

Nutrition

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EYEING the Possibilities

Suppliers innovate ingredients & tackle delivery challenges to meet a growing vision health market.

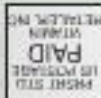
Also Inside:

Proprietary Ingredients

Healthy Blood Sugar

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Partnering for the BLOOD SUGAR BOUT

Suppliers offer clinically proven ingredients providing manufacturers formulation flexibility for the exponential blood sugar market.

By Kate Quackenbush

According to the World Health Organization, the frequency of diabetes is rising around the globe—about 350 million people worldwide have the illness, a number likely to more than double in the next 20 years.

What was once considered an adult onset disease is widening its scope as studies are showing children are at increasing risk of developing the disease. The National Diabetes Fact Sheet of 2011 estimated that one in every 400 children has diabetes.

Further, the Centers for Disease Control and Prevention reported that there were as many as 79 million pre-diabetics in 2011, and that number is on the rise as well.

So it should come as no surprise that the blood sugar management category of dietary supplements is a fast-growing segment—in 2012, it was estimated to be \$126 million, and is forecasted to double year by year by 2019—showing that more people are moving toward the preventive health care system.

“Diabetes prevention is one of the major public health investments. There is a worldwide public campaign underway to help educate people about

how to live a healthier lifestyle, emphasizing the importance of losing weight, exercising and a healthy diet low in sugar and fat to decrease their risk,” said Thomas Ughetto, business manager, nutrition & health with New Jersey-based Naturex Inc. “Balancing blood sugar levels is one of the key issues to improving health, so the market potential is huge for food supplements that can help regulate blood sugar levels. Looking at the increasing incidence of diabetes, we feel that this category will grow quickly in the coming years.”

Yet high blood sugar is not solely a concern reserved for those with a diabetes or prediabetes diagnosis, according to Barbara Lamberti, business development manager food Ingredients at Wacker Biosolutions, a division of Wacker Chemie AG in Germany. “With the higher awareness regarding diabetes and blood sugar-related diseases, even people that do not have diabetes register the problem and, as a result, prefer to take precautions and preventive measures,” she said. “Therefore, we see a growth in preventive medication and precautionary measures, such as blood sugar supplements.”

A Challenging Market

While the blood sugar market shows great potential, it has also garnered added attention from the U.S. Food and Drug Administration (FDA). Ughetto pointed out that the agency recently intensified its controls in the blood sugar category and sent 11 warning letters in July to companies that were selling mainly food supplements or topical creams and making diabetes-related claims. “Such claims are not permitted in food supplements since these products are not intended for the cure, mitigation, treatment or prevention of disease,” he said. “The market is heavily regulated and limited to the food supplement claim: decreasing blood sugar to prevent a risk of diabetes and cardiovascular disorders.”

Lamberti explained that, in the EU, some products cannot claim a blood sugar effect anymore due to the new EU Health Claim regulation. “The EU Health Claim regulations are currently the main driver in the market for blood sugar supplements,” she said. “[The regulation] is intended to ensure that the same standards on nutrition and health information on foods apply across all EU member states and that food manufacturers EU-wide only make

scientifically substantiated claims.”

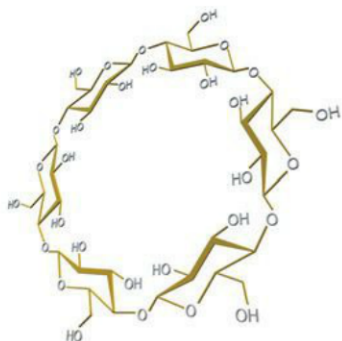
Wacker is a leading global manufacturer of cyclodextrins and their complexes, which are used widely in the food and dietary supplement industry. In 2000, scientific studies showed that alpha-cyclodextrin (also called alphasoltrin), a soluble dietary fiber, can reduce the glycemic response after starch-containing meals. More studies and research followed, resulting in an official EU health claim in June 2013 for Wacker's CAVAMAX W6 ingredient: The Commission Regulation (EU) No. 536/2013 on the list of permitted health claims made on foods ascribes a scientifically accepted blood-sugar-regulating effect to alphasoltrin: “Consumption of alpha-cyclodextrin as part of a starch-containing meal contributes to the reduction of the blood sugar rise after that meal.”

