisture
Inactive ingredients D&C yellow no. 10, lactose, regulators, pregelatinized starch	magnesium stearate, microcrystallin

Dietary Supplement

No requirement for evidence of safety or efficacy



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What is NOT a Dietary Supplement?

- Patches
- Injectables
- Lotions
- Creams
- · Sprays?



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FDA Can...

Take action to remove products from market, if product is:

- Adulterated (e.g., the product is unsafe)
- Misbranded (e.g., the labeling is false or misleading)
- Associated with adverse events

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Key Topics Related to Health & Performance Products

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Issues of Concern

- Limited federal resources to monitor health and performance products
- Misinformation
- High-risk products
- Contaminants and adulterants: e.g. steroids, stimulants, prescription drugs, unapproved drugs, unapproved ingredients, heavy metals
- Potential for adverse events/reactions (AEs)
- Direct marketing to/discounts for Service Members

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What Products are Considered "High-Risk"?

- Bodybuilding, weight loss, and sexual enhancement
- Any product with an ingredient on the DoD Prohibited Dietary Supplement Ingredients List
- Combinations of multiple ingredients/products

Contaminants and Adulterants

- Anabolic steroids
- SARMs (selective androgen receptor modulators)
- Aromatase inhibitors
- Pro-hormones
- Synthetic stimulants
 - Betaphrine, BMPEA, DMAA, DMBA, DMHA, methylsynephrine, ... (Ingredients typically ending in "ine")
- Prescription drugs
- · Heavy metals, etc.

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Adverse Events

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What is an Adverse Event?

<u>ANY</u> unfavorable or unusual reactions, effects, or illnesses that can occur with the use of some health and performance products

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Adverse Events Associated with Dietary Supplements

· Rapid or irregular heart beat · Rhabdomyolysis

Chest painHeat injury

High blood pressure
 Seizures

Stroke
 Liver injury/failure

Heart attack
 Kidney injury/failure

Tingling/prickling sensation
 Fainting/passing out





Other Products of Concern

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Energy Drinks

What's in them?

- Caffeine
- Guarana
- Sweeteners (sugar, low and no calorie sweeteners)
- B-vitamins (niacin, B6, B12, etc.)
- Taurine
- Inositol
- Glucuronolactone
- L-carnitine
- Panax ginseng
- Others might include: amino acids, choline, Ginkgo biloba, green tea, milk thistle, quercetin, ribose, yerba mate, yohimbe, other stimulants, etc.



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Supplement Facts
Serving Size 8.0 fl.oz. (240 mL)
Servings Per Container: 2

% Daily Value Amount Per Serving Calories 100 **Total Carb** 9%* 27g Sugars 27g Riboflavin Vit B2 1.7mg 100% Niacin Vit B3 20ma 100% Vitamin B6 2mg 100% Vitamin B12 100% 6mcg 180mg Sodium 8% Taurine 1000ma Panax Ginseng 200ma 2500mg Energy Blend L-Carnitine, Glucose, Caffeine, Guarana, Inositol, Glucuronolactone, Maltodextrin *Percent Daily Values are based on a 2000 calorie diet. † Daily Value not established.

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Considerations with Energy Drinks

- There is little evidence for the combination of ingredients
- May not provide any additional benefit for physical and mental performance when compared to caffeine alone
- Can cause fatigue from poor sleep quality and sleep disturbances
 - Stop using at least 6 hours before bedtime
- Should not be used for hydration
- · Should not be used before, during, or after strenuous physical activity
- Should not replace meals or healthy dietary habits
- Should not be mixed with alcohol

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Considerations with Energy Drinks

Consider how much caffeine you are consuming in 24 hours

Look for energy drinks with 200 mg or less of caffeine

Too much caffeine can cause side effects such as:

- Headaches
- Insomnia
- Nervousness
- Irritability
- Fast heartbeat



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Energy Drink Position Statement

Department of Defense Nutrition Committee Energy Drinks and Energy Shots Position Statement

Prepared by CHAMP and the Performance Nutrition Working Group under the DoD Food and Nutrition and Dietary Supplements and Other Self-Care Products Subcommittees

1. Introductory Statement

Energy products are heavily used by many Military Service Members. When energy products are overconsumed and/or used inappropriately they can pose a risk to the Military Service Member's health and negatively impact mission readiness.

