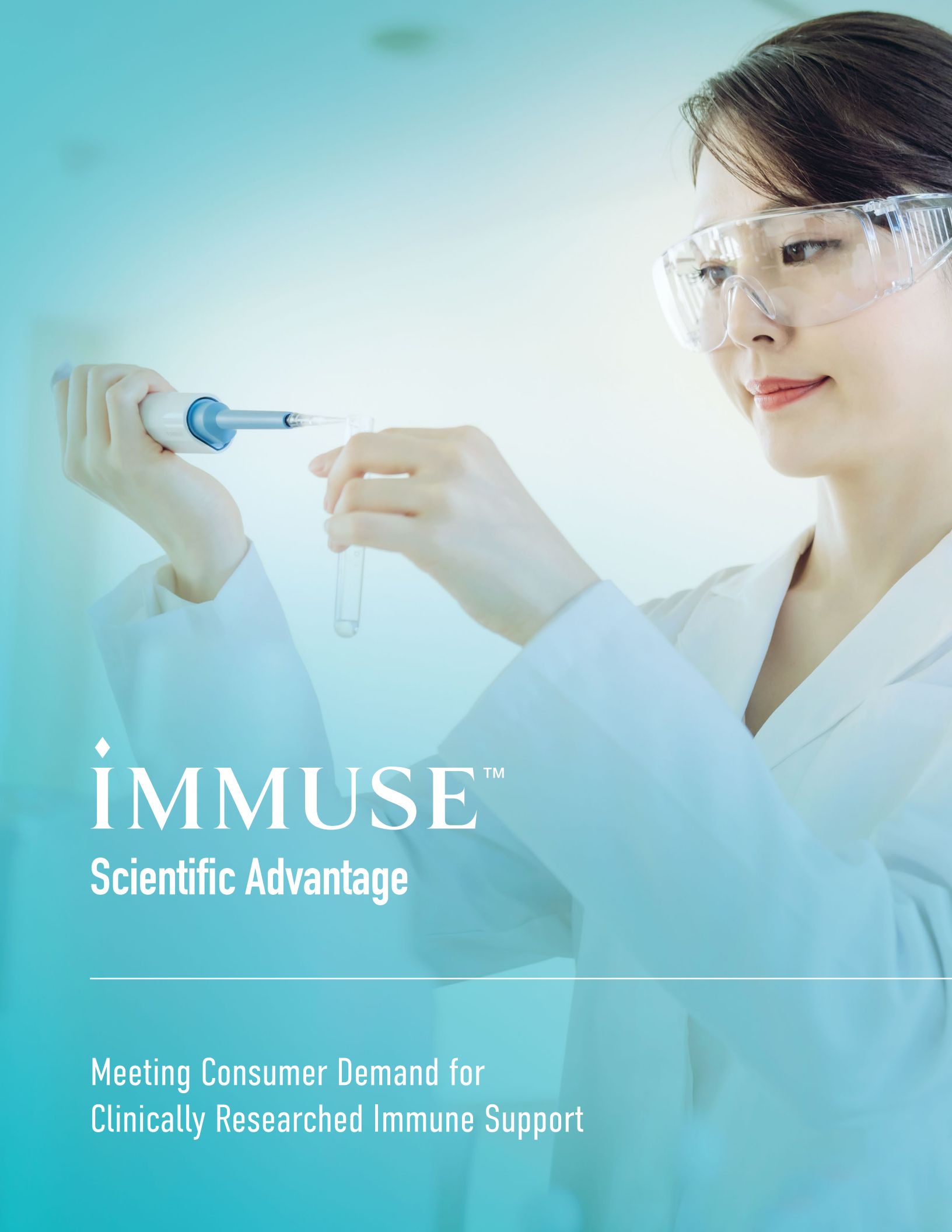

iMMUSE™

Scientific Advantage

Meeting Consumer Demand for
Clinically Researched Immune Support

The demand for immune supplements has surged since the start of the pandemic, alongside consumer awareness of immune health, and the increased spending dollars are here to stay.[1,2]

Today's consumers understand the importance of maintaining a healthy, well-functioning immune system and are adopting a proactive, long-term approach to their immune health. They are making necessary lifestyle and dietary changes, as well as taking daily nutritional supplements for additional immune support.[3]

But they want to see the proof. Not only are consumers more aware of the importance of immune health, they are also more knowledgeable, better informed and, as a result, more skeptical. They are doing their own research, and want to see scientific evidence and clinical research validating a product's effectiveness when shopping for an immune support supplement.[4,5]

In a crowded market, IMMUSE™ (LC-Plasma) stands out as a science-based food and dietary ingredient with a novel mechanism of action for more comprehensive immune support.

