

Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **Diastat® (diazepam rectal gel)**

Product Code • 366490650201; NDC 66490-650-20

Product Description • Prescription pharmaceutical product.

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

Recommended use • Finished Pharmaceutical Product; Diastat gel is intended for rectal administration to control bouts of increased epileptic seizure activity.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS

- Skin Irritation 2
Eye Irritation 2A
Reproductive Toxicity 2

Label elements

UN GHS

WARNING



Hazard statements • Causes skin irritation
Causes serious eye irritation

Suspected of damaging fertility or the unborn child.

Precautionary statements

Prevention ● Do not handle until all safety precautions have been read and understood.
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.

Response ● IF exposed or concerned: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation occurs: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Take off contaminated clothing and wash before reuse.

Storage/Disposal ● Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Benzoic acid	CAS:65-85-0 EINECS:200-618-2	<= 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Benzyl alcohol	CAS:100-51-6 EINECS:202-859-9	1.5%	UN GHS: Acute Tox. Oral 4; Acute Tox. Inhal. 4
Diazepam	CAS:439-14-5 EINECS:207-122-5	0.483%	UN GHS: NDA
Ethyl alcohol	CAS:64-17-5 EINECS:200-578-6	10%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Muta. 1B; Repr. 1B
Hydroxypropyl methylcellulose	CAS:9004-65-3	< 5%	UN GHS: NDA
Propylene glycol	CAS:57-55-6 EINECS:200-338-0	35% TO 45%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Sodium benzoate	CAS:532-32-1 EINECS:208-534-8	< 5%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	< 50%	UN GHS: not classified

Diastal delivers 2.5 mg diazepam in 0.5 ml of gel.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

Skin

- Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse.

Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

- If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- Contact with this product can irritate the nose, throat, eyes skin and other contaminated tissues. Skin absorption may cause nervousness, euphoria, dizziness, drowsiness, headache, pain, flushing, diarrhea, slurred speech, incoordination, asthma, runny nose and rash. Diazepam is a reproductive toxin by ingestion and intravenous injection and causes fetal developmental abnormalities. Diazepam is an allergen; subsequent exposures to very small amounts may cause allergic reaction in sensitive individuals.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Additional details are available on the product package insert or the Physicians Desk Reference.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media

- SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media

- No data available

Firefighting Procedures

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards

- None known - product is not flammable or combustible.

Hazardous Combustion Products

- No data available

Advice for firefighters

- Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions

- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Evacuate immediate area. Ventilate enclosed areas.

Emergency Procedures

- Keep unauthorized personnel away. For bulk material spills: Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an

appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Ventilate closed spaces before entering.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete. Refer to Section 13 for appropriate disposal procedures.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Use only in well ventilated areas (preferably in a chemical fume hood). Do not breathe dusts, vapors or mists. Do not get in eyes, on skin, or on clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Ethyl alcohol (64-17-5)	TWAs	Not established	1000 ppm TWAEV; 1880 mg/m ³ TWAEV	1000 ppm TWA; 1900 mg/m ³ TWA	1000 ppm TWA; 1900 mg/m ³ TWA
	STELs	1000 ppm STEL	Not established	Not established	Not established

Exposure controls

Engineering Measures/Controls

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Pictograms

- 

Respiratory

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. Not required during normal clinical use.

Hands

- Wear protective gloves .

Skin/Body

- Wear protective gloves/protective clothing/eye protection/face protection. Not required during normal clinical use.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke during work. Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties**Information on Physical and Chemical Properties**

Material Description			
Physical Form	Liquid Gel	Appearance/Description	Clear, colorless to pale yellow gel.
Color	Colorless to slightly yellow.	Odor	Mild alcohol odor.
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	pH	6.5 to 7.2
Specific Gravity/Relative Density	No data available	Water Solubility	Completely soluble
Viscosity	No data available	Oxidizing Properties:	No data available
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	No data available	UEL	No data available
LEL	No data available	Flame Height	No data available
Autoignition	No data available	Flammability (solid, gas)	No data available
Environmental			
Octanol/Water Partition coefficient	No data available	Persistence	No data available

Section 10: Stability and Reactivity**Reactivity**

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and humidities.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- This product is generally compatible with other common materials in a medical facility.

