



US - OSHA SAFETY DATA SHEET

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Version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Diazepam Rectal Gel

Other means of identification

Synonyms None known.

Recommended use of the chemical and restrictions on use

Recommended Use Not available.

Uses advised against Not available.

Details of the supplier of the safety data sheet

Address Lupin Somerset, LLC
400 Campus Drive
Somerset, NJ 08873

Emergency telephone number

Company Phone Number 908-603-6066

24 Hour Emergency Phone Number 908-603-6029

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Classified.

Serious Eye Damage/Eye Irritation	Category 2A
Skin sensitization	Category 1
Reproductive Toxicity	Category 1B
Specific target organ toxicity (repeated exposure) - Eyes	Category 1

Physical Hazards

Not classified.

Label elements

Emergency Overview

Danger

Hazard Statements

Causes serious eye irritation.

May cause an allergic skin reaction

May damage fertility or the unborn child.

Causes damage to eyes through prolonged or repeated exposure



Appearance Gel.

Physical state Liquid

Odor Not available.

Precautionary Statements - Prevention

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Use personal protective equipment as required
 Wash face, hands, and any exposed skin thoroughly after handling.
 Contaminated work clothing should not be allowed out of the workplace
 Wear protective gloves
 Do not breathe dust/fume/gas/mist/vapors/spray
 Do not eat, drink, or smoke when using this product.

Precautionary Statements - Response

If exposed or concerned: Get medical attention.
 Specific treatment.
 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 attention.
 If on skin: Wash with plenty of soap and water
 If skin irritation or rash occurs: Get medical advice/attention
 Take off contaminated clothing and wash it before reuse

Precautionary Statements - Storage

Keep tightly closed.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal facility.

Other information

Contains flammable material like Benzyl alcohol but does not classify the product as flammable due to the component concentration in the mixture.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200; Revision 3).

Chemical name	CAS No	Weight-%
Diazepam, USP	439-14-05	<1
Propylene glycol, USP	57-55-6	45-50
Polyethylene glycol, 400, NF	25322-68-3	5-15
Benzyl alcohol, NF	100-51-6	<2
Benzoic acid, USP	65-85-0	<2
Povidone, USP	9003-39-8	<10
Sodium benzoate, NF	532-32-1	2-5
Purified water, USP	7732-18-5	>28

*Exact component concentration has been withheld as a trade secret

4. FIRST AID MEASURES

Description of first aid measures**Eye Contact**

In case of eye contact of broken tablets, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact

Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. If symptoms persist, call a physician.

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. Move to fresh air in case of accidental inhalation of vapors or decomposition products.

Ingestion

If swallowed, wash out mouth with water provided person is fully conscious. Provide plenty of water to drink. Call a physician and/ or poison control center.

Self-Protection of the First Aider Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms 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.

Indication of any immediate medical attention and special treatment needed

Note to Physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. SMALL FIRES: Dry chemical, CO₂, water spray or regular foam. LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media Caution: Use of water spray when fighting fire may be inefficient as the burning material may be spread.

Specific hazards arising from the chemical

Not available.

Explosion data

Sensitivity to Mechanical Impact None known.

Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Ensure adequate ventilation, especially in confined areas.

Environmental precautions

Environmental precautions Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil. See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for Containment 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. Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up 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.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool, and well-ventilated place.

Incompatible Materials None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any materials with Occupational Exposure Limits (OEL) established by region-specific regulatory bodies.

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/Face Protection In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information. It is recommended that an eyewash station should be located in the vicinity of the occupational setting in order to provide immediate access to emergency decontamination in case of accidental eye exposure.

Skin and Body Protection In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hoods, or head coverings may be necessary. Contact a health and safety professional for specific information. It is recommended that a safety shower should be located in the vicinity of the occupational setting in order to provide immediate access to emergency decontamination in case of accidental skin/body exposure.

Respiratory Protection Not required for normal handling of packed product. Respirators/ PAPR may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance indicated by OSHA Standard 29 CFR 1910.134.

General Hygiene Considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	Odor	Not available.
Appearance	Gel.	Odor Threshold	Not available.
Color	Not available.		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No information available	
Melting point/freezing point	No information available	
Boiling point/boiling range	No information available	
Flash point	No information available	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	No information available	
Lower flammability limit:	No information available	
Vapor pressure	Not available.	
Vapor density	No information available	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	No information available	
Hyphen	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive Properties	Not available.	
Oxidizing Properties	Not available.	

Other information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	No information available
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity

No data available

Chemical stability

Stable under recommended handling and storage conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to Avoid

Extremes of temperature and direct sunlight.

Incompatible materials

None known.