Backed by 29 published studies, including 14 human trials consisting of 12 efficacy studies and 2 safety studies, IMMUSE™ is the first lactic acid bacteria clinically researched to activate plasmacytoid dendritic cells (pDCs), a rare subset of immune cells that act as leaders of the immune system.

Demand for Immune Health Products is Here to Stay

The pandemic propelled explosive growth in the immune health supplement market. Sales in the US reached close to $6 billion, growing by 72.3% in 2020. And while growth is expected to return to pre-pandemic rates, spending on immune health products will continue to increase.[7]

On a global scale the immune health supplement market is projected to grow from $16.8 Billion in 2020 to $27.6 Billion by 2026, growing at a CAGR of 8.4% over the 6 year time period.[8]

Consumers worldwide have become more aware of their overall wellness, and plan to maintain a healthier lifestyle in the future. They're conscious of their immune health and making it a daily priority, banking on the long-term benefits of building a strong, resilient immune system.[9]

71% of global consumers are interested in products with immune supporting benefits.[10]

67% of global consumers are willing to purchase immune boosting products, even when they don't exhibit symptoms.[11]

83% of global consumers who take immune supplements, do so daily and purchase more upon running out.[12]

More than ever before consumers are making the connection between their immune health and overall quality of life, taking proactive steps to protect their immunity.[13]

One in four people worldwide have become more conscious of their immune health since prior to the pandemic. Consumers are recognizing the negative impacts of stress and a fast-paced lifestyle, and looking for food and beverages that can provide added immune support.[14,15]

"With more consumers looking for ways to enhance their immune system and stay healthy throughout the year, we are confident that IMMUSE™, backed by both Kirin Holdings and Kyowa Hakko Bio, will open new doors for consumers desiring a novel approach to broad-range immune support."

– Maria Stanieich, Marketing Manager, Kyowa Hakko USA

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Scientific Evidence is Top Priority

Health-minded consumers are actively researching and educating themselves on different immune health ingredients.[16,17]

They're connecting immune health to overall health, and associating a weakened immune system with catching an illness and feeling chronically fatigued. As a result, consumers are searching for safe and effective ways to help strengthen their immune system year-round.[18]

However, with such a wide array of products to choose from, consumers have become increasingly discerning when it comes to purchasing dietary supplements for immune support, and preference products that present scientific data to substantiate their claims.[19]

48% of global consumers say they regularly research the functional food and dietary supplement brands that they purchase.[20]

73% of global consumers that have not purchased a dietary supplement in the last 12 months say they would be enticed to purchase one for immune support if there was a scientific claim associated with the product.[21]

#1 Consumers in the U.S. rate **new scientific research** as the #1 reason for switching brands.[22]

As consumer awareness continues to grow, and more immune health products become available, brand loyalty will become less important as shoppers make better informed decision.

Immune support claims backed by clinical research will become increasingly important.[23,24]

Give consumers the scientific evidence they demand and differentiate your next immunity product with IMMUSE™ — a clinically-validated food and dietary ingredient delivering the latest breakthrough approach in immune health.

Kyowa Hakko USA named by Frost & Sullivan as the **2021 North American New Product Innovator** in the immune health ingredient industry for its novel postbiotic, IMMUSE™ (LC-Plasma), and awarded Excellence in Best Practices for its commitment and investment toward clinically validating the ingredient's efficacy and safety.

Meet IMMUSE™, a Cutting-Edge Postbiotic Backed by Science

IMMUSE™ (LC-Plasma) is a unique, patent-protected, heat-killed lactic acid bacteria strain, more commonly referred to as a postbiotic, with a novel mechanism of action that stimulates immune function at the cellular level for broad-range immune support.**

What is a Postbiotic?

Along with immune health, consumers have become increasingly aware of the connection between gut health (the microbiome) and immune function. Nearly two-thirds of global consumers associate probiotics with immune health, which opened the doors for an emerging class of exciting new ingredients called postbiotics.[26]

Google Search of the term 'postbiotic' has seen a nearly 1,300% increase over the last two years, according to new data from Lumina Intelligence.

Postbiotics are defined by the International Scientific Association for Probiotics and Prebiotics (ISAPP) as preparation of inanimate microorganisms and/or their components that confers a health benefit to the host.

