

*Probiotics for daily maintenance
And balance of intestinal health of elderly*

Megaflora Senior

APPLICATION

Megaflora Senior is a probiotic formulation specially developed for the daily maintenance and balance of intestinal health of the elderly.

COMPOSITION

Megaflora Senior contains the following 10 probiotic strains:

- *Bifidobacterium animalis* W53
- *Bifidobacterium bifidum* W23
- *Bifidobacterium lactis* W51
- *Bifidobacterium lactis* W52
- *Lactobacillus acidophilus* W22
- *Lactobacillus plantarum* W1
- *Lactobacillus paracasei* W20
- *Lactobacillus rhamnosus* W71
- *Lactobacillus salivarius* W24
- *Lactococcus lactis* W19

Organic and mineral matrix:

- Carrier material: maize starch and maltodextrins
- Strain specific prebiotics: Inulin P2 and Fructo-oligosaccharides (FOS) P1
- Mineral mix: magnesium sulphate, manganese sulphate and potassium chloride
- Vegetable protein
- Vitamin D3



The total cell count of **Megaflora Senior** ensure at the end of the shelf life of the product is $> 1 \times 10^9$ cfu/g.

SPECIAL PREBIOTIC MATRIX

We do not only select the best probiotic bacteria, also the other ingredients in the formulations are carefully selected by a proprietary technology. This special and unique technology provides bacteria with specific protection and nutrition.

All ingredients in the probiotic formulations have a special function and we continually improve them in terms of stability, survival through the GI tract and metabolic activity. By these means we continue improving the quality and efficacy of the probiotic formulations.

All the ingredients that are part of **Megaflora** formulations have a special function that produces:

- High level of stability.
- High survival through the gastrointestinal tract.
- High metabolic activity.

In **Megaflora Senior**, the special technology applied includes the special matrix of maize starch and maltodextrins that guarantee stability of the product at room temperature. Furthermore, the strain specific prebiotics inulin P2 and polydextrose P4 are included as extra nutrients for the bacteria. The vegetable protein and minerals in the product

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increase the metabolic activity of the probiotic strains in **Megaflora Senior**. Vitamin D3 is added because many elderly do not have adequate serum vitamin D levels.

PRE-CLINICAL EVIDENCE

Inhibition of *Clostridium difficile*

In the elderly, the immune system's responsiveness decreases making them more susceptible to *Clostridium difficile* infections.

Therefore, the capacity of three strains of **Megaflora Senior** (*L. paracasei* W20, *L. salivarius* W24 and *L. rhamnosus* W71) to reduce the concentration of *C. difficile* was evaluated, as well as the production of its enterotoxins after 24 and 48 hours incubation (figure 1).

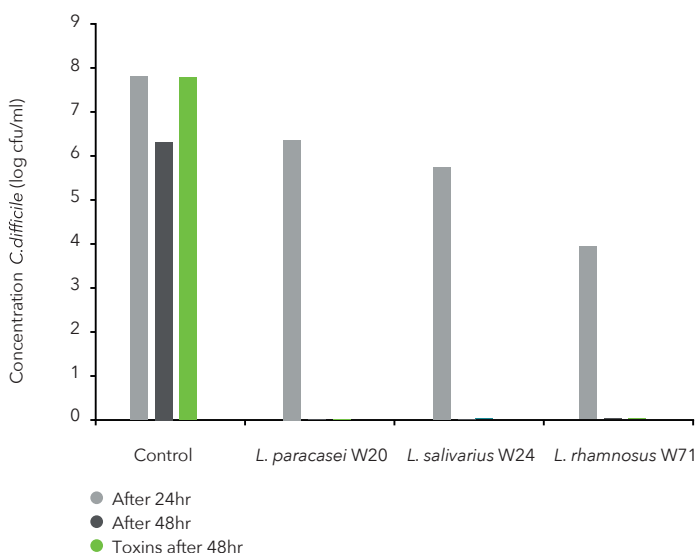


Figure 1. *In vitro* inhibition of growth and toxin production of *C. difficile* by probiotic strains.

Figure 1 shows that, after 48 h of incubation, the three strains reduced the concentration of *C. difficile* to zero. In addition, toxin production was completely reduced in the strains analyzed.

Enhancement of the barrier function: TEER

To measure the effects of bacteria at the epithelial barrier level, an *in vitro* assay is used by which trans-epithelial electrical resistance (TEER) is

measured in a system consisting of a cellular monolayer of intestinal cells of the caco-2 colon.

Exposure to a stressful agent or pathogenic bacteria, such as *Salmonella enteritidis*, causes an alteration of the epithelial barrier of the intestine that manifests with a decrease in TEER.

To evaluate the efficacy of **Megaflora Senior** in maintaining the integrity of the intestinal epithelial membrane, several strains were incubated together with a monolayer of caco-2 cells followed by an exposure to *S. enteritidis*.

Figure 2 shows that the *Bifidobacterium bifidum* W23, *L. salivarius* W24 and *B. lactis* W52 strains present in **Megaflora Senior** have the ability to strengthen the intestinal barrier function against pathogens.