Hazardous decomposition products

None known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute Toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Diazepam 439-14-5	= 249 mg/kg (Rat)	-	-	-
Benzyl Alcohol, NF 100-51-6	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	= 8.8 mg/L (Rat) 4 h	-
Benzoic Acid, USP 65-85-0	= 1700 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 12.2 mg/L (Rat) 4 h	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

Diazepam is a Schedule IV controlled substance that may cause abuse and dependence. Frequent effects include drowsiness, sedation, muscle weakness, and loss of muscle coordination. Less frequent effects include vertigo, headache, confusion, depression, slurred speech, changes in libido, tremor, visual disturbances, urinary retention or incontinence, gastrointestinal disturbances, changes in salivation, and amnesia. Withdrawal symptoms may occur with sudden discontinuation

Delayed and immediate effects as well as chronic effects from short- and long-term exposure

Irritation

May cause irritation to skin and eyes. Diazepam therapy have caused blurred vision, double vision, and nystagmus.

**Sensitization
Genotoxicity**

As per reports, Diazepam use have also caused skin reactions including rash and urticaria. In one set of studies the following results were produced: Positive in the In vitro mouse micronucleus assay. Negative in an In vivo mouse chromosomal aberration study , an In vivo mouse micronucleus study, and an In vivo direct DNA damage study in rats . However, in other studies Diazepam has shown genotoxic potential with positive In vivo results for micronuclei in mouse bone marrow, positive results for micronuclei, aneuploidy, and chromosomal aberrations in Chinese Hamster cells in vitro , and positive results for sister chromatid exchange in human lymphocytes.

Carcinogenicity

In studies in mice and rats' dietary diazepam given at a dose of 75 mg/kg/day for 80 and 104 weeks respectively, increased the incidence of liver tumors in males but not females of both species. Two additional 2-year studies were conducted in mice and hamsters with negative results. IARC concluded that there was sufficient evidence from human studies that diazepam did not produce breast cancer, and that there was inadequate data to support its potential carcinogenicity. The product contains the following chemicals listed by IARC that are not classifiable as to its carcinogenicity to humans (Group 3).

Chemical name	ACGIH	IARC	NTP	OSHA
Diazepam 439-14-5		Group 3		

Reproductive Toxicity

Although suspected of adversely affecting fertility and the unborn child, results were mixed in study meta-analysis that tracked the occurrence of major malformations in infants of mothers who used a benzodiazepine in early pregnancy. There have been reports of newborns exhibiting flaccidity, breathing, and feeding problems, and hypothermia after maternal use of benzodiazepines in late pregnancy. An increased risk of developmental effects has been associated with diazepam in animal studies (see below) with production of cleft palate, but this effect has not been reported in humans. A neonatal withdrawal syndrome has been described. Diazepam is compatible with breastfeeding if used in a single dose. However, large maternal diazepam doses or prolonged maternal use may result in sedation, apnea, bradycardia, and poor suckling in infants, particularly in newborn or premature infants. Libido changes and priapism have been reported with diazepam.
US FDA Pregnancy Category – D.

**STOT - Single Exposure
STOT - Repeated Exposure**

Not available.
Considered to be STOT-Re Category 1 for eyes due to concentration of Benzoic Acid in the final product.

Aspiration Hazard Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Benzyl Alcohol, NF 100-51-6		10: 96 h Lepomis macrochirus mg/L LC50 static 460: 96 h Pimephales promelas mg/L LC50 static		23: 48 h water flea mg/L EC50
Benzoic Acid, USP 65-85-0		44.6: 96 h Lepomis macrochirus mg/L LC50 static		860: 48 h Daphnia magna mg/L EC50 Static

Persistence and degradability

Not available.

Bioaccumulation

Chemical name	Partition coefficient
Benzyl Alcohol, NF 100-51-6	1.1
Benzoic Acid, USP 65-85-0	1.9

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of Wastes

Disposal should be in accordance with applicable regional, national, and local laws and regulations. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state, and local environmental regulations.

Contaminated Packaging

Do not reuse container/vial.

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMO/MDG</u>	Not regulated
<u>TDG</u>	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Does not comply
ENCS	Complies
IECSC	Does not comply
KECL	Complies
PICCS	Does not comply
AICS	Does not comply

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substance which is regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Benzoic Acid, USP 65-85-0	5000 lb			X

CERCLA

This material, as supplied, contains the following substance(s) regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Benzoic Acid, USP 65-85-0	5000 lb		RQ 5000 lb final RQ RQ 2270 kg final RQ

US State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemical(s).

Chemical name	California Proposition 65
Diazepam - 439-14-5	Developmental

U.S. State Right-to-Know Regulations

This product contains the following substance(s) regulated by state right-to-know regulations.

Chemical name	New Jersey	Massachusetts	Pennsylvania
Diazepam 439-14-5		X	
Benzyl Alcohol, NF 100-51-6		X	X
Benzoic Acid, USP 65-85-0	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Issue Date	16-May-2023
Revision Date	NA
Revision Note	New SDS.

Disclaimer

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 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.

End of Safety Data Sheet