“Food containing at least 5 g of alphasoltrin per 50 g of starch in a quantified portion as part of a meal may now carry a label claiming the blood-sugar-lowering effect of the product,” said Lamberti. “Furthermore, alphasoltrin does not have an E number, and its efficacy has been clinically proven and confirmed by the European Food safety authority.

“Especially when it comes to functional food ingredients or dietary supplements, consumers want to make sure the products they consume are safe, healthy and efficient at the same time,” she added. “That’s why for these products, scientific studies play a growing role to demonstrate efficacy.”

Edible Opportunities

Euromonitor International statistics report fortified/functional products as a \$246 billion segment of health and wellness-positioned packaged foods and beverages, equaling about one third of the category globally. Between 2007-12, this segment showed a 42 percent sales



Model of an alphasoltrin: In its capacity as a water-soluble dietary fiber, alphasoltrin exerts a scientifically accepted blood-sugar-regulating effect after meals containing starch. (photo: Wacker Chemie AG).

increase, and functional foods/beverages now comprise about five percent of the overall U.S. food market.

According to Abunda Solutions, an integrated consulting group, functional foods offer a “lifestyle antidote.”

“Managing chronic conditions such as diabetes with foods that can offset the effects of the condition is a simple, self-directed concept. These products will take much of the guesswork out of the equation for diabetics, allowing them to lead a more ‘normal’ life, while enjoying their diet,” said Abunda Founder Peter Leighton in his article “How to Succeed in Function Foods: Seven Consumer Platforms.”

One company helping manufacturers serve this market is Illinois-based VDF FutureCeuticals, Inc., a leader in the development, manufacture and research of fruit, vegetable and grain-based nutritional ingredients for approximately 15 years.

“Our success with products in the healthy glucose and energy metabolism categories reflects the increased sophistication of consumers and their strong demand for all-natural products that can contribute to a healthy lifestyle,” said Brad Evers, VDF’s director of business development. “For example, the glycemic index is a widely understood concept today and consumers are becoming more selective and skeptical of products dominated by simple sugars. To that end, we offer our manufacturer partners safer, more wholesome ingredient solutions targeted to specific end-points and marketing platforms.”

VDF’s interest in healthy energy metabolism and the potential for the complex carbohydrates in grains to play a role resulted in an arrangement with the U.S. Department of Agriculture (USDA), whereby the company exclusively licensed its patented production method for improving the functional and formulation capabilities of whole grains, and specifically oats and barley. Evers explained that the VDF’s BarleyTrim ingredient, an all-natural, barley beta-glucan-rich powder for functional foods and beverages, was the subject of a 2006 study on human subjects, organized by the USDA, which showed that it may support healthy glucose and insulin response.

Most recently, VDF expanded its offerings with ModCarb, an all-natural powder from whole grains designed to provide sustained energy release from the complex carbohydrates in oats, amaranth, buckwheat, millet, quinoa and chia.

“Whereas simple sugars are quickly converted to glucose, creating an

“The glycemic index is a widely understood concept today and consumers are becoming more selective and skeptical of products dominated by simple sugars.”

— Brad Evers, Director of Business Development, VDF Futureceuticals, Inc.

insulin spike followed by a crash (rebound hypoglycemia), complex carbs are converted into glucose at a more moderate, sustained pace, modulating the release of insulin and contributing to a healthier, sustained production and utilization of energy,” said Evers. “ModCarb has enjoyed success as a value-add for protein products both for the benefits of complex carbs and for its ability to improve the mouth feel of existing formulations at manageable serving sizes.”

Ingredient Innovations

While the Fraxinus leaf is well-documented and traditionally used for its diuretic and anti-inflammatory properties in joint health, Naturex started its scientific program on Fraxinus seeds to develop a new and unique natural ingredient capable of decreasing post-prandial high blood sugar levels.

“Naturex has explored the properties of Fraxinus seeds that are lightly documented but known for being used mostly in the Mediterranean basin for its blood glucose-lowering property. Thanks to our research department’s three year investigations (*in vitro* and clinical trials) to further demonstrate Fraxinus seed efficacy and mechanism of action, we developed new ingredients that will contribute to answer to a major public health issue: lowering blood sugar levels,” said Ughetto, adding that due to the company’s highly advanced gentle extraction process, it developed a patented extract standardized for the first time to 10 percent nuzhenide and GI3. “These actives have been discovered and isolated by Naturex and are mainly responsible of the effect of our product.”

