TECHNICAL BRIEF

Active Material Science: Proven Solution to Maximize Probiotic Protection

Situation

In the U.S., the use of probiotics quadrupled in the five years to 2012[1] and it has sustained an upward trajectory both in that territory and across the world. In 2020, probiotic consumption witnessed an exponential surge with the number of U.S. consumers taking probiotics increasing by 66%. Other countries, like Italy, experienced a 188% increase in new users while China experienced a 108% increase in users.[2]

With this strengthening demand, consumers have become more knowledgeable about the qualities and characteristics of particular probiotics as they look to extract the maximum available benefits. Terminology like colony forming units (CFUs), once perhaps a specialist technical term, is now increasingly familiar to a more knowledgeable audience of probiotic users. These consumers are keen to know that label claims regarding the quantity of live microbial cells available from their chosen supplement are not only accurate, but sustained over the product's entire shelf life.

Your product, actively protected™

Aptar CSP Technologies

TECHNICAL BRIEF // ACTIVE MATERIAL SCIENCE: PROVEN SOLUTION TO MAXIMIZE PROBIOTIC PROTECTION

Challenge

In order to maintain therapeutic value and deliver on end of shelf life CFU claims that consumers are now more focused on, probiotic manufacturers and their partners in the supply chain are challenged to manage a complex mix of scientific, environmental, and commercial factors that can impact the integrity and efficacy of probiotics. Exposure to heat and moisture over time degrades product potency, and ineffective packaging can exacerbate degradation, destabilizing the formulation and affecting performance, particularly at the end of shelf life.

To address these challenges, probiotic manufacturers often employ mitigation strategies like adding 2 to 10 times CFU count overages, using a desiccant canister or sachet, or managing cold-chain during distribution that limits geographic reach. These solutions can be costly and complex.

Solution: Material Science Technology

Aptar CSP Technologies' active material science solutions are proven to protect probiotic stability across a variety of primary package formats, including bottles, blister packs, stick packs and probiotic baby oil drops. The technology is engineered to create the microclimate needed to ensure probiotic potency and can be deployed in a range of forms such as CSP™ Activ-Vials and Bottles, flexible film solutions for stick packs and blister packs, and Activ-Polymer™ molded tablets for probiotic baby oil. The following data explores the efficacy of CSP's material science solutions vs. traditional probiotic packaging options for maintaining viability of cultures and meeting end of shelf life CFU claims.

Aptar CSP Technologies

1 https://www/nccih.nih.gov/health/probiotics-what-you-need-to-know
2 https://www.grandviewresearch.com/industry-analysis/probiotics-market

Data Review: CSP™ Activ-Vial™ vs. Alu/Alu Blister Packaging

Aptar CSP's Activ-Vials and Bottles feature an Activ-Polymer™ liner that completely surrounds the product to scavenge moisture. In a study exploring the performance of probiotics packaged in Aptar's CSP™ Activ-Vial™ versus Alu/Alu blister packaging, analysis of the total viable cell count (TVCC) showed that the decline in potency after two years was markedly lower for probiotic capsules packaged in CSP™ Activ-Vials than those using aluminum (Alu/Alu) blister packs (Figure 1). The product using Alu/Alu blisters also showed increased water activity over the first six months with overall levels registering higher at the end of the test period. In contrast, the probiotic product using the CSP™ Activ-Vial™ technology recorded steep declines in water activity over the first month and remained lower throughout the entire test period (Figure 2).

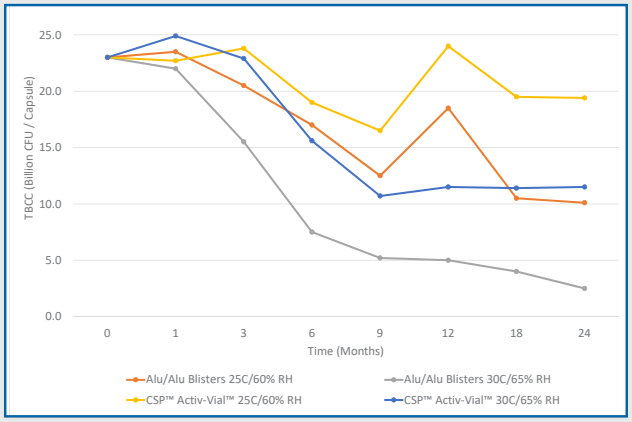

Figure 1: Probiotic Capsule - Potency (CSP™ Activ-Bottle vs. Alu/Alu Blisters)

