1. Product Information

Product name	**Recombinant spCas9**
Internal product code	BMC9
Catalog numbers (aliquot sizes)	140-001-RUO (0.1 mg) 140-005-RUO (0.5 mg) 140-010-RUO (1 mg) 140-025-RUO (2.5 mg) 140-050-RUO (5 mg)
Quality grade	**Research use only (RUO)**
Description	Recombinant wild type Cas9 nuclease from *Streptococcus pyogenes* with nuclear localization sequence (NLS-spCas9-NLS)
Molecular weight	162 kDa
Concentration	10 mg/mL solution in buffer (frozen)
Storage buffer	25 mM Tris, 300 mM NaCl, 0.1 mM EDTA, 50% glycerol, pH 7.4 buffer solution
Storage temperature	-75 ± 15 °C
Lot. Nr.	Specified on product label
Use by date	Specified on product label
Manufacturer	Biomay AG, Ada-Lovelace-Straße 2; 1220 Vienna, Austria; www.biomay.com; info@biomay.com

2. Description

CRISPR nuclease Cas9 (spCas9 from *Streptococcus pyogenes*, uniprot Q99ZW2 (CAS9_STRP1)) with nuclear localization sequences (NLS) on the N- and C-terminus. The product has been expressed as recombinant protein in *Escherichia coli*, purified by chromatography, filtered (0.2µm) and filled as a low-bioburden product.

3. Intended Use / Application

Research use only: product is a recombinant protein that has been manufactured and tested under laboratory conditions. It was designed and is intended to be used for gene-editing of eukaryotic cells with a specific guide RNA (gRNA), for research and development. **The material is intended for research and development use only.**

The material may not be used:

- **(i)** for administration to humans, or in human clinical trials (Phases I, II or III), nor for any commercial applications, neither directly (as protein) nor indirectly (Cas9 gene-edited products from cell culture), and
- **(ii)** in the area of hemoglobinopathies, in addition to (i), also for preclinical use.

Clients are required to acknowledge and accept these specific terms related to Biomay's Cas9 with the acquisition of the material.

4. Quality Control and Specifications

Parameter	Quality Control Method	Specification *Research grade*
Appearance	Visual inspection	Clear and colourless liquid, free of visible particles
pH-value	pH potentiometric (Ph. Eur. 2.2.3)	7.4 ± 0.3
Content (concentration)	UV spectrophotometric (UV 280 nm / Ph. Eur. 2.2.25)	9.0 - 11.0 mg/ml
Homogeneity (aggregates)	Size exclusion chromatography (HP-SEC)	≥ 95% monomer
Identity	Western blot	Positive reaction of the main band with the Cas9 specific antibody
		Migration of the main band conforms to reference
Purity	SDS-PAGE	Migration of the main band conforms to reference
		Purity: ≥ 95%
Host cell protein	E. *coli* host cell protein ELISA	≤ 350 ng/mg (≤ 0.035 % w/w)
Endotoxins	LAL test (Ph. Eur. 2.6.14 method D)	< 5 EU/mg
Residual RNase	Fluorimetric	< 5 mU/ml
Residual DNase	Fluorimetric	No DNase activity detectable
Host cell DNA	qPCR	≤ 30 ng/mg (≤ 0.003 % w/w)
Bioburden	Membrane filtration (Ph. Eur. 2.6.12)	< 1 cfu/ml
Functionality assay	RP-HPLC	70 – 150% relative EC_{50}

5. Safety information

Material is considered non-infectious, non-toxic and non-pathogenic under the conditions of the intended applications. General safety procedures should still be followed to maintain a safe working environment. Always wear appropriate personal protective equipment (PPE), including lab coats, gloves, and safety glasses, to avoid contamination and accidental exposure. Work in a clean, organized space, and handle reagents with care, avoiding direct contact. Dispose of all waste materials, including gloves and pipette tips, in designated biohazard containers, even though the commodity is non-hazardous, to prevent cross-contamination. Always wash hands after handling any biological material and before leaving the lab. The material **may not be administered to humans or used human clinical trials**. The material may be used for laboratory research only.