Science has confirmed that many of the health benefits obtained from live bacteria can also be obtained from nonviable cells. However, postbiotics provide the added advantage of being more stable and convenient than probiotics. They also have clear chemical structures, well-defined safety dose parameters and distinct signaling molecules that, in the case of IMMUSE™, have immunomodulatory activities.[27,28]

A unique strain of lactic acid bacteria scientifically known as *Lactococcus lactis* strain Plasma (LC-Plasma), IMMUSE™ is the first lactic acid bacteria clinically tested to directly activate pDCs, a key leader of the immune system.

Discovered by Kirin Holdings, and cultivated using Kirin's proprietary cultivation process, the strain was then heat-killed, turning it into a postbiotic that's much easier to formulate with. As a postbiotic, the ingredient is also more stable at room temperature compared to probiotics, which means no refrigeration is required.

"The Key component of pDC activation is retained in the LC-Plasma's cell particle," explains researcher and director of technical affairs with Kyowa Hakko USA, Shintaro Ichikawa, PhD. "Since the heat treatment process does not break the cell particle, both the live and heat-treated LC-Plasma work the same way."

IMMUSE™ is self-affirmed GRAS, vegetarian, non-GMO, allergen-free and applicable to a wide variety of applications including tablets, capsules and foods — offering brands versatile formulation options.

What is More Comprehensive Immune Support?

An immune activator, IMMUSE™ safely stimulates plasmacytoid dendritic cells (pDCs) to provide more comprehensive immune support across both innate and adaptive immune systems.

The immune system is a complex, dynamic structure that exists throughout the body for one purpose: to protect our health. **It contains a variety of different immune cell types, each with their own specialized role in identifying, signaling, engulfing and destroying foreign invaders before they can cause harm.**

Most cells are divided between the two main branches of the immune system, innate and adaptive. Natural killer (NK) cells and macrophages, for example, are part of the innate immune system; while B and T cells act as part of the adaptive immune system. **pDCs, however, straddle between the two branches, playing a pivotal role in the overall immune response.**

Plasmacytoid dendritic cells (pDCs) are known as the 'commander-in-chief' of the

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** Kirin Holdings Company, Limited owns the global patent (US9549956) on IMMUSE™.

immune system — recruiting, communicating and directing an entire army of key immune cells involved in both the innate and adaptive immune responses.

When pDCs detect an invading pathogen, these influential cells secrete large quantities of type-1 interferon (IFN-α), an important signally molecule that stimulates nearly every type of immune cell for full, broad-range defense — bridging the gap between innate and adaptative immunity.

Scientists at Kirin knew that if they could find a strain of lactic acid bacteria that safely stimulated pDC activity, they could provide an ingredient that offered an unprecedented level of immune support. **After testing hundreds of strains, they found LC-Plasma, which was then cultivated, heat-treated and branded IMMUSE™.**

"We believe this may be the most comprehensive immune activator on the market today. With 29 published studies, these studies are repetitively and consistently demonstrating the benefits in immune health in healthy subjects." – Danielle Citrolo, PharmD, Vice President of Scientific and Regulatory Affairs, Kyowa Hakko USA

Discovered by scientists in the 1990s, pDCs have three defining characteristics:

1. Once stimulated, they rapidly secrete more interferons than any other immune cell.
2. They are considered the most efficient antigen-presenting cells.
3. They act as leaders, recruiting and activating almost all immune cell types.[29]

Innate vs. Adaptive

Innate vs. Adaptive Immune System

The innate immune system is responsible for the body's first-line of defenses, launching a generalized attack on all foreign invaders. Whereas the adaptive immune system is more specialized, creating specific defense strategies for each pathogen that allows the immune system to mount an immediate, stronger and more targeted attack the next time it encounters an invader. Together, the innate and adaptive immune system work to keep our bodies healthy as we move through changing environments and seasons.

IMMUSE™ Leads the Way in Immune Health Research

With over a decade of scientific research behind it, IMMUSE™ (LC-Plasma) is one of the most comprehensively studied immune health ingredients. The novel postbiotic has been the subject of 29 published studies, including 14 human clinical trials substantiating the ingredient's efficacy and safety. Overall, the studies have demonstrated that it is safe and well tolerated.

14 Human Clinical Trials

Study #1

Immunomodulatory Effect of LC-Plasma on Human pDCs

The first randomized, placebo-controlled, double-blind clinical study was published in 2013. Thirty-eight healthy volunteers who were randomly assigned to consumed either a yogurt drink fermented with LC-Plasma (approximately 100 billion cells) or a drink without daily for 4 weeks. The cumulative days of cold symptoms was significantly lower in the LC-Plasma group compared to the placebo group.[30]

Study #2

Effects of Oral Intake of LC-Plasma on Influenza Symptoms

In 2013 researchers examined the effects of LC-Plasma on flu-like symptoms in a randomized controlled trial (RCT) with 213 healthy participants who were randomly assigned to consumed either a yogurt drink fermented with LC-Plasma (approximately 100 billion cells) or a drink without every day for 10 weeks.

