

E-BOOK

LifeinU[®] BSCU1:

**The immunity
probiotic made
for you!**



What is LifeinU[®] BSCU1 and what are its benefits?

LifeinU[®] BSCU1, offered by Gnosis by Lesaffre, contains a **specific strain of the bacterium *Bacillus subtilis* CNCM I-2745**. This probiotic may **strengthen immune defenses** by increasing the immune system's Secretory immunoglobulin A (sIgA) antibody levels in the intestine and saliva.

What is sIgA?

sIgA is the first line of defense against pathogens in the intestine. It is a **vital player in the immune-exclusion mechanisms that stop microorganisms from accessing and crossing the intestinal barrier**. Positive modulation of sIgA release following exposure has been demonstrated in healthy and diseased states.

Have the effects of **LifeinU[®] BSCU1** been supported through clinical trials?

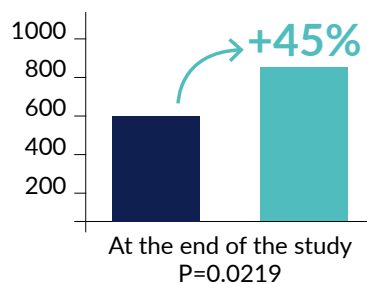
The effects of **LifeinU[®] BSCU1** on **common winter infections in seniors** have been studied in a clinical trial conducted by Professor Philippe Marteau (Saint Antoine Hospital, Paris, France).⁽¹⁾ This randomized, double-blind, placebo-controlled trial demonstrated how this product can stimulate the immune system and has the potential to decrease the frequency of winter infections. This study showed that **LifeinU[®] BSCU1 can reduce the frequency of upper respiratory tract infections in healthy, free-living seniors by up to 45%!**⁽²⁾

With LifeinU® *Bacillus subtilis* CU1, A PROBIOTIC BACTERIA TO BOOST YOUR EVERYDAY HEALTH!

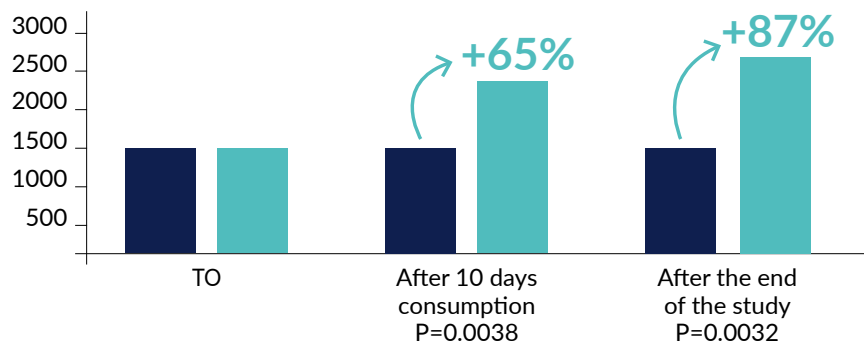
LifeinU® BSCU1 supports mucosal immune responses as observed in our clinical study which showed increased sIgA levels in the intestine and saliva.

■ Placebo ■ LifeinU® BSCU1

sIgA concentration in human saliva (µg/ml)

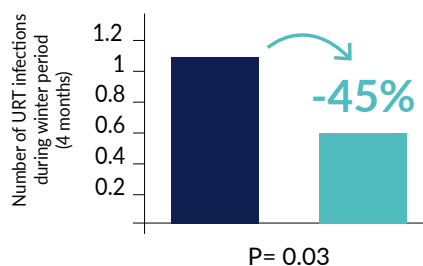


sIgA concentration in human stools (µg/ml)



