



# FACT SHEET

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## GanedenBC<sup>30</sup>® (*Bacillus coagulans* GBI-30, 6086)

- GanedenBC<sup>30</sup> is the registered trademarked name for the patented strain of probiotic bacteria, *Bacillus coagulans* GBI-30, 6086.<sup>1</sup>
- GanedenBC<sup>30</sup> is a probiotic, otherwise known as “good” bacteria that can help maintain digestive health.
- GanedenBC<sup>30</sup> survives manufacturing, shelf life and digestive transit to germinate and proliferate, providing benefit throughout the small and large intestine.<sup>1</sup>

## Consumer Uses

- GanedenBC<sup>30</sup> is not a drug and is designed to help support digestive health and maintain the immune system (as part of a balanced diet and healthy lifestyle).
- GanedenBC<sup>30</sup> is a calorie-free, lactose-free, kosher, non-GMO probiotic ingredient that can be easily added to most manufacturing processes including baking, freezing, boiling and extrusion.
- GanedenBC<sup>30</sup> is shelf-stable and does not require refrigeration.
- GanedenBC<sup>30</sup> is available in probiotic-fortified functional foods and beverages.

## Clinical Trials

- To date, fourteen peer reviewed studies have been published on GanedenBC<sup>30</sup> (*Bacillus coagulans* GBI-30, 6086).<sup>1</sup>
- Three of those studies show a relationship between GanedenBC<sup>30</sup> and the immune system.<sup>3,7</sup>
- Three clinical studies have shown that *Bacillus coagulans*, the specific bacterial strain inside GanedenBC<sup>30</sup>, helps improve abdominal pain and bloating and symptoms of diarrhea in patients with IBS.<sup>2,5,6</sup>
- A study by Dr. Glenn Gibson reviews the science of GanedenBC<sup>30</sup>.<sup>8</sup>

## Safety

- An independent panel of scientists awarded GanedenBC<sup>30</sup> self-affirmed GRAS (Generally Recognized As Safe) status after an extensive evaluation of research studies and toxicology data.<sup>1,9</sup>
- A one-year chronic oral toxicity study combined with a one-generation reproduction study was conducted to further investigate safety of long-term consumption of GanedenBC<sup>30</sup>. It was determined that GanedenBC<sup>30</sup> is safe for chronic consumption at up to 9.38 x 10<sup>10</sup> CFUs per day.<sup>10</sup>
- *Bacillus coagulans* has been added by the European Food Safety Authority (EFSA) to their Qualified Presumption of Safety (QPS) list.<sup>4</sup>

1 [www.ganedenlabs.com](http://www.ganedenlabs.com), accessed on 3.7.2011

2 Larysa Hun, MD, FAAP, *Bacillus coagulans* Significantly Improved Abdominal Pain and Bloating in Patients with IBS; *Postgraduate Medicine*, Vol. 121, Issue 2, March 2009

3 Mira Baron, MD, A Patented Strain of *Bacillus coagulans* Increased Immune Response to Viral Challenge; *Postgraduate Medicine*, Vol. 121, Issue 2, March 2009

4 The maintenance of the list of QPS microorganisms intentionally added to food or feed - Scientific Opinion of the Panel on Biological Hazards; Question number: EFSA-Q-2008-006; Adopted: 10 December 2008

5 B.J. Dolin, Effects of a Proprietary *Bacillus Coagulans* Preparation on Symptoms of Diarrhea-Predominant Irritable Bowel Syndrome; *Methods and Findings in Experimental and Clinical Pharmacology*, Vol. 31, Issue 10, 2009

6 M. Kimmel, A Controlled Clinical Trial to Evaluate the Effect of GanedenBC<sup>30</sup> on Immunological Markers; *Methods and Findings in Experimental and Clinical Pharmacology*, Vol. 32, Issue 2, 2010

7 Gitte S. Jensen, GanedenBC<sup>30</sup> Cell Wall and Metabolites: Anti-inflammatory and Immune Modulating Effects In Vitro; *BMC Immunology*, Vol. 11 2010

8 Glenn Gibson, *Bacillus coagulans* as a probiotic; *Food Science & Technology Bulletin: Functional Foods* 2010, 7 (7): 103-109

9 John Endres, Safety Assessment Of A Proprietary Preparation Of A Novel Probiotic, *Bacillus Coagulans*, As A Food Ingredient; *Food and Chemical Toxicology*, 2009; 47: 1231–1238

10 John Endres, One-Year Chronic Oral Toxicity With Combined Reproduction Toxicity Study Of A Novel Probiotic, *Bacillus Coagulans*, As A Food Ingredient; *Food and Chemical Toxicology Article in Press*