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components	
Diazepam (0.483%)	439-14-5
<p>Acute Toxicity: Ingestion/Oral-Rat LD50 • 249 mg/kg; Reproductive: Ingestion/Oral-Woman TDLo • 22800 µg/kg (25-36W preg); <i>Reproductive Effects:Effects on Newborn:Drug dependence;</i> Ingestion/Oral-Woman TDLo • 5 mg/kg (36W preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Cardiovascular (circulatory) system;</i> Intravenous-Woman TDLo • 400 µg/kg (39W preg); <i>Reproductive Effects:Specific Developmental Abnormalities:Cardiovascular (circulatory) system;</i> Tumorigen / Carcinogen: Ingestion/Oral-Mouse TDLo • 42 g/kg 80 Week(s)-Continuous; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria; Liver:Tumors</i></p>	

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Irritation 2
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 2
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2A

Potential Health Effects

Inhalation

- Acute (Immediate)**
- May mildly irritate the respiratory tract. Symptoms may include coughing and congestion.
- Chronic (Delayed)**
- No data available

Skin

- Acute (Immediate)**
- Causes skin irritation.
- Chronic (Delayed)**
- Repeated and prolonged exposure may cause sensitization. Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Eye

- Acute (Immediate)**
- Causes serious eye irritation.
- Chronic (Delayed)**
- No data available

Ingestion

- Acute (Immediate)**
- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)**
- No data available

Carcinogenic Effects			
	CAS	IARC	NTP
Diazepam	439-14-5	Group 3-Not Classifiable	Not Listed
Benzyl alcohol	100-51-6	Not Listed	Evidence of Carcinogenicity
Ethyl alcohol	64-17-5	Group 1-Carcinogenic	Evidence of Carcinogenicity

Reproductive Effects

- Reproduction studies in rats showed decreases in the number of pregnancies and in the number of surviving offspring following administration of an oral dose of 100 mg/kg/day (approximately 16 times the maximum recommended dose) prior to and during mating and throughout gestation and lactation. No adverse effects on fertility or offspring viability were noted at a dose of 80 mg/kg/day (approximately 13 times the maximum recommended dose). Nursing mothers: Diazepam and its metabolites may be present in human breast milk for prolonged periods of time after acute use of Diazepam rectal gel.

Section 12 - Ecological Information**Toxicity**

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	not regulated	NDA	NDA	NDA
TDG	NDA	not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	not regulated	NDA	NDA	NDA

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Propylene glycol	57-55-6	Yes	Yes	Yes
Diazepam	439-14-5	Yes	Yes	Yes
Benzoic acid	65-85-0	Yes	Yes	Yes
Sodium benzoate	532-32-1	Yes	Yes	Yes
Benzyl alcohol	100-51-6	Yes	Yes	Yes
Ethyl alcohol	64-17-5	Yes	Yes	Yes
Hydroxypropyl methylcellulose	9004-65-3	Yes	No	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Hydroxypropyl methylcellulose	9004-65-3	Uncontrolled product according to WHMIS classification criteria
• Benzoic acid	65-85-0	D2B
• Sodium benzoate	532-32-1	Uncontrolled product according to WHMIS classification criteria
• Propylene glycol	57-55-6	Uncontrolled product according to WHMIS classification criteria
• Ethyl alcohol	64-17-5	B2, D2B
• Benzyl alcohol	100-51-6	B3, D2B
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	1 %
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	1 %
• Ethyl alcohol	64-17-5	0.1 %
• Benzyl alcohol	100-51-6	1 %
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	T; R48/23 Xi; R38-41
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	F; R11
• Benzyl alcohol	100-51-6	Xn; R20/22
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	T R:38-41-48/23 S:(1/2)-26-39-45-63
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	F R:11 S:(2)-7-16
• Benzyl alcohol	100-51-6	Xn R:20/22 S:(2)-26
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	S:(1/2)-26-39-45-63
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	S:(2)-7-16
• Benzyl alcohol	100-51-6	S:(2)-26
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	5000 lb final RQ; 2270 kg final RQ
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	Not Listed
• Benzyl alcohol	100-51-6	Not Listed
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

U.S. - RCRA (Resource Conservation & Recovery Act) - List for Hazardous Constituents

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	Not Listed
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	Not Listed
• Benzyl alcohol	100-51-6	Not Listed
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

U.S. - RCRA (Resource Conservation & Recovery Act) - TSD Facilities Ground Water Monitoring

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	Not Listed
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	Not Listed
• Benzyl alcohol	100-51-6	
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	Not Listed
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	carcinogen, initial date 4/29/11 (in alcoholic beverages)
• Benzyl alcohol	100-51-6	Not Listed
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	Not Listed
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	developmental toxicity, initial date 10/1/87 (in alcoholic beverages)
• Benzyl alcohol	100-51-6	Not Listed
• Diazepam	439-14-5	developmental toxicity, initial date 1/1/92
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	Not Listed
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	Not Listed
• Benzyl alcohol	100-51-6	Not Listed
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Benzoic acid	65-85-0	Not Listed
• Sodium benzoate	532-32-1	Not Listed
• Propylene glycol	57-55-6	Not Listed
• Ethyl alcohol	64-17-5	Not Listed
• Benzyl alcohol	100-51-6	Not Listed
• Diazepam	439-14-5	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

- Last Revision Date**
- 13/April/2015
- Preparation Date**
- 13/April/2015
- Disclaimer/Statement of Liability**
- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.
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