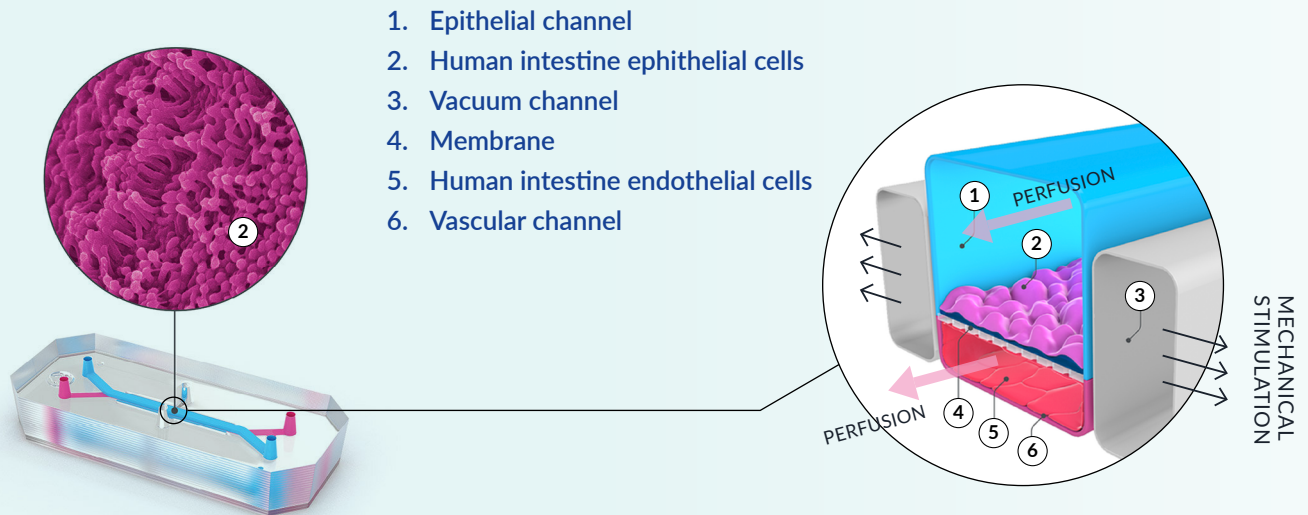
Frequency of Upper Respiratory Tract Infections

This protective effect of **LifeinU® BSCU1** is confirmed by a 45% reduction in the frequency of Upper Respiratory Tract Infections



Gnosis by Lesaffre is working in collaboration with Emulate, a Harvard start-up that developed a new dynamic model that comes as close as possible to mimicking the human model in preclinical stages, which they call the “**intestine-chip model.**”⁽³⁾ The principle consists of **recreating cellular microenvironments with 3D human-derived cells.** It allows for a deeper understanding of the clinically observed impacts of **LifeinU® BSCU1** on the gut immune system.

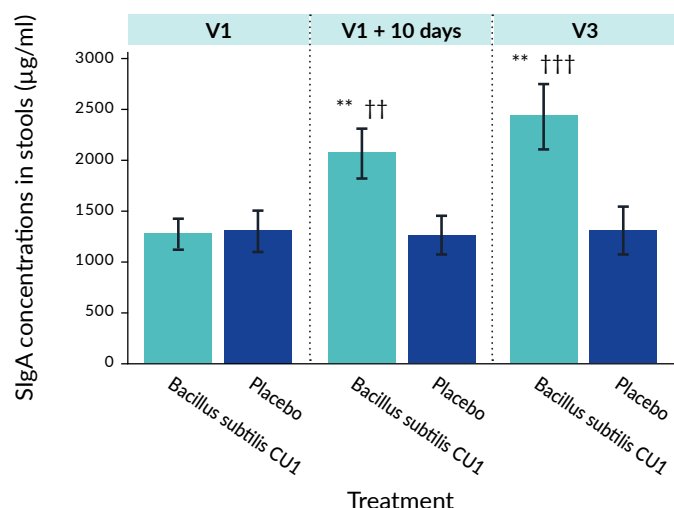
Concept of 3D gut-on chip:



This study showed that **LifeinU® BSCU1** contributes to **reducing gut permeability** in the intestine-chip model. Further research is required to ensure the same results are found in the human body. However, these findings are important as increased gut permeability has been associated with impaired immune responses. This study also proved that the probiotic affects the integrity of the gut mucosal barrier and confirms that **LifeinU® BSCU1** significantly increases the concentration of sIgA in the intestinal lumen, which is consistent with the human clinical trial.