Unlike many blood-sugar-lowering



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Amla	Haritaki
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Andrographis	Green Tea
Asparagus	Inula racemosa
racemosus	Mucuna pruriens
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Bitter melon	Neem
Boswellia	Noni
Bahera	Phyllanthus
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Centella asiatica	Tinospora
Curcumin 95%	cordifolia
Eclipta alba	Tribulus
Garcinia	terrestris
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remedies that work either by stimulating insulin production or by reducing the absorption of carbohydrates, Ughetto said that the company's Fraxinus seed extract is different: it works mainly on

the liver and can reduce the peak of glucose normally observed after a sugar-rich meal.

Most importantly, the efficacy of the product has been demonstrated in two clinical studies. The first¹ was an acute, double-blind, randomized, crossover, placebo-controlled clinical trial on 16 healthy people and showed Fraxinus immediately reduces the incremental glucose area under the curve (AUC) by 8.8 percent compared to placebo. "This interesting result was then confirmed in a new double-blind, randomized, crossover (21 days for each arm), placebo-

The Blood Sugar-Dementia Link

One of the most common forms of dementia is Alzheimer's disease and diabetes is a known risk factor for the disease. On August 2, 2013, *The New England Journal of Medicine (NEJM)* published novel research suggesting higher glucose levels may be a risk factor for dementia, even among persons without diabetes.¹

The *NEJM* published study involved more than 2,000 people and tracked blood sugar over time in people with and without diabetes to see how it affects risk for Alzheimer's disease. Among participants with diabetes, those with higher blood sugar were 40 percent more likely to develop dementia than people with diabetes, with lower glucose levels. After nearly seven years of follow-up, one-quarter of participants (524 people) developed dementia, mostly Alzheimer's disease. Among participants who started out without diabetes, those with higher glucose levels over the previous five years had an 18 percent greater risk of developing dementia than those with lower glucose levels.

Type 2 diabetes, the most common form, reduces the body's ability to utilize insulin properly. This may result in elevated blood sugar levels, which in turn may cause damage to the major organs including the brain, and may even lead to death. Research over the last decade shows that proper cognitive function requires consistent healthy glucose metabolism in the brain. As a result, compromised metabolism of glucose can lead to a breakdown in cognitive function and have a harmful effect on overall brain health by significantly reducing brain glucose transporters.

Chromium is an essential mineral for the proper utilization of insulin in the body and maintaining healthy glucose metabolism, and clinical studies have

shown chromium picolinate has significant absorption when compared to other chromium forms.

There is a vast body of evidence supporting the role of Chromax chromium picolinate (from New York-based Nutrition 21) in healthy glucose metabolism and in maintaining healthy blood glucose levels. Additionally, a number of studies have contributed to the understanding of Chromax chromium picolinate's role in brain neurotransmission and have uncovered key insights into the beneficial role Chromax chromium picolinate supplementation plays in the metabolic and biochemical pathways of the brain. Robert Krikorian, PhD, from the Department of Psychiatry and Behavioral Neuroscience, University of Cincinnati Academic Health Center concluded that his research has shown the benefits of metabolic intervention with Chromax chromium picolinate supplementation in supporting the improvement of age-related memory decline.² This conclusion suggests that metabolic disturbances can be corrected with dietary modification and dietary supplementation.

"The *NEJM* article, 'Glucose Levels and Risk of Dementia,' has drawn national and local media attention," said Bill Levi, the company's vice president of strategy and business development. "Nutrition 21 has invested in research and products that support this emerging understanding of the correlation between healthy glucose metabolism and a healthy brain."

References:

1 Crane P, et al. Glucose Levels and Risk of Demetia. *N Engl J Med.* 2013; 369:540-548.

2 Krikorian R, Eliassen JC, Boespflug EL, Nash TA, Shidler MD. Improved cognitive-cerebral function in older adults with chromium supplementation. *Nutr Neurosci.* 2010 Jun;13(3):116-22. doi: 10.1179/147683010X12611460764084.

controlled, intervention study² on 17 people that will be published soon," said Ughetto. "Incremental glucose AUC was significantly reduced by 28.2 percent following three weeks administration of Fraxinus. In both studies, the daily dose was 1,000 mg of Fraxinus seed extract."

