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New Study Highlights Safety of Probiotic Strain *Bacillus coagulans*
Consuming large doses of Bacillus coagulans deemed safe for humans

CLEVELAND (April 7, 2009) – The results of a safety study to be published in the May issue of *Food and Chemical Toxicology* demonstrate that the probiotic strain, GanedenBC30™ (*Bacillus coagulans* GBI-30, 6086), is safe for human consumption, even in massive amounts. Many experts recognize the health benefits of probiotics, but some have stressed that probiotic strains must first demonstrate safety before recommendations can be made about their widespread use. The new study also sets the stage for the incorporation of GanedenBC30 into a wide variety of foods. Unlike many other probiotic strains, [GanedenBC30](#) easily survives the challenges of food manufacturing, extreme temperatures, and the gastric environment.

[Probiotics](#), also referred to as friendly bacteria, are becoming increasingly popular with consumers for several health benefits. However, safety studies do not exist for many strains of probiotics because there are no regulations requiring them. Most food manufacturers require some evidence of safety for any ingredient they put into their products, but few probiotic manufacturers are able to cite safety testing on their particular probiotic strains and instead refer to the safe history of use of probiotic strains in general. “Some probiotics manufacturers want things both ways, suggesting, for example, that clinical studies done on their particular strains apply only to their probiotics, but then staking claim to safety studies conducted on different strains,” said Andrew Lefkowitz, president and CEO of Ganeden Biotech, the largest seller of [over-the-counter probiotics](#) in the U.S. and sponsor of the study. “It is our belief that both the benefits and the safety of probiotics are specific to individual strains and should be demonstrated by studies.”

Study data showed that administering GanedenBC30 to rats at nearly 100,000 times the recommended dose for humans produced no harmful effects. “The results we saw with GanedenBC30 were off the charts compared to what we see with other common food ingredients and nutrients used to fortify foods” said Dr. John R. Endres, Chief Scientific Officer of AIBMR Life Sciences and one of the authors of the study. “We saw safety factors ranging up to 95,000 times the typical dose. These types of numbers are unprecedented in toxicology studies of this type.”

GanedenBC30 is the probiotic contained in [Digestive Advantage®](#) and [Sustenex®](#) products, which have already been demonstrated safe and effective in clinical trials. The new study sets the stage for widespread incorporation of GanedenBC30 into foods. “It was important to us to confirm the safety of consuming large amounts of GanedenBC30, since it may exist in several foods that might be consumed at the same time,” said Sean Farmer, Ganeden’s Chief Scientific Officer. “But the results were not surprising given the historical consumption of GanedenBC30 by large populations of people over long periods of time with no adverse events.”

The addition of probiotics into yogurts helped fuel huge growth in the yogurt industry overall, and food manufacturers have long wanted to add probiotics into other foods but have been challenged to find a probiotic strain that can survive typical manufacturing processes, including baking, boiling, and freezing. GanedenBC30 has been shown to survive such conditions hundreds of times better than other [probiotic strains](#). Now that GanedenBC30 has also been affirmed safe for use in foods, the range of foods utilizing probiotics is expected to grow.

“While [Bacillus coagulans](#) has always intrigued me as a probiotic strain due its ability to survive commercial conditions and gastric acidity, I didn’t know much about its safety and efficacy because there was little published data to review,” stated Dr. Gary B. Huffnagle, one of the leading researchers in the field of probiotics and author of *The Probiotics Revolution*. “Now that the studies are being published, it will be much easier to recommend it to consumers and to food manufacturers looking to enhance their foods with probiotics.”

About Ganeden Biotech

Founded in 1996, Ganeden Biotech Inc. is a private company based in Cleveland, Ohio, and is the largest seller of over-the-counter probiotics in the U.S. through its Digestive Advantage and Sustenex brands. It also licenses its patented probiotic bacteria, GanedenBC30, for use in commercial food and beverage applications as well as in medical foods and dietary supplements. Digestive Advantage and Sustenex are available at over 40,000 retailers nationwide including Walmart, CVS/pharmacy, Walgreens, Rite-Aid, Stop & Shop, Giant, Publix, Kroger, and Target. For more information, visit digestiveadvantage.com, sustenex.com, or ganedenlabs.com.