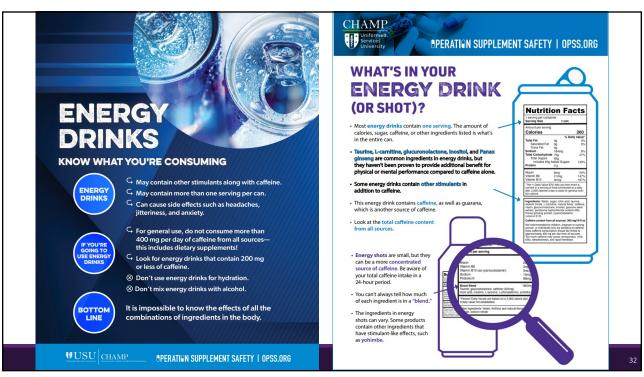
2. Recommended Position

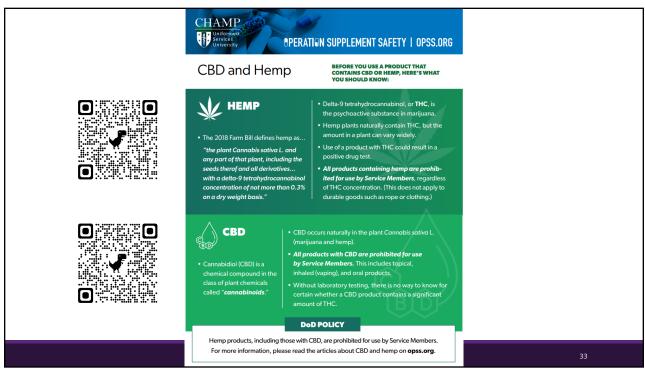
- Military Service Members (enlisted and officers) should receive education about safe use of energy drinks and energy shots and caffeine early in their careers.
- Healthcare providers should be educated about energy drinks, energy shots, and caffeine and encouraged to talk to Military Service Members, their families, and their patients (both young and old) about safe use of these products.
- Healthcare providers should report any adverse events they note in association with energy drinks to the Food & Drug Administration through their portal for dietary supplements (https://www.safetyreporting.hhs.gov).



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Resources and Tools to Evaluate Dietary Supplements

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Operation Supplement Safety

OPSS is the DoD's **go-to program** for anything related to health, wellness, and performance products. OPSS partners with other federal departments, professional organizations, and academic institutions to **provide evidence-based information**, resources, and tools for education and

decision making.



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OPSS.org Website

- Evidence-based articles
- Ask the Expert portal
- Other resources
 - Videos
 - Handouts
 - Infographics
 - More



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DoDI 6130.06: Use of Dietary Supplements in the DoD



DoD Instruction 6130.06

USE OF DIETARY SUPPLEMENTS IN THE DOD

Originating Component: Office of the Under Secretary of Defense for Personnel and Readiness

Effective: March 9, 2022

Releasability: Cleared for public release. Available on the Directives Division Webs

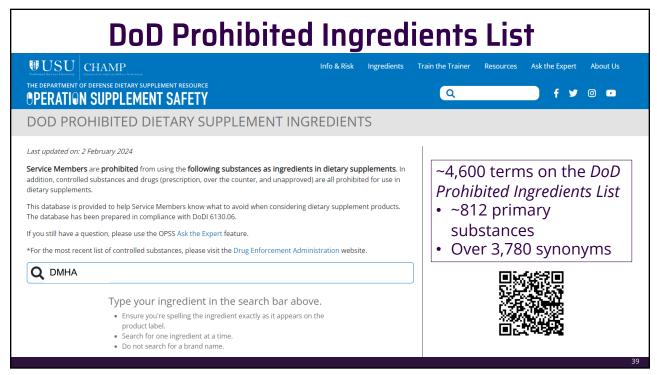
Cleared for public release. Available on the Directives Division Website at https://www.esd.whs.mil/DD/.

