



March 25, 2024

The only Japanese company*1 to obtain approval for the use of Bifidobacteria in Brazil
Three *Bifidobacterium* strains, BB536, M-16V, and M-63, approved for use by Brazil’s “ANVISA”*1
Approval also given for stating on the label the health benefits of digestive and intestinal care.

Morinaga Milk Industry Co., Ltd. has received approval from the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, hereinafter referred to as ANVISA) to use its unique *Bifidobacterium* strains, *Bifidobacterium longum* subsp. *longum* BB536, *Bifidobacterium breve* M-16V, and *Bifidobacterium longum* subsp. *infantis* M-63, as ingredients combined with other food products for sale as general food items in Brazil. These strains have been registered on the permitted list.

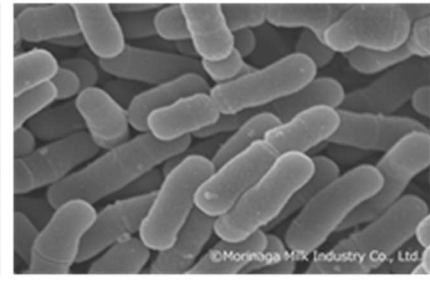
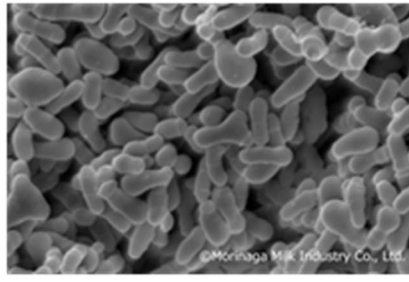
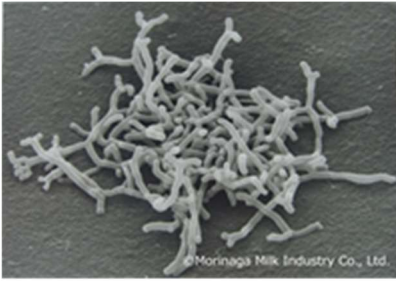
*1 Source: Public announcement on ANVISA's website (as of March 12, 2024).

One of the Morinaga Milk Group's 10-year visions is to become a globally recognized company with a unique presence in the world with overseas sales accounting for over 15% by the end of March 2029. As part of the Group's overseas business strategy, we are strengthening our efforts to expand our probiotics business, including collaborations with major infant milk manufacturers and enhanced sales of supplements in various countries outside Japan.

Companies intending to sell pharmaceuticals, drug ingredients, and food products containing ingredients such as probiotics in Brazil, must obtain approval for their use from ANVISA for both imported and domestically produced goods.

With this approval, the company's three bacterial strains can now be used in Brazil as ingredients in general food products such as supplements and yogurts. This demonstrates that these strains are safe to use in general food products in that country. Furthermore, for general food products using these three bacterial strains as ingredients in Brazil, health claims targeting individuals aged 4 to 18 can now be made regarding digestive and intestinal care, making it possible to effectively communicate the product's functionality to consumers. Additionally, the combination of these three bacterial strains is widely used in supplements and sold in various countries around the world. With the addition of these approved strains and health claims, Morinaga Milk aims to strengthen its probiotics business further in Brazil's rapidly growing probiotic supplement market. The goal is to contribute to the health and nutrition of the country's population.

Morinaga Milk is the only Japanese company that has *Bifidobacterium* strains approved by ANVISA for use*1. This is the third approval for the use of *Bifidobacterium* strains following the approval of *Bifidobacterium breve* M-16V and *Bifidobacterium longum* subsp. *longum* BB536 as single strains.



Bifidobacterium longum BB536

Bifidobacterium breve M-16V

Bifidobacterium infantis M-63

<About the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária)>

ANVISA is an affiliated agency of the Federal Ministry of Health in Brazil. It is responsible for regulating and overseeing food safety and related matters across the entire country.

<About *Bifidobacterium*>

Bifidobacteria primarily reside in the intestines of humans and animals, producing organic acids such as acetic acid and lactic acid, which help maintain intestinal balance. While it's widely known that lactic acid bacteria are necessary for making yogurt, not all yogurts contain the beneficial bacteria *Bifidobacterium*. Yogurts containing *Bifidobacterium* are specially manufactured by adding *Bifidobacterium* during production. *Bifidobacterium* is a representative beneficial bacterium that contributes to health.

● *Bifidobacterium longum* subsp. *longum* BB536

This *Bifidobacterium* strain was discovered in infants in 1969 and is found in the human gut. Generally, *Bifidobacterium* strains found in the human gut are sensitive to acids and oxygen. However, *Bifidobacterium longum* BB536 is resistant to acids and oxygen, making it widely used in products such as yogurt and supplements.

● *Bifidobacterium breve* M-16V

This is a type of *Bifidobacterium* that is particularly abundant in infants and young children. Consumption of *Bifidobacterium breve* M-16V has been reported to maintain a healthy gut flora that is rich in *Bifidobacterium*, thereby efficiently enhancing nutrient absorption. Moreover, it has been used under medical supervision in over 150 medical facilities worldwide, including NICUs (Neonatal Intensive Care Units), as a probiotic supplement.

● *Bifidobacterium longum* subsp. *infantis* M-63

This is one of the types of *Bifidobacterium* that primarily resides in the intestines of human infants. It has a high capability to utilize human milk oligosaccharides found in breast milk. When consumed in combination with other *Bifidobacterium* strains (such as *Bifidobacterium longum* BB536 and *Bifidobacterium breve* M-16V), it has been reported to promote early colonization of *Bifidobacterium* in the intestines of low birth weight infants and alleviate abdominal symptoms of digestive disorders in children.

<Morinaga Milk Industry's *Bifidobacterium* Research>

In more than 50 years since its discovery, *Bifidobacterium longum* BB536 has been studied in numerous human clinical trials and has been reported to be beneficial in reducing digestive disorders, improving the intestinal environment, regulating immunity, preventing infectious diseases, and providing anti-allergy benefits. There are

already more than 250 original research papers published (as of September 2023). Morinaga Milk Industry Co., Ltd., along with ongoing research worldwide, continues to study this specific strain of *Bifidobacterium*.

Morinaga Milk discovered *Bifidobacterium longum* BB536 in infants in 1969 and has been researching *Bifidobacterium* and gut flora for over 50 years. In terms of the number of clinical research papers related to *Bifidobacterium* in humans, Morinaga Milk is ranked No. 1 globally*2.

*2: According to a survey by KnowledgeWire as of January 2024, based on research paper counts by companies on PubMed and Ichushi-Web, a collection of Japanese biomedical literature.

Disclaimer: This English translation is provided for the benefit of readers. In the case that discrepancies exist between the original Japanese version and the English translation, precedence goes to the original Japanese version.