The study, which was published in 2015, found that there were significantly fewer cumulative days of cough, sore throat and feverishness symptoms in the LC-Plasma group compared to the placebo group. IFN-α gene expression levels were significantly higher in the LC-Plasma group as well, further affirming LC-Plasma's novel mechanism of action for immune support.[31]

Study #3

Effects of LC-Plasma on Antiviral Immune Response

A second RCT was published in 2015 with 100 volunteers who were randomly assigned to drink a beverage containing approximately 100 billion cells of LC-Plasma or one without daily for 8 weeks. Researchers evaluated antiviral immune response by measuring CD86 and HLA-DR expression levels.

After the 8 week trial period, CD86 and HLA-DR expression levels in the LC-Plasma group were significantly higher compared to the placebo group. So was the expression level of ISG15, an antiviral factor known to be induced by IFN-α. Furthermore, the LC-Plasma group also showed a significant reduction of cumulative days with cold-like symptoms compared to the placebo group.[32]

Study #4

Long-Term Use and Excessive Intake Trials (Safety Data)

The first clinical study on long-term and excessive use was also published in 2015, showing that there are no safety concerns associated with intake of LC-Plasma. Two randomized, placebo-controlled, double blind clinical trials were conducted with 44 subjects divided into 2 groups (LC-Plasma and placebo). In the first, the LC-Plasma group was given one bottled beverage containing approximately 100 billion cells of LC-Plasma every day for 12 weeks. In the second RCT, the LC-Plasma group was given 3 bottled beverages containing the 100 billion cells of LC-Plasma every day for 4 weeks.

Physical, blood and urinary examinations and medical interviews were used to evaluate safety. There were no abnormal changes caused by LC-Plasma compared to the placebo group in either trial.[33]

Study #5

Effects of LC-Plasma on Cold and Flu Prevention

This 2016 RCT study looked at heat-killed LC-Plasma's effect on cold and flu prevention in healthy young adults, who have a higher infection rate of influenza than their middle-aged counterparts. A total of 657 participants consumed a capsule containing approximately 100 billion cells of

LC-Plasma or a placebo capsule every day for 12 weeks. There were significantly fewer days of cough and sore throat, as well as a significantly higher IFN-α gene expression levels, in the LC-Plasma capsule group compared to the placebo capsule group.[34]

Study #6

Preventative Effects of LC-Plasma on Influenza Among Schoolchildren

The first community-based intervention study was published in 2017 to examine the ability of LC-Plasma to reduce the incidence of the flu in elementary and junior high school students.

Schoolchildren in the Japanese town of Shizukuishi were given yogurt with approximately 100 billion cells of LC-Plasma 3 times a week for 10 weeks. The number of students diagnosed with the flu was measured and compared to students in a neighboring town over the same 10-week period.

Results showed that the intake of LC-Plasma significantly reduced the rate of absence from school due to the flu, and was associated with two-thirds reduction in flu incidence rates compared with schoolchildren in the neighboring town who did not consume yogurt with LC-Plasma.[35]

Study #7

Effects of LC-Plasma on Mucosal and Systemic Immune Parameters

In 2017 researchers also investigated at the effect of oral intake of LC-Plasma on mucosal and systemic immune parameters in a randomized, placebo-controlled double blind clinical trial with 111 healthy adult volunteers. The 4 week study showed that LC-Plasma induced a significant antiviral response, increasing IgA levels in saliva, compared to the control group. The severity of sore throat was also lower in the LC-Plasma group compared to the placebo group.[36]

Study #8

LC-Plasma Effects on Fatigue and Body Conditioning During High Intensity Training Periods

Fifty-one male members of a university sports club in active training participated in this 2018 RCT to evaluate the effects of LC-Plasma on body conditioning and fatigue during periods of high intensity exercise. Participants consumed capsules containing approximately 100 billion cells of LC-Plasma or placebo capsules containing cornstarch every day for two weeks.

