Version	Revision Date:	SDS Number:	Date of last issue: 2021/02/09
3.5	2021/02/11	100000015774	Date of first issue: 2020/05/05

SECTION 1. IDENTIFICATION

Substance name : Ad26.COV2.S Drug Product
Also known as Ad26COVS1

Reference number : JNJ-78436735-AAA

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560
US

Telephone : (609) 730-2000

E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Emergency telephone number : CHEMTREC US: 1-800-424-9300
CHEMTREC International: +1 703-527-3887

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical, intended for medical use
Recombinant, replication-incompetent human adenoviral vector type 26 (Ad26) vaccine.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization in susceptible persons.
Health Hazards, Risk Group 2
Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Substance name : Ad26.COV2.S Drug Product

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
ethanol	64-17-5	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	This material is being evaluated for use as a biological agent or in the manufacturing of a biological agent. If accidently injected (needle prick): Wash off immediately with plenty of water. Consult a physician.
If inhaled	:	If breathed in, move person into fresh air. Consult a physician.
In case of skin contact	:	Take off contaminated clothing and shoes immediately. Immediately wash with water a 10% povidone solution (Betadine) ~20 minutes. Consult a physician. Wash contaminated clothing before re-use.
In case of eye contact	:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses. Consult a physician.
If swallowed	:	If swallowed, rinse mouth with water (only if the person is conscious). Call a physician immediately.
Most important symptoms and effects, both acute and delayed	:	No information available.
Notes to physician	:	Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during firefighting	:	The product is not flammable.
Further information	:	No information available.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Special considerations for Biological Risk from any particular micro-organism is based on several factors including amount of infectious material present, infectious dose, mode of transmission, seriousness of illness, susceptibility of the host and availability of vaccines or drugs. In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate. Avoid direct contact with broken glass, plastic and other sharps. Avoid splashes and spray formation. Evacuate personnel to safe areas. Avoid direct contact and significant aerosol exposure.
Environmental precautions	:	Should not be released into the environment. Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Allow aerosols to settle and cover the spill with absorbent. Apply for disinfection of surfaces and spills, 0.1 M resp. 0.25M NaOH or 1% Virkon S for at least 15 min. Alternatively, use appropriate validated disinfectants and methods against adenoviral vectors according to local legislation.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	The product is not flammable.
Advice on safe handling	:	Avoid splashes. Avoid formation of aerosol. To avoid thermal decomposition, do not overheat. Avoid inhalation, ingestion and contact with skin and eyes. Use personal protective equipment as required.
Conditions for safe storage	:	To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat. Keep locked up. Keep frozen.
Recommended storage temperature	:	-13 - 5 °F / -25 - -15 °C
Further information on storage stability	:	Drug product short-term storage : -13 - 5 °F / -25 - -15 °C Drug product long-term storage : -121 - -67 °F / -85 - -55 °C Drug product storage at local site prior to use : 36 - 46 °F / 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
ethanol	64-17-5	TWA	1,000 ppm	ACGIH
		STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m3	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m3	OSHA Z-1
		TWA	1,000 ppm 1,900 mg/m3	OSHA P0

Engineering measures : All open manipulations and process (and process related) activities must be carried out in physical containment device or ventilated enclosure (e.g. Biosafety cabinet).

Personal protective equipment

Respiratory protection : Engineering controls should always be the primary method of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.

Hand protection

Remarks : Disposable gloves

Eye protection : Safety glasses

Skin and body protection : Lab coat

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Specific safety testing of the Product confirmed the absence of replication competent adenovirus (RCA) (< 1 RCA/3E10 vp) and therefore allows handling under BSL-1/contained use level 1 conditions or best medical practices for vaccine administration and related procedures depending on local legislation or requirements.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : frozen, liquid

Colour : clear, to, opalescent

pH	:	6.5

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Heat, flames and sparks. Exposure to light.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute toxicity (other routes of administration)	:	Remarks: Acute toxicity studies are generally not conducted for vaccines.

Components:

ethanol:

Acute oral toxicity	:	LD50 (Rat): 7,060 mg/kg Symptoms: nausea Assessment: The substance or mixture has no acute oral toxicity
Acute inhalation toxicity	:	LC50 (Rat): 2,000 mg/l Exposure time: 4 h Test atmosphere: vapour Assessment: The substance or mixture has no acute inhalation toxicity LC50 (Mouse): > 20 mg/l Exposure time: 4 h Test atmosphere: vapour
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Components:

ethanol:

Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation

Components:

ethanol:

Result: Eye irritation

Respiratory or skin sensitisation

Components:

ethanol:

Result: Does not cause skin sensitisation.

