

Product Name: Atrasentan Hydrochloride
Issued: Dec-18-2012

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Atrasentan Hydrochloride
Synonyms: Endothelin Antagonist: Atrasentan: Atrasentan Hydrochloride
Drug Code Number: 61233

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
1-800-255-5162
+1-847-937-7433
Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433
E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute oral toxicity	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Reproductive toxicity	Category 1B

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Xi - Irritant
Xn - Harmful
Risk Phrases: R22 - Harmful if swallowed
R36/38 - Irritating to eyes and skin
R60 - May impair fertility
R61 - May cause harm to the unborn child

2.2 Label elements

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Section 2. Hazards identification



Signal Word: Danger

Hazard Statements:
H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H360 - May damage fertility or the unborn child

P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308 + P313 - IF exposed or concerned: Get medical advice/attention

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Atrasentan hydrochloride 195733-43-8	100	NA	Xn, R22; Xi, R36/38; R62/63	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Acute Tox. 4 (H302)	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Occupational exposure has resulted in the following: flushing, headaches. Clinical data suggests the following: nausea, vomiting, headaches, decreased blood pressure, dizziness, chills, lightsensitive eyes, nasal congestion. Direct contact with the eyes could result in the following: eye irritation. Animal data suggest that exposure may result in the following: abnormal liver function, abnormal kidney function, altered testicular function, fetal abnormalities, alterations in blood chemistry.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: eyes, kidney, male reproductive system, cardiovascular system, pregnancy,

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: The bulk powder was not readily combustible in a burning rate test.

Explosivity: Fine dust clouds may form explosive mixtures with air.

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: Use personal protective equipment identified in Section 8.

6.2. Environmental precautions

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Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Allow dust or aerosol to settle. Use large, disposable absorbant paper towels moistened with 10% (v/v) bleach to collect spilled product and clean the affected area. Recover product and place in an appropriate container for disposal. Dispose of material as directed in Section 13.

Incompatibilities: Oxidizers.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Atrasentan hydrochloride 195733-43-8	0.6 mcg/m ³ in 8-hr TWA	None

8.2. Exposure controls

Engineering Controls: Use inside a hood, glovebox or process enclosure.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

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Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	White to off-white Powder
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Freely soluble in: alcohol. Slightly soluble in: water.
Partition coefficient: n-octanol/water	Not determined.
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	Not determined.
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

9.2. Other information

Explosivity: Fine dust clouds may form explosive mixtures with air.

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Thermally stable up to .? degrees C. Decomposed to inactive compounds by bleach.

10.3. Possibility of hazardous reactions

Hazardous reactions: None under normal processing

10.4. Conditions to avoid

Dust formation Avoid contact with heat, sparks, open flame, and static discharge.

10.5 Incompatible materials

Oxidizing agents

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10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO_x), Hydrogen chloride

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Not determined.
Inhalation: Not determined.

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Atrasentan hydrochloride 195733-43-8	ALD >	4530	ml/kg	Rats
	ALD =	1812		Mice

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

Corrosivity: Not determined.

Dermal Irritation: Produced mild skin irritation in rabbits.

Eye Irritation: Produced mild to moderate eye irritation in rabbits. Recovery after 7 days.

Sensitization: Negative in the maximization assay in guinea pigs at challenge concentrations.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration		
Atrasentan hydrochloride 195733-43-8	Blood	Mice	15	mg/kg/day	Oral	3 months		
	Female	Rats	5			6 months		
	Reproductive System Male	Dogs	10			9 months		
	Reproductive System Liver							

Reproductive Effects: In animals adverse reproductive effects include: reduced fertility in females, male reproductive system, fetal abnormalities.
Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Atrasentan hydrochloride 195733-43-8	Rats	0.1	mg/kg	Oral	Variable Treatment Regimens
	Rabbits	0.1			

Carcinogenicity: Not determined.

Mutagenicity: Data for component (s) given below.

Aspiration hazard: Not determined

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Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- | | |
|------------------------------------|----------------|
| 14.1. UN Number: | Not applicable |
| 14.2. Proper shipping name: | Not applicable |
| 14.3. Hazard class: | Not applicable |
| 14.4. Packing group: | Not applicable |
| 14.5. Environmental hazard: | Not applicable |
| 14.6. Special Provisions: | Not applicable |

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14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Atrasentan hydrochloride 195733-43-8	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Atrasentan hydrochloride 195733-43-8	-	-	-	-	-	

Legend

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

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

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Atrasentan hydrochloride	100	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Atrasentan hydrochloride	100	No	Not Applicable	Not applicable

Immediate Health: Yes

Delayed Health: No

Fire: No

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 1

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Fire: 1
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R22 - Harmful if swallowed, R36/38 - Irritating to eyes and skin, R60 - May impair fertility, R61 - May cause harm to the unborn child

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