Athletes who took LC-Plasma showed significant improvements in physical condition, and less fatigue overall compared to the placebo group. The study also found that the intake of LC-Plasma significantly reduced sneeze or runny nose symptoms compared to the placebo group; and, significantly higher CD86, a key activation marker of pDCs.[37]

Study #9

Safety Evaluation of Excessive Intake of LC-Plasma

In 2018, a randomized, placebo-controlled, double blind clinical trial showed that LC-Plasma was safe to take at 5 times the recommended dose. A total of 40 volunteers were randomly assigned to take 5 capsules containing 50 mg (100 billion cells) of LC-Plasma per capsule or 5 placebo capsules every day for 4 weeks.

Physical, blood, biochemical and urinary examinations and medical interviews were used to evaluate safety. there were no abnormal differences after excessive intake of LC-Plasma capsules when compared to the intake of placebo capsules.[38]

Study #10

LC-Plasma Improves Physical State and Presenteeism Among Office Workers

In 2020 researchers published an open-lab cross over study among 153 healthy office workers to determine if intake of LC-Plasma could improve their work performance and physical condition. Participants were randomly assigned to one of two groups: (1) a intake period (consumption of yogurt containing LC-Plasma) followed by non-intake period; and (2) a non-intake period followed by a period of intake. Each period was 4 weeks with a 4 week "washout" period between each.

The study found that office workers showed significantly higher absolute presenteeism (as assessed by the World Health Organization Health and Work Performance Questionnaire) and exhibited more vigor (as assessed by The Profile of Mood States questionnaire) during the intake period than the non-intake period. Participant's physical health, which was assessed by typical common cold and flu symptoms and physical condition, was also superior during the period of intake, suggesting LC-Plasma improves office productivity via overall immune support.[39]

Study #11

The Effects of LC-Plasma on Skin Conditions

Aside from being the first defense barrier against foreign invaders, the skin is home to a diverse population of microbes that play a crucial role in maintaining healthy skin by preventing the colonization of bad bacteria. They also regulate skin pH and contribute to the immune response.

A randomized, placebo-controlled, double-blind clinical study with 70 healthy participants was published in 2021. Skin conditions were evaluated by a dermatologist before and after the 8-week trial. Results showed that erythema (superficial reddening of the skin) was significantly improved by the intake of LC-Plasma. Researchers also found that LC-Plasma prevented the decrease of good skin microbes, as well as the overgrowth of bad bacteria on the skin, suggesting LC-Plasma intake stimulated skin immunity.[40]

Study #12

The Effects of LC-Plasma on The Skin Microbiome

A second 8-week RCT, published in 2021, with 71 healthy volunteers was also conducted to further determine the impact of LC-Plasma on the skin microbiome. Results showed that the proportion of microbes that changed significantly during the test period was 10 times smaller in the LC-Plasma group compared to the placebo, suggesting that LC-Plasma may maintain skin microbiome homeostasis.[41]

Study #13

Effects of LC-Plasma effects on Dengue Fever-like Symptoms

Dengue fever is a tropical, mosquito-borne disease that infects nearly 400 million people worldwide per year.[42] However, there is still no effective treatment or vaccine for dengue. Based on the outcomes of previous clinical studies, showing that the intake of LC-Plasma reduced the incidence of influenza, researchers set out to determine LC-Plasma's effectiveness against dengue fever.

A randomized, placebo-controlled, double-blind trial with 320 health subjects in Malaysia was published in 2021. Study participants were either given a placebo or LC-Plasma tablets (approximately 100 billion cells) daily for 8 weeks. Results showed a significant reduction in the cumulative number of days of dengue fever-like symptoms, including fever, muscle pain, joint pain and pain behind the eyes, in participants who took LC-Plasma daily for 8 weeks compared to the placebo group.[43]

Study #14

Effect of LC-Plasma Intake on infectious Disease in Schoolchildren

In 2022, a randomized, placebo-controlled, double-blind study was published which had been designed for elementary schoolchildren, grades 1 to 3, in Vietnam to determine the impact of LC-Plasma intake on absentee rates due to infectious disease. Approximately 1,000 schoolchildren were given a placebo beverage or beverage containing 100 billion cells of LC-Plasma every day for 8 weeks.

There was a significant reduction in cumulative number of days absent from school due to infectious disease during the first 4 weeks of intervention, especially upper respiratory disease in the LC-Plasma group compared to the placebo group. LC-Plasma intake also significantly reduced the number of fever incidence during the first 4 weeks of intervention, as well as the number of days with diarrhea during the last 4 weeks of the intervention period. Furthermore, the number of positive general well-being days was significantly improved for schoolchildren in the LC-Plasma group compared to the placebo group.[44]

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IMMUSE™

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