



**Art.no.: 2582**

**Lactose monohydrate**

**Residual Solvents Statement** (EMA/CHMP/ICH/735038/2018, ICHQ3C)

we hereby confirm that the product complies with the current edition of the ICH-Q3C guideline for residual solvents.

**BSE Statement** (Note (EMA/410/01 Rev. 3))

we hereby certify that the product was manufactured without materials from animals where there is a risk of BSE. A BSE risk assessment is therefore not required.

**GMO Statement** (EU-regulations 1829/2003 and 1830/2003)

we hereby confirm that the product is not subject to labeling and according to the Genetic Engineering Ordinance and can be labeled as "free from genetically modified organisms".

**Elemental Impurities Statement** (EMA/CHMP/ICH/353369/2013, ICHQ3D)

we hereby certify that the above mentioned raw material complies with the concentration limits for elements as defined in the ICH Guideline Q3D on elemental impurities.

**Nitrosamine Statement** (Article 5 (3) of Regulation (EC) No 726/2004)

not applicable

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