

PRODUCT SPECIFICATION

NuCLEANase, food grade

Art. No.: 20804-4

Recombinant *Serratia marcescens* endonuclease produced by microbial fermentation with a *Bacillus* species. The production strain employed in the manufacturing of the product is a Genetically Modified Organism (GMO) of safety level S1. The product (food enzyme preparation) is free of the production strain and supplied as liquid formulated in potassium phosphate buffer pH 8.0, 50 % (v/v) glycerol.

This product is supplied in food grade quality and conforms to the recommended purity criteria for enzyme preparations given in the Food Chemicals codex (FCC) and the General Specifications and Considerations for Enzyme Preparations used in Food Processing of the Joint WHO/FAO Expert Committee on Food Additives (JECFA).

It shall be the responsibility of the user to determine the suitability and legal status of this product for the intended use. The content of this document is subject to change without further notice and does not constitute a representation or warranty of any kind.

Parameter	Method	Specification
Activity	c-LEcta SOP-QC-34 ¹	≥ 30 MU/L
Total viable count	Colony forming units (cfus)/g product resulting from plating a product sample on Plate-Count-Agar acc. to DIN EN ISO 4833-2 or equivalent	< 5x10 ⁴ cfus/g
Salmonella	Colony forming units (cfus)/25 g product resulting from plating a product sample on selective medium acc. to DIN EN ISO 6579-1 or equivalent	Absent in 25 g
<i>Escherichia coli</i>	Colony forming units (cfus)/25 g product resulting from plating a product sample on selective medium acc. to DIN EN ISO 10183-3 or equivalent	Absent in 25 g
Total coliforms	Colony forming units (cfus)/g product resulting from plating a product sample on selective medium acc. to ISO 4832 or equivalent	≤ 30 cfus/g

Parameter	Method	Specification
<i>Enterobacteriaceae</i>	Colony forming units (cfus)/g product resulting from plating a product sample on selective medium acc. to DIN ISO 21528-2 or equivalent; detection limit: 10 cfus/g product	Absent by test
Antimicrobial activity	Visually clear zones around test disk, indicating presence of antibacterial components (>16 mm) acc. to Combined Compendium of Food Additives of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)	Negative
Lead (Pb)	Determined by AAS/ ICP-AES/ ICP-MS	≤ 5 mg/kg
Cadmium (Cd)	Determined by AAS/ ICP-AES/ ICP-MS	≤ 0.5 mg/kg
Mercury (Hg)	Determined by AAS/ ICP-AES/ ICP-MS	≤ 0.5 mg/kg
Arsenic (As)	Determined by AAS/ ICP-AES/ ICP-MS	≤ 3 mg/kg

¹ Unit definition: One unit (U) will digest salmon sperm DNA to acid-soluble oligonucleotides equivalent to 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 product release under proper storage conditions.
BSE / TSE:	The manufacturing process is free 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.
Allergens:	No allergen labelling is required according to Regulation (EU) No 1169/2011.
Kosher/Halal:	The product is kosher and halal certified.

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