

SAFETY DATA SHEET



Version 1.3 Revision Date: 28.05.2021 SDS Number: 25943 Date of last issue: 18.03.2021
Date of first issue: 16.09.2020

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

AZD1222

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD Emergency Telephone
PO Box 131 +44 (0) 1235 239 670
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

ChAdOx1 nCoV-19
Also valid for:
AZD2816
AZD3990
CAS No. : Not applicable

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : COVID-19 Vaccine

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

The product does not meet the definition of a hazardous chemical.
Based on the replication deficient nature of the adenovirus vector, there is no risk of pathogenicity and virulence in case of an incidental occupational exposure.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	<= 7.5
Ethanol	64-17-5	<= 0.5
AZD1222	Not Assigned	<= 1

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest.
Obtain medical attention if ill effects occur.

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 18.03.2021
1.3	28.05.2021	25943	Date of first issue: 16.09.2020

- In case of skin contact : Wash skin with soap and water for at least 15 minutes. Seek medical attention for cuts, abrasions, punctures or material contact with broken skin.
- In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. Obtain medical attention if ill effects remain.
- If swallowed : Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention if ill effects occur.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
- Notes to physician : Symptomatic treatment and supportive therapy as indicated. Emergency medical treatment advice varies within different countries. For further information consult the Local National Poisons Information Services.
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use suitable extinguishing media for the surrounding fire.
- Unsuitable extinguishing media : -
- Specific hazards during firefighting : Low fire hazard.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages. See Section 8.
- Environmental precautions : Prevent entry into drains unless inactivated or denatured.
- Methods and materials for containment and cleaning up : Absorb spillages onto sand, earth or any suitable adsorbent material. Transfer to a container for disposal. Spills should be disinfected with an appropriate antiviral disinfectant.
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SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid contact with skin and eyes.
- Conditions for safe storage : Keep containers properly sealed when not in use.
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Version 1.3 Revision Date: 28.05.2021 SDS Number: 25943 Date of last issue: 18.03.2021
Date of first issue: 16.09.2020

Further information on storage stability : Long term storage of the bulk vaccine vector solutions should be stored frozen at ≤ -65 °C.
Protect from light.
Short-term use, bulk vaccine vector solution may be thawed and refrigerated at 2 - 8 °C.

Vaccine vector Drug product in glass vials should be stored as directed on the label.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m ³	AU OEL
		Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica		
		TWA	10 mg/m ³	ACGIH
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m ³	AU OEL
		STEL	1,000 ppm	ACGIH

Engineering measures : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Handle at Biosafety Level 1 (BSL1).
Where there may be a risk of aerosol generation a Biosafety Level 2 (BSL2) is recommended.
Prevent entry into drains unless inactivated or denatured.

Personal protective equipment

Respiratory protection : Use appropriate respiratory protective equipment.

Eye protection : Wear appropriate eye protection.

Skin and body protection : Wear appropriate protective clothing and gloves.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

Version 1.3 Revision Date: 28.05.2021 SDS Number: 25943 Date of last issue: 18.03.2021
Date of first issue: 16.09.2020

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : 6.6

Melting point/range : Not applicable

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : Not applicable

Lower explosion limit / Lower flammability limit : Not applicable

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)

 Water solubility : No data available

 Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : Not applicable.

Decomposition temperature : Not applicable

Viscosity

 Viscosity, dynamic : No data available

Version	Revision Date:	SDS Number:	Date of last issue: 18.03.2021
1.3	28.05.2021	25943	Date of first issue: 16.09.2020

Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	None known.
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Remarks: Unlikely to be toxic if swallowed.
Acute inhalation toxicity	:	Remarks: No information available on acute toxicity. May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: No information available.

Components:

Ethanol:

Acute oral toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute inhalation toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: Unlikely to be hazardous by skin absorption.

11.2 Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks	:	Unlikely to be corrosive to the skin. Signs of local (injection site) effects were reported from studies on animals receiving repeated intramuscular
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Version	Revision Date:	SDS Number:	Date of last issue: 18.03.2021
1.3	28.05.2021	25943	Date of first issue: 16.09.2020

injections.

Local injection site reactions reported in humans.
May cause effects as described under single exposure.(STOT)

Components:

Ethanol:

Remarks : Slight/mild irritant.
Repeated or prolonged contact may cause defatting of the skin resulting in dryness, cracking and dermatitis.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks : Unlikely to be a severe irritant to the eye.
In case of exposure, mild conjunctivitis is possible.

Components:

Ethanol:

Remarks : The vapour and liquid are irritant.
May cause strong stinging and burning sensation.

11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Remarks : May cause effects as described under single exposure.(STOT)

Components:

Ethanol:

Remarks : No information available.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Product:

Germ cell mutagenicity - Assessment : Not expected to be genotoxic.

