

**Physical chemistry and analytical methods**

Please report the packaging material used for the shelf life study. The shelf life should be determined in the commercial packaging material (PET).

Furthermore, the following properties should be determined before and after storage:

- Acidity/alkalinity/pH range
- pourability
- spontaneity of dispersion
- suspensibility
- wet sieve test

The following properties should be determined before and after storage at 0°C:

- suspensibility
- wet sieve test

Please report the suspensibility found.

Furthermore, the limitations of the TaqMan RT-qPCR method do not infer the lack of significant sedimentation.

Please report the spontaneity of dispersion found.

Furthermore, the limitations of the TaqMan RT-qPCR method do not infer an acceptable dispersion of the tank-mix.

Particle size distribution has to be addressed for an SC type formulation.

Effectiveness of the cleaning procedure cannot be demonstrated by a statement 'from experience' (Anecdotal evidence)