

1. Product Information

Product name	Cas9 mRNA (Cap3)		
Internal product code	BMr08r		
Catalog numbers (aliquot sizes)	561-xxx-GMP (variable sizes)		
Quality grade	current Good Manufacturing Practice (cGMP)		
Description	mRNA coding for wild type Cas9 nuclease from <i>Streptococcus</i> pyogenes with nuclear localization sequence (NLS-spCas9-NLS), human codon optimization		
Length	4492nt		
5'-Cap	Cap3 (CAP3011™, Areterna)		
3' Poly(A) tail	120 nt		
Base modification	N1-methylpseudouridine (m1Ψ)		
Concentration	1 mg/mL solution in buffer (frozen)		
Storage buffer	1 mM sodium citrate pH 6.4		
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

Human codon-optimized Cas9 mRNA is translated to a CRISPR nuclease Cas9 (spCas9 from *Streptococcus pyogenes*, uniprot Q99ZW2 / CAS9_STRP1) with nuclear localization sequences (NLS) on the N- and C-termini. The mRNA is capped with CAP3011 cap analog (Areterna; molecular formula: C₃₂H₄₃N₁₅O₂₄P₄) providing Cap-0 (N7-methyl guanosine analog connected to the 5' nucleotide through a 5' to 5' triphosphate linkage analog) and Cap-1 (2'-O-methylation at the first position following the Cap-0 analog) structures. The product has been manufactured by in vitro transcription using a linear DNA

Cap-1 structure of Cas9 mRNA: CAP3011 from Areterna (www.areterna.com)

template, purified by chromatography, filtered (0.2µm) and filled as a low-bioburden product.

3. Intended Use / Application

Product is mRNA that has been manufactured and quality-controlled under the conditions of current Good Manufacturing Practice (GMP). It has been certified and released by a Qualified Person (QP) under EMA law (EMA directive 2001/83/EC). It was designed and is intended to be used for gene-editing of eukaryotic cells with a specific guide RNA (gRNA).



Note: Biomay places no restrictions on the use of its Cas9 mRNA products. Depending on the application, end users may need to secure appropriate third-party licenses related to CRISPR/Casmediated gene editing or the use of modified nucleosides from the relevant intellectual property holders.

4. Quality Control and Specifications

	Method	Specification	Results
Appearance	Visual inspection	Clear and colorless solution	Clear and colorless solution
pH-value	pH potentiometric Ph. Eur. 2.2.3	6.4 ± 0.5	6.4
mRNA identity	Denaturing RNA agarose gel	Conforms to reference	Conforms to reference
	electrophoresis	Single distinct band visible	Single distinct band visible
	Capillary electrophoresis	Size ± 15% of theoretical size	Conforms
Sequence identity	Sanger sequencing after reverse transcription	Conforms to theoretical sequence	Conforms
mRNA concentration	UV spectrophotometry (UV absorbance A _{260nm} / Ph. Eur. 2.2.25)	0.8 – 1.2 mg/ml	1.04 mg/ml
mRNA homogeneity	Capillary electrophoresis	Homogeneity ≥ 80%	94%
mRNA purity	UV spectrophotometric (UV absorbance A _{260nm} /A _{280nm})	1.8 – 2.3	1.9
5´- Capping efficiency	LC/MS	≥ 80%	99 %
3´ - Poly(A)-tail length	LC/MS	≥ 90% (of theoretical poly(A) tail length)	Conforms
Residual protein	Nano Orange assay	< 1.0 % w/w	< 0.3 % w/w
Residual template DNA	qPCR	< 1 ng/mg RNA	0.016 ng/mg RNA
dsRNA	ELISA	≤ 0.150%	0.068 %
Endotoxin	LAL test Ph. Eur. 2.6.14 method D	≤ 1.0 EU/mg RNA	< 0.1 EU/mg RNA
Bioburden	Membrane filtration Ph. Eur. 2.6.12	< 1 cfu/ml	< 1 cfu/ml

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.