



# SAFETY DATA SHEET

Revision date 18-May-2022

Version 3

Page 1 / 11

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Regadenoson Injection (Hospira, Inc.)  
**Product Code(s)** PZ03515  
**Trade Name:** Not applicable  
**Chemical Family:** Not determined

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product

### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

### 2.2. Label elements

**Signal word** Not Classified

**Hazard statements** Not classified in accordance with international standards for workplace safety.

### 2.3. Other hazards

**Other hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 2 / 11  
Version 3

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

**Substances** Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Regadenoson 313348-27-5	0.008		Not Listed	Repr. 2 (H361d)	Not Listed	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water 7732-18-5	*		231-791-2	No data available	Not Listed	No data available	No data available
Propylene glycol 57-55-6	*		200-338-0	No data available	Not Listed	No data available	No data available
Sodium Phosphate Monobasic, Monohydrate 10049-21-5	*		Not Listed	No data available	Not Listed	No data available	No data available
Sodium phosphate, dibasic 7558-79-4	*		231-448-7	No data available	Not Listed	No data available	No data available
Edetate disodium 139-33-3	*		205-358-3	No data available	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

#### Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Propylene glycol 57-55-6	20000	20800	No data available	No data available	No data available

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 3 / 11  
Version 3

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sodium phosphate, dibasic 7558-79-4	17000	No data available	No data available	No data available	No data available
Edetate disodium 139-33-3	2000	No data available	No data available	No data available	No data available

## Additional information

\* Proprietary  
Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Move to fresh air. If discomfort occurs, get medical attention.
<b>Eye contact</b>	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
<b>Skin contact</b>	Rinse with plenty of water. If skin irritation persists, call a physician.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 4 / 11  
Version 3

## 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.  
**For emergency responders** Use personal protection recommended in Section 8.

## 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

## 6.3. 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** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.  
**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

## 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

#### **Advice on safe handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

Refer to available public information for specific member state Occupational Exposure Limits.

#### **Regadenoson**

Pfizer OEL TWA-8 Hr: 1 µg/m<sup>3</sup>

#### **Propylene glycol**

Ireland

10 mg/m<sup>3</sup>  
150 ppm  
470 mg/m<sup>3</sup>  
STEL: 1410 mg/m<sup>3</sup>  
STEL: 30 mg/m<sup>3</sup>  
STEL: 450 ppm

Latvia

Poland

7 mg/m<sup>3</sup>  
100 mg/m<sup>3</sup>

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 5 / 11  
Version 3

Russia  
United Kingdom

MAC: 7 mg/m<sup>3</sup>  
TWA: 150 ppm  
TWA: 474 mg/m<sup>3</sup>  
TWA: 10 mg/m<sup>3</sup>  
STEL: 450 ppm  
STEL: 1422 mg/m<sup>3</sup>  
STEL: 30 mg/m<sup>3</sup>

## Sodium phosphate, dibasic

Russia

MAC: 10 mg/m<sup>3</sup>

## Edetate disodium

Russia

MAC: 2 mg/m<sup>3</sup>

## Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

## Sodium phosphate, dibasic

Pfizer Occupational Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

## 8.2. Exposure controls

### Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

### Environmental exposure controls

No information available.

### Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

### Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

### Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

### Skin and body protection

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

### Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 6 / 11  
Version 3

<b>Physical state</b>	Liquid
<b>Color</b>	Clear, colorless
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture

<u>Property</u>	<u>Values</u>
<b>pH</b>	6.3-7.7
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	1.0
<b>Water solubility</b>	Soluble
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## **Partition Coefficient: (Method, pH, Endpoint, Value)**

Regadenoson  
Predicted 7.4 Log D -1.828

## **9.2. Other information**

No information available

### **9.2.1. Information with regard to physical hazard classes**

**Oxidizing properties** None

### **9.2.2. Other safety characteristics**

No information available

## **Section 10: STABILITY AND REACTIVITY**

### **10.1. Reactivity**

**Reactivity** No data available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

### **Explosion data**

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### **10.3. Possibility of hazardous reactions**

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 7 / 11  
Version 3

**Possibility of hazardous reactions** No information available.

## **10.4. Conditions to avoid**

### **Conditions to avoid**

Fine particles (such as mists) may fuel fires/explosions.

