



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
US - OSHA Hazard Communication Standard (29 CFR 1910.1200)

Issuing Date 23-Mar-2023

Revision Date 23-Mar-2023

Revision Number 1

1. Identification

Product identifier

Product Name Regadenoson Injection

Other means of identification

Synonyms Lexiscan; Regadenoson; Adenosine, 2-[4[(methylamino)carbonyl]-1H-pyrazol-1-yl]-, monohydrate

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical
Prescription (Rx)

Restrictions on use Use as prescribed only

Details of the supplier of the safety data sheet

Supplier Address

Hikma Pharmaceuticals USA Inc
200 Connell Drive
Berkeley Heights, NJ 07992
1.908.673.1030

E-mail customerservice@hikma.com

Emergency telephone number

Emergency telephone Adverse Event: 1.877.845.0689, 1.800.962.8364: 9AM-5PM, Monday-Friday

2. Hazard(s) identification

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)

Not applicable.

Label elements

None

Hazard statements

Not classified.

Other information

No information available.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

The product contains no substances which at their given concentration, are considered to be hazardous to health

4. First-aid measures

Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids.
Skin contact	Wash skin with soap and water.
Ingestion	Rinse mouth.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
Effects of Exposure	No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	No information available.
Specific hazards arising from the chemical	No information available.
Explosion data	
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
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Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. Handling and storage**Precautions for safe handling**

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
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8. Exposure controls/personal protection**Control parameters**

Exposure Limits	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
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Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
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Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Hand protection	Wear suitable gloves.
Skin and body protection	No special protective equipment required.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties**Information on basic physical and chemical properties**

Appearance	Liquid, Clear and Colorless
Physical state	Liquid
Color	Clear and Colorless
Odor	No data available
Odor threshold	No data available

Property	Values	Remarks • Method
pH	6.3 - 7.7	
pH (as aqueous solution)		No data available

Melting point / freezing point		No data available
Initial boiling point and boiling range	100 °C / 212 °F	
Flash point		No data available
Evaporation rate		No data available
Flammability		No data available
Flammability Limit in Air		
Upper flammability or explosive limits		No data available
Lower flammability or explosive limits		No data available
Vapor pressure		No data available
Vapor density		No data available
Relative density	1.020	g/mL
Water solubility	Soluble in water	
Solubility(ies)		No data available
Partition coefficient		No data available
Autoignition temperature		No data available
Decomposition temperature		No data available
Kinematic viscosity		No data available
Dynamic viscosity		No data available
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	408.37	
VOC content	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

Reactivity	None under normal use conditions.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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Acute toxicity

Numerical measures of toxicity

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	No information available.
Other adverse effects	No information available.

13. Disposal considerationsWaste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

<u>DOT</u>	Not regulated
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IATA Not regulated

IMDG Not regulated

15. Regulatory information

International Inventories

Contact supplier for inventory compliance status

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 which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Propylene glycol 57-55-6	X	-	X
Sodium phosphate dibasic 7558-79-4	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

<u>NFPA</u>	Health hazards 0	Flammability 0	Instability 0	Special hazards -
<u>HMIS</u>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGl(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

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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 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.

End of Safety Data Sheet