# Safety Data Sheet

## SECTION 1: Identification

**Contact information**

**General**


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|---|---|
| **Product identifier** | Respiratory Syncytial Virus (RSV) vaccine |
| **Synonyms** | mRNA-1345 |
| **Trade name** | Not applicable |
| **Chemical family** | Mixture - contains ribonucleotides |
| **Recommended uses and restrictions** | Bulk formulated pharmaceutical mixture OR Formulated pharmaceutical product/mixture packaged in final form for patient use; under investigation for the treatment of respiratory syncytial virus (RSV). |
| **Note** | This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations. This SDS will be revisited if more data become available. |

## SECTION 2: Hazard(s) identification

**Classification of the substance or mixture**

Not classified

**Label elements**

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| **GHS Hazard pictograms** | Not applicable |
| **GHS Signal word** | Not applicable |
| **GHS Hazard statements** | Not applicable |
| **GHS Precautionary statements** | Not applicable |
| **Other hazards** | Respiratory Syncytial Virus (RSV) vaccine is an mRNA vaccine against RSV. This mRNA drug product is a lipid nanoparticle (LNP) based delivery system that is non-viral and non-infectious and does not include the possibility of DNA integration. The LNP is comprised of several lipids, including a novel lipid. RSV vaccine has not been tested in humans.<br><br>The mRNA in the RSV vaccine is not viral or pathogenic and does not require specific biosafety handling recommendations.<br><br>As an mRNA molecule with a large molecular weight, little to no systemic absorption is expected to occur in a workplace setting. It is also expected to rapidly degrade in the digestive tract following accidental ingestion. |
| **Note** | This mixture does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). Nevertheless, it should be handled with caution as it is pharmacologically active. This mixture does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). Nevertheless, it should be handled with caution as it has not yet been fully tested and is pharmacologically active. |

## SECTION 3: Composition/Information on ingredients

| Ingredient | CAS number | EINECS/ELINCS# | Amount | GHS classification |
|---|---|---|---|---|
| mRNA | N/A | N/A | 0.01 – 1 % | Not classified |
| Lipids | N/A | N/A | 1 – 10% | Not classified |
| Sucrose | 57-50-1 | 200-334-9 | 1 – 10 % | Not classified |

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| **Note** | The ingredients listed above are not classified, but are listed because they are pharmacologically active and the toxicologic properties have not yet been fully characterized. Sucrose is included because it has an OEL and is present at or above 1%. The remaining components are not hazardous and/or are present at amounts below reportable limits.<br>Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. See Section 16 for full text of GHS classifications. |

## SECTION 4: First-aid measures

**Description of first aid measures**

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| **Immediate medical attention and special treatment, if necessary** | No. |
| **Inhalation** | Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor. |
| **Skin contact** | Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor. |
| **Eye contact** | If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor. |
| **Ingestion** | If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor. |
| **Most Important Symptoms/Effects** | Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively. |
| **Expected Symptoms/Effects, Acute and Delayed** | See Sections 2 and 11 |

## SECTION 5: Fire-fighting measures

**Suitable (and unsuitable) extinguishing media**

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| **Suitable extinguishing media** | Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials. |
| **Specific hazards arising from the chemical** | No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and other nitrogen-containing compounds. |
| **Fire hazard** | No information identified. |
| **Explosion hazard** | No information identified. |

**Special protective equipment and precautions for fire-fighters**

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| **Firefighting instructions** | In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use. |

## SECTION 6: Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

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| **Protective equipment** | If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. |
| **Emergency procedures** | Do not breathe vapors/mist/spray. |
| **Environmental precautions** | Do not empty into drains. Avoid release to the environment. |

**Methods and material for containment and cleaning up**

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| **Methods for cleaning up** | DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g, paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9). |
| **Other information** | Dispose of materials or solid residues at an authorized site. |
| **Reference to other sections** | See Sections 8 and 13 for more information. |

## SECTION 7: Handling and storage

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| **Precautions for safe handling** | Follow recommendations for handling pharmaceutical agents (i.e, use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin, and other mucous membranes. Wash thoroughly after handling. Do not breathe vapor/mist/spray. |

