

## In-Vitro-Transcription (IVT) Enzymes Emprove® Expert

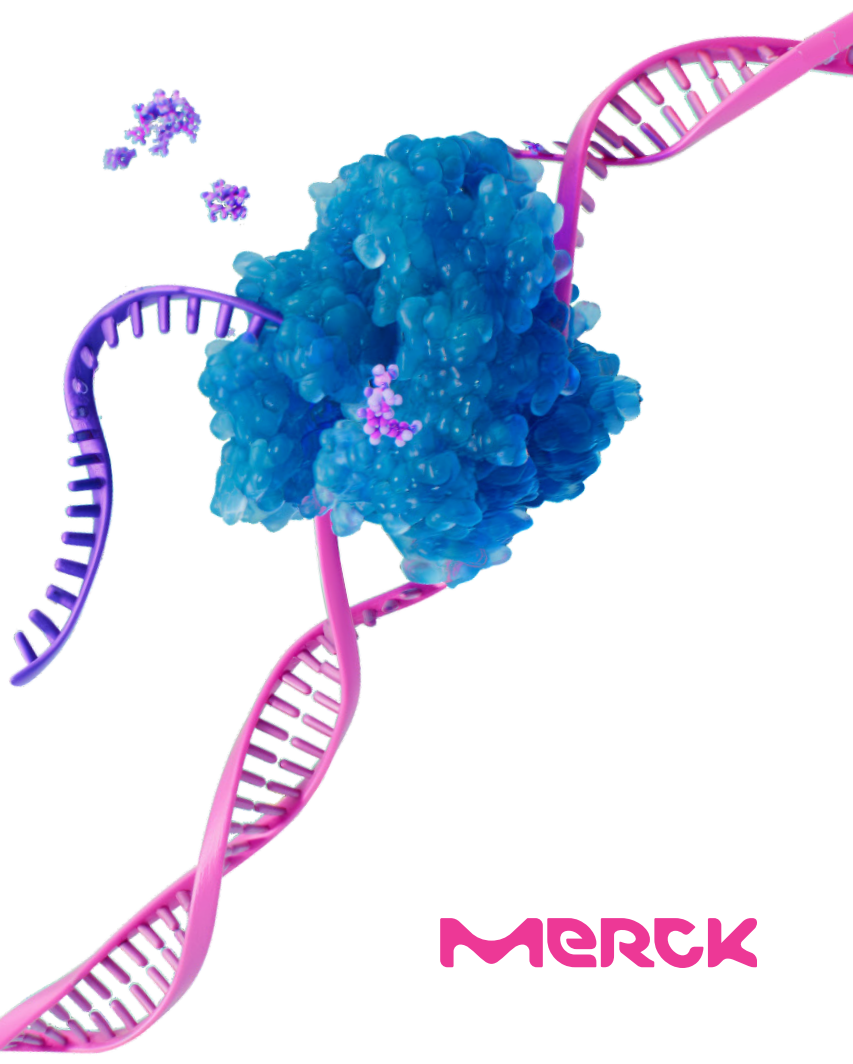
mRNA technologies represent a revolutionary approach for both prophylactic vaccines and for therapeutics such as cancer treatments and immunotherapies. As global interest in mRNA manufacturing grows and regulatory expectations become more stringent, manufacturers require high-quality, high-purity raw materials suitable for pharmaceutical use. A major challenge in IVT is the formation of unintended double-stranded RNA (dsRNA) that directly impacts product quality—it lowers translation efficiency, activates innate immune pathways, and significantly increases the downstream purification burden. For many manufacturers, controlling dsRNA formation remains one of the most persistent issues across scale-up and commercialization.

In response, we have developed the high-purity IVT enzyme Emprove® Expert portfolio, manufactured in compliance with IPEC-PQG GMP guidelines, to help ensure batch-to-batch consistency in your mRNA manufacturing processes. These critical raw materials are accompanied by comprehensive Emprove® Dossiers, providing essential regulatory support to navigate the complexities of the biopharmaceutical industry while facilitating compliance and accelerating time to market.

The IVT enzyme Emprove® Expert portfolio includes the following products:

- **T7 RNA Polymerase Emprove® Expert**
- **Inorganic Pyrophosphatase (IPP) Emprove® Expert**

Together, these enzymes form the core of a robust IVT reaction and are designed to support reliable and efficient mRNA manufacturing workflow from early development to commercial production.



