



An die interessierte Partei / To whom it may concern

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Quality Unit / Regulatory Affairs

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Page 1/1
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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® 140, InhaLac® 150, 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 product

- is 100% Lactose.
- is listed in the CosIng database with the INCI-Name LACTOSE.
- is not a substance and does not contain a substance as intentionally compound listed in Annexes II and III of Regulation (EC) No 1223/2009,
- does not contain nanomaterial according Art. 2 No. 1 (k) of Regulation (EC) No 1223/2009,
- is not a "preservative", "colorant", UV-filter in the meaning of Art. 2 No. 1 (l) – (m) of Regulation (EC) No 1223/2009,
- is not classified as CMR substances of category 1A, 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Animal testing is neither performed nor 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

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