Germ cell mutagenicity

Product:

Germ cell mutagenicity - Assessment	:	No data available, but unlikely to be mutagenic due to the nature of the product., Nonclinical biodistribution studies did not show distribution of the Ad26 vector to the gonads.

Components:

ethanol:

Genotoxicity in vitro	:	Test Type: Ames test Species: Mutagenicity (Salmonella typhimurium - reverse mutation assay) Result: negative

Carcinogenicity

Product:

Carcinogenicity - Assessment	:	No data available, but unlikely to be carcinogenic due to the nature of the product.

IARC	Group 1: Carcinogenic to humans	
	ethanol	64-17-5
	Group 1: Carcinogenic to humans	
OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.	

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Product:

Reproductive toxicity - Assessment : Animal testing with another Ad26-based vaccine did not show any effects on female fertility (male fertility is not tested).

Teratogenicity - Assessment : Animal experiments with another Ad26-based vaccine did not show teratogenic effects.

STOT - single exposure

Components:

ethanol:

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Product:

Remarks: No significant adverse effects were reported

Components:

ethanol:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Product:

Remarks: Did not cause specific target organ toxicity in experimental animal studies.

Aspiration toxicity

Components:

ethanol:

No aspiration toxicity classification

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

ethanol:

Toxicity to fish	:	(Leuciscus idus (Golden orfe)): 8,140 mg/l Exposure time: 96 h Test Type: LC50
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 9,268 - 14,221 mg/l Exposure time: 48 h
Toxicity to algae	:	EC50 (Chlorella pyrenoidosa (aglae)): > 100 mg/l Exposure time: 72 h

Persistence and degradability

Components:

ethanol:

Biodegradability	:	Biodegradation: > 70 % Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

ethanol:

Bioaccumulation	:	Remarks: Accumulation in aquatic organisms is unlikely.
Partition coefficient: n-octanol/water	:	log Pow: -0.35 (20 °C) Method: OECD Test Guideline 117

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	In accordance with National, Federal, State and Local regulations. Decontaminate all waste before disposal (steam sterilization, chemical disinfection and/or incineration).

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good
Remarks : IATA §3.9.2.5.5 COVID-19 vaccines containing GMOs or GMMOs, including those in clinical trials, are not subject to these Regulations.
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IMDG-Code
Not regulated as a dangerous good
Remarks : IMDG §2.9.2.2

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know
No components are subject to the Massachusetts Right to Know Act.

Massachusetts Right To Know
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5
Sodium chloride (NaCl)	7647-14-5
L-Histidine	71-00-1

Pennsylvania Right To Know

water	7732-18-5
Sodium chloride (NaCl)	7647-14-5
L-Histidine	71-00-1

New York City Hazardous Substances

ethanol	64-17-5

New York City Hazardous Substances

ethanol	64-17-5

California Prop 65 , which is/are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

ethanol 64-17-5

, which is/are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

ethanol 64-17-5

Other regulations : Restricted to professional users.

Biosafety Regulations and Guidelines:
World Health Organization, Laboratory biosafety manual. - 3rd ed., ISBN 92 4 154650 6 (LC/NLM classification: QY 25) WHO/CDS/CSR/LYO/2004.11.
U.S. Department of Health and Human Services Public Health Services, Biosafety in Microbiological and Biomedical Laboratories (BMBL) - 5th ed., HHS Publication No. (CDC) 21-1112

TSCA list

Not relevant

SECTION 16. OTHER INFORMATION

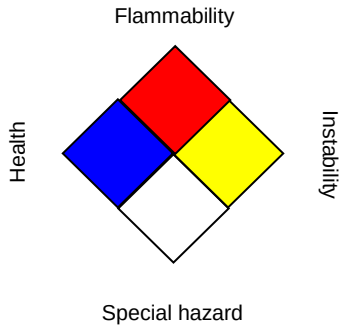
Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Sub-

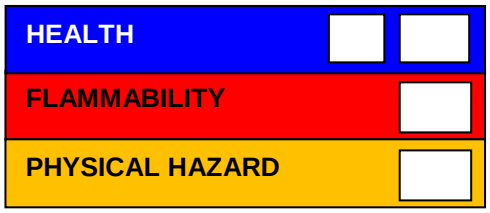
stance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

NFPA:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

For research use only.
This SDS received a major version update triggered by a change in Section 1.

Revision Date : 2021/02/11

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

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