## **10.5. Incompatible materials**

### **Incompatible materials**

As a precautionary measure, keep away from strong oxidizers.

## **10.6. Hazardous decomposition products**

**Hazardous decomposition products** None known.

## **Section 11: TOXICOLOGICAL INFORMATION**

### **11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

#### **General Information:**

The information included in this section describes the potential hazards of the individual ingredients

#### **Known Clinical Effects:**

Adverse effects associated with therapeutic use include facial flushing, shortness of breath (dyspnea), headache, lightheadedness, increased heart rate (tachycardia), dizziness, irregular heartbeat (cardiac arrhythmia), nausea.

#### **Acute Toxicity: (Species, Route, End Point, Dose)**

##### **Propylene glycol**

Rat Oral LD 50 22,000 mg/kg

Mouse Oral LD 50 24,900 mg/kg

Rabbit Dermal LD 50 20,800 mg/kg

##### **Edetate disodium**

Rat Oral LD50 2000-2200 mg/kg

##### **Regadenoson**

Rat IV Minimum Lethal Dose > 1.4 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Propylene glycol	= 20 g/kg ( Rat )	= 20800 mg/kg ( Rabbit )	-
Sodium phosphate, dibasic	= 17 g/kg ( Rat )	-	-
Edetate disodium	= 2 g/kg ( Rat )	-	-

#### **Acute Toxicity Comments:**

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### **Irritation / Sensitization: (Study Type, Species, Severity)**

##### **Propylene glycol**

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

#### **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

##### **Regadenoson**

7 Day(s) Rat Intravenous 0.02 mg/kg/day NOAEL Skin, Blood

7 Day(s) Dog Intravenous 0.002 mg/kg/week NOAEL Skin

28 Day(s) Rat Intravenous 0.02 mg/kg/day NOAEL Decreased body weight

28 Day(s) Dog Intravenous 0.02 mg/kg/day NOAEL Heart, Skin

#### **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

##### **Regadenoson**

Prenatal & Postnatal Development Rabbit No route specified 0.1 mg/kg/day NOEL Maternal toxicity, Fetotoxicity

Prenatal & Postnatal Development Rat No route specified 0.1 mg/kg/day NOEL Maternal Toxicity, Fetotoxicity

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 8 / 11  
Version 3

Embryo / Fetal Development Rabbit Intravenous 0.1 mg/kg/day LOAEL Maternal Toxicity  
Embryo / Fetal Development Rabbit Intravenous 0.1 mg/kg/day NOAEL Fetotoxicity  
Embryo / Fetal Development Rat Intravenous 0.1 mg/kg/day LOAEL Maternal Toxicity  
Embryo / Fetal Development Rat Intravenous 0.1 mg/kg/day NOAEL Fetotoxicity

## Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

### Regadenoson

Bacterial Mutagenicity (Ames) Not specified Negative  
*In Vivo* Micronucleus Mouse Negative  
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

**Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

### 12.1. Toxicity

**No information available**

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

#### Bioaccumulation

#### Partition Coefficient: (Method, pH, Endpoint, Value)

##### Regadenoson

Predicted 7.4 Log D -1.828

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

#### **PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
Propylene glycol	The substance is not PBT / vPvB PBT assessment does not apply
Sodium phosphate, dibasic	PBT assessment does not apply



# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 9 / 11  
Version 3

Edetate disodium	The substance is not PBT / vPvB
------------------	---------------------------------

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## **Section 14: TRANSPORT INFORMATION**

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## **Section 15: REGULATORY INFORMATION**

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

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

Propylene glycol

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-338-0
<b>AICS</b>	Present

Sodium Phosphate Monobasic, Monohydrate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present

Sodium phosphate, dibasic

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 10 / 11  
Version 3

<b>EINECS</b>	231-448-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
Edetate disodium	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	205-358-3
<b>AICS</b>	Present
Regadenoson	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

## France

### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Propylene glycol 57-55-6	RG 84	-

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

### Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information.

# SAFETY DATA SHEET

Product Name Regadenoson Injection (Hospira, Inc.)  
Revision date 18-May-2022

Page 11 / 11  
Version 3

---

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Revision date** 18-May-2022

**Prepared By** Pfizer Global Environment, Health, and Safety

**Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.**