



LNP 2.0 platform for RNA Technology

INSTRUCTIONS FOR USE (IFU)

LipTx™ Ionizable Lipid for Lipid Nanoparticle (LNP) Formulation

Document No.: IFU-NVIL Revision: 1.0 Effective Date: JUL/2026

1 Introduction

LipTx™ ionisable lipids are engineered for the formulation of advanced lipid nanoparticle (LNP) delivery systems for nucleic acid therapeutics. Acting as the functional core of the LNP, these ionisable lipids facilitate efficient encapsulation of nucleic acid cargos during formulation while promoting intracellular delivery through pH-responsive endosomal escape mechanisms. In combination with optimized helper lipids, cholesterol, and PEG-lipids, LipTx™ ionisable lipids support the generation of LNPs with reproducible physicochemical characteristics, including controlled particle size, narrow size distribution, high encapsulation efficiency, and excellent colloidal stability. The platform is intended to support research, process development, preclinical studies, and clinical translation of RNA medicines, including mRNA, saRNA, circRNA, siRNA, antisense oligonucleotides (ASOs), and gene-editing payloads such as CRISPR-associated nucleic acids.

1.1 Description

Ionizable lipids are designed to remain predominantly neutral at physiological pH (7.4) while becoming protonated under acidic conditions (typical pKa is in the range of 6.4-7.0) to facilitate efficient (>90%) nucleic acid (such as pDNA, siRNA, mRNA, CRISPR-Cas etc.) encapsulation and endosomal release of nucleic acids.

1.2 Safety information

Refer to the Material Safety Data Sheet (MSDS).

1.3 Storage

Recommended Storage: **-80°C**

Protect from moisture, oxygen, and prolonged light exposure. Avoid repeated freeze-thaw cycles.

1.4 Shelf life

Recommended shelf life: **12 months** from date of manufacture when stored as supplied.



INSTRUCTIONS FOR USE (IFU)

LipTx™ Ionizable Lipid for Lipid Nanoparticle (LNP) Formulation

Document No.: IFU-NVIL Revision: 1.0 Effective Date: JUL/2026

2 **Material required but not provided**

2.1 List of equipment

- Vortex mixer
- Heating bath

2.2 List of reagents

- Absolute Ethanol (≥99.5%)

3 **Instructions for Use**

3.1 Stock solution preparation

Allow the lipid material and ethanol to equilibrate to room temperature before opening the containers to minimize moisture condensation. Using a pipette, add the required volume of ethanol to the vial containing the lipid mixture (e.g., 1 mL of ethanol for the preparation of a 25 mg/mL lipid stock solution). Mix thoroughly by pipetting up and down, followed by gentle vortexing until all lipids are completely dissolved and a clear, homogeneous solution is obtained.

If the solution is not clear or visible particles remain, heat the lipid solution at 45 °C for 2 minutes, then mix again until the solution becomes clear, visually inspect the solution prior to use. The stock solution should be free of visible particles, precipitates, or turbidity. Do not use solutions containing persistent particulate matter.

Filter the prepared lipid stock solution through a sterile 0.22 µm PTFE syringe filter into a clean, RNase/DNase-free container to remove any particulate contaminants prior to LNP manufacturing or other downstream applications.

Prepare stock solutions immediately before use whenever possible. If temporary storage is required, transfer the solution to tightly sealed amber glass vials or other solvent-compatible containers to minimise ethanol evaporation and protect the lipid from prolonged exposure to moisture, light, and air. Allow refrigerated or frozen stock solutions



LNP 2.0 platform for RNA Technology

INSTRUCTIONS FOR USE (IFU)

LipTx™ Ionizable Lipid for Lipid Nanoparticle (LNP) Formulation

Document No.: IFU-NVIL Revision: 1.0 Effective Date: JUL/2026

to return to room temperature and mix thoroughly before use. Discard any stock solution showing evidence of precipitation, phase separation, or discoloration.

3.2 Recommendations / Handling suggestions

Use appropriate personal protective equipment (PPE) including nitrile gloves, laboratory coat, and safety glasses. Avoid contact with eyes, skin, and clothing. Use within a laboratory fume hood or suitably ventilated area. troubleshooting guide.

Not more than 4 freeze – thaw cycles will be ideal; however, we recommend aliquoting the stock solution to minimize repeated freeze – thaw cycles. The stock solution should be mixed gently by brief pipetting, followed by mild vortexing, until the solution becomes clear before use.

4 Troubleshooting Guide

4.1 Documentation

- Material Safety Data Sheet (MSDS)
- Certificate of Analysis (CoA)
- Regulatory Package (Optional) – available for GMP products under the CDA.

4.2 Legal and Ordering information

This product is supplied for research and development use only. **NOT FOR CLINICAL USE.**

4.3 Disclaimer

NeoVac products are supplied For Research Use Only (RUO) and are not intended for use in humans or animals for therapeutic, diagnostic, or clinical purposes.

These products are intended solely for laboratory research by qualified personnel using appropriate laboratory practices and in accordance with the applicable Instructions for Use (IFU), Material Safety Data Sheet (MSDS), and all relevant product documentation. Users are solely responsible for determining the suitability of the product for their intended





LNP 2.0 platform for RNA Technology

INSTRUCTIONS FOR USE (IFU)

LipTx™ Ionizable Lipid for Lipid Nanoparticle (LNP) Formulation

Document No.: IFU-NVIL Revision: 1.0 Effective Date: JUL/2026

research application and for ensuring compliance with all applicable laws, regulations, and institutional requirements.

NeoVac shall not be liable for any direct, indirect, incidental, consequential, or special damages arising from the misuse of the product, use outside its intended purpose, unauthorized modification or alteration, improper storage or handling, or failure to follow the applicable Instructions for Use (IFU) or other product documentation. Any use of the product that deviates from the manufacturer's published specifications or recommendations is undertaken solely at the user's own risk.

Except as expressly stated in the applicable product documentation or required by applicable law, NeoVac makes no representations or warranties, express or implied, including, without limitation, any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

4.4 Contact and Technical support

info@neovac.co.uk

