

Introduction

About dotFIT Worldwide

- Evidence-based research and support for Fitness Professionals and their clientele
 - See dotFIT Worldwide Faculty and Advisory Board below
- Exercise content and support from the National Academy of Sports Medicine (NASM)
 - The market leader in Fitness, Sports Medicine and Sports Performance credentials
 - NASM activates over 25,000 credentials annually with over 100,000 professionals worldwide
 - Works with over 6,000 health clubs and professional sports organizations
- Sports Science and Human Performance Resource and Partner: Fusionetics
- Evidence-based tools and applications
 - R&D and support for nutrition, weight control, performance and exercise programming
 - Web-based, client- and trainer-centric programming: exercise, menu plans with supplement screening, continuous feedback to client and/or trainer based on measurement inputs and goals
- Worldwide professional delivery network
 - Health clubs, clinical settings, hands-on fitness professionals as well as phone and e-coaching platforms
- Programs can connect to body sensing/tracking devices
 - Free living calorie expenditure, steps, physical activity, sleep efficiency, etc.
- Unlimited support and education for consumers and professionals via website, webinars, workshops, certifications, and direct access to R&D team. Toll-free (877.436.8348) and email address: support@dotfit.com
- Complete pharmaceutically manufactured and holistically integrated dietary supplement Practitioner Product line and foods including home delivery platform offered through practitioners only

dotFIT Worldwide Faculty and Advisory Board

INSTITUTIONAL RELATIONSHIPS AND ADVISORY RESOURCES University of Berkeley University of Hawaii	CHIROPRACTIC HEALTH AND WELLNESS Eric Plasker, DC
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dotFIT Worldwide's Position on Use, Recommendations & Manufacturing of Dietary Supplements

The function of dietary supplement preparations is to provide a safe vehicle for delivering precise amounts of desired isolated nutrients and compounds in a low to no calorie form with the purpose of complementing the diet in order to enhance health, sport and fitness goals, i.e. dietary support.

Individual outcomes from the use of dietary supplements are often predicated upon the physiological and psychological state of the recipient as well as dosages, regimen compliance, manufacturing processes, including the use of proper delivery systems and ingredient forms or origins.

dotFIT Worldwide's Position on Overall Dietary Supplement Use and Recommendations

Dietary supplement products must be 100% defensible through scientific research, not used to treat medical conditions and only recommended in support of the following goals:

- Preserving health
 - Objective: potentially help stave off chronic or age-related disease by improving the daily nutrient intake achieved through diet alone
- Safely enhance sport and fitness outcomes
 - Objective: hasten and support fitness/weight control goals
 - Objective: improve training-induced performance results

dotFIT Worldwide's Position on the Use of Supplements for Health

Multivitamin and mineral formulas (MVM) are simply part of a healthy lifestyle. Unless precluded due to a medical condition, all persons of all ages should use a daily MVM to complement one's best efforts to define^{1,2} and consume a proper diet.^{3,4,5}

At a minimum, MVM supplementation is insurance against common and unavoidable shortcomings driven by typical daily diets and local food supply or availability^{6,7} because regular MVM use can raise blood/tissue levels to what has been shown to reduce risk of disease.^{8,9,10,11} Furthermore, there appears to be no downside to daily use.¹² At best, the daily increased level of all known vital nutrients supplied by the MVM may indeed allow optimal cellular performance. Levels of nutrients which are significantly higher but well within a safe range that are delivered by diet combined with a MVM have more potential than diet alone (especially within a range of total calories that maintains proper weight and lean body mass during energy restriction^{13,14}) to supply all cellular entities/enzymes with enough materials to operate at full capacity thus avoiding a potential triage effect that may be at the root of many chronic and age-related diseases. 7^{,7,9,15,16,17,18,19,20,21} MVM supplementation as a primary prevention strategy should begin as early as possible (e.g. prenatal) and be consistent throughout one's lifespan.^{12,22} (See Appendix 1: dotFIT Worldwide's Position on Vitamin & Mineral Supplementation).

