

# INFORMATION

Quality Management



EIP-1012-USA

Revision 2

Date of issue: 12.09.2023

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## REACH

MEGGLE USA Products:

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

The Regulation (EC) No 1907/2006 ("REACH") addresses the production and use of chemical substances, and their potential impacts on both human health and the environment via registration, evaluation and approval procedures of chemical substances for the EU market.

The intended use of the above mentioned MEGGLE USA Products is relevant under REACH. According to Regulation (EC) No 1907/2006, Art. 2 No. 5 a) and b), the provisions of Titles II (registration), V (downstream users), VI (evaluation) and VII (authorisation) do not apply to the extent that a substance is used in medicinal products for human or veterinary use and to the extent that a substance is used in food or feedingstuffs.

Furthermore, lactose is included to Annex IV of Regulation (EC) No 1907/2006. According to Regulation (EC) No 1907/2006 Art. 2 No. 7, the provisions of Titles II (registration), V (downstream users), VI (evaluation) do not apply to substances listed in Annex IV as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties. Thus, the mentioned MEGGLE Products may be used in any application, even outside the scope mentioned above.

Safety data sheets are available on request.

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