**Conditions for safe storage, including any incompatibilities**

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| **Storage conditions** | Protect from light. Store in a dry, cool and well-ventilated place. Keep/Store away from incompatible materials. |

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| **Storage temperature** | Please refer to the Summary of Analysis documentation. |
| **Specific end use(s)** | Pharmaceuticals. |

## SECTION 8: Exposure controls/personal protection

**Note** Dispose of broken vials in a sharps container.

**Control parameters/Occupational Exposure Limits**

| Name | Issuer | Value |
|---|---|---|
| **mRNA** | No data available | No data available |
| **Lipids** | No data available | No data available |
| **Sucrose** | ACGIH TWA | 10 mg/m³ |
| | NIOSH REL (TWA) | 10 mg/m³ (total dust) |
| | OSHA PEL (TWA) | 15 mg/m³ (total dust) |

**Appropriate engineering controls**
None required for normal handling of packaged product. If handling bulk product and/or vials are open/crushed/broken: selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Use engineered local exhaust ventilation (LEV) and/or enclosure for procedures where aerosolization may occur such as opened transfers, pumping, and spraying. Solutions can be handled outside a containment system or without LEV during procedures with no potential for aerosolization. All containers for solutions and slurries must be covered while being transferred.

**Respiratory protection**
None required for normal handling of packaged product. If handling bulk product and/or vials are open/crushed/broken: choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For bulk manufacturing operations, a tight-fitting full-face respirator with HEPA filters may be required if performing aerosol generating operations. For liquid spill clean-up using gentle application of sorbent materials, standard PPE should be used.

**Hand protection**
None required for the normal handling of packaged product. If handling bulk product and/or vials are open/crushed/broken: wear nitrile or other impervious gloves if skin contact is possible. When the material is diluted in an organic solvent, wear gloves that provide protection against the solvent.

**Eye protection**
None required for normal handling of packaged product. If handling bulk product and/or vials are open/crushed/broken: wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin and body protection**
None required for normal handling of packaged product. If handling bulk product and/or vials are open/crushed/broken: wear disposable coveralls appropriate to the task, booties, and safety glasses with side shields. Ensure gloves are protective against solvents in use. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. Employees must be trained in proper gowning and degowning practices

**Other protective measures**
Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

**Environmental exposure controls**
Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

## SECTION 9: Physical and chemical properties

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| **Physical state** | Liquid |
| **Appearance** | Liquid, packaged in glass vial |
| **Formula** | Mixture - Not applicable |
| **Molecular mass** | Mixture - Not applicable |
| **Color** | White to off-white |
| **Odor** | No data available |
| **Odor threshold** | No data available |
| **pH** | 7-8 |
| **Melting point** | Not applicable |
| **Freezing point** | No data available |
| **Boiling point** | No data available |
| **Flash point** | No data available |
| **Relative evaporation rate (butyl acetate=1)** | No data available |
| **Flammability (solid, gas)** | Not applicable |
| **Vapor pressure** | No data available |
| **Relative vapor density at 20 °C** | No data available |

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|---|---|
| **Relative density** | No data available |
| **Solubility** | Soluble in water |
| **Log Pow** | No data available |
| **Auto-ignition temperature** | No data available |
| **Decomposition temperature** | No data available |
| **Viscosity, kinematic** | Not applicable |
| **Viscosity, dynamic** | Not applicable |
| **Explosion limits** | Not applicable |
| **Explosive properties** | No data available |
| **Oxidizing properties** | No oxidizing properties. |

## SECTION 10: Stability and reactivity

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| **Reactivity** | The product is non-reactive under normal conditions of use, storage and transport. |
| **Chemical stability** | Stable under normal conditions. |
| **Possibility of hazardous reactions** | No dangerous reactions known under normal conditions of use. |
| **Conditions to avoid** | (See section 7: Handling and Storage). |
| **Incompatible materials** | No data available |
| **Hazardous decomposition products** | Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

## SECTION 11: Toxicological information

**Likely routes of exposure**

mRNA-1345, its variant, as well as other multi-valent mRNA products, are expected to degrade in gastric fluids, and consequently the drug is not expected to be absorbed by ingestion. As a large molecular weight compounds, they are not likely to be systemically absorbed through inhalation and skin contact.