B. subtilis CU1 has been tested and is **safe and well-tolerated** in clinical subjects **without undesirable physiological effects** on markers of liver and kidney function, complete blood counts, hemodynamic parameters, and vital signs.⁽⁴⁾

Therefore, **LifeinU® BSCU1** is a great solution **for everyone!**⁽⁵⁾



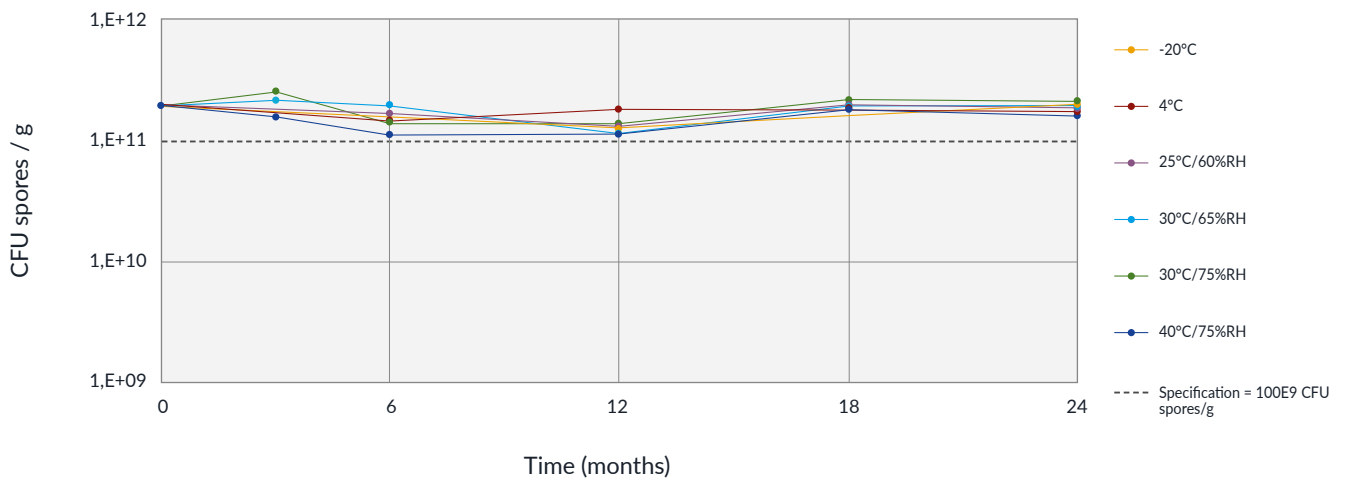
Fecal SIgA concentrations were significantly higher in the probiotic group compared to the placebo group (**P < 0.01), and significantly increased in the probiotic group during the study (†† P < 0.01, ††† P < 0.001)

LifeinU® BSCU1 is a stable probiotic

LifeinU® BSCU1 is an innovative product that is stable for 24 months in its original packaging under various climatic conditions and even under extreme conditions such as 40°C/75% RH. **LifeinU® BSCU1** in its various packaging formats has been tested and is stable at a number of different standardized temperatures and humidity levels (ICH Stability Zones I-IVb).