## Key Benefits

### High Performance and Quality

- Superior performance of T7 RNA Polymerase: Higher yield with reduced dsRNA, improving IVT efficiency and mRNA quality
- Improved batch-to-batch consistency through manufacturing aligned with IPEC-PQG GMP guidelines, supported by validated QC methods, manufacturing processes, and stability studies

### Enhanced Safety and Compliance with Reduced Risk

- Animal Origin-Free (AOF) to minimize contamination risks and support safety of high-risk applications
- Beta-lactam free manufacturing to avoid cross-contamination, advancing patient safety and regulatory compliance
- Triton™ X-100-free formulation—avoiding a banned SVHC (Substance of Very High Concern) in the EU and reducing regulatory risk

### High Purity for High-Risk Applications

- High purity ( $\geq 95\%$ ) with specified low microbial and endotoxin levels
- Specified absence of nuclease activity to minimize contamination risk
- Extended impurity testing including specified low levels of residual solvents

Our Emprove® Expert IVT enzymes are backed by the Emprove® Program which provides comprehensive regulatory, technical, and supply information to support your risk assessment, material qualification, and process optimization efforts.

## Product Application

**T7 RNA Polymerase** catalyzes the core reaction step in mRNA manufacturing—*in vitro* transcription (IVT)—by synthesizing RNA from DNA templates containing a T7 promoter. During this process, wild-type T7 RNA polymerases can generate unwanted dsRNA, which reduces mRNA yield and can trigger innate immune activation. The enhanced T7 RNA Polymerase Emprove® Expert minimizes dsRNA formation and supports higher transcription yields, enabling a more efficient and consistent IVT process.<sup>[1-3]</sup>

**Inorganic Pyrophosphatase** supports IVT by hydrolyzing pyrophosphate (PPi), a reaction byproduct that inhibits RNA polymerases and slows RNA synthesis. By removing PPi, this enzyme drives the reaction equilibrium forward, helping increase mRNA yield and improving process robustness.<sup>[4]</sup>

## Product Properties

	T7 RNA Polymerase Emprove® Expert	Inorganic Pyrophosphatase Emprove® Expert
<b>Biological Source</b>	Bacteriophage T7	<i>Escherichia coli</i>
<b>Expression System</b>	<i>Escherichia coli</i>	<i>Escherichia coli</i>
<b>Form</b>	Aqueous solution	Aqueous solution
<b>Storage Buffer</b>	20 mM Tris-HCl pH 8, 0.1 mM EDTA, 150 mM NaCl, 5 mM DTT, 0.05 % Tween® 20, 50 % glycerol	20 mM Tris-HCl pH 8, 0.1 mM EDTA, 100 mM NaCl, 1 mM DTT, 50 % glycerol
<b>Concentration</b>	$\geq 0.08$ mg/mL	$\geq 0.25$ mg/mL
<b>Molecular Weight</b>	99 kDa	19.7 kDa
<b>Specific Activity</b>	$\geq 50,000$ units/mL	$\geq 100$ units/mL
<b>Assay</b>	$\geq 95\%$ (SDS-PAGE)	$\geq 95\%$ (SDS PAGE)

- Storage:  $-20$  °C
- Shelf-life: 6 months for T7 RNA Polymerase; extension to 2 years after completion of stability studies; 2 years for Inorganic Pyrophosphatase.

## The Improve® Program

### The Smart Way to Master Compliance and Control

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time-consuming and resource-intensive. To help facilitate and accelerate your risk-assessment continuum, we have developed the Improve® Program, offering ready access to reliable information for a broad portfolio of products.

Each product in the portfolio is complemented with different types of dossiers: Material Qualification Dossier, Quality Management Dossier, and Operational

Excellence Dossier. They provide information on the manufacturing process, stability data, elemental impurity information, product quality reports, analytical procedures, and much more.

The dossiers can be accessed online in our new Improve® Suite, our information-as-a-service digital platform. A subscription can help you stay current. In addition to viewing and downloading dossiers, you can also receive notification updates on changes to documents, as well as generate metrics and reports.

For more information, please visit:  
[SigmaAldrich.com/improve-program](https://SigmaAldrich.com/improve-program)

## Ordering Information

Product Description	Material Number	Pack Size (mL)
T7 RNA Polymerase Improve® Expert	137228.0001	1
	137228.0010	10
	137228.0050	50
Inorganic Pyrophosphatase (IPP) Improve® Expert	137229.0001	1
	137229.0010	10
	137229.0050	50

## References

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3. Lenk R, Kleindienst W, Szabó GT, et al. Understanding the impact of *in vitro* transcription byproducts and contaminants. *Front Mol Biosci*. 2024;11:1426129. Published 2024 Jul 10. doi:10.3389/fmolb.2024.1426129
4. Tersteeg S, Mrozowich T, Henrickson A, Demeler B, Patel TR. Purification and characterization of inorganic pyrophosphatase for *in vitro* RNA transcription. *Biochem Cell Biol*. 2022;100(5):425-436. doi:10.1139/bcb-2022-0118

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