Meanwhile, for the past year, Polyphenolics in California has developed a unique grape seed polyphenolic ingredient for maintaining the glucose in the blood by increasing insulin sensitivity called MegaNatural-GL, which has gone through two clinical trials and is showing its ability for normal glucose maintenance.

According to Anil Shrikhande, the company's president, the first clinical trial demonstrated the mode of action to be a strong antioxidant mechanism. "Postprandial plasma oxygen radical absorbance capacity (ORAC) values were considerably decreased after consumption of high fat-carbohydrate breakfast meal with the grape seed extract. Postprandial or LDL were significantly decreased at five hours after the breakfast meal," said Shrikhande. "In a second clinical work with 16 male and 16 female participants, the research was focused upon the potential links between novel markers of vascular risk such as endothelial dysfunction, oxidation stress, inflammation and insulin resistance in the pathogenesis of type 2 diabetes. MegaNatural-GL significantly improved markers of inflammation and glycemia (hsCRP) and sole marker of oxidative stress in type 2 diabetic subjects."

MegaNatural-GL goes through its quality checks during manufacturing at Polyphenolics, which provides COA, SIDI package, etc., to dietary supplement companies encompassing a variety and chemical and physical tests, Shrikhande said.

Manufacturer Considerations

For formulators, Wacker's Lamberti noted that side effects regarding the processing or the end product—like browning, viscosity, heat sensitivity or off-taste—are very important considerations.

"Alphadextrin is a soluble dietary fiber with a neutral taste that doesn't show any side effects like undesirable browning or discoloration or an unpleasant off-taste, plus it is highly stable to both heat and a low pH. That's why it can easily be used in supplements and functional foods, including beverages," she said, noting that companies choosing to partner with Wacker are not alone in this process. "We give intense formulation support and offer our customers and partners the possibil-

ity for tailor-made developments and solutions. With development laboratories for food and beverage applications located in Adrian (Michigan, USA) and Burghausen (Germany), Wacker is able to work on made-to-order solutions for its customers."

Similarly, Polyphenolics takes a multifaceted approach to assist its customers. "We form a close partnership with customers' R&D and marketing staff. A thorough presentation by the Polyphenolics technical sales team addresses key differences between clinically proven MegaNatural-GL and other products within the ingredient class with an emphasis on the molecular basis for the beneficial effect, and how to administer tests for accurate measurement after consumption of a formula containing our biologically active grape products," said Shrikhande. "We remain available to our customer partners during all phases of product development for technical questions and support."

Bill Levi, vice president of strategy and business development with New York-based Nutrition 21, stressed that product efficacy must be substantiated with human clinical studies, and that it is critical to formulate ingredients that benefits consumers at the appropriate dosing levels. As example, the company's Chromax chromium picolinate has been studied in more than 15 human clinical studies supporting glucose metabolism, as well as studies showing chromium picolinate has significant absorption when compared to other chromium forms.³

"Due to the depth and breadth of clinical studies done on Chromax

chromium picolinate, we can provide manufactures with strong, substantiated, meaningful claims," said Levi.

In conclusion, while the final consumer is more aware about blood sugar control and the health disorders associated with high glucose concentration, Naturex's Ughetto expressed that there is still a significant proportion of people who think that managing blood sugar level is only relevant to people with diabetes. "So, more education is needed and this is exactly what we plan to do," he said. "Naturex is the leading company in natural ingredients manufacturing and therefore will continue to support manufacturer's in their market education task." **NIE**

References:

- 1 Visen et al. (2009) *J. Ethnopharmacol.* 126:226-232.
- 2 Zulet et al, pending.
- 3 DiSilvestro RA, Dy E. Comparison of acute absorption of commercially available chromium supplements. *J Trace Elem Med Biol.* 2007;21(2):120-4. Epub 2007 Mar 19.

Extra! Extra!

Visit www.niemagazine.com to read about researchers examining a specific part of a balanced diet—magnesium—lowering the risk of developing diabetes

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