



PRODUCT SPECIFICATION

DENARASE High Salt 1 MU / 5 MU, GMP

Art. No.: 22002-1M, 22002-5M

Recombinant *Serratia marcescens* endonuclease, genetically engineered for higher salt tolerance, produced by microbial fermentation with *Bacillus* sp. The production strain employed in the manufacturing of the product is a Genetically Modified Organism (GMO) of safety level S1.

The enzyme is supplied as liquid and formulated in 20 mM Tris-HCl pH 7.4 ± 0.2, 250 mM NaCl, 5 mM MgCl₂, 50 % glycerol (v/v).

The product is produced under EU GMP.

Parameter	Method	Specification
Appearance	visual	Clear, transparent solution
Activity	photometric ¹	> 250 U/μl
Purity	Protein purity determined by SDS-PAGE and silver staining	≥ 98 %
Specific Activity	Activity per protein content determined photometrically at 280 nm with a molar extinction coefficient of 45,170 L x mol ⁻¹ x cm ⁻¹	≥ 4 x 10 ⁵ U/mg
Endotoxin level	LAL-Test acc. to Ph. Eur. 2.6.14/USP <85>, Method C	< 0.25 EU/kU
Total microbial count	TAMC/TYMC acc. to Ph. Eur. 2.6.12/USP <61>	Aerobic bacteria: < 5 cfu/200 μl Yeast/moulds: < 5 cfu/200 μl

¹ Unit-Definition: One unit (U) will digest salmon sperm DNA to acid-soluble oligonucleotides equivalent to a ΔA260nm of 1.0 in 30 min at pH 8.0 at 37 °C.

Storage	Store at -20°C ± 5°C.
Stability	Stable within specification range for a period of at least 24 months from the date of manufacture under proper storage conditions.
BSE / TSE / Animal derived material:	The manufacturing process is free of materials with TSE/BSE risk and of raw materials from animal origin.
GMO-Statement	The product is free of the production strain.
Antibiotics	No antibiotics are used in the manufacturing process.

This document is subject to change. The latest version can be provided upon request. Without separate, written agreement between the customer and c-LEcta GmbH, this document does not constitute a representation or warranty of any kind.