



Art.no.: g67

Hawthorn leaf and flower liquid extract, (45%)

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 may contain components of genetically modified organisms and cannot 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)

Neither the product itself nor the raw materials are of synthetic origin. For this reason, contamination with nitrosamines in the above product is excluded.

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