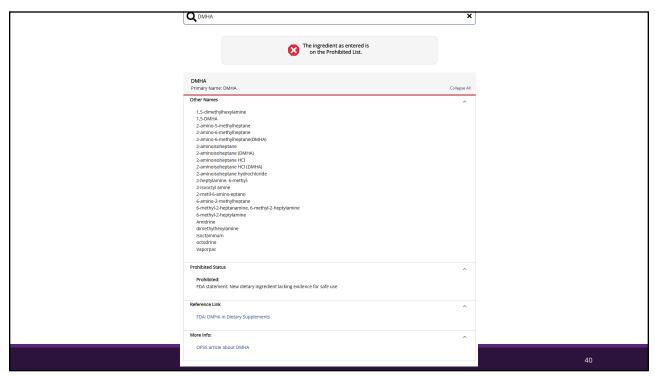
Gilbert R. Cisneros, Jr., Under Secretary of Defense for Personnel and

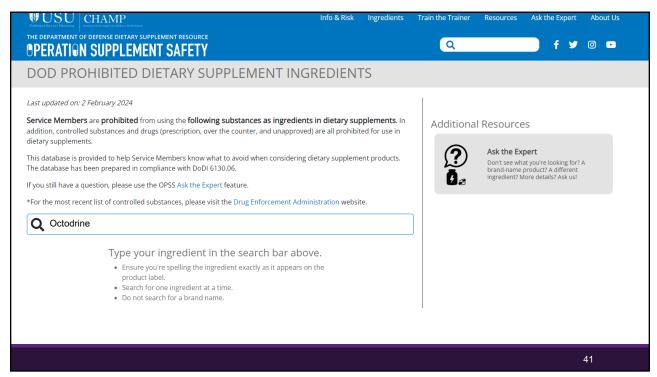
Approved by: Gilbert R. Cisneros, Jr., Under Secretary of Defense for Personnel and Readiness

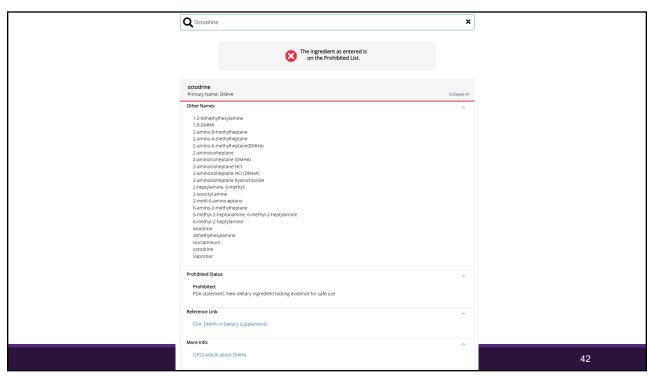
- Formalizes OPSS as the DoD program for dietary supplements
- Requires education for Service Members, healthcare providers, and allied health professionals
- Mandates adverse event reporting by healthcare providers
- Establishes OPSS website as host for DoD Prohibited Dietary Supplement Ingredients List

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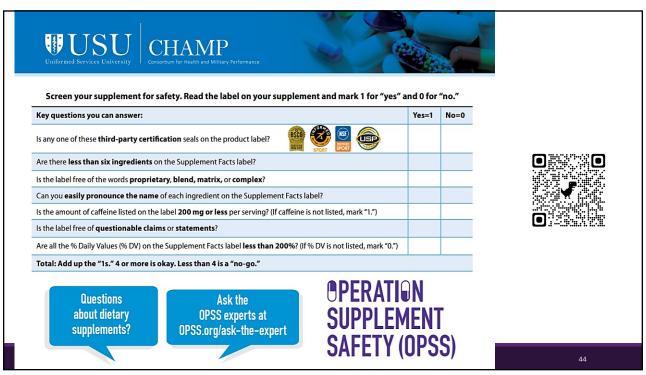


OPSSupp App

- Will provide the ability to search for a dietary supplement based on its name or by scanning its barcode
- · Will provide information about:
 - Prohibited ingredients
 - · Safety concerns
 - Third-party certification
 - FDA warnings and alerts



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OPSS Scorecard Questions

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Third-Party Certification

- Products with third-party certification/ verification seals have been evaluated for *quality* and *purity*:
 - Banned Substances Control Group (BSCG)
 - · Informed-Choice
 - NSF International
 - · United States Pharmacopeia









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What do these seals mean?