A HIGHLY STABLE PROBIOTIC

LifeinU® BSCU1 - ingredient stability under various conditions



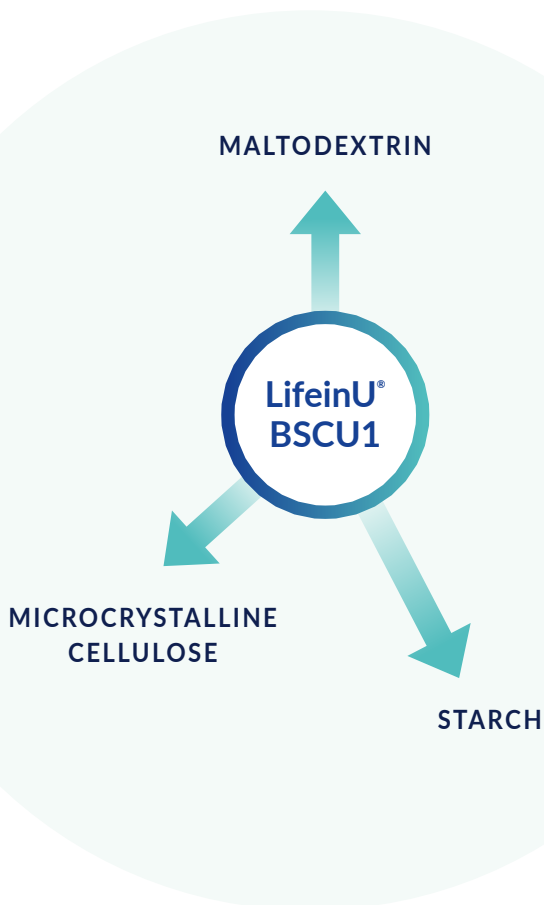
Additionally, this product has been tested to be stable at temperatures between -20°C and 4°C. The stability of **LifeinU® BSCU1** in HPMC capsules has been tested in many packaging formats:

- Alu/Alu blister
- PVC /PVdC blister
- HDPE bottle with desiccant
- HDPE bottle without desiccant

In all these packaging formats **LifeinU® BSCU1** is stable for 24 months at 25°C/60% RH and 30°C/75% RH. Therefore, it does not require special or expensive packaging formats to remain stable.

Is LifeinU® BSCU1 suitable for dietary supplements and functional foods?

LifeinU® BSCU1 can be formulated in **capsules** and is **compatible** with commonly used carriers such as **maltodextrin**, **starch**, and **microcrystalline cellulose**.



LifeinU® BSCU1 is also suitable for **sachets and sticks**. In this form, we recommend water-soluble filling agents (e.g., maltodextrin, dextrose, lactose).

LifeinU® BSCU1 is **unique** compared to classical probiotics due to its **robust and stable nature**, as described above, which allows it to retain its beneficial properties even after many industrial processes (heat treatment, humidity, etc.).

It is also more easily incorporated into many food matrices and has a relatively long shelf life in finished products, such as **cereal bars**. In cereal bars, LifeinU BSCU1 is stable at a temperature close to 60°C or 140°F.

LifeinU® BSCU1 is the perfect choice for functional foods!