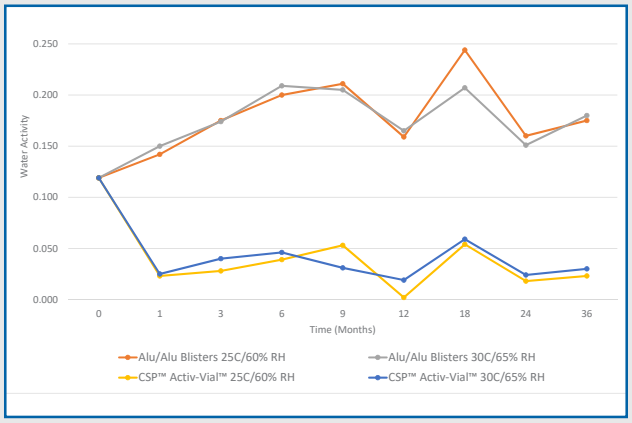

Figure 2: Probiotic Capsule - Water Activity (CSP™ Activ-Vial™ vs. Alu/Alu Blisters)

Data Review: CSP™ Activ-Vial™ vs. Amber Glass with Desiccant

In an analysis comparing performance of probiotic capsules with cranberry powder packaged in CSP™ Activ-Vials versus an amber glass bottle with a desiccant canister the CSP™ Activ-Vial™ clearly outperformed its glass competitor in the temperatures and humidity conditions tested. The probiotic in the Activ-Vial™ registered an overall decrease in water activity while also limiting any decline in potency (Figures 3 & 4).

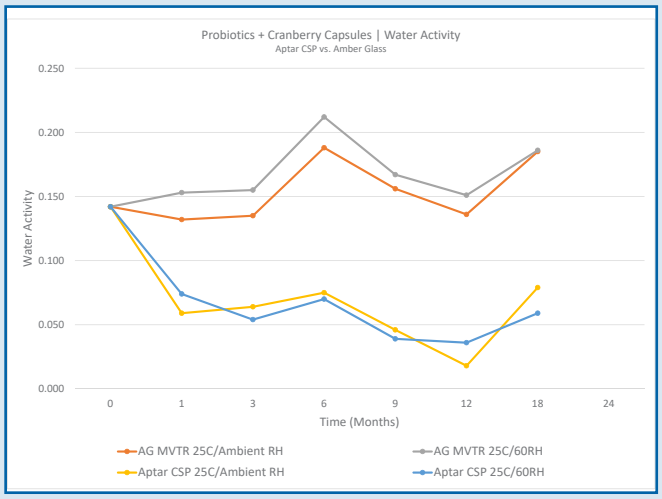

Figure 3: Probiotic Capsule - Water Activity in Probiotics + Cranberry (CSP™ Activ-Vial™ vs. Amber Glass with Desiccant)

Data Review: Activ-Blister™ Solutions vs. Standard Blister Packaging

Aptar CSP's Activ-Polymer™ technology can also be applied in a flexible film format. This form factor enables manufacturers to integrate the technology into traditional blister packaging to create an individualized microclimate for each individual blister cavity (Activ-Blister™ Solutions). As evidenced in Figures 5 and 6, the use of CSP's Activ-Blister™ solution reduced water activity and maintained the CFU count for a multi-strain probiotic product with a 10 Billion CFU claim. This data set clearly demonstrates the ability of Activ-Blister™ solutions to reduce water activity (Aw) and improve probiotic stability within a PVC/PVdC blister pack.

