



Morinaga Milk Obtains Self-Affirmed GRAS Status for Its Proprietary Immunogenic Ingredient LAC-Shield(TM)

LAC-Shield helps enhance immunity in a wide range of food and beverage applications

TOKYO--Morinaga Milk Industry Co., Ltd., today announced it has attained self-affirmed GRAS (generally recognized as safe) status in the United States for LAC-Shield, a unique **immunogenic** ingredient. This development opens the door for manufacturers of dietary supplements, functional foods and beverages in the U.S. to include LAC-ShieldTM in products designed to enhance immune function.

Thanks to mounting research demonstrating the positive health benefits of probiotics, the probiotics market has experienced explosive growth over the past decade. In fact, according to *Nutrition Business Journal*, probiotics posted 17 percent year-over-year growth from 2015 to 2016 in the United States — the highest of any supplement category. BCC Research predicts the global market will grow to USD \$50 billion in 2020, as people’s awareness of and interest in healthful products continues to increase. However, the market is evolving beyond conventional probiotics to include metabolites of probiotics and non-viable microbes — called “immunogenics” or “immunobiotics.”

LAC-Shield (*Lactobacillus paracasei* MCC1849), widely recognized in Japan for its ability to enhance immunity, is one such ingredient. Unlike live cultures, LAC-Shield is rendered non-viable by heat treatment. Yet LAC-Shield still induces the production of a cytokine which activates and stimulates immune function.

LAC-Shield’s immune-boosting power was recently demonstrated in a human clinical study Morinaga Milk conducted with Kyushu Women’s University, which found it can lower the risk of contracting the common cold in susceptible subjects (Murata *et al.*, *Benef Microbes*. 2018, in press). Another human clinical study, reported by Maruyama *et al.* (*Int J Food Sci Nutr*. 2016), found LAC-Shield may enhance the immune responses of the flu vaccine in the elderly with immunosenescence.

One of the most noteworthy aspects of LAC-Shield is the diversity of its potential applications. Usually, probiotics are difficult to incorporate into functional foods and beverages because of their intolerance of high temperatures and moisture. However, since LAC-Shield is pasteurized, it is highly tolerant of high heat and humidity, making it easy for manufacturers to incorporate it into a wide variety of products.

“In recent years, people have been demanding additional value and health benefits from the foods they consume. LAC-Shield has excellent potential to respond to those needs in the global market,” said Ko Shiino, General Manager of the International Division at Morinaga Milk. “Achieving GRAS status enables LAC-Shield to be included in a wide variety of functional foods and beverages. We will continue our efforts to gain GRAS status for other probiotics in our portfolio so that we can contribute to healthier and brighter futures of people throughout the world.”

Morinaga Milk has a solid track record with GRAS ingredients. It attained GRAS status for its flagship probiotic ***Bifidobacterium longum BB536*** (GRAS Notice No. GRN 000268) in 2007 and for *Bifidobacterium breve M-16V* (GRAS Notice No. GRN 000453 and GRN 000454) in 2013. BB536 is well-known for its stability, quality and wide-ranging functional effects, as shown by 160 scientific reports, including numerous clinical studies. M-16V is well-known for its strong safety profile and its efficacy in infants, having been used in more than 120 Neonatal Intensive Care Unit (NICU) hospitals in Japan for low-birth-weight infants to support healthy growth. As a result, Morinaga Milk attained not only FDA-notified GRAS status for M-16V, but also GRAS status for infants.

About LAC-Shield

LAC-Shield is an immunogenic ingredient made from *Lactobacillus paracasei* MCC1849 that has been rendered non-viable by heat treatment. Morinaga launched LAC-Shield into the global marketplace in September 2017 and has received a high level of interest in the ingredient from all over the world. To date, over 250 food companies in Japan have included LAC-Shield into their products.

About Morinaga Milk

Morinaga Milk Industry Co., Ltd., one of the largest dairy product companies in Japan, has celebrated its 100 years anniversary in 2017. Morinaga Milk excels in innovative technology and offers various dairy products and other beneficial functional ingredients to customers throughout the world. Morinaga Milk started research of bifidobacteria in 1960s. In 1969, Morinaga Milk isolated its flagship strain *Bifidobacterium longum* BB536 from a healthy infant. Since that time, Morinaga Milk has been conducting research, including clinical studies not only on probiotic ingredients, but also non-viable microbes and functional ingredients.

If you would like to have more information about our probiotics and functional ingredients, please send an e-mail to: interntl@morinagamilk.co.jp Also, we will set up the booth for coming event IFT 2018 in Chicago, USA so if you would like to have a meeting with us, please kindly visit us on booth S1360.

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