NanOZ LNP Selection Kit 5 formulations with mRNA OVA MSDS Last Revision: 31-Oct-2024



MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT AND COMPANY INFORMATION

Product name: LNP Selection Kit 5 formulations with mRNA OVA (mRNA41).

- Catalog number: LNP5XMRNA41
- Chemical name or synonyms:
- **Contact:**

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SECTION 2 – HAZARDS IDENTIFICATION

GHS Classification			
Not classified as Hazardous			

GHS Label element

Signal Word:	None
Hazard Statements:	None
Pictograms:	None

This product contains hazardous ingredients (Yes; No; Not Applicable or no information): No.

This product contains hazardous carcinogens (Yes; No; N/A): No

This product contains hazardous ingredients to the environment. (Yes; No; N/A): No

SECTION 3 - COMPOSITION, INFORMATION ON INGREDIENTS

Description: methoxy-uridine modified mRNA encoding Ovalbumin protein formulated in Lipid Nanoparticle (0.1 mg/mL RNA in LNPs); 3 different formulations enclosing 5 different lipidic compositions.

Note: the table below is valid for the five different compositions.

Chemical	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH RegistrationNumber
Water	231-791-2	7732-18-5	**	Not Listed	
Sucrose	200-334-9	57-50-1	<10	Not Listed	
Sodium Chloride	231-598-3	7647-14-5	<10	Not Listed	
OZB Ionizable lipid***	Not Listed	Not Assigned	<2	Not Listed	
moU modified (OVA) mRNA	Not Listed	Not Assigned	<1	Not Listed	
Cholesterol	200-353-2	57-88-5	<1	Not Listed	
Potassium dihydrogenophosphate	231-913-4	7778-77-0	<1	Not Listed	
Potassium Chloride	231-211-8	7447-40-7	<1	Not Listed	
Disodium hydrogenophosphate dihydrate	Not Listed	10028-24-7	<1	Not Listed	
1,2-Dimyristoyl-rac- glycero-3- methoxypolyethylene glycol-2000 (DMG- PEG-2000)	Not Listed	160743-62-4	<1	Not Listed	
1,2-Distearoyl-sn- glycero-3 - phosphocholine	212-440-2	816-94-4	<1	Not Listed	

Ingredients are not hazardous or their concentrations do not exceed the limit specified according to 29 CFR 1910.1200 Hazard Communication Standard (USA) and Directive 1999/45/EC-2001/59/EC (EU).

**This is proprietary and confidential information.

***The chosen ionizable lipid is different in each composition and is proprietary from OZB.

SECTION 4 – FIRST AID MEASURES

Effects and symptoms:

0	Inhalation	May be harmful if inhaled. Material may be irritating to mucous membranes and upper respiratory tract.
0	Ingestion	May be harmful in case of ingestion.
0	Skin contact	May cause skin irritation, redness, itching.
0	Eye contact	Slightly hazardous in case of eye contact.
0	Aggravating conditions	Chronic exposure may develop allergic reactions in sensitive individuals.
First-Ai	d measures:	
0	Inhalation	If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.
0	Ingestion	If swallowed, wash out mouth with water provided person is conscious. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.
0	Skin contact	In case of contact, immediately wash skin with soap and copious amounts of water.
0	Eye contact	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately.
0	Notes to physician	Not available.
0	Protection of first-aiders	Not available

SECTION 5 – FIRE FIGHTING MEASURES

- **Extinguishing media:** Water spray, carbon dioxide, dry chemical powder or appropriate foam.
- Flammability of the product: Not available.

- **Flash Point:** Not available.
- Fire hazards in presence of various substances: Not considered to be flammable.
- Fire fighting media and instructions: Use an extinguish agent suitable for surrounding fires.
- **Protective clothing (fire):**

Be sure to use an approved/certified respirator or equivalent.

Hazardous thermal decomposition products: Not available.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Personal precautions: Safety glasses, lab coat and gloves.
- Environmental precautions and clean-up methods: Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow evacuating through the sanitary system.
- Small spill and leak: Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.
- Additional information: No dangerous substances are released.

SECTION 7 – HANDLING AND STORAGE

- Handling: Avoid contact with skin, eyes and clothing. Avoid prolonged or repeated exposure.
- Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Store at 80°C for long-term storage.
- Intended use: Refer to the instruction booklet for proper and intended use. Otherwise, contact supplier for specific application.
- Packaging materials

Suitable: Use original container.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION

- Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. Ensure that eyewash stations and safety showers are proximal to the work-station location.
- **Personal protection**

0

0

- Eyes: Safety glasses. Body: Lab coat and gloves.
- Respirator is not needed under normal and intended conditions of use, if exposures are kept below established **Respiratory:** limits.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

• <u>Appearance</u>

- Physical State:
- Color: Colorless
- **Odor:** Not available.
- **Taste:** Not available.
- Molecular weight: Not available.
- **pH: 7**.4

0

- **Boiling point:** 100°C
- **Decomposition temperature:** Not available
- Melting point: Not available.
- **Flash point:** Not available.
- **Dispersion properties:** Not applicable.
- Solubility: Readily soluble in water.