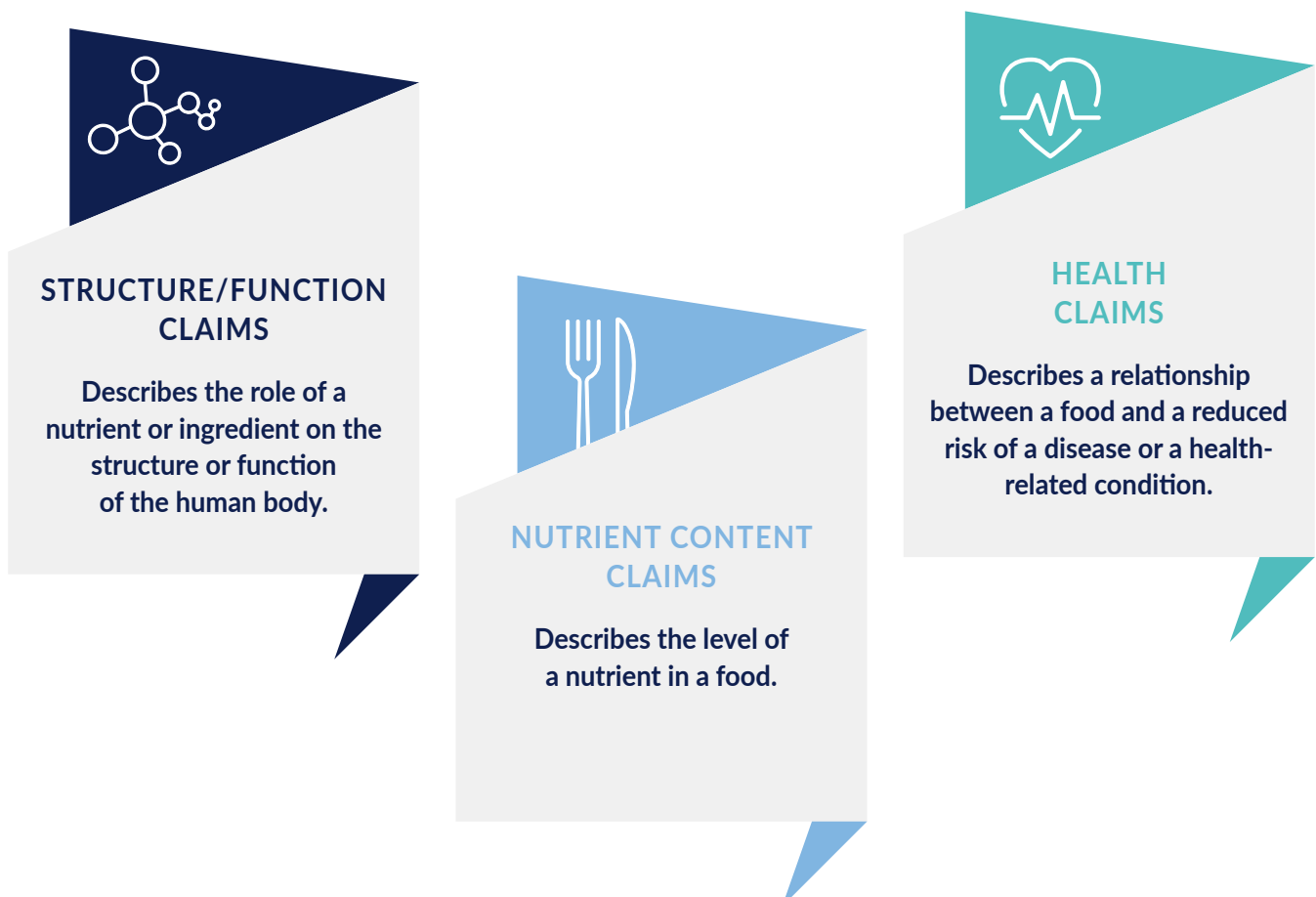
How to Make Different Claims for LifeinU[®] BSCU1 in the United States and Europe

Making a structure/function claim in the United States

In the United States, you can make a structure/function claim with **LifeinU[®] BSCU1**.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) established regulatory requirements and processes for structure/function claims and two other types of dietary supplement labeling claims, including, claims of general well-being and claims related to a nutrient deficiency disease.⁽⁶⁾

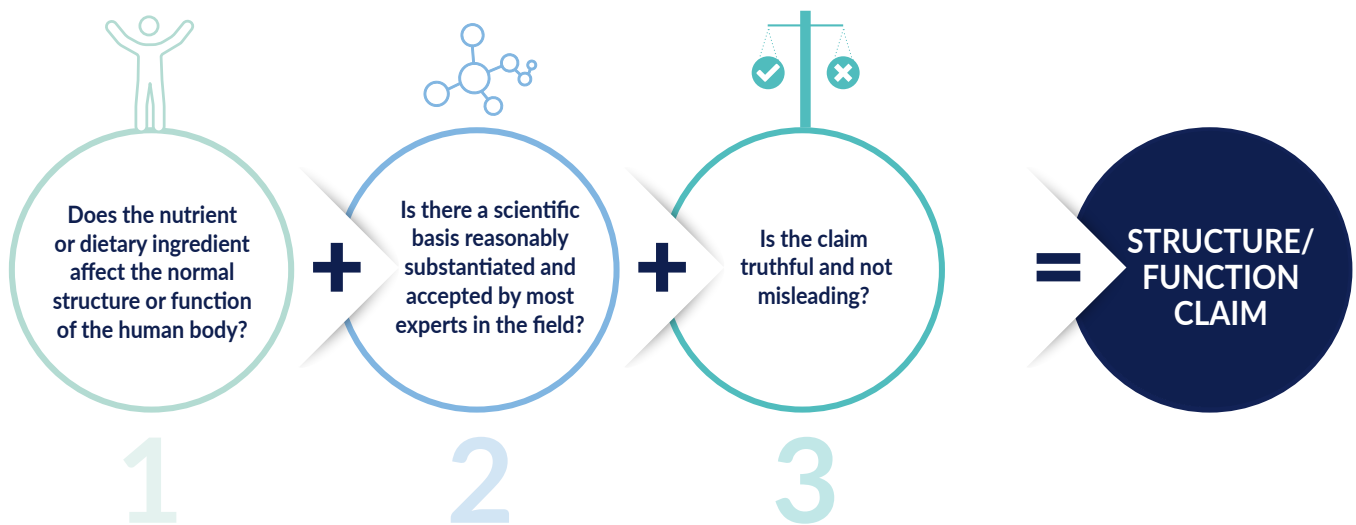
This regulation covers **three main types of health-related statements**:



Which claims can be used for LifeinU® BSCU1 and what is it based on?

LifeinU® BSCU1, offered by Gnosis by Lesaffre, contains a specific strain of the bacterium *Bacillus subtilis* CNCM I-2745 which shows some effects (human clinical studies and review of scientific literature) and therefore allows for a **structure/function claim** to be made.

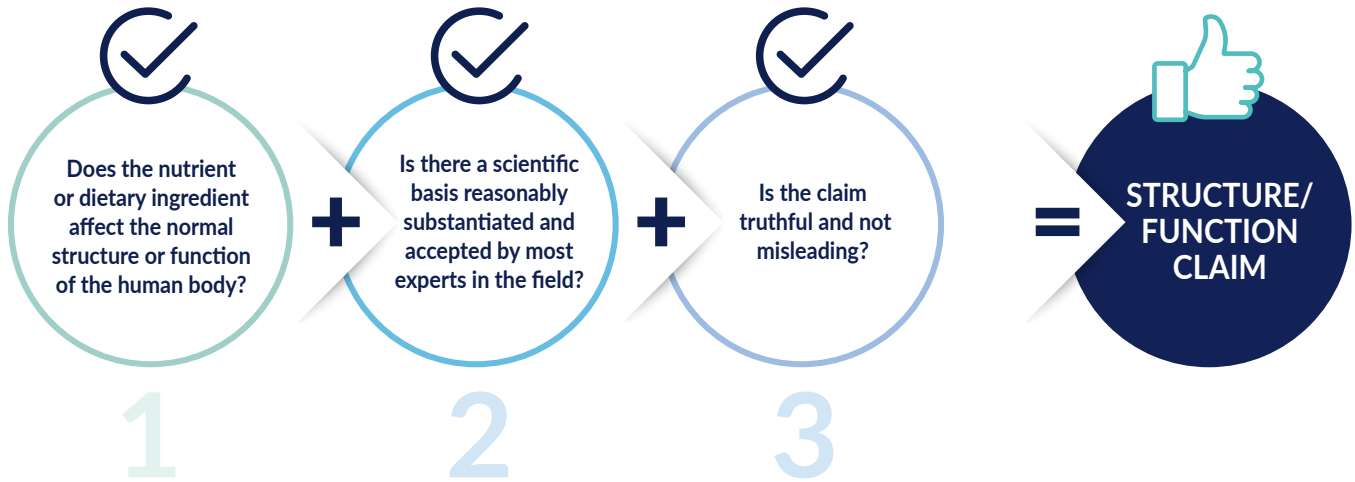
So, how does this solution meet a structure/function claim?



1. Does **LifeinU® BSCU1** affects the normal structure/function of the human body: **LifeinU® BSCU1** may strengthen immune defenses by increasing the immune system's sIgA antibody levels in the intestine and saliva.
2. Is there a scientific basis that is reasonable and substantiated for **LifeinU® BSCU1**: The effect of **LifeinU® BSCU1** on common winter infections in seniors was studied in a clinical trial conducted by Professor Philippe Marteau (Saint Antoine Hospital, Paris, France).⁽³⁾ This randomized, double-blind, placebo-controlled trial showed immune stimulation, with the potential to decrease the frequency of winter infections. Gnosis by Lesaffre working in collaboration with Emulate, a Harvard start-up that developed a new dynamic model that comes as close as possible to mimicking the human model in preclinical stages, which they call the "intestine-chip model." It allows for a deeper understanding of the clinically observed impacts of **LifeinU® BSCU1** on the gut immune system. This study showed that **LifeinU® BSCU1** contributes to reducing gut permeability in the intestine-chip model (increased gut permeability has been associated with impaired immune responses). It also suggests that the probiotic affects the integrity of the gut mucosal barrier and confirms that **LifeinU® BSCU1** significantly increases the concentration of sIgA in the intestinal lumen, which is consistent with the human clinical trial.