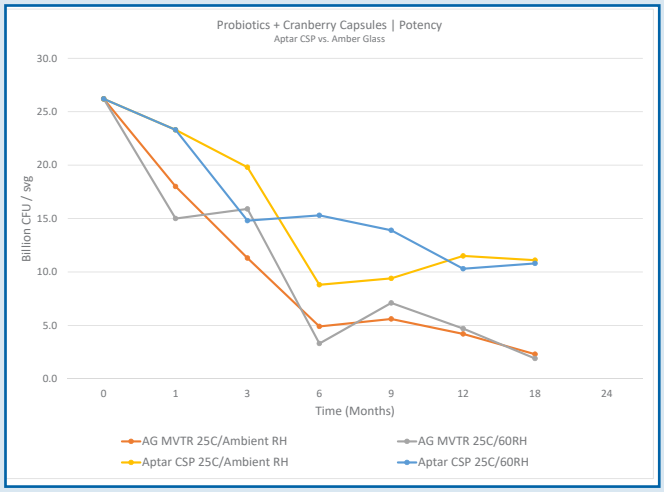

Figure 4: Probiotic Capsule - Potency of Probiotics + Cranberry (CSP™ Activ-Vial™ vs. Amber Glass with Desiccant)

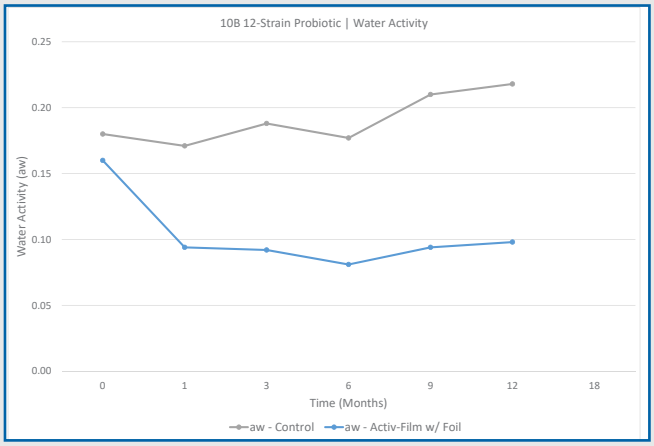

Figure 5: Probiotic Capsule - Water Activity (Standard Blister Packaging vs. Activ-Blister™ Packaging with CSP™ Activ-Film™)

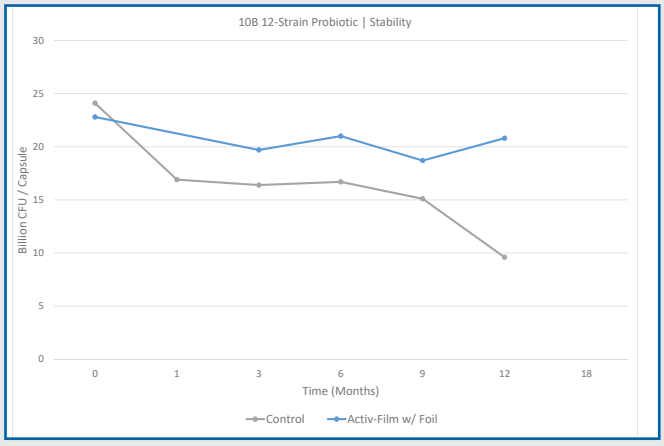

Figure 6: Probiotic Capsule - Potency (Standard Blister Packaging vs. Activ-Blister™ Packaging with CSP™ Activ-Film™)

Data Review: Standard Probiotic Stick Pack Packaging vs. Activ-Film™ Integrated Solution

Activ-Film™ technology offers a method for protecting stability of powder-based probiotics packaged in a stick pack format. A comparison of a powder probiotic packaged with and without Activ-Film™ shows that the integration of CSP's technology yields an immediate decrease in water activity. Notably, where the standard stick pack showed an increase in water activity over the 8 week study, the probiotic packaged with Activ-Film™ showed a marked decrease (Figure 7). Live culture stability is also significantly improved in the probiotic packaged with Activ-Film™ technology (Figure 8).

Data Review: Oil-Based Probiotics with Activ-Polymer™ Component vs. Control

A study exploring the effect adding a CSP Activ-Polymer™ molded tablet would have on cell viability over time in an oil-based probiotic showed the technology delivered improved stability over the control. This difference was particularly prominent at the end of the study where the control showed a precipitous drop in live culture viability (Figure 9).