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Combination of Ingredients

- More ingredients = Higher risk of interactions
 - Interactions could occur from mixing together the ingredients in the product itself, other dietary supplements, medications, etc.
- "Other Ingredients" not included in total

Percent Daily Value (%DV)

- How much of a nutrient in a single serving of a dietary supplement contributes to your daily diet.
- 35 nutrients have established daily values

% Da	aily Value
Total Fat 9g	12%
Saturated Fat 4.5g	23%
Trans Fat 0g	
Cholesterol 35mg	12%
Sodium 850mg	37%
Total Carbohydrate 34g	12%
Dietary Fiber 4g	14%
Total Sugars 6g	
Includes 0g Added Sugars	0%
Protein 15g	
Vitamin D 0mcg	0%
Calcium 320mg	25%
Iron 1.6mg	8%
Potassium 510mg	10%

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Proprietary Blends

- The amount of each individual ingredient does not have to be listed
- · May be listed as a
 - 。 "Blend"
 - o "Complex"
 - o "Matrix"
 - o "Formulation"
- Especially important in the case of stimulants

Supplement Facts Serving Size: 1 Capsule Servings per Bottle: 60	
Amou	nt Per Servin
Proprietary Blend	377m
1,3,7 - Trimethylxanthine; Beta-Phenylethyla Synephrine HCL; N,N-dimethyl-4-hydroxyph ethylamine; Schizandrol A; 5-Hydroxytrypto Yohimbine HCL	nenyl-
** Daily Value Not Established	

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Caffeine

Other sources/names of caffeine:

- Cacao
- Caffeine anhydrous
- Coffee
- · Green coffee bean
- Guarana
- Kola nut
- Methylxanthine
- Trimethylxanthine
- Xanthiné
- Yerba maté



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Questionable Claims

- Prevents severe memory loss
- Boosts testosterone levels and sex drive
- Lose weight 6x faster
- Maximizes muscle recovery and growth
- Rapid sleep enhancer
- Legal steroid
- Natural cure for diabetes
- Cures COVID-19



Practical Application

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Scoring Products with the OPSS Scorecard



Prohibited Ingredients: None

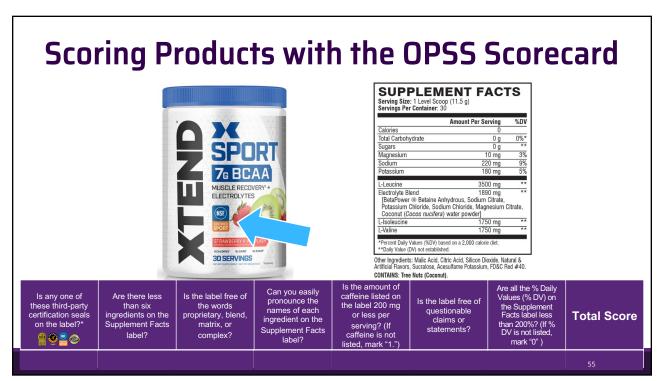
SUPPLEMENT FACTS

Serving Size: 1 Level Scoop (11.5 g) Servings Per Container: 30

	Amount Per Serving	%DV
Calories	0	
Total Carbohydrate	0 g	0%*
Sugars	0 g	**
Magnesium	10 mg	3%
Sodium	220 mg	9%
Potassium	180 mg	5%
L-Leucine	3500 mg	**
Electrolyte Blend	1890 mg	**
[BetaPower ® Betaine Anh	vdrous, Sodium Citrate.	
Potassium Chloride, Sodiu		Citrate.
Coconut (Cocos nucifera)		,
L-Isoleucine	1750 mg	**
L-Valine	1750 mg	**
*Percent Daily Values (%DV) base **Daily Value (DV) not established		

Other Ingredients: Malic Acid, Citric Acid, Silicon Dioxide, Natural & Artificial Flavors, Sucralose, Acesulfame Potassium, FD&C Red #40. CONTAINS: Tree Nuts (Coconut).

