



To whom it may concern

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Quality Unit / Regulatory Affairs

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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® 80, 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): Lactose monohydrate Low Endotoxin
- Inhaler Grade 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

The products are manufactured as excipients for pharmaceutical industry. They conform 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 substances and does not contain a substance as intentionally compound listed in Annexes II and III of Regulation (EC) No 1223/2009,
- do not contain nanomaterial according Art. 2 No. 1 (k) of Regulation (EC) No 1223/2009,
- are not a "preservative", "colorant", UV-filter in the meaning of Art. 2 No. 1 (l) – (m) 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.

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.

Best regards

MEGGLE GmbH & Co. KG

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