

Specification

1.01695.0000 Benzonase® endonuclease EMPROVE® EXPERT

Specification

Appearance (description)	clear

Appearance (color) colorless Activity (DNA; pH 8.0; 30 min; 37 °C) ≥ 250 U/µI Spec. activity (calc. on protein) ≥ 1.1•10⁶ U/mg Identity (electrophoresis) passes test Purity (calc. on protein) ≥ 99 Proteases not detectable ≤ 50 Al (Aluminium) ppm Co (Cobalt)* ≤ 0.5 ppm Cr (Chromium)* ≤ 110 ppm Cu (Copper)* ≤ 30 ppm Fe (Iron) ≤ 130 ppm Mn (Manganese) ≤ 25 ppm Mo (Molybdenum)* ≤ 150 ppm ≤ 2 Ni (Nickel)* ppm Zn (Zinc) ≤ 130 ppm Residual solvents (ICH Q3C) excluded by production process Colony count (aerobic bacteria) ≤ 10 CFU in 100 000 U ≤ 10 CFU in Colony count (Yeasts and moulds)

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

The original manufacturer name and address will be disclosed subsequent to signing a confidentiality agreement.

100 000 U ≤ 0.25 EU in

1000 U

Dr. Timm Schlegelmilch

Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.

Endotoxins (LAL-test)