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OPSS SCORECARD: CHECK YOUR DIETARY SUPPLEMENT				_
Are you considering using a dietary supplement as a pre-workout, for weight loss, or to improve your health goals? Read the label of your pr	roduct and answer	7 questions abou	out topics such	
as third-party certification and proprietary blends to help screen your supplement for safety.		0.0		
is any one of these third-party certification seals on the product label?		\otimes		
Are there less than six ingredients on the Supplement Facts labe?	Yes	No		
	Yes	No		
is the label free of the words proprietary, blend, matrix , or complex?		×		
	Yes	No		
Can you essily pronounce the name of each ingredient on the Supplement Facts label?		\approx		
is the amount of caffeine listed on the label 200 mg or less per serving? (If caffeine is not listed, mark "Yes")	Yes	No No		
	Yes	No		
is the label free of questionable claims or statements?	1	\approx		
	Yes	No		
Are all the % Daily Values (% DV) on the Supplement Facts label less than 200%? (if % DV is not listed, mark "No")		\approx		
SUPPLEMENT SCORE	Yes	No		
4 or more is okay. Less than 4 is a "no-go." It's also a "no-go" if it contains any ingredients on the Prohibited List. Use the button below to check.		5		
				ĺ

Ask the Expert Questions

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Dietary Supplement Ask the Expert (ATE)

Questions about dietary supplements?

- Submit questions about anything related to dietary supplements
- Receive evidencebased responses

PPERATION SUPPLEMEN	T SAFETY	
ASK THE EXPERT		
with an evidence-based response. Please ID, name, or date of birth (including for cli	Your question is important to us. Please allo do not include personal identifying or health inical consults). e Military Crisis Line at 800-273-8255, or Mili	n information (PII or PHI) such as DoD
* * * * * * * * * * * * * * * * * * * *	e Military Crisis Line at 600-273-6255, Or Mili	tary Offesource at 600-542-9647.
What is your current role? Select Role		
Status		
Active Duty		
Reserve		
Veteran		
○ N/A		
Are you a healthcare provider?		
○ Yes		
○ No		
Subject line of the email		
Enter your subject here		
*Select <i>Email Us</i> to open your default email	l and ask your question	
server amon os to open your default efficie	and ask your question.	

I wanted to know if I'm able to take a pre workout called XXX it says it has new ingredients that removed DMAA. Can you please let me know? Thank you.

- AD Guardian

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Concerns with Pre-Workout

Ingredients on the DoD Prohibited List

- 2-aminoisoheptane (DMHA)
- Geranium extract (DMAA?)

Other Ingredients of Concern

- Agmatine sulfate
- Quebracho blanco (contains yohimbine)

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Are any of these ingredients from a fat burner can show positive on a drug test? Please advise. Thank you!

- AD Sailor

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Concerns with Fat Burner

Ingredients on the DoD Prohibited List

- 2-aminoisoheptane (DMHA)
- Higenamine
- Hordenine
- Vinpocetine

Other Ingredients of Concern

- Caffeine Anhydrous (300 mg)
- Huperzine A
- Synephrine
- Yohimbine

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A local supplement retail shop has recently opened and provided a variety of free samples. I simply wanted to run a quick background check on the products to ensure its safety for other service members and poolees in the delayed entry program:

- 1. Pre-workout
- 2. Post-workout
- 3. Pre-workout
- 4. Protein powder

- AD Marine

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Concerns with Pre-Workout

Ingredients on the DoD Prohibited List

Isopropylnorsynephrine

Other Ingredients of Concern

- Agmatine Sulfate
- Beta phenylethylamine
- Caffeine anhydrous (450 mg)
- Huperzine A

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Hello. Wondering if this pre workout is safe DoD wide, including all branches based on the ingredients. Doesn't appear to have DMAA or any of that meth stuff. Please let me know!

- Military Status Unknown

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Concerns with Pre-Workout

Ingredients on the DoD Prohibited List

- Higenamine
- Isopropylnorsynephrine

Other Ingredients of Concern

- Caffeine anhydrous (350 mg)
- Huperzine A

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I was most recently looking into the dietary supplement XXX by XXX. After reviewing the ingredients I did find one ingredient outlined as banned. However the bottle says FDA Approved so I'm just trying to ensure it's within our DoD Policy and not a banned supplement.

