

## AUSTRALIAN MANUFACTURING COMPANY PTY LTD

Probiotic Viability – BioMedica.
Official Statement November 2017

Probiotics are actually more sensitive to moisture than to temperature. From a stability perspective large swings in temperature may be deleterious through the creation of condensation. Our packaging has been designed to minimise water activity in our probiotic products, but we suggest shipping with cold packs in order to reduce the rate at which the temperature inside the shipping carton changes. However, long term therapeutic potential is generally maximised by storing in refrigerated conditions.

Many of the probiotic strains used in our refrigerated probiotics tolerate ambient temperatures quite effectively, showing little viable cell loss when kept for 24 months (2 years) at 23-25°C. Indeed, this stability data was a significant factor in the choice of these particular strains for the products; all BioMedica products are formulated in the knowledge that they will be shipped around Australia (including the tropical far north), and internationally (including Singapore), and will need to maintain efficacy after having been exposed to variable conditions for a few weeks.

TriFlora has been formulated to not require refrigeration at all, so it can be unrefrigerated for its entire shelf life. Ideally it should be kept at or below 25°C for long term storage, to maintain optimal viability throughout its shelf life.

Stability testing is only performed on products which have been stored according to the prescribed storage instructions specified on the product labels, so we don't have stability data specific to our products which have been stored under a variety of conditions. Note that as cell viability is affected by a range of factors – the specific levels of humidity, the exact temperatures, the speed at which the temperature changes, and the susceptibility of the various strains in each formula to each of these variations – even if it were possible to estimate the effects of every combination of such variables on each of the strains, if the product is not refrigerated then the combinations of these variables will have varied over time. For example, it is likely to have been colder and drier overnight, more humid on some days than others, and temperatures will change more quickly in some buildings/rooms than in others. This adds a level of complexity which makes it impossible to calculate specific time-frames for viability when products are not stored under the conditions specified on their labels.

If you have any further technical enquiries please do not hesitate to contact the BioMedica technical support team on (02) 8339 0539 or on technicalsupport@biomedica.com.au

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