



An die interessierte Partei / To whom it may concern

Dr. Stefan Dreiheller
Quality Unit / Regulatory Affairs

Date of issue: 01.12.2015
Page 1/1
Doc.-No. EIP-5012
Revision 2

REACH

Meggle products:

- Co-processed excipients: RetaLac[®]

The product is a mixture in the meaning of Regulation (EC) No. 1907/2006, Art.3 No. 2 of the substances lactose and hypromellose (hydroxypropyl methylcellulose).

The intended use of the above mentioned product is relevant regarding registration 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 (authorization) 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 (a) , 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).

Freundliche Grüße / Best regards

Dr. Stefan Dreiheller