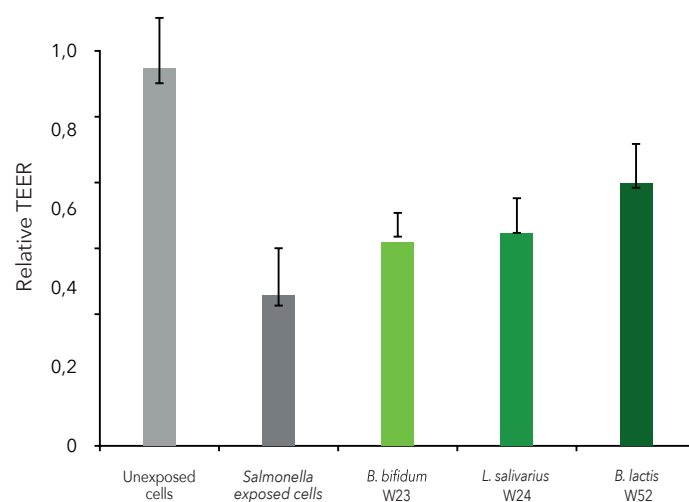


Figure 2. TEER data of several strains in **Megaflora Senior** against the stressor *Salmonella enteritidis* 857.

Boost of the immune system

Probiotics can stimulate the immune system by sending signals from the intestinal lumen by interacting with the dendritic cells of the immune system that have terminations in the lumen of the intestine.

To determine the ability of **Megaflora Senior** strains to trigger an immature T lymphocyte response in Th1, Th2 or regulatory lymphocytes,

a study was conducted in collaboration with the Wilhelmina Children's Hospital in Utrecht (The Netherlands).

For this, a culture of different probiotic bacteria was carried out in the presence of peripheral mononuclear blood cells (PMC) to observe the induction of subtypes of CD4 T cells.

Figure 3 shows the induction of Th1 lymphocytes, or helper T lymphocytes, in the presence of probiotic strains. Values greater than 1 indicate that the strain stimulates the induction of the specific T cell compared to the medium alone, to which the value of 1 was attributed.

The *Lactococcus lactis* W19 and *Lactobacillus acidophilus* W22 strains present in **Megaflora Senior** demonstrated ability to stimulate the lighting system.

SAFETY

Bacterial strains containing **Megaflora Senior** have the qualification of QPS (Qualified Presumption of Safety).

RECOMMENDED DOSE

Elderly:

- Maintenance dose: 1-2 g per day (equivalent to 2-4 billion bacteria).
- Treatment dose: 4 g (2 g in the morning before lunch, 2 g in the evening before dinner).

HOW TO USE

Dissolve the mixture in water, milk or yogurt before ingesting it and wait 1 minute before taking it to activate the probiotics.

HEALTH CLAIMS

1 g of Megaflora SENIOR supplies 3.33 mcg vitamin D3, which allows to use the following approved health claims by EFSA:

- *Vitamin D contributes to the absorption and normal use of calcium and phosphorus.*
- *Vitamin D contributes to maintenance of normal function of the immune system and inflammatory response.*

OBSERVATIONS

Genetic tests have been carried out on all probiotic strains of **Megaflora Senior** to ensure that they are free of the genes necessary to produce histamine, so **Megaflora Senior** is safe for people with histamine intolerance.

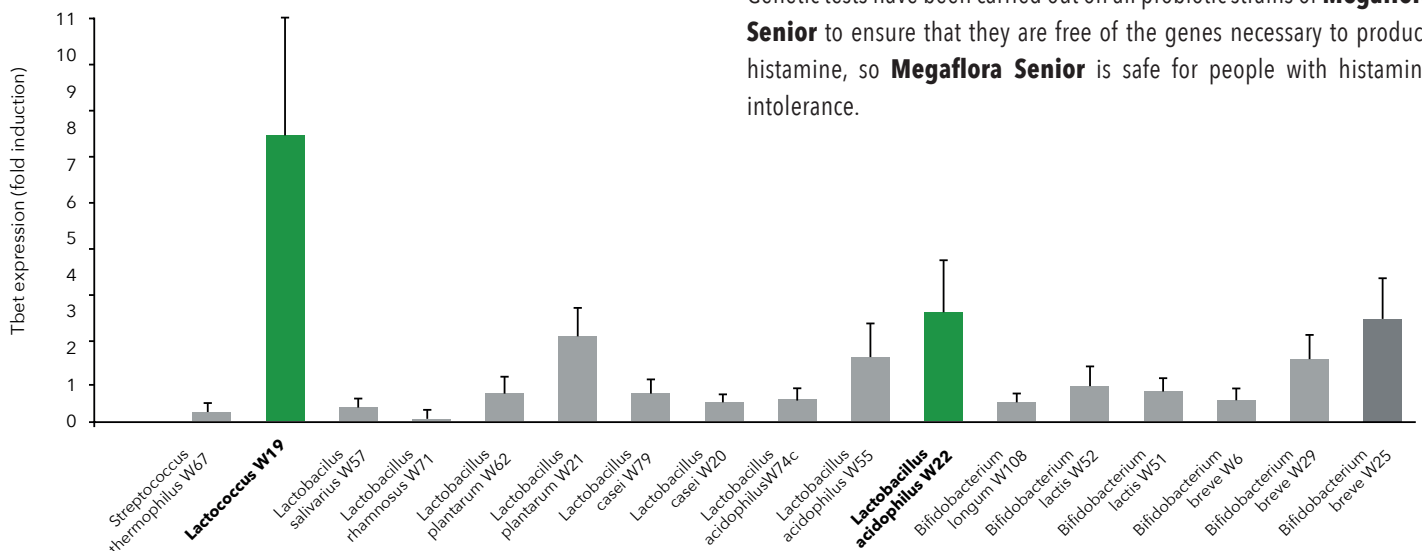


Figure 3. The induction of regulatory T-cells. Values higher than 1 means that the probiotic strain stimulates the induction of this specific T-cell compared to medium alone (= set at 1).

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