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
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>EINECS/ELINCS Number</th>
<th>EEC Classification</th>
<th>EU - GHS Substance Classification</th>
<th>REACH No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>100</td>
<td>NA</td>
<td>T; R23, R48/25, Xi; R36; R42, R43, R62, R63</td>
<td>Eye Irrit. 2 (H319) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) Acute Tox. 3 (H331)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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

Page 2 of 10
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
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:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Employee Exposure Limit</th>
<th>Skin Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>20 mcg/m³ in 8-hr TWA</td>
<td>None</td>
</tr>
</tbody>
</table>

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.
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.
Partition coefficient: n-octanol/water
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
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 (NOx), 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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate</td>
<td>LO =</td>
<td>200</td>
<td>mg/kg</td>
<td>Mice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100</td>
<td></td>
<td>Rats</td>
</tr>
</tbody>
</table>

Acute Toxicity - Dermal: Not determined.

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate</td>
<td>L50 =</td>
<td>63</td>
<td>mg/m³, 4 hour</td>
<td>Rats</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Test Type</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate</td>
<td>LD Lo (po)</td>
<td>100 - 200</td>
<td>mg/kg</td>
<td>Rats Mice</td>
<td>None.</td>
</tr>
<tr>
<td></td>
<td>LD Lo (ip)</td>
<td>75</td>
<td></td>
<td>Rats</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Target Organs</th>
<th>Species</th>
<th>Dosage</th>
<th>Units</th>
<th>Route</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>Liver Central Nervous System</td>
<td>Rats Mice Dogs Monkeys</td>
<td>&gt;=1 mg/kg</td>
<td>&gt;=10</td>
<td>Oral</td>
<td>Variable exposure periods</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Species</th>
<th>Dosage</th>
<th>Units</th>
<th>Route</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>Rats</td>
<td>&gt;=1 mg/kg</td>
<td>Oral</td>
<td>Variable Treatment Regimens</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rabbits</td>
<td>&gt;12</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Carcinogenicity:  
Not carcinogenic in animal study.

Mutagenicity:  
Data for component(s) given below.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Micronucleus Assay</th>
<th>Ames Test:</th>
<th>Mouse Lymphoma Assay</th>
<th>Chromosomal Abbr. Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>Negative</td>
<td>Negative</td>
<td>No Data.</td>
<td>Negative</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>EC 50 (mg/l)</th>
<th>Species</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>100</td>
<td>1.8</td>
<td>Daphnia magna</td>
<td>48 Hours</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

Not readily biodegradable.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>% Degradation</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>100</td>
<td>0</td>
<td>28 days</td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential

Data for components given below.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>Log Po/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>100</td>
<td>&lt; 3</td>
</tr>
</tbody>
</table>
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:

Section 15. Regulatory Information

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

International Inventories

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>EINECS/ELINCS</th>
<th>TSCA</th>
<th>DSL</th>
<th>NDLS</th>
<th>PICCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Not listed.</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ENCS</th>
<th>ISHL</th>
<th>IECSC</th>
<th>AICS</th>
<th>KECL</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate 125494-59-9</td>
<td>-</td>
<td>7-(3)-853</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
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
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:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>NTP:</th>
<th>IARC:</th>
<th>ACGIH:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate</td>
<td>100</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

SARA 313 Information

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>SARA 313 Chemical</th>
<th>CERCLA RQ/SARA EHS RQ (lbs)</th>
<th>SARA EHS TPQ (lbs):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibutramine Hydrochloride Monohydrate</td>
<td>100</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.

15.2. Chemical safety assessment

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

Section 16. Other information
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

Document Authored By: Global Occupational Toxicology (D-03QC)

Issued: Dec-18-2012

Supersedes the SDS dated: Dec-14-2010

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