

ABOUTPRODUCTSCATEGORIESOwho we arewhat we dohow we help

get in touch

Nutrition 21 / About Us / Newsroom / 03/31/2015

NEWSROOM

PURCHASE, NEW YORK – MARCH 30, 2015 – Nutrition 21, LLC ("**Nutrition 21**") is proud to announce the presentation of new clinical study results supporting the efficacy of Nitrosigine® bonded arginine silicate (ASI), titled, "Arginine Silicate Supplementation Decreases Markers of Cardiovascular, Renal and Metabolic Dysfunction and Increases Markers of Vasodilation and Cardiovascular Health in Healthy Adult Males." The study will be presented today to scientists and other professionals at the acclaimed Experimental Biology 2015 annual meeting and the abstract will be published in the *Federation of American Societies for Experimental Biology Journal (FASEB).* The demonstrated connections between Nitrosigine® bonded arginine silicate supplementation and various protein levels contributes to the understanding of the ingredient's mechanism of action.

The clinical study examined over 100 proteins and demonstrated that a single dose of Nitrosigine® bonded arginine silicate supplementation resulted in statistically significant changes in over 70 key proteins measured from baseline to 6-hours post-dose at the first treatment visit. After 14 days of product use, the levels of over 80 proteins changed significantly from baseline. The proteins significantly affected by Nitrosigine® bonded arginine silicate included biomarkers of vasodilation, vascular wound-healing and cardiovascular health (Table 1 and Figure 1).^{1,2,3}

The protein Kallistatin, a potent vasodilator,³ was significantly increased by Nitrosigine® bonded arginine silicate. Vasodilation is known to increase blood flow and vessel flexibility⁴, key factors in sports nutrition and bodybuilding. Changes in proteins like Kallistatin⁵ are indicative of possible pathways by which Nitrosigine® bonded arginine silicate may influence muscular function and cardiovascular health, further supporting its role as a key ingredient in sports nutrition products.⁵

Table 1.

Protein	6-hours Change*	14-days Change*	Function
Kallistatin	27%	32%	Promotes Vasodilation
Paraoxonase (PON1)	23%	31%	Promotes Cardiovascular Health
Paraoxonase (PON3)	21%	34%	Promotes Cardiovascular Health
Fibrinogen Beta Chain	15%	53%	Enhances Vascular Wound Healing
Alpha-2-antiplasmin	29%	40%	Enhances Vascular Wound Healing
Fibrinopeptide-A	20%	53%	Enhances Vascular Wound Healing
Fibrinogen gamma chain	23%	70%	Enhances Vascular Wound Healing
Alpha-2-HS-glycoprotein	62%	69%	Enhances Insulin Function
Cystatin-C	67%	70%	Promotes Cardiovascular Health

Figure 1.





The percent change of select protein levels from baseline to 6-hours post dose at the first treatment visit and with 14 days of product use. All changes from baseline were significant (*P<0.01 for all).

James Komorowski, MS, CNS, Vice President, Scientific & Regulatory Affairs of Nutrition 21 commented, "We are extremely pleased with the presentation of these important clinical results, indicating Nitrosigine® supplementation significantly improves plasma protein concentrations associated with cardiovascular health after a single dose, and to a greater extent, after 14 days of usage. These results enhance our knowledge of the positive effects of Nitrosigine® in humans. Specifically, they continue to show sports nutrition benefits associated with increased nitric oxide (NO) levels, and provide further support for its impact on increased vessel flexibility and blood flow to working muscles."

"Nutrition 21 is thrilled to have the benefits of Kallistatin and other key proteins as support for our NDI-accepted, Nitrosigine®. Nitrosigine® provides the benefits of arginine and silicon, plus additional benefits from its unique combination. Nitrosigine® has already been formulated into many workout products marketed by leading sports nutrition companies. Consumers should look for the Nitrosigine® logo on workout products to get more out of their fitness training. We anticipate continued high market interest with robust customer sales," said Bill Levi, Vice President, Strategy & Business Development at Nutrition 21.

Consumer benefits of Nitrosigine® bonded arginine silicate supplementation directly linked to clinical study findings include:

- Nitrosigine® significantly affects many protein concentrations in the blood, including Kallistatin⁵
- Nitrosigine® significantly enhances nitric oxide (NO) levels⁵
- Nitrosigine® is a safe, bioavailable source of arginine and silicon⁶
- Nitrosigine® significantly increases plasma arginine levels in 30 minutes⁵
- Nitrosigine® significantly increases plasma arginine levels for up to 3 hours⁵
- Nitrosigine® significantly increases silicon levels for up to 1.5 hours⁵

About Experimental Biology 2015

The Experimental Biology (EB) meeting is a multi-society, interdisciplinary, biomedical, scientific meeting featuring plenary and award lectures, symposia, oral and poster sessions, a placement center, and an exhibit of scientific equipment, supplies, and publications. The meeting is one of the largest to date with over 14,000 attending scientists and researchers represented by over 65 countries in the fields of anatomy, physiology, biochemistry, pathology, nutrition, and pharmacology. The Experimental Biology (EB) 2015 meeting held at the Boston Convention and Exhibition Center, March 28 – April 1, 2015.

