

Safety Data Sheet

GVOKE VialDx, 5mg/mL

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**1.1 Product Identifier**

Trade Name:	GVOKE VialDx
Product Code(s):	1 Pack: 0517-2901-01 10 Pack: 0517-2901-10
SDS Date:	12 Oct 2021

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Product Use:	Pharmaceutical product
Uses Advised Against:	All other uses

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer / Responsible Party:	Xeris Pharmaceuticals, Inc. 1375 W. Fulton St. Suite 1300 Chicago, IL 60607
Distributed by:	American Regent, Inc. Shirley, NY 11967

1.4 Emergency Telephone Number

+1 877-937-4737 (9 AM - 5 PM US Central Time, M-F)

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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

CLP/OSHA/WHMIS/GHS Classification (1272/2008): Flammable liquid Category 4

2.2 Label Elements:

Warning

- H227 Combustible Liquid
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P280 Wear protective gloves.
- P370+P378 In case of fire: Use carbon dioxide, alcohol-resistant foam, dry chemical or water spray to extinguish.
- P403 Store in a well-ventilated place.
- P501 Dispose of contents and containers in accordance with national and local regulations.

2.3 Other Hazards

None known.

SECTION 3: COMPOSITION / INFORMATION OF INGREDIENTS

3.1 Substances

N/A

3.2 Mixtures:

Chemical Name	CAS / EINECS / REACH Reg. Number	% (w/w)	CLP/GHS Classification (1272/2008)
Dimethyl Sulfoxide	67-68-5 / 200-664-3	Proprietary	Flammable liquid Category 4 (H227)
Trehalose Dihydrate	99-20-7 / 200-739-6	Proprietary	Not classified as hazardous
Mannitol	69-65-8 / 200-711-8	Proprietary	Not classified as hazardous
Glucagon	16941-32-5	Proprietary	Not classified as hazardous
Sulfuric Acid	7664-93-9 / 231-639-5	Trace	Skin Corrosive Category 1A (H314) Eye Damage Category 1 (H318)

The exact percentage is a trade secret. See Section 16 for full text of GHS hazard phrases.

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SECTION 4: FIRST-AID MEASURES

4.1 Description of First Aid Measures

First Aid

Eye Contact:	Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.
Skin Contact:	Wash with soap and water. Remove contaminated clothing. Get medical attention if irritation develops or persists. Launder clothing before reuse
Inhalation:	Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.
Ingestion:	In the case of accidental ingestion, do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur.

See Section 11 for more detailed information on health effects.

4.2 **Most important symptoms and effects, both acute and delayed:**

May cause mild eye and skin irritation. Swallowing or prolonged skin contact may cause nausea, vomiting, diarrhea, and increased blood pressure.

4.3 **Indication of any immediate medical attention and special treatment needed:**

Medical advice is recommended for ingestion or widespread skin contact.

SECTION 5: FIRE FIGHTING MEASURES

5.1 **Extinguishing Media**

Use carbon dioxide, alcohol-resistant foam, dry chemical, or water spray to extinguish.

5.2 **Special Hazards Arising from the Substance or Mixture**

Fire and Explosion Hazards:	Combustible liquid.
Combustion Products:	Carbon oxides, Sulfur oxides

5.3 **Advice for Fire-Fighters**

Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water

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SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1 **Personal Precautions, Protective Equipment and Emergency Procedures**
Evacuate the area of all unprotected people. Wear appropriate protective equipment. Eliminate all ignition sources.
- 6.2 **Environmental Precautions**
Prevent entry in storm sewers and waterways. Report spill as required by local and national regulations.
- 6.3 **Methods and Material for Containment and Cleaning Up**
Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.
- 6.4 **Reference to Other Sections**
Refer to Section 8 for personal protective equipment, and Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

- 7.1 **Precautions for Safe Handling**
Avoid contact with eyes, skin, and clothing. Wash thoroughly with soap and water after handling. Handle product with care to avoid needle contact. Keep product away from heat and flames.
- 7.2 **Conditions for Safe Storage, Including any Incompatibilities**
Store as indicated on product packaging in a secure location. Store at room temperature in a well-ventilated area. Keep away from heat and ignition sources.

