Art.no.: 7163
CETIOL® HE

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 requirements according to the Genetic Engineering Regulation 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)

we hereby confirm that considering the raw materials, solvents, reagents in the manufacturing process and the process related steps and the final product itself, there is no possibility that nitrosamine will be generated.

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