SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Contact information

General

Par Sterile Products
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Chemtrec (24-hour availability):
+1 (800) 424-9300 (USA and Canada)
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Product identifier

Trimethobenzamide hydrochloride (HCl) for Injection (100 mg/mL)

Synonyms

For trimethobenzamide HCl: N-[4-(2-Dimethylaminoethoxy)benzyl]-3,4,5-trimethoxybenzamide hydrochloride

Trade names

Tigan®

Chemical family

Mixture - contains a modified benzamide (a monoethanolamine derivative)

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

Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product packaged in final form for patient use; indicated for the treatment of nausea and vomiting (including postoperative cases).

Note

The physical, chemical, toxicological and ecological properties of this product/mixture has not been fully characterized. This SDS will be revisited as more data become available.

Issue Date

14 October 2014

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Please consult the prescribing/packaging information. The classification and labeling listed below is for bulk Trimethobenzamide HCl Injection.
### SECTION 2 - HAZARDS IDENTIFICATION …continued

| Regulation (EC) 1272/2008 [GHS] | Not classified |

**Label elements**

- **CLP/GHS hazard pictogram**: None required
- **CLP/GHS signal word**: None required
- **CLP/GHS hazard statements**: None required
- **CLP/GHS precautionary statements**: None required
- **EU symbol/indication of danger**: None required
- **Risk (R) Phrase(s)**: None required
- **Safety Advice**: None required

**Other hazards**

Trimethobenzamide HCl is a sedating antihistamine. It is administered by deep intramuscular injection at very high daily doses (usually 600-800 mg). Common adverse effects reported with use are typical of all antihistamines, primarily including drowsiness, as well as dizziness, incoordination, headache, dry mouth, blurred vision, constipation, and other occasional gastrointestinal disturbances (nausea, vomiting, and epigastric pain). Injection site reactions were also noted. Hypersensitivity reactions have also occurred.

**US Signal word**: None required

**US Hazard overview**: None required

**Note**

This mixture does not meet criteria for classification according to directive 1999/45/EC and Regulation EC No 1272/2008 (EU CLP). Nevertheless, it should be regarded as dangerous/hazardous because it contains a pharmacologically active substance and should be handled with care. The GHS classifications are based on Regulation (EC) 1272/2008. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 1999/45/EC.
SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS #</th>
<th>EINECS/ELINCS#</th>
<th>Amount</th>
<th>EU Classification</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimethobenzamide HCl</td>
<td>554-92-7</td>
<td>209-075-6</td>
<td>~10 %</td>
<td>Harmful - Xn: R22</td>
<td>A4: H302</td>
</tr>
</tbody>
</table>

Note

The ingredient(s) listed above are considered dangerous/hazardous. The remaining components are non-dangerous/not hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed

Yes

Eye Contact

If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

Skin Contact

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation

Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Ingestion

Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

Protection of first aid responders

See