- AD Soldier

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Concerns with Brain Health Product

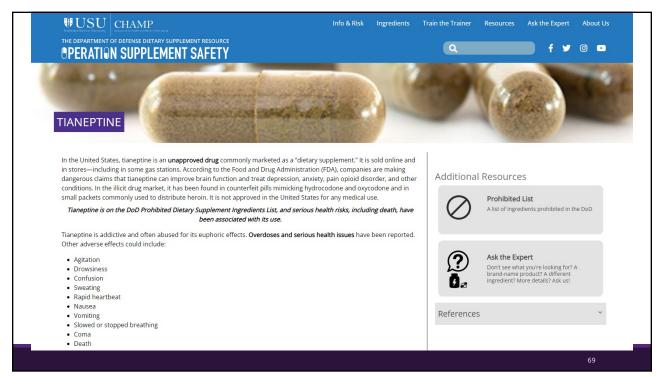
Ingredients on the DoD Prohibited List

- Dimethylbutylamine (DMBA)
- Nefiracetam
- Tianeptine

Other Ingredients of Concern

- 1-benzoyl-4-propanoylpiperazine
 - May be similar to unapproved drug Sunifiram
- Rauwolscine
- Undisclosed amount of caffeine

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Questions From the Field

Are any of these ingredients [on attached image] banned?

- AD Airman

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Concerns with "Research" Product

Ingredient on the DoD Prohibited List

MK-677 (Ibutamoren)

Other Concerns

Research Facts label

Research Facts

Serving Size: 1 Capsule Servings Per Container: 45

Amount Per Serving

Ibutamoren (MK677)

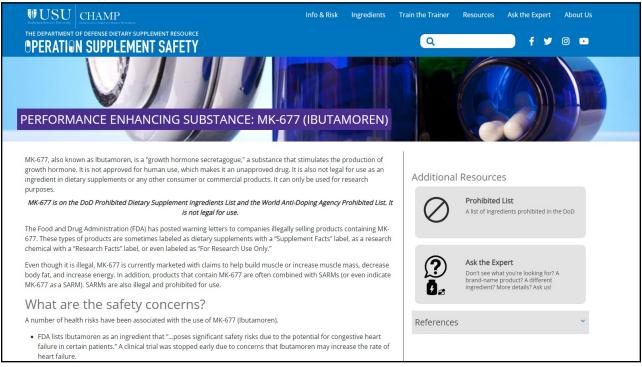
25mg

2-amino-2-methyl-N-[(2R)-1-(1-methylsulfonylspiro [2H-indole-3,4'-piperidine]-1'-yl)-1-oxo-3-phenylmethoxypropan-2-yl]propanamide

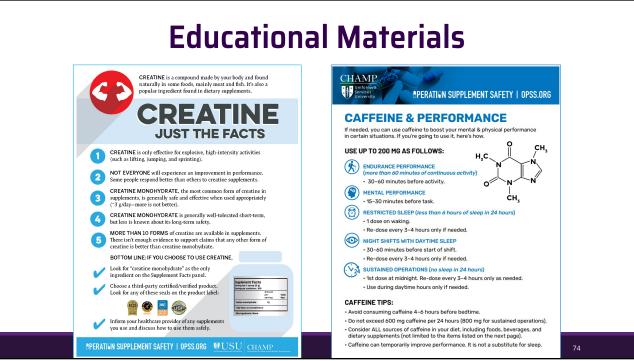
Other Ingredients: Rice flower, gelatin, calcium silicate.