Calcium intake for optimal bone health, potential reduction of stroke and fractures should be 1,000-1,200 mg/day.^{23,24} If the diet falls short the gap should be filled by supplementing but not to exceed 1,200 mg total intake of supplements and diet.²⁵ Males should not exceed 500 mg of calcium from supplements unless advised by a qualified physician.²⁶ There is almost no reason to take a calcium-only supplement. Calcium supplementation should be accompanied with adequate amounts of Vitamin D for proper absorption and utilization.²⁷



Vitamin D daily intakes of 600 IU up to age 70 and 800 IU over 70 years of age are the current recommendations.²⁸ The Institute of Medicine (IOM) suggests that a 25-hydroxyvitamin D blood level of 20 ng/mL (50nmol/L) is sufficient for bone health based on integrated measures of calcium absorption, bone mineral density, osteomalacia, and rickets.²⁹ Based on current data many experts disagree with the IOM recommendation and suggest a 25-hydroxyvitamin D blood level of at least 30 ng/mL ,(75nmol/L)^{30,31} a level associated with up to a 31% risk reduction in all cause mortality, falls and fractures.^{31,32,33} Generally supplementation would be required to achieve and maintain³⁴ this potentially beneficial blood level.^{35,36}

dotFIT Worldwide's Position on Use of Supplements in Support of Weight Control

Dieting to lose weight without financial motivation is difficult for most everyone and generally ends with much of the weight regained within the first year. 37,38,39,40,41

The goal of incorporating a dietary supplement or prescription drug into a weight loss program is to assist the participant in complying with the daily routine that leads to weight reduction. The supplement ingredients must have safely demonstrated the potential to act in one or more of the following ways:

- Help create and maintain a calorie deficit by increasing daily calorie expenditure when compared to a nonsupplemented state
- Raise energy levels that may make one more active throughout the day
- Reduce the drive to consume food
- Decrease calorie absorption

The dieter would cease supplementation once the weight goal is reached or when s/he has established a daily routine which allows continual progress and/or maintenance without supplements.

dotFIT Worldwide's Position on Use of Supplements for Enhancing Performance

Sports at all levels have become fiercely competitive, primarily because the rewards for winning continue to expand into previously unimaginable economic territories. Giving athletes the necessary "edge" to compete now requires sophisticated evolving nutrition and exercise protocols including the proper integration of individualized dietary supplements. Additionally, because of improved methods and frequency of drug testing, athletes are seeking healthy legal alternatives to help enhance performance. Maximizing potential during high-level competition involves athletes and qualified trainers leveraging all available resources. In fact, surveys from the 2008 Olympics showed at least 90% of the 11,000 athletes reported regularly using dietary supplements.⁴² Other polls of competitive athletes of all ages show the same numbers.^{43,44,45,46} Additionally, approximately 85% of health club participants regularly use dietary supplements to enhance health or exercise outcomes.⁴⁷

There is now strong scientific and empirical evidence that a limited number of natural substances prepared in formulations matched from positive clinical trials and ingested properly into a training and nutrition plan can safely improve recovery, ^{48,49,50,51} muscle protein synthesis, ^{52,53,54,55,56,57,58} time to exhaustion ^{59,60,61,62,63,64,65} and training-induced size or performance for many athletes. ^{66,67,68,69} The rationale behind using nutritional strategies to avoid training *plateaus* centers around findings that the extent of muscle damage induced by exercise appears to remain constant throughout a prolonged training regimen. Meaning, repeated exercise sessions continue to "open the door" for the building process even if no muscle or strength gains are being produced. ⁷⁰ Therefore, when the benefits of training and diet on muscle mass and performance have stabilized, specific nutrient supplement regimens may play a role in plateau avoidance and progressive development for many athletes.



dotFIT Worldwide's Position on Final Individual Recommendations

All dotFIT programs prepared by dotFIT Worldwide are designed to screen individuals based on medical history, physical characteristics, exercise experience and goals in order to safely and properly integrate dietary supplements into their fitness programs delivered by certified practitioners to accomplish the above stated outcomes.