7.3 **Specific end use(s)**

Industrial Uses:	None
Professional Uses:	Pharmaceutical Product

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SECTION8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Chemical Name	US OEL	EU OEL
Dimethyl Sulfoxide	250 ppm TWA AIHA WEEL	50 ppm TWA skin DFG MAK
Trehalose Dihydrate	None Established	None Established
Mannitol	None Established	None Established
Glucagon	None Established	None Established
Sulfuric Acid	1 mg/m ³ TWA OSHA PEL 0.2 mg/m ³ (thoracic) TWA ACGIH TLV	1 mg/m ³ TWA, 3 mg/m ³ STEL Belgium, Spain 0.05 (thoracic) TWA EU IOEL< France 0.1 mg/m ³ (inhalable) DFG MAK

8.2 Exposure Controls

Recommended Monitoring Procedures

None

Appropriate Engineering Controls

Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Personal Protective Measures

Eye/Face Protection	Safety glasses with sideshields in accordance with EN166, NIOSH or equivalent.
Skin Protection	Impervious clothing recommended if needed to avoid skin contact.
Hands	Impervious gloves such as rubber are recommended if needed to avoid skin contact during bulk processing.
Respiratory Protection	If the exposures are high, use an approved respirator with an organic vapor/ particulate filter or supplied air respirator. Selection of respiratory protection depends on the contaminant type, form, and concentration. Select in accordance with good Industrial Hygiene practice. Use respirators tested under appropriate government standards such as NIOSH or CEN.
Other Protection	Suitable eye and skin washing facilities should be available in the work area.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties

Appearance	Clear Solution
Autoignition Temperature:	~300°C (572°F)
Boiling Point:	~189°C (372°F)
Decomposition Temperature:	Not established
Evaporation Rate:	Not established
Explosive Properties:	None
Flash Point:	~90°C (194°F)
Lower Flammability Limit:	2.60%
Upper Flammability Limit:	28.50%
Melting/Freezing Point:	Not established
Molecular Formula:	Mixture
Molecular Weight:	Mixture
Octanol/Water Partition Coefficient:	Not established
Odor Threshold	Not applicable
Odor:	Odorless
Oxidizing Properties:	None
pH:	Not established
Relative Density:	~1.1
Solubility:	Soluble in water
Specific Gravity (H2O= 1):	Not established
Vapor Density(Air=1):	>1
Vapor Pressure:	0.56 hPa@20 °C
Viscosity:	Not established

9.2 Other Information

None known.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not reactive under normal conditions.

10.2 Chemical Stability

Stable.

10.3 Possibility of Hazardous Reactions

None known.

10.4 Conditions to Avoid

Heat and open flames.

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10.5 Incompatible Materials

Incompatible with strong oxidizing agents, acid chlorides, phosphorus halides, strong acids, strong reducing agents.

10.6 Hazardous Decomposition Products

Carbon dioxide, carbon monoxide, sulfur oxides. Thermal decomposition will release formaldehyde, methyl mercaptan, and sulfur dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects

