Safety Data Sheet

SECTION 1: Identification

Contact information

General

Moderna, Inc.
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Emergency telephone number +1 (617) 714-6500 (Availability: Monday-Friday, 9 am to 5 pm EST)

Product identifier	SARS-CoV2 vaccine
Synonyms	mRNA-1273 and its variants
Trade name	Spikevax
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.
Note	This SDS is written to address potential worker health and safety issues associated with the handling of the mixture.

SECTION 2: Hazard(s) identification

Classification of the substance or mixture

Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Consult prescribing/packaging information. The classification and labeling listed below is for bulk drug product.

Not classified

Label elements

GHS Hazard pictograms	Not applicable
GHS Signal word	Not applicable
GHS Hazard statements	Not applicable
GHS Precautionary statements	Not applicable

Other hazards

SARS-CoV2 vaccine is an mRNA vaccine against the 2019 novel coronavirus. 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. Commonly observed adverse effects include injection site reactions, fatigue, headache, chills, muscle/joint pain, nausea/vomiting, axillary swelling/tenderness, and fever.

The mRNA in SARS-CoV2 vaccine is not viral or pathogenic and does not require specific biosafety handling recommendations.

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.

SECTION 3: Composition/information on ingredients

Ingredient	CAS number	EINECS/ELINCS#	Amount	GHS classification
Sucrose	57-50-1	200-334-9	5 – 10 %	Not classified
Lipids	N/A	N/A	1 – 3 %	Not classified
mRNA	N/A	N/A	0.01 – 1 %	Not classified

Note The primary ingredient in this mixture is sterile water. The remaining components are not hazardous and/or are

present at amounts below reportable limits. Sucrose is included because it has an OEL and is present at or above 1%. 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

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

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. As product is an aqueous solution, it is not expected to be flammable.
Explosion hazard	No information identified. As product is an aqueous solution, it is not expected to be explosive.

Special protective equipment and precautions for fire-fighters

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

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

Methods for cleaning up	If vials are broken or crushed, 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

Precautions for safe handling	If vials are crushed or broken, drug substance may be released. Follow recommendations for handling bulk formulated/packaged 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 vapors/mist/spray.

Conditions for safe storage, including any incompatibilities

Storage conditions	Protect from light. Store in a dry, cool and well-ventilated place. Keep/Store away from incompatible materials.
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	BE - Limit value	10 mg/m³
	ES - VLA-ED	10 mg/m³
	FR - VME	10 mg/m³
	IE - OEL (8 hours ref)	10 mg/m³
	IE - OEL (15 min ref)	20 mg/m³
	LT - IPRV	10 mg/m³
	PT - OEL TWA	10 mg/m³
	GB - WEL TWA	10 mg/m³
	GB - WEL STEL	20 mg/m³

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

Physical state	Liquid
Appearance	Liquid, packaged in glass vial
Formula	Mixture - Not applicable
Molecular mass	Micture - Not applicable
Colour	White to off-white
Odour	No data available
Odour threshold	No data available
pH	7.5
Melting point	Not applicable
Freezing point	No data available
Boiling point	No data available
Flash point	As product is an aqueous solution, it is not expected to be flammable.
Relative evaporation rate (butylacetate=1)	No data available
Flammability (solid, gas)	Not applicable

Vapour pressure	No data available
Relative vapour density at 20 °C	No data available
Relative density	No data available
Solubility	Water: oluble
Log Pow	No data available
Auto-ignition temperature	As product is an aqueous solution, it is not expected to auto-ignite.
Decomposition temperature	No data available
Viscosity, kinematic	Not applicable
Viscosity, dynamic	Not applicable
Explosive limits	Not applicable
Explosive properties	As product is an aqueous solution, it is not expected to be explosive.
Oxidising properties	No oxidizing properties.

SECTION 10: Stability and reactivity

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, 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

Additional information	No data available
Serious eye damage/irritation	No data available
Skin corrosion/irritation	No data available
Sensitisation	No data available
STOT-single exposure	No data available
STOT-repeated exposure	No data available for this product. For other chemically similar mRNA vaccines using the same LNP platform: Rat (up to 4 doses), IM occupationally relevant LOAEL: 8.9 µg/dose 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 this product. For other chemically similar mRNA vaccines using the same LNP platform: Rat, IM NOAEL: 150 µg/dose (highest dose tested) Effects: None reported.
Developmental toxicity	No data available for this product. For other chemically similar mRNA vaccines using the same LNP platform: Rat (4 doses: 28 and 14 days prior to mating and gestation days 1 and 13) Fetal IM NOAEL: 152 µg/dose (highest dose tested) Maternal IM LOAEL: 152 µg/dose Effects: Injection site reactions, abnormal gait, piloerection, transient effects on body weight.
Genotoxicity	No data available for this product. As a ribonucleotide it is not expected to be genotoxic. For the novel lipid in the mRNA product: *In vitro:* Bacterial reverse mutation assay (e.g., Ames test): negative Micronucleus test (peripheral human lymphocytes): negative For other chemically similar mRNA vaccines using same LNP platform: Equivocal results likely due to systemic inflammatory response with IV administration.

	Overall, genotoxic risk is considered low due to minimal systemic exposure, minimal duration of exposure, and negative *in vitro* results.
Carcinogenicity	No data available for this product. None of the components of this 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".
Other information	The toxicological properties of this mixture have not been fully characterized.

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

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 considerations

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.

SECTION 14: Transport information

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

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 data available.

SECTION 16: Other information

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

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
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