

INFORMATION

Quality / Regulatory Affairs



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REACH

MEGGLE Product:

Co-processed Excipient: CombiLac®

The MEGGLE Product is a co-processed, directly compressible spray agglomerate containing

- 70 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP),
- 20 % Cellulose, Microcrystalline (Ph. Eur. / USP-NF / JP) and
- 10 % Maize Starch (Ph. Eur. / USP-NF / JP).

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 MEGGLE Product is a "mixture" in the meaning of Regulation (EC) No. 1907/2006, Art.3 No. 2 of the lactose, cellulose and starch.

The intended use is important for REACH relevance. 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.

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. Lactose, cellulose pulp and starch are included in Annex IV.

According to Regulation (EC) No. 1907/2006 Art. 2 No. 9, the provisions of Titles II (registration), V (downstream users), VI (evaluation) do not apply to polymers. Cellulose and starch correspond to the relevant definition in Regulation (EC) No. 1907/2006 Art. 3 No. 5.

Thus, the mentioned MEGGLE Product may be used in any application, even outside the scope mentioned above.

Safety data sheets are available on request.

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