



An die interessierte Partei / To whom it may concern

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Content of Lactose

MEGGLE products: InhaLac[®] 70, InhaLac[®] 120, InhaLac[®] 160, InhaLac[®] 230, InhaLac[®] 250, InhaLac[®] 251, InhaLac[®] 400, InhaLac[®] 500, Lactose monohydrate Low Endotoxin

The above mentioned designations are MEGGLE's brand names for "Lactose Monohydrate" as defined in the monograph "Lactose Monohydrate" in the United States Pharmacopeia – National Formulary (USP-NF). This monograph is harmonized with Ph. Eur. and JP.

The content of lactose is minimum 99%. This is based on the following specification parameters:

| Specification parameter | Value | Method |
|-------------------------|--|--|
| Optical rotation | +54.4° – +55.9 (calculated on the anhydrous basis) | USP-NF (781S) <i>Specific rotation</i> |
| Loss on drying | NMT 0.5% | USP-NF (731) |
| Residue on ignition | NMT 0.1% | USP-NF (281) |

Freundliche Grüße / Best regards


Dr. Stefan Dreiheller