Conclusion

CSP's portfolio of Activ-Polymer™ Solutions offers proven material-science based active packaging solutions that create an optimal microclimate within primary packaging to ensure probiotic stability. The flexible deployment options enable probiotic companies to adopt the technology with minimal impact on their current packaging design or manufacturing processes. By leveraging this technology to minimize moisture exposure and preserve CFU counts over time, probiotic manufacturers can reduce the overages they might typically include in their product to meet end of shelf-life potency claims, develop more complex formulations, and eliminate cold chain challenges.

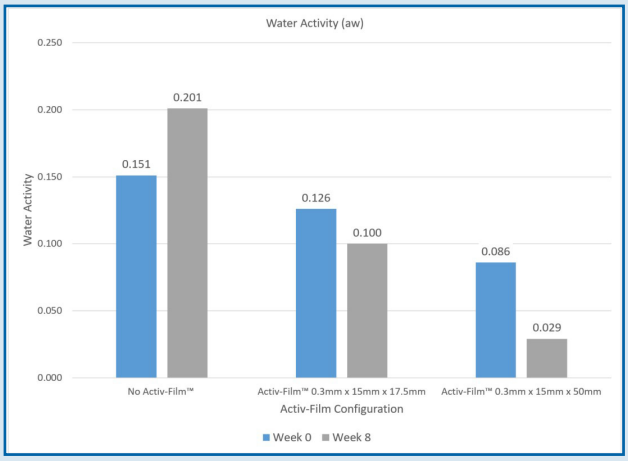

Figure 7: Probiotic Stick Pack Water Activity
(CSP Activ-Film™ vs. Standard Foil Packaging without Activ-Film™)

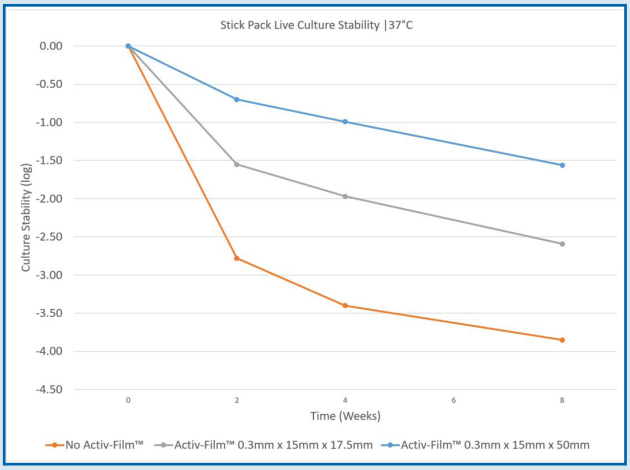

Figure 8: Probiotic Stick Pack Live Culture Stability
(CSP Activ-Film™ vs. Standard Foil Packaging without Activ-Film™)

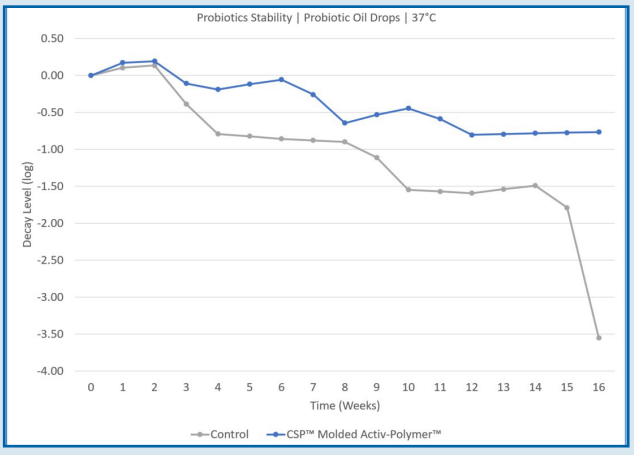

Figure 9: Probiotic Baby Oil Drop Stability
(CSP Activ-Polymer™ Tablet vs. Control)

For more information, contact:
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