REACh

MEGGLE Product:
Co-processed Excipient: RetaLac®

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 substances lactose and the hydroxypropyl methylcellulose.

The intended use 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.

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. This exemption from registration includes natural polymers which are chemically modified (e.g. post-treatment of natural polymers), (ECHA Guidance for monomers and polymers) incl. hydroxypropyl methylcellulose.

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

Safety data sheets are available on request.

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