

INFORMATION

Quality Management



EIP-0061-USA

Revision 1

Date of issue: 05.12.2023

1/1

Storage and Transport Conditions

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose: DuraLac® H

Stability studies according to ICH are installed. Initial stability testing is performed as follows:

- Long-term conditions: 25 °C ± 2 °C and 60 % ± 5 % RH until end of shelf life
- Intermediate conditions: 30 °C ± 2 °C and 65 % ± 5 % RH for 6 months if all acceptance criteria are met at the accelerated conditions or for 12 months
- Accelerated conditions: 40 °C ± 2 °C and 75 % ± 5 % RH for 6 months.

Ongoing stability studies are performed at 25 °C ± 2 °C and 60 % ± 5 % RH or under warehouse conditions until end of shelf life.

In accordance with EMA CPMP/QWP/609/96/Rev 2 and based on the stability studies mentioned above any specific advice on storage and transport conditions is not required.

Storage conditions are given in the specification:

- *“Tight container. Storage in an unopened, originally packed MEGGLE container at room temperature under dry and odour-free conditions.”*

It is recommended to store and transport the MEGGLE USA Products at “room temperature” primarily to indicate that specific temperature conditions for storage and transports e.g. refrigerated warehouses and vehicles are not necessary for the products. The term “room temperature” (“ambient”) is defined as temperature ranges for certain products and processes in industry, science, and consumer goods which may be summarized as a range between 15 to 25 °C, with excursions between 1 to 30 °C. Furthermore, a specific temperature range is not given as this indication would imply temperature controls and deviation procedures along the complete supply chain which is an unnecessary burden.

The following limits are installed for the storage of the products of MEGGLE USA at the manufacturer:

Temperature: 30 – 60 °F (-1 – 16 °C) / Relative Humidity: max. 80 %

Typical values of the monthly average temperature are below 20 °C with short exceedances > 25°C under certain circumstances. Typical values of the relative humidity are 70 – 75%.

Exceedances of the above mentioned temperature conditions during transport have no impact on product quality based on the stability studies under accelerated conditions.

MEGGLE USA as an export-oriented company is aware that the typical temperature and relative humidity in different regions are higher or lower than in the north of the United States of America. The packages are optimised to meet these requirements. In any case, the products must be protected from moisture, freezing, and excessive heat and must not be stored and transported outside without protection.

This MEGGLE USA Information was electronically released and is valid without signature.