



To whom it may concern

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Revision 2

Genotoxic impurities

(CPMP/SWP/5199/02, EMEA/CHMP/QWP/251344/2006)

MEGGLE Products:

- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose (USP-NF / Ph. Eur. / JP): DuraLac® H

The substances are used as excipients for which – according chapter 2 – the guideline is not applicable. Substances which can induce damage to the genetic material in the cells through interactions with the DNA sequence and structure are not used in the manufacturing process of the products.

Furthermore, the products as such and the components in the co-processed excipients respectively are well known and safe as food or food additive according to US and EU legislation.

Best regards

MEGGLE USA inc.

A handwritten signature in blue ink, appearing to read "G Müller", with a long horizontal stroke extending to the right.

Dr. Gabriele Müller