Version	Revision Date:	SDS Number:	Date of last issue: 18.03.2021
1.3	28.05.2021	25943	Date of first issue: 16.09.2020

Components:**Ethanol:**

Germ cell mutagenicity - Assessment : No information available.

11.6 Carcinogenicity

Not classified based on available information.

Product:

Carcinogenicity - Assessment : Not expected to be carcinogenic.

Components:**Ethanol:**

Carcinogenicity - Assessment : No information available.

11.7 Reproductive toxicity

Not classified based on available information.

Product:

Reproductive toxicity - Assessment : Studies in mice (intramuscular injection) have shown no reproductive or developmental toxicity.

Components:**Ethanol:**

Reproductive toxicity - Assessment : No information available.

11.8 STOT - single exposure

Not classified based on available information.

Product:

Exposure routes : Inhalation
Remarks : In case of exposure, flu-like symptoms are possible.

Remarks : Following intramuscular injection, rare cases of hypersensitivity (including anaphylactic reaction and angioedema), and thrombosis (in combination with thrombocytopenia) have been reported.

Based on human experience.

Components:**Ethanol:**

Exposure routes : Inhalation, Ingestion
Remarks : The vapour has anaesthetic properties and when inhaled at high concentrations, it may cause respiratory irritation, headache, fatigue, dizziness and incoordination.

SAFETY DATA SHEET



Version 1.3 Revision Date: 28.05.2021 SDS Number: 25943 Date of last issue: 18.03.2021
Date of first issue: 16.09.2020

Minute amounts aspirated into the lungs during ingestion may cause pulmonary injury.

11.9 STOT - repeated exposure

Not classified based on available information.

Product:

Remarks : Studies in animals have shown that repeated doses produce no significant effects.
May cause effects as described under single exposure.(STOT)

Components:

Ethanol:

Exposure routes : Inhalation
Target Organs : Liver
Remarks : Repeated exposure to high levels may produce adverse effects on the liver.

11.10 Aspiration toxicity

Not classified based on available information.

Product:

No information available.

Components:

Ethanol:

No information available.

Further information

Product:

Remarks : This health hazard assessment is based on a consideration of the composition of this preparation.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish :
Remarks: Unlikely to be toxic to aquatic organisms.

Components:

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 13,500 - 14,900 mg/l
Exposure time: 96 h

SAFETY DATA SHEET



Version 1.3 Revision Date: 28.05.2021 SDS Number: 25943 Date of last issue: 18.03.2021
Date of first issue: 16.09.2020

LC50 (Danio rerio (zebra fish)): 14,200 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9,268 - 14,221 mg/l
Exposure time: 48 h
Test Type: static test

Persistence and degradability

Product:

Biodegradability : Remarks: Expected to be biodegradable

Components:

Ethanol:

Biodegradability : Remarks: The substance is substantially biodegradable in water.
There is evidence of photodegradation in air.

BOD/COD : BOD/COD: 0.57 %

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: Unlikely to be bioaccumulative.

Components:

Ethanol:

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

Mobility in soil

Product:

Mobility : Remarks: No information available.

Distribution among environmental compartments : Remarks: No information available.

Components:

Ethanol:

Mobility : Remarks: Water solubility \geq 1 mg/l.
Liquid with high volatility.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

Version 1.3 Revision Date: 28.05.2021 SDS Number: 25943 Date of last issue: 18.03.2021
Date of first issue: 16.09.2020

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Waste material should be disposed of in accordance with local requirements in a clinical waste bin. Disposal should be in accordance with local, state or national legislation.
- Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.
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SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

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

In order to comply with legal duties it is necessary to consult local and national legislation.

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components of this product are reported in the following inventories:

- TCSI : Not listed
- TSCA : Substance(s) not listed on TSCA inventory
- AICS : Not listed
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
-

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 18.03.2021
1.3	28.05.2021	25943	Date of first issue: 16.09.2020

AZD1222

ENCS	:	Not listed
ISHL	:	Not listed
KECI	:	Not listed
IECSC	:	Not listed
CHINV	:	Not in compliance with the inventory
REACH	:	Not in compliance with the inventory
TRINV	:	Not in compliance with the inventory

SECTION 16. OTHER INFORMATION

Further information

Revision Date	:	28.05.2021
Other information	:	Minor changes: 6 11 13
Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
AU OEL / TWA	:	Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CHINV - China Inventory; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM - In-house occupational exposure limit; CPR - Controlled Products Regulations; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; HYG - Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 18.03.2021
1.3	28.05.2021	25943	Date of first issue: 16.09.2020

Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen - Capable of causing respiratory sensitization; Sk - Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV - Threshold Limit Value (ACGIH); TLV-C - Threshold Limit Value Ceiling limit (ACGIH); TRINV - Turkey Inventory; TSCA - Toxic Substances Control Act (United States); TWA - Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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