



**An die interessierte Partei / To whom it may concern**

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## **REACH**

- Co-processed excipients: StarLac®

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

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 and starch are 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.

Freundliche Grüße / Best regards



Dr. Stefan Dreiheller