

Product Name: Sibutramine Hydrochloride Monohydrate
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: Sibutramine Hydrochloride Monohydrate
Synonyms: Sibutramine HCl Monohydrate; Sibutramine HCL
List Number: 2080
Drug Code Number: 20208

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 3
Serious eye damage/eye irritation	Category 2
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Reproductive toxicity	Category 2
Specific target organ systemic toxicity (repeated exposure)	Category 1

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

Indication of danger: T - Toxic
Xi - Irritant

Product Name:
Issued:

Sibutramine Hydrochloride Monohydrate
Dec-18-2012

Section 2. Hazards identification

Risk Phrases:

R25 - Toxic if swallowed
R36 - Irritating to eyes
R42 - May cause sensitization by inhalation
R43 - May cause sensitization by skin contact
R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed
R62 - Possible risk of impaired fertility
R63 - Possible risk of harm to the unborn child

2.2 Label elements



Signal Word:

Danger

P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P309 + P311 - IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician

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.
Sibutramine Hydrochloride Monohydrate 125494-59-9	100	NA	T; R23, R48/25, Xi; R36; R42, R43, R62, R63	Eye Irrit. 2 (H319) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) Acute Tox. 3 (H331)	No data available

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

Product Name: Sibutramine Hydrochloride Monohydrate
Issued: Dec-18-2012

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.

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: None known from occupational exposure. Clinical data suggests the following: headaches, fast heart rate, increased blood pressure, drowsiness, dizziness, diarrhea, palpitation, lightheadedness, dry mouth, dilated pupils, insomnia.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Medical conditions exacerbated due to exposure to the following organs: cardiovascular system, gastrointestinal system, respiratory system, liver. Concurrent use of medications.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Monitor cardiovascular and respiratory system.

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: This material is capable of forming explosive dust clouds in air, therefore, measures must be taken to avoid ignition. This material is particularly sensitive to ignition by electrostatic discharge.

5.3 Advice for firefighters

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

Product Name: Sibutramine Hydrochloride Monohydrate
Issued: Dec-18-2012

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

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: Recover product and place in an appropriate container for disposal. Clean contaminated surface thoroughly

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

Avoid dust formation. 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
Sibutramine Hydrochloride Monohydrate 125494-59-9	20 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.

Product Name: Sibutramine Hydrochloride Monohydrate
Issued: Dec-18-2012

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

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	White to off-white Crystalline Powder
Odor:	Characteristic 'damp' odor.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	193 - 195.5 (deg C)
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.
Bulk Density at 20°C:	0.33 g/ml
Specific Gravity:	Not determined.
Solubility(ies):	Slightly soluble in: water. Highly soluble in: ethanol.
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

Maximum Pressure Rise (bar):	7.9
Kst Value (bar.m/s):	233
Min. Ignition Energy-Cloud (mJ):	6-8
Min. Ignit. Temp. Dust Cloud (°C):	230

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

Product Name: Sibutramine Hydrochloride Monohydrate
Issued: Dec-18-2012

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Strong oxidizing agents

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
Sibutramine Hydrochloride Monohydrate 125494-59-9	LDLo =	200	mg/kg	Mice
		100		Rats

Acute Toxicity - Dermal: Not determined.

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

Chemical Name	Test	Value	Units	Species
Sibutramine Hydrochloride Monohydrate 125494-59-9	LC 50 =	63	mg/m ³ , 4 hour	Rats

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Sibutramine Hydrochloride Monohydrate 125494-59-9	LD Lo (po) =	100 - 200	mg/kg	Rats Mice	None.
	LD Lo (ip) =	75		Rats	

Corrosivity: Not determined.

Dermal Irritation: Not an irritant.

Eye Irritation: Produced mild to moderate eye irritation in rabbits.

Sensitization: Reported to be weak sensitizer in animals. May cause allergic respiratory and skin reactions.

Toxicokinetics/Metabolism: Not determined.

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

Product Name: Sibutramine Hydrochloride Monohydrate
Issued: Dec-18-2012

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Sibutramine Hydrochloride Monohydrate 125494-59-9	Liver Central Nervous System	Rats Mice Dogs Monkeys	>=1 >=10	mg/kg	Oral	Variable exposure periods

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

Chemical Name	Species	Dosage	Units	Route	Duration
Sibutramine Hydrochloride Monohydrate 125494-59-9	Rats Rabbits	>= 1 >12	mg/kg	Oral	Variable Treatment Regimens

Carcinogenicity: Not carcinogenic in animal study.

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Sibutramine Hydrochloride Monohydrate 125494-59-9	Negative	Negative	No Data.	Negative

Aspiration hazard: Not determined

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

Data for component (s) given below.

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Sibutramine Hydrochloride Monohydrate 125494-59-9	100	1.8	Daphnia magna	48 Hours

12.2. Persistence and degradability

Not readily biodegradable.

Chemical Name	Percent	% Degradation	Duration
Sibutramine Hydrochloride Monohydrate 125494-59-9	100	0	28 days

12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Percent	Log Po/w
Sibutramine Hydrochloride Monohydrate 125494-59-9	100	< 3

Product Name: Sibutramine Hydrochloride Monohydrate
Issued: Dec-18-2012

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: Regulated

- 14.1. UN Number:** UN2811
14.2. Proper shipping name: Toxic solid, organic, n.o.s. (Sibutramine Hydrochloride Monohydrate)
14.3. Hazard class: 6.1
14.4. Packing group: III
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
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
Sibutramine Hydrochloride Monohydrate 125494-59-9	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sibutramine Hydrochloride Monohydrate 125494-59-9	-	7-(3)-853	-	-	-	

Product Name: Sibutramine Hydrochloride Monohydrate
Issued: Dec-18-2012

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:
Sibutramine Hydrochloride Monohydrate	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):
Sibutramine Hydrochloride Monohydrate	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: 2

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

Product Name: Sibutramine Hydrochloride Monohydrate
Issued: Dec-18-2012

Section 16. Other information

Risk Phrases: R25 - Toxic if swallowed, R36 - Irritating to eyes, R42 - May cause sensitization by inhalation, R43 - May cause sensitization by skin contact, R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed, R62 - Possible risk of impaired fertility, R63 - Possible risk of harm to the unborn child

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