Eye Contact	May cause slight irritation.
Skin Contact	May cause slight irritation. Prolonged or widespread skin contact may cause effects similar to ingestion.
Inhalation	Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract and symptoms similar to ingestion.
Ingestion	Swallowing may cause nausea, vomiting, headache, diarrhea, increased blood sugar, high blood pressure.
Acute Toxicity	Dimethyl sulfoxide: LD50 oral rat 28,300 mg/kg; LD50 dermal rat 40,000 mg/kg; LC50 inhalation rat >5.3 mg/L/4 hr. (no mortality)
Skin Corrosion / Irritation	Components are not skin irritants.
Eye Damage / Irritation	Components are not eye irritants.
Respiratory Irritation	Components are not respiratory irritants.
Respiratory Sensitization	Components are not respiratory sensitizers.
Skin Sensitization	Components are not skin sensitizers.
Germ Cell Mutagenicity	None of the components have been shown to cause germ cell mutagenicity. Synthetic glucagon was negative in the bacterial reverse mutation assay but positive in the Chinese Hamster Ovary Cell assay in the absence of metabolic activation. Glucagon was slightly positive in the mouse micronucleus test in males but negative in females. Dimethyl sulfoxide is not mutagenic in-vitro or in-vivo.
Reproductive Toxicity	No teratogenic effects were observed in rats or rabbits given glucagon at doses up to 10 mg/kg. No adverse reproductive effects were observed in a 90 day study in rats with dimethyl sulfoxide at concentrations up to 2800 mg/m ³ .
Carcinogenicity	Sulfuric acid is the form of a strong acid mist is classified by IARC and NTP as a known human carcinogen. None of the other components are classified as carcinogens by IARC, NTP, OSHA or EU CLP. Glucagon has not been tested for carcinogenicity.
Specific Target Organ Toxicity	<i>Single Exposure:</i> Components are not classified as target organ toxins. <i>Repeat Exposure:</i> Components are not classified as target organ toxins.
Aspiration Toxicity	Components are not aspiration hazards.

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SECTION 12: ECOLOGICAL INFORMATION

- 12.1 Toxicity**
Dimethyl sulfoxide: LC50 fish 25,000-43,000 mg/L/96 hr; EC50 daphnia magna 24,600 mg/L/48 hr; ErC50 algae 17,000 mg/L/72 hr.
- 12.2 Persistence and Degradability**
Dimethyl sulfoxide is readily biodegradable.
- 12.3 Bioaccumulative Potential**
Dimethyl sulfoxide is not bioaccumulative.
- 12.4 Mobility in Soil**
No data available.
- 12.5 Results of PBT and vPvB Assessment**
Components do not meet the criteria of PBT or vPvB.
- 12.6 Other Adverse Effects:**
No data available.

SECTION 13: DIPSOAL CONSIDERATIONS

- 13.1 Waste Treatment Methods**
Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: TRANSPORATION INFORMATION

		US DOT (non-bulk)	US DOT (bulk)	Canadian TDG	EU ADR/RID	IMDG
14.1	UN Number	N/A	NA1993	N/A	N/A	N/A
14.2	UN Proper Shipping Name	NR	Combustible liquid, n.o.s.(dimethylsulfoxide)	NR	NR	NR
14.3	Transport Hazard Class(es)	N/A	Comb. Liq	N/A	N/A	N/A
14.4	Packing Group	N/A	III	N/A	N/A	N/A
14.5	Environmental Hazards	No	No	No	No	No

N/A – Not Applicable

NR – Not Regulated

- 14.6 Special Precautions for User:**
None
- 14.7 Transport in Bulk According to Annex II MARPOL 73/78 and the IBC Code:**
Not applicable – product is transported only in packaged form.

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SECTION 15: REGULATORY INFORMATION

16.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

US Regulations

CERCLA:

This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state, and local regulations.

SARA Hazard Category (311/312):

Refer to Section 2 for the OSHA Hazard Classification.

EPA SARA 313:

This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory:

This product is a human drug and not subject to TSCA.

CANADA

Canadian CEPA:

This product is a human drug and not subject to CEPA regulations.

EU Regulations

This SDS was prepared in compliance with Regulation (EC) No. 1907/2006 (REACH) and its amendments and Regulation (EC) No 1272/2008 (CLP).

This product is a human medicinal and not subject the REACH registration.

SECTION 16: OTHER INFORMATION

CLP/GHS Hazard Statements for Reference (See Section 3):

H227 Combustible liquid.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.