For more information about the Experimental Biology 2015 annual meeting, please visit: www.experimentalbiology.org

About the Federation of American Societies for Experimental Biology (FASEB) Journal

FASEB represents over 120,000 researchers across 27 member societies. The FASEB Journal is one of the world's most cited biology journals. It is a preferred venue for the latest research reports and reviews of epigenetics, iRNA mechanics, histone acetylation, nitric oxide signaling, eicosanoid biochemistry, angiogenesis, tumor suppressor genes, apoptosis, cytoskeletal function, and human stem cell research. The journal publishes peer-reviewed, multidisciplinary original research articles, as well as editorials, reviews, and news of the life sciences.

For more information about the Federation of American Societies for Experimental Biology, please visit: www.FASEB.org

About Nitrosigine®

Nitrosigine, a patented complex of bonded arginine silicate with FDA New Dietary Ingredient (NDI) notification status⁶; now affirmed as Generally Recognized As Safe (GRAS) at the level of 1,500 mg per day for use in nutritional bars and beverages.⁶ Nitrosigine is scientifically engineered to boost nitric oxide levels.⁵ The Nitrosigine complex bonds arginine and silicate – unlocking powerful synergistic effects. Manufactured in the U.S., Nitrosigine is a safe, non-stimulant, effective ingredient that is easy to formulate into new and existing products for sports nutrition, men's health and cardiovascular health.

Nitrosigine® was recently selected as a finalist for the 2015 Best New Functional Ingredient NutrAward. Four finalists from more than 100 submissions were selected based on scientific merit, efficacy, market potential, safety, innovation, and ability to increase market credibility.

For more information, please visit: www.Nitrosigine.com

About Nutrition 21, LLC

Nutrition 21, a wholly owned subsidiary of JDS Therapeutics, is a leader in the nutritional supplement industry. The Company is a developer and marketer of efficacious, high-value, clinically substantiated ingredients for dietary supplements, medical foods and beverages, including Chromax[®] chromium picolinate and Nitrosigine[®] bonded arginine silicate. In 2013, Nitrosigine received FDA New Dietary Ingredient Notification (NDI) status.

With many years of biotechnology and pharmaceutical experience, the Company's scientific platform has created unique, patented products that are safe and clinically effective. Rigorous preclinical and clinical trials are a key part of its product development strategy to ensure product safety and consumer trust.

Nutrition 21 currently holds over 100 domestic and international issued and pending patents for products. Many support unique claims associated with, among others, glucose metabolism, weight management, brain health, cardiovascular health, and sports nutrition.

For more information, please visit: www.Nutrition21.com

Contact Information

Bill Levi Nutrition 21, LLC Vice President, Strategy & Business Development 914-701-4549 blevi@Nutrition21.com

James Komorowski, MS, CNS Nutrition 21 LLC Vice President, Scientific & Regulatory Affairs 914-701-4519 jkomorowski@Nutrition21.com

END

REFERENCES:

- Proctor SD, Kelly SE, Russell JC. A novel complex of arginine-silicate improves micro- and macrovascular function and inhibits glomerular sclerosis in insulin-resistant JCR:LA-cp rats. *Diabetologia*. 2005; 48:1925-1932.
- 2. Zhou C, Cao J, Shang L, Tong C, Hu H, Wang H, Fan D, Yu H. Reduced paraoxonase 1 activity as a marker for severe coronary artery disease. *Dis Markers*. 2013; 35(2): 97-103.
- 3. Chao J, Stallone JN, Liang YM, Chen LM, Wang DZ, Chao L. Kallistatin is a potent new vasodilator. J Clin Invest. 1997; 100:11-17.
- 4. Cooke, JP. The pivotal role of nitric oxide for vascular health. Can J Cardiol. 2004; 20 Suppl B: 7B-15B.
- 5. Kalman D, Feldman S, Samson A, Krieger D. A clinical evaluation to determine the safety, pharmacokinetics and pharmacodynamics of an inositol-stabilized arginine silicate dietary supplement in healthy adult males. *The FASEB Journal* 2014; 28(1):SLB418.
- 6. Food and Drug Administration New Dietary Ingredient notification to Nutrition 21. Dated March 13, 2013.

Source: Nutrition 21, LLC

N21 Proudly Supports the Following Industry Associations



CONNECT WITH US

f Facebook in Linkedin

CONTACT

500 Mamaroneck Ave. Suite 510 Harrison NY 10528 Phone: (914)-701-4500 Fax: (914)-696-0860 info@nutrition21.com