



An die interessierte Partei / To whom it may concern

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Suitability as ingredient in cosmetic products

MEGGLE products:

- Lactose Monohydrate Ph. Eur. / USP-NF / JP: CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 100, GranuLac[®] 70, GranuLac[®] 140, GranuLac[®] 200, GranuLac[®] 230, PrismaLac[®] 40, SacheLac[®] 80, SorboLac[®] 400, SpheroLac[®] 100, Tablettose[®] 70, Tablettose[®] 80, Tablettose[®] 100
- Lactose Monohydrate USP-NF / Ph. Eur. / JP: InhaLac[®] 70, InhaLac[®] 120, InhaLac[®] 160, InhaLac[®] 230, InhaLac[®] 250, InhaLac[®] 251, InhaLac[®] 400, InhaLac[®] 500, Lactose monohydrate Low Endotoxin
- Anhydrous Lactose USP-NF / Ph. Eur. / JP: DuraLac[®] H

The products are manufactured as excipients for pharmaceutical industry. It conforms to the relevant monographs as mentioned above. The use for which other regulations are applicable underlies the responsibility of the customer.

The products

- are 100% Lactose.
- are listed in the CosIng database with the INCI-Name LACTOSE.
- are not listed in Annexes II to VII of Regulation (EC) No 1223/2009 and may be used without any legally defined restrictions.
- are not produced from material mentioned in entry 419 of Annex II of Regulation (EC) No 1223/2009
- are not classified as CMR substances of category 1A, 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008.
- do not contain nanomaterial according Art. 2 No 1 (k) of Regulation (EC) No 1223/2009.

Animal testing is not performed or planned.

Restrictions regarding the use as cosmetic ingredient within any other worldwide cosmetics regulations e.g. USA, China, Japan, Canada are not known and are unlikely.

Freundliche Grüße / Best regards

Dr. Stefan Dreiheller