

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Lexiscan (regadenoson) Injection

Material Name: CVT-3146 Intravenous Formulation

Formula: C₁₅H₁₈N₈O₅•H₂O

Chemical Name of Active Ingredient: Adenosine, 2-[4[(methylamino)carbonyl]-1H-pyrazol-1-yl]-, monohydrate

1.2. Intended Use of the Product

Use of the substance/mixture: A pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Astellas US LLC

1 Astellas Way

Northbrook, IL 60062

Tel.: 800-888-7704

www.us.astellas.com

1.4. Emergency Telephone Number

Emergency Number : 800-727-7003 Medical Communications

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Overexposure may affect the cardiovascular system and the central nervous system (seizures). Symptoms may include increased heart rate, palpitations, flushing, nausea, hyperventilation, and headache.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	82.5	Not classified
1,2-Propylene glycol	(CAS No) 57-55-6	15	Not classified
Phosphoric acid, monosodium salt	(CAS No) 7558-80-7	< 1	Not classified
Sodium phosphate dibasic	(CAS No) 7558-79-4	< 0.9	Not classified
Phosphoric acid, monosodium salt, monohydrate	(CAS No) 10049-21-5	0.5	Not classified
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	(CAS No) 6381-92-6	0.1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 Aquatic Chronic 3, H412
Regadenoson	(CAS No) 313348-27-5	0.008	Repr. 2, H361

Full text of H-phrases: see section 16

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SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Rinse immediately with plenty of water. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: May cause respiratory irritation. May cause increased heart rate, palpitations, flushing, nausea, hyperventilation, and headache.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

Symptoms/Injuries After Accidental Injection: May cause increased heart rate, palpitations, flushing, nausea, hyperventilation, and headache.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all contact with skin, eyes, or clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Stop leak if safe to do so. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clear up spills immediately and dispose of waste safely. Spills should be contained with mechanical barriers. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Products: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

A pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls

: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Protective goggles. Gloves. Protective clothing.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear chemically resistant protective gloves.

Eye Protection

: Chemical goggles or safety glasses.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: In case of insufficient ventilation, wear suitable respiratory equipment.

Environmental Exposure Controls

: Do not allow the product to be released into the environment.

Consumer Exposure Controls

: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear
Odor	: None
Odor Threshold	: No data available
pH	: 6.3 - 7.7
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: ≈ 100 °C (212 °F)
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Specific Gravity	: ≈ 1
Solubility	: Already in water
Partition Coefficient: N-Octanol/Water	: No data available

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Viscosity : No data available

Percent Volatility : None

Molecular Weight : 408.37

9.2. Other Information No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products: Thermal decomposition generates: Carbon oxides (CO, CO₂), sodium acid pyrophosphate.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified (Single IV doses of up to 1.5 mg/kg in rats and 2.4mg/kg in dogs did not cause lethality. Minimal cardiomyopathy [myocyte necrosis and inflammation] was observed in rats following single dose intravenous administration of Lexiscan at doses >0.08 mg/kg. Mean arterial pressure was decreased by 30 to 50% for up to 90 minutes at doses >0.2mg/kg. Intravenous administration, of single doses up to 2400 µg/kg in dogs, caused pharmacological effects including decreased blood pressure and T-wave inversion.)

Phosphoric acid, monosodium salt (7558-80-7)	
LD50 Oral Rat	8290 mg/kg
LD50 Dermal Rabbit	> 7940 mg/kg
Sodium phosphate dibasic (7558-79-4)	
LD50 Oral Rat	> 2000 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
1,2-Propylene glycol (57-55-6)	
LD50 Oral Rat	20000 mg/kg
LD50 Dermal Rabbit	20800 mg/kg
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)	
Acute Toxicity Estimate (Oral)	500.00 mg/kg body weight
Acute Toxicity Estimate (Dermal)	1,100.00 mg/kg body weight
Acute Toxicity Estimate (Dust/Mist)	1.50 mg/l/4h

Skin Corrosion/Irritation: Not classified (Intravenous administration of Lexiscan to rabbits resulted in perivascular hemorrhage, vein vasculitis, inflammation, thrombosis and necrosis. Perivascular administration resulted in hemorrhage, inflammation, pustule formation, and epidermal hyperplasia. Subcutaneous administration resulted in hemorrhage, acute inflammation, and necrosis.)

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified (Negative in several short-term screening tests for genetic damage [Ames bacterial cell test for point mutations, mouse micronucleus test for chromosomal aberrations, and Chinese hamster ovary test for chromosomal aberrations].)

Carcinogenicity: Not classified (No studies conducted.)

Reproductive Toxicity: Not classified (Fertility studies were not performed. Pregnant rabbits treated with Lexiscan exhibited tachypnea, soft, liquid or scant feces, localized alopecia, and reduction in body weight and feed consumption at 0.3 and 0.5 mg/kg/day. Fetal toxicity included decreased number, reduced body weight, and variations and malformations; increased fetal resorptions occurred at 0.5 mg/kg. The no effect dose level (NOEL) for fetal toxicity is 0.1 mg/kg. The NOEL was not identified for maternal toxicity. Decreased motor activity, difficulty breathing, increased limb extension, excess salivation, and decreased body weight and feed consumption were noted in treated pregnant rats at >0.5 mg/kg. Deaths occurred in the >0.8 mg/kg/day group. Decreased fetal body weights and ossification delays in fore- and hindlimb phalanges and metatarsals were observed at doses ≥0.5 mg/kg. The NOEL for maternal and fetal toxicity is 0.1 mg/kg/day.)

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified (Decreased weight gain, and increased serum creatine kinase, alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase and chloride were observed in rats treated intravenously with Lexiscan at 0.2mg/kg. Repeated dose studies have shown similar pharmacological effects studies of the drug as in acute studies.)

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Aspiration Hazard: Not classified

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Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

Symptoms/Injuries After Accidental Injection: May cause increased heart rate, palpitations, flushing, nausea, hyperventilation, and headache.

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

1,2-Propylene glycol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [static])

12.2. Persistence and Degradability No additional information available.

12.3. Bioaccumulative Potential

1,2-Propylene glycol (57-55-6)	
BCF fish 1	< 1
Log Pow	-0.92

12.4. Mobility in Soil No additional information available.

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport.

14.2. In Accordance with IMDG Not regulated for transport.

14.3. In Accordance with IATA Not regulated for transport.

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Phosphoric acid, monosodium salt (7558-80-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium phosphate dibasic (7558-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
1,2-Propylene glycol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2 US State Regulations

Sodium phosphate dibasic (7558-79-4)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

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1,2-Propylene glycol (57-55-6)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 07/06/2015
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 2	Reproductive toxicity Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H312	Harmful in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)