The Practitioner Product Channel - Evidence Based Rules

Before nutritional compounds become Practitioner Products and recommended for consumer use, all formulas/ingredients must survive rigorous legal and scientific review and testing. Practitioner Product guidelines are as follows:

- Identify best, current clinical research demonstrating benefit for using active ingredients (evidence-based).
- Identify data supporting safety and efficacy including long-term empirical data (see Table 1 below and Evaluation Guidelines).
- Identify and recommend proper ingredient dosing and forms matched to positive outcomes from clinical data
- As evidence-based science progresses, products must be routinely updated.
- Products are designed in appropriate delivery forms established by each product's ingredients, desired
 target tissues, and the amounts required in specific time periods to deliver on the product claims. In other
 words, validate that the right ingredients and amounts get to the right places at the right times.
- Customized finished products are tested to validate whether release patterns match their respective designed criteria in order to assure the desired results.
- Dietary supplement products and powders are manufactured in regularly audited FDA-registered pharmaceutical and NSF Certified for Sport facilities in compliance with current Good Manufacturing Practices (cGMP).
- Ingredient testing for purity, potency and delivery from raw materials to finished product.
- The final product undergoes rigorous testing, both in-house and through a 3rd-party including outside NSF Certified laboratories, Health Canada Laboratories, and NSF Certified For Sport Program testing which assure users that all label claims are met and surpass FDA guidelines, USDA guidelines, and industry norms.
- All formulas must be able to work in synergy with other dotFIT™ products in order to avoid nutrient overages, which are common with typical, indiscriminate supplement use.^{71,72}
- dotFIT programs consider diet, medications, and other dotFIT products before a personalized dietary supplement recommendation is generated. This assures the user remains in a safe and optimal nutrient range throughout the day.
- dotFIT foods cannot be "spiked" with unnecessary substances/nutrients. Most other products in this space
 (e.g. bars, shakes, ready-to-drinks, etc.) are heavily spiked with many nutrients that can lead to undesirable
 levels within the body when combining products from multiple manufacturers and normal food intake.⁷³
 When consuming only dotFIT products, as directed with one's normal daily food intake, the recipient can be
 assured of keeping the body at a safe and optimal nutrient level.
- dotFIT must provide complete practitioner and customer product/program education and support, including full disclosure regarding product ingredients, proposed mechanisms of action, contraindications, safety, manufacturing processes and visibility.

Product Testing Documentation

• Tests that include disintegration, dissolution, stability, purity (no contaminants) and potency, which includes the finished product's certificate of analysis.



- In-house and 3rd party product validation and testing methods based on all available certified protocols including applicable USPs (United States Pharmacopeia, an official compendia of standards) and other international compendia.
- 3rd party NSF Certification for Sport testing for banned substances and label claims.
- 3rd party Health Canada product testing for ingredients matched to clinical trials, label claims and safety.
- Appropriate peer-review research that supports the dosage and purpose of the compound.
 - Proof of equivalence or evidence that a given dose of a product must contain a certain amount of key ingredients in order to produce a known effect.
- Proof that products will be absorbed and utilized by the body.
- Assurance that the substance is nontoxic, along with list of any known potential side effects and drug interactions.
- Qualified personnel and support documents available to all consumers via www.dotFIT.com or 877.436.8348.

Product Evaluation Guidelines and Scoring

Only products/ingredients that score a four or five out of five possible points are potential dotFIT Worldwide-authorized products and may become integrated into holistic fitness planning (e.g. combined with diet and activity/exercise planning) and delivered by certified practitioners. See Table 1.

Review of Products

- A. Criteria for evaluation: to establish product integrity
 - 1. History of safe use
 - 2. Cultural or traditional medicine
 - 3. Anecdotal or empirical reports
- B. Product formulation
- C. Individual ingredients

Research documenting claims, performed on humans

- D. Published in peer reviewed literature citation(s)
 - 1. Product formulation
 - 2. Individual ingredients
- E. Books/brochures and company marketing brochures or sales sheets
 - 1. Product formulation
 - 2. Individual ingredients
- F. Privately sponsored, unpublished reports or studies
 - 1. Product formulation
 - 2. Individual ingredients
- G. Research supporting either a biochemical or physiological rationale

Research documenting claims, performed on animals

H. All same as above

Safety Studies

- I. Animal toxicology studies
- J. In vitro toxicology studies
- K. Human clinical evaluations
 - 1. Dosage and route of administration



- 2. Toxicity
- L. Human anecdotal/empirical reports
 - 1. Dosage and route of administration
 - 2. Toxicity

Adverse Event Reports

- M. Center for Disease Control (CDC) and Med Watch
- N. Food and Drug Administration (FDA)
- O. World Health Organization (WHO)
- P. State Health Departments
- Q. Trial Lawyers Association: personal injury litigation groups

Food and Drug Administration

The regulatory agency for approved claims with medical – scientific evidence for documentation of educational marketing claims in advertising and 'third party' literature under DSHEA*.