**Toxicological information**

**Acute toxicity**

| Component | Type | Dose |
|---|---|---|
| **mRNA** | No data available | No data available |
| **Lipids** | No data available | No data available |
| **Sucrose** | LD50 oral rat | 29700 mg/kg |

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| **Additional information** | No data available |
| **Serious eye damage/irritation** | No data available |
| **Skin corrosion/irritation** | No data available |
| **Sensitization** | No data available |
| **STOT-single exposure** | No data available |
| **STOT-repeated exposure** | No data available for mRNA-1345. For another chemically similar, same platform mRNA vaccine:<br>Rat (4 doses), IM LOAEL: ≥9 µg/dose<br>Effects: Hematology changes, reversible effects on lymph node, spleen, liver, and bone marrow, and inflammation at the site of injection. |
| **Reproductive toxicity** | No data available for mRNA-1345. For another chemically similar, same platform mRNA vaccine:<br>Rat, IM NOAEL: 100 µg/dose<br>Effects: none reported on fertility parameters. |
| **Developmental toxicity** | No data available for mRNA-1345. For another chemically similar, same platform mRNA vaccine:<br>Rat (4 doses) IM Fetal NOAEL: 150 µg/dose (highest dose tested)<br>Maternal IM LOAEL: 15 µg/dose<br>Effects: Injection site reactions, abnormal gait, piloerection, transient effects on body weight. |
| **Genotoxicity** | No data available for mRNA-1345. For another chemically similar, same platform mRNA vaccine:<br><br>*In vitro:*<br>Bacterial reverse mutation assay (e.g. Ames test): negative<br>Micronucleus test (peripheral human lymphocytes): negative<br><br>*In vivo:*<br>IV dosed up to 2.6 mg/kg (female) and 5.2 mg/kg (male) rat micronucleus test: positive<br>Effects: Results were not dose dependent and were associated with minimal bone marrow toxicity in the animals. |

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| **Carcinogenicity** | No data available<br>None of the components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen. |
| **Aspiration hazard** | No data available |
| **Experience with humans** | See "Section 2 - Other Hazards". |

## SECTION 12: Ecological information

**Toxicity**

| Component | Type | Concentration |
|---|---|---|
| **mRNA** | No data available | No data available |
| **Lipids** | No data available | No data available |
| **Sucrose** | No data available | No data available |

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| **Persistence and degradability** | Ribonucleotide in water expected to degrade rapidly in environment. |
| **Bioaccumulative potential** | Not expected to bioaccumulate. |
| **Mobility in soil** | No data available |
| **Results of PBT assessment** | No data available |
| **Other adverse effects** | No data available |
| **Note** | No special precautions are necessary. |

## SECTION 13: Disposal conside ations

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| **Waste treatment methods** | Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g, appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g, appropriately permitted municipal or on-site wastewater treatment facility. |

## SECTION 14: Transport information

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| **Transport** | Based on the available data, this mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG. |
| **UN number** | None assigned. |
| **UN proper shipping name** | None assigned. |
| **Transport hazard class(es) (DOT)** | None assigned. |
| **Packing group** | None assigned. |
| **Marine pollutant** | Based on the available data, this mixture is not regulated as an environmental hazard or a marine pollutant. |
| **Special transport precautions** | Avoid release to the environment. |
| **Transport in bulk according to Annex II of Marpol and the IBC Code** | Not applicable. |

## SECTION 15: Regulatory information

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| **Safety, health and environmental regulations/legislation specific for the substance or mixture** | This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information. |
| **Chemical safety assessment** | No chemical safety assessment has been carried out. |
| **TSCA** | Drugs are exempt from TSCA. |
| **SARA Section 313 - Emission Reporting** | This substance or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372. |
| **California Proposition 65** | California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm. |
| **Additional information** | No additional information available. |

## SECTION 16: Other information

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| **Full text of H phrases and GHS classification** | Not applicable. |
| **Data sources** | Information from published literature and internal company data. |

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| **Abbreviations and acronyms** | ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System |
| **Issue date** | 18 January 2024 |
| **Current revision** | 2.1 |
| **Indication of changes** | All sections of this SDS have been updated. |
| **Disclaimer** | The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel. |