3.

Is the claim for **LifeinU® BSCU1** truthful and not misleading: because of the positive outcomes of human clinical studies and review of scientific literature, a truthful and non-misleading claim can be made in the following way, "***Bacillus subtilis* CU1 supports immune health.**"



Making a health claim on immunity in the EU

In the **European Union (EU)**, the Commission authorizes various nutrition and health claims, provided they are based on scientific evidence and can be easily understood by consumers. The **European Food Safety Authority (EFSA)** is responsible for evaluating the scientific evidence supporting health claims. The Commission has established a list of permitted health claims for food and food supplements.⁽⁷⁾

Some micronutrients are allowed to use a claim related to immunity. This is the case for several B vitamins, zinc, and selenium, which can claim that they contribute to the normal function of the immune system. Therefore, they can use the term "immunity" on the pack.

With its **Lynside®** range, Gnosis by Lesaffre offers high-quality **B vitamins, zinc, and selenium** in the form of **fortified yeast**. The combination of **LifeinU® BSCU1** with one or more of these fortified yeasts in immunity products is **compliant for the EU claim "contributes to the normal function of the immune system."**

Lynside® range of
fortified yeasts



LifeinU® BSCU1



EU claim "contributes to the normal
function of the immune system."



LEARN MORE about **Gnosis**
by Lesaffre's **Lynside®** range to
combine with **LifeinU® BSCU1**



An exceptional immunity probiotic for the future!

Immunity is one of the most important health concerns for consumers today!

Since the COVID-19 outbreak, **45% of consumers in Europe have decided to add additional nutrients to their diet** and 29% reported being more interested in foods that support their immune systems.⁽⁸⁾ Furthermore, 36% of Americans have already reported an increase in their use of dietary supplements since the beginning of the COVID situation.⁽⁹⁾



LifeinU® BSCU1 is one of Gnosis by Lesaffre's most innovative products and serves to meet the increased demands of our customers looking for a **stable probiotic, with real health claims**, which is suitable for numerous solutions including dietary supplements and functional foods!

LifeinU® BSCU1 is a true probiotic for the future!

For more information about our products, assistance from our customer service, or to begin your new product innovation, contact us on our website and your message will be routed to the member of our team best suited to help you!

<https://gnosisbylesaffre.com/contact-us/>

You can also contact your local sales representative to find out more.

Find all the news about our latest products and innovations by Gnosis by Lesaffre [HERE](#)



REFERENCES

- (1) [Probiotic strain Bacillus subtilis CU1 stimulates immune system of elderly during common infectious disease period: a randomized, double-blind placebo-controlled study - PubMed \(nih.gov\)](#)
- (2) [Probiotic strain Bacillus subtilis CU1 stimulates immune system of elderly during common infectious disease period: a randomized, double-blind placebo-controlled study - PubMed \(nih.gov\)](#)
- (3) <https://emulatebio.com/colon-intestine-chip/>
- (4) <https://pubmed.ncbi.nlm.nih.gov/27825987/>
- (5) LifeinU® BSCU1 should not be used by children under three years old.
- (6) <https://www.fda.gov/food/food-labeling-nutrition/structurefunction-claims#supplements>
- (7) Commission Regulation (EU) No 432/2012 of 16 May 2012
- (8) <https://www.cbi.eu/news/increase-demand-immunity-boosting-spices>
- (9) New Hope, April 2020



www.gnosisbylesaffre.com

Using what's alive so that we can thrive

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