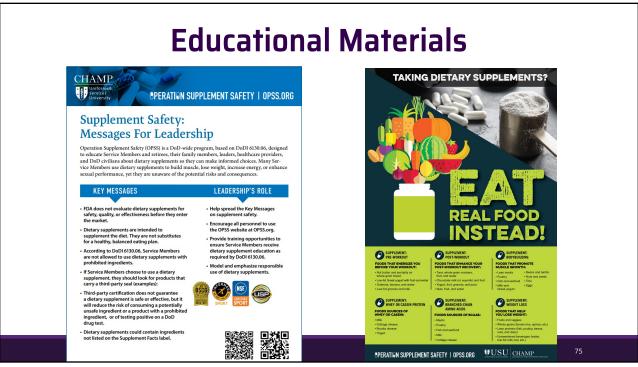
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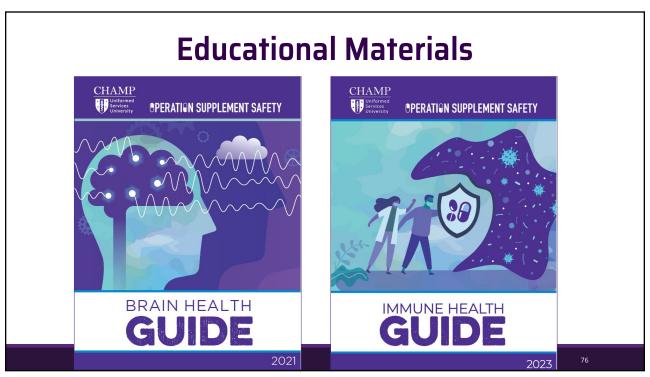
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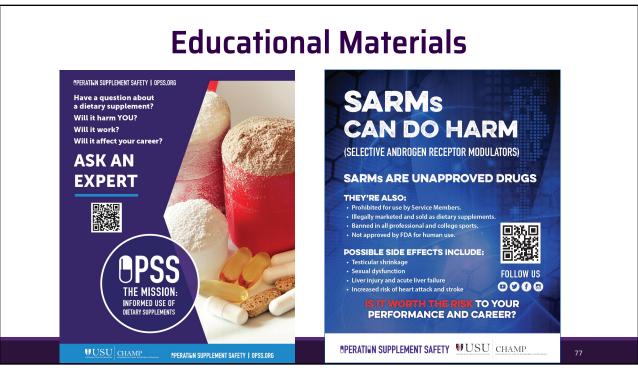


Other Tools and Resources



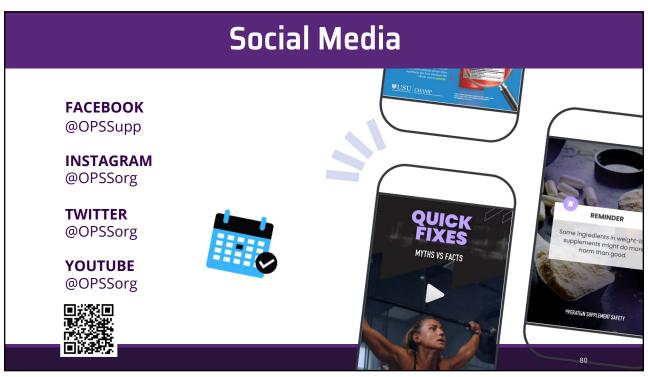


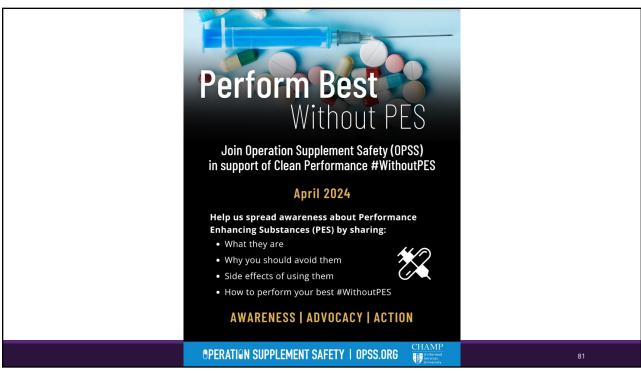












For Further Information

Visit the Operation Supplement Safety website at **OPSS.org**OR

Contact:

Andrea Lindsey, MS Director, OPSS

Andrea.lindsey.ctr@usuhs.edu

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Questions?

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Upcoming Event



Food Allergies: An Overview and Update

Thursday, April 25, 2024

Food allergies are a growing global health concern. In the last decade, there has been a paradigm shift in the prevention, diagnosis, and management of food allergy. Attend this webinar to learn state of the art, evidence-based practical approaches to common pediatric food allergies.

Continuing education credit will be available for this session!

Oneop.org/learn/160038/

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Continuing Education



This webinar has been approved for the following continuing education (CE) credits:

- 1.5 CPEU from the **Commission on Dietetic Registration** for RDNs
- 1.5 CE from the American Association for Family & Consumer Sciences (AAFCS) for CFCS.
- 1.5 CE from the American Association for Family & Consumer Sciences (AAFCS) for CNWE.
- · Certificate of attendance

Evaluation Link

Go to the event page for the evaluation and post-test link.



Questions?

Email Bethany Daugherty:
OneOpNutritionWellness@gmail.com

Oneop.org/learn/160021/

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