- R. Structure (anatomy) claims
- S. Function (physiology) claims
- T. 'Life Event' claims
- U. Fitness claims
- V. Anabolic/weight gain claims
- W. Androgenic/strength and endurance claims
- X. Fat loss (lipolysis) claims
- Y. Metabolic rate (BMR) and lean body mass claims
- Z. Cardiovascular tone/'aerobic' fitness claims
- AA. Recovery time/'muscle burn' claims
- * DSHEA is the Dietary Supplement Health Education Act of 1994. The DSHEA established a formal definition of "dietary supplement" using several criteria. A dietary supplement:
- is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients
- Is intended for ingestion in pill, capsule, tablet, or liquid form
- Is not represented for use as a conventional food or as the sole item of a meal or diet
- Is labeled as a "dietary supplement"
- Includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision)



Table 1—Product Evaluation Score: Rating of Evidence

Only products that score a four or five rating are potential dotFIT authorized products.

SCORE	RATING	DOCUMENTATION/ EVIDENCE CRITERIA
5	Excellent (>90% Probability)	Product formulation claims documented by human studies
4	Very Good (>70%<90% Probability) (High Probability)	At least two (2) of the product's formulated ingredients claims documented by human studies
3	Good (<70%>30% Probability) (Medium Probability)	One of the product's formulated ingredients claims documented by human studies
2	Fair (>10%<30% Probability) (Low Probability)	No human studies. However, at least two (2) of the product's formulated ingredients have a biochemical- physiologic rationale
1	Poor <10% Probability) (Questionable Probability)	No human studies. However, at least one (1) of the product's formulated ingredients have a biochemical— physiologic rationale
0	Fails (Zero Probability – "Hype")	No documented human studies, and no biochemical – physiologic rationale for any ingredients

The Products

Included in this guide are the following for each dotFIT product:

- Goal
- Rationale
- Typical Use
- Dosage
- **Definitions**
- **Precautions**
- Contraindications
- **Adverse Reactions**
- **Upper Limits/Toxicity**



Definitions:

Goal

Describes the purpose of the formulation, including each product's intended outcome.

Rationale

Lists the ingredient's basic mechanisms of action and their respective function in participating in the product's intended outcome or goal.

Typical Use

Describes the known group of users that may experience the product's potential listed benefits.

Dosage

Lists the dosages used in studies and historically with the greatest potential for safety and efficacy.

Precautions

The compounds in this Practitioner's Dietary Supplement Reference Guide (SRG) are considered safe for the general population at the proper dosage. Under this heading and the subheadings below, a summary of safety considerations will be called out for potential vulnerable subpopulations.

Contraindications

Describes conditions in which the compound might be avoided or signal caution, including people with unique genetic predispositions, certain pre-existing disease states or persons taking specific prescription medications.

Adverse Reactions

Lists possible side effects and/or explains commonly reported reactions that may not be clinically supported or causally related to the compound. Case reports may be used to explain theoretical risk when clinical trials or specific studies are not available. Case reports are not considered scientifically valid for proving efficacy or documenting risks, but may be used to highlight an unlikely but potential safety issue.

Upper Limit/Toxicity

Gives the highest known dose that still maintains a large margin of safety and any known toxicity data. When available the Recommended Daily Allowance (RDA), No Observed Adverse Effect Level (NOAEL), Lowest Observed Adverse Effect Level (LOAEL) and the lethal dose 50 (LD50) values will be given. The LD is the dose at which 50% of the test animals (rats or mice) died and is usually only used as a reference for the relative toxicity of a substance.

The Tolerable Upper Intake Level or Upper Limit (UL) is the maximum level of total chronic (long-term) daily intake judged unlikely to pose a risk of adverse health effects to most of the healthy population, including sensitive individuals, throughout their life stages. The UL is intended to provide a safety standard for dietary supplements such that no significant or unreasonable risk of illness or injury would arise at or below this intake level.



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