

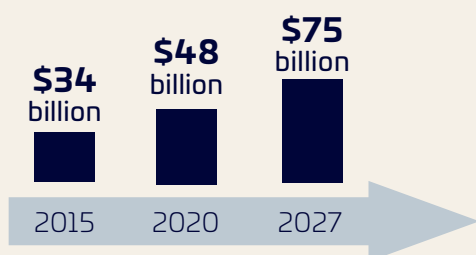


NEXT GENERATION
PROBIOTIC EXCIPIENT



PROBIOTICS: MARKET TRENDS, DRIVERS AND CHALLENGES

A flourishing market



The global probiotics market is still booming with an estimated annual growth of 7%.



In terms of product type, the medical and dietary supplements segment (sachets, capsules, tablets...) has the highest overall annual growth rate for the coming years.

Drivers and opportunities



Evolution towards personalized medicine



The rise in clinical evidences of cause and effect



Participation of populations in the acquisition of knowledge on microbiota



Move towards healthier food consumption



Education and scientific popularization



The rise in consumer awareness & incidences of diseases

The challenges of probiotic formulation



GASTRORESISTANCE

Probiotic strains are very sensitive to acidity. Nowadays current gastroresistant solutions are generally expensive and/or do not allow a good stability over time.



STABILITY OVER TIME

To counteract lifelong loss of viability of the finished product, a significant overdosing must be practiced, strongly impacting the price of probiotic formulas.



EFFECTIVITY

With the burgeoning supply of new products on the market, it is increasingly important to demonstrate the real efficacy of one's product on a clinical level.

2 INGREDIENTS FOR 1 SYNERGY

Algalithe P is an overdried mix of 2 ingredients:

- **Lithothamnion**, a calcified red algae known for its antiacid properties,
- **Pregelatinized corn starch**, an excipient used in probiotic formulations.

Algalithe P is an excipient specially designed by Nuwen to **improve the efficacy of probiotic formulations** by minimizing strain(s) amount. Indeed, its design is based on the 2 pillars of an efficient probiotic formulation:

- **Gastroresistant properties** maintaining the cellular integrity and the viability of the strains until their target site of action,
- **A low Aw** maximizing the survival of the strains throughout the life of the finished product.

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Patented
exclusive
product from
NUWEN*

THE AMAZING GASTRORESISTANCE OF ALGALITHE P

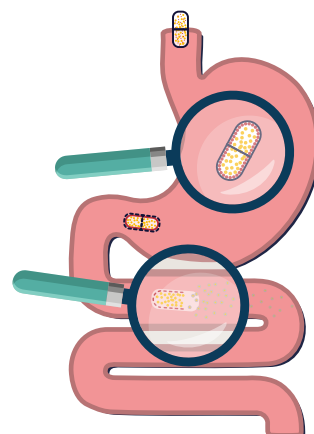
The creation of an ephemeral protective structure

PROTECTION STEP

When in contact with stomach acid, an alkaline gel is formed inside the capsule, thus protecting the probiotic strains from this extreme environment.

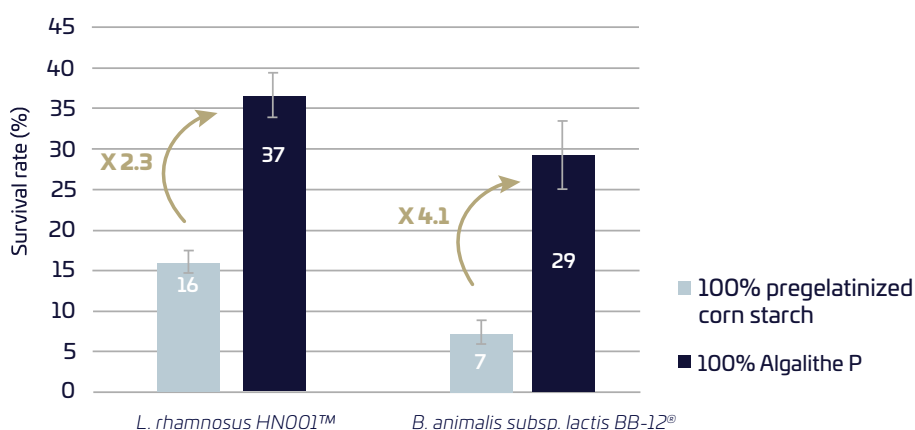
RELEASE STEP

This gel disappears when the neutral pH of the intestines is reached, allowing the probiotics to be released in conditions that are much more favorable to their survival.



UP TO MORE THAN 300% SURVIVAL RATE GAIN!

Impressive survival rates



CFU survival rates of *L. rhamnosus* HN001™ (good acid resistance) and *B. animalis* subsp. *lactis* BB-12® (poor acid resistance) at the end of an in vitro digestion model, with pregelatinized corn starch and Algalithe P (HPMC capsules)

AW AND STABILITY OF ALGALITHE P

In order to economically benefit of the gastroresistant feature of Algalithe P (lower amount of strain in the formula), it is important to have a **low Aw** to preserve the strain amount and quality all along the finished product life. That is the reason why the development of Algalithe P has also been focus on a low Aw.

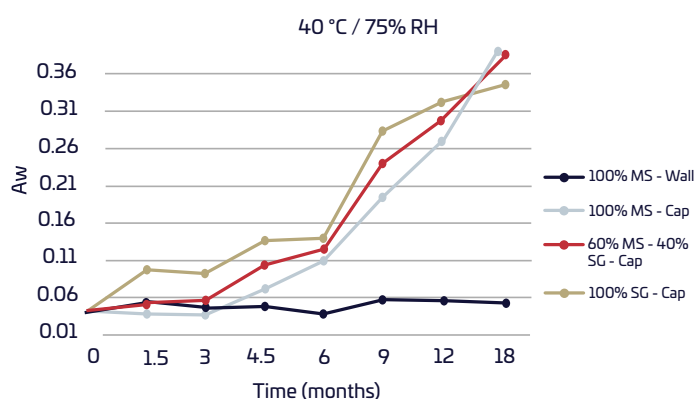
In order to help you with your probiotic formulation containing Algalithe P has an active excipient, a **stability study in HPMC capsule in 4 different desiccant pots** is currently in progress:

The tested packaging (polypropylene tube)

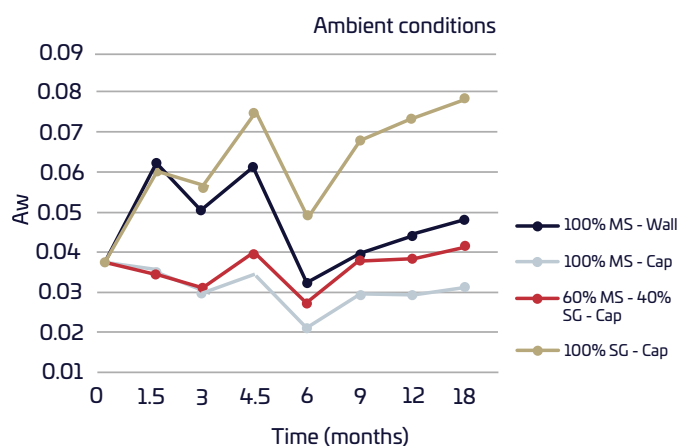
Nature of the desiccant material	Localization of the desiccant material
100% silica gel	Cap
40% silica gel & 60% molecular sieve	Cap
100% molecular sieve	Cap
100% molecular sieve	Wall

The tested conditions

Temperature (°C)	Relative humidity (%)
40 (+/-1)	75 (+/-3)
20 (+/-2)	50 (+/-10)
5 (+/-2)	40 (+/-10)



Evolution of the Aw of overdried Algalithe P in HPMC capsule in the different packaging at 40°C / 75 % RH



Evolution of the Aw of overdried Algalithe P in HPMC capsule in the different packaging in ambient conditions

After 1 year the moisture recovery of overdried Algalithe P is very satisfactory in the different packaging tested for probiotic formulas.



Ask an Algalithe P sample to realize your stability study with your formula and wanted packaging!

A REAL ECONOMIC INTEREST

The winning combination of gastroresistance and stability over time

GASTRORESISTANCE / HEALTH EFFECT


2 to 4 times less probiotic bacteria are required with Algalithe P vs. standard excipient.



STABILITY OVER TIME

The low A_w (<0.06) of Algalithe P protects the probiotic bacteria for a longer period.

Algalithe P vs. standard excipient and delayed release capsules

	Standard excipient	 Algalithe P	Delayed release capsules
Amazing gastroprotection properties	X	✓	✓
Overdried to maximize the finish product shelf-life	X	✓	-
Possibility to reduce the initial probiotic amount in the formula while preserving the health benefit	X	✓	X (stability issue over time)
Possibility of obtaining calcium claims	X	✓	X



Do not hesitate to contact our Health & Food Market Managers to discuss the economic aspect that the Algalithe P solution will bring to your projects!

GALENIC AND CLAIMS

Algalithe P has been developed and is particularly **suitable for capsules**.

Algalithe P is not recommended for stick or sachet. For these forms we recommend the use of our Algalithe to benefit of its antacid properties (overdried or mixed with overdried maltodextrins).

Thanks to the **high calcium content of lithothamnion**, the use of Algalithe P allows access to various claims:

CLAIMS according to EU Regulation	Required calcium content (mg/d)	Required Algalithe P content (g/d)
« Calcium source »	120	0.75
« High in Calcium »	240	1.50
« Reduction of disease risk »	400	2.50

These data are given as an indication for adults > 25 years old.

Regulations may vary from country to country: always consult the local legislation related to products claims and use.

- 8 health claims can be used for the overall population when the finished product is admitted at least as a calcium source (EU Regulation N° 432/2012)
- 1 health claim can be used for kids when the finished product is admitted at least as a calcium source (EU Regulation N° 983/2009)
- 1 reduction of disease risk health claim for post-menopausal women

5 REASONS TO CHOOSE ALGALITHE P AS EXCIPIENT



Excellent gastroresistant properties



Low Aw for maximizing the survival of the strains throughout the life of the finished product



Simple & safe composition for a real innovative solution



Patented excipient guaranteeing the performance & reliability of the studies performed



Economically attractive solution

