

Supporting Information

Supporting Information Table S1. Exclusion criteria for women participating in the study.

| Exclusion criteria for women participating in the study |
|--|
| <ol style="list-style-type: none">1) Pre-gravid body mass index (BMI)<18 or >30;2) Use of probiotic supplements during the third trimester of current pregnancy¹;3) Enhanced chance of premature delivery (before 37 weeks + 0 days of gestation);4) Current or previous illnesses which could interfere with the study, like other mammary pathologies (e.g. abscesses, Raynaud's syndrome, breast cancer);5) Short bowel syndrome;6) Impaired intestinal epithelial barrier (e.g. diarrheal illness, intestinal inflammation);7) Serious underlying disease predisposing to infection (e.g. HIV, auto-immune diabetes, multiple organ failure, malignancy, severe burns, severe acute pancreatitis);8) Heart failure and cardiac medical history (e.g. artificial heart valve, medical history of infectious endocarditis, rheumatic fever and cardiac malformation);9) History of aggressive immunosuppressive therapy (e.g. radiotherapy, cancer chemotherapy);10) Traumatic injury of the gastrointestinal tract;11) Surgery, including dental surgery, within one month prior to inclusion (Visit 1);12) Investigator's uncertainty about the willingness/ability of the subject to comply with protocol requirements;13) Participation in any other clinical trial within two weeks prior to entry into the study. |

¹Criterion referred to products (supplements) that are bought in the pharmacy and/or health drug store. It did not involve food product supplemented with 'live bacteria'.

Supporting Information Table S2. Hazard ratio of incidence of mastitis between study groups (mITT)

| | Placebo (N=144) | Probiotic (N=156) | P-value |
|-------------------------------------|----------------------------|--------------------------|----------------|
| Mastitis incidence | | | |
| No, n (%) | 124 (86.1%) | 147 (94.2%) | |
| Yes, n (%) | 20 (13.9%) | 9 (5.8%) | |
| Age adjusted HR (CI) [†] | 1.000 | 0.415 (0.189-0.912) | 0.0285 |
| Fully adjusted HR (CI) [‡] | 1.000 | 0.352 (0.156-0.793) | 0.0117 |
| Fully adjusted HR (CI) [§] | 1.000 | 0.417 (0.190-0.915) | 0.0293 |

N=Number of subjects of the analysis population, [n]=number of subjects per category.
HR=Hazard Ratio, CI=Confidence Interval

[†]Cox PH regression model stratified by sub-site and includes study group and age at delivery as covariates.

[‡]Fully adjusted Cox PH regression model, adding the following potential covariates to the model: use of antibiotics, type of delivery, number of previous breastfed infants, duration of breastfeeding, breastfeeding stop, previous mastitis, and duration of study product intake before delivery.

[§]Fully adjusted Cox PH regression model, adding the potential covariates and applying backward selection.

Supporting Information Table S3. Duration of partial (mixed with formula feeding) and exclusive breastfeeding (mITT)[†]

| | | Placebo (N=144) | Probiotics (N=156) | P-value* |
|---|------------|----------------------------|-------------------------------|-----------------|
| Duration of any breastfeeding (including mixed), days [‡] | n (n miss) | 137 (7) | 151 (5) | |
| | Mean (SD) | 77.2 (19.6) | 77.3 (19.2) | |
| | Median | 84.0 | 83.0 | 0.765 |
| | (Q1, Q3) | (79.0, 86.0) | (80.0, 85.0) | |
| | Min - Max | 5.0 - 104.0 | 5.0 - 105.0 | |
| Duration of exclusive breastfeeding, days [§] | n (n miss) | 137 (7) | 151 (5) | |
| | Mean (SD) | 61.6 (29.8) | 58.1 (32.6) | |
| | Median | 77.0 | 76.0 | 0.559 |
| | (Q1, Q3) | (41.0, 83.0) | (30.0, 83.0) | |
| | Min - Max | 0.0 - 103.0 | 0.0 - 99.0 | |

* P-value of Mann-Whitney U-test

N=number of subjects of the analysis population, n=number of subjects per category, n miss=number of missing values per category, SD=Standard Deviation, Q1, Q3=Quartile1, Quartile 3

[†]) Data collection was limited to the 12-week follow-up of subjects. If subjects were still breastfeeding at the last visit this was recorded as the end of the breastfeeding period

[‡] Duration of any breastfeeding (including mixed) was calculated as: date of last breastfeeding - date of delivery.

[§] Duration of exclusive breastfeeding was calculated as: date of last breastfeeding – date of delivery - number of days with formula feeding.