SECTION 10 – STABILITY AND REACTIVITY

- Stability and reactivity: The product is stable under recommended storage conditions.
- Conditions to avoid: Exposure to light, air or moisture over prolonged periods.
- Materials to avoid: Strong acids, strong bases, strong oxidizing agents.

Liquid

- Hazardous polymerization: Will not occur.
- Hazardous decomposition products: Will not occur.

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

- General Information: Toxicological properties have not been thoroughly investigated. The following information is available for the individual ingredients.
- Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following intravenous exposure to this compound may include: muscle pain, abnormal redness of skin (erythema), fever, and sleep disturbances.
- Acute Toxicity: (Species, Route, End Point, Dose)

Sucrose

Rat Oral LD 50 29,700 mg/kg

Sodium Chloride

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m3 Rat Oral LD 50 3 g/kg Mouse Oral LD 50 4 g/kg Rabbit Dermal LD 50 > 10 g/kg

Potassium Chloride Rat Oral LD50 2600 mg/kg

Potassium dihydrogenophosphate

Rat Oral LD50 3200 mg/kg Rabbit Dermal LC50 > 4640 mg/kg

• Irritation / Sensitization: (Study Type, Species, Severity)

Sodium Chloride

Skin Irritation Rabbit Mild Eye Irritation Rabbit Mild

Potassium Chloride

Eye Irritation Rabbit Mild

• Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Potassium dihydrogenophosphate

Reproductive & Fertility Rat No route specified 282 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus Reproductive & Fertility Mouse No route specified 320 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

• Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Potassium dihydrogenophosphate

Bacterial Mutagenicity (Ames) Salmonella Negative

• Carcinogenicity See below

Cholesterol

IARC Group 3 (Not Classifiable)

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

12.1. Toxicity Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Potassium Chloride Gambusia affinis (Mosquitofish) LC50 96 hours 920 mg/l Lepomis macrochirus (Bluegill Sunfish) LC50 96 hours 2010 mg/L Daphnia Magna (Water Flea) EC50 48 hours 825 mg/l Scenedesmus subspicatus (Green Alga) EC50 72 Hours 2500 mg/L

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other adverse effects No information available.

SECTION 13 – DISPOSAL CONSIDERATIONS

- Waste stream: Not available.
- Waste disposal method: Contact a licensed professional waste disposal service to dispose of this material. Dispose in accordance with governmental environmental regulations. Observe all federal, state, and local environmental regulations.
- European waste catalogue (EWC): Not available.
- Hazardous waste: Will not occur.

SECTION 14 – TRANSPORT INFORMATION

Note Please see current shipping paper for most up to date shipping information, including exemptions and special circumstances.

D.O.T.: Not regulated.

IATA .: Not regulated.

IMDG: Not regulated.

SECTION 15 – OTHER INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS

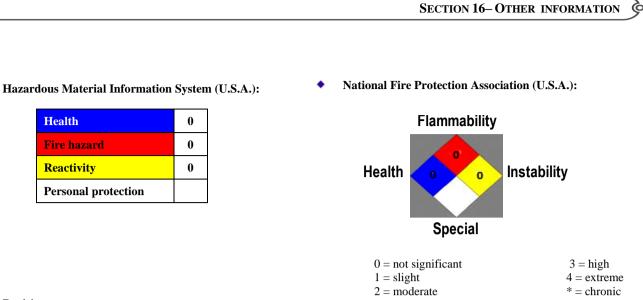
Not Listed Not Listed Present 231-791-2 Present

Sucrose

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CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS	Not Listed Not Listed Present 200-334-9 Present
<u>Sodium Chloride</u> CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS	Not Listed Not Listed Present 231-598-3 Present
<u>Potassium dihvdrogenophosphate</u> CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS	Not Listed Not Listed Present 231-913-4 Present
Potassium Chloride CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Not Listed Not Listed Present 231-211-8 Present Schedule 4
Disodium phosphate dihydrate CERCLA/SARA Section 313 de minimus % California Proposition 65 EINECS AICS Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Not Listed Not Listed Not Listed Present Schedule 5
<u>Cholesterol</u> CERCLA/SARA Section 313 de minimus % California Proposition 65 TSCA EINECS AICS Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Not Listed Not Listed Present 200-353-2 Present Schedule 4
<u>1.2-Distearoyl-sn-glycero-3-phosphocholine</u> CERCLA/SARA Section 313 de minimus % California Proposition 65 EINECS	Not Listed Not Listed 212-440-2
15.2. Chemical safety assessment Chemical Safety Report	No information available

• This product is not classified according to the EU regulations.



• Revisions:

Issue Date: 31-Oct-2024 Last Revision Date: N/A Revision note: N/A

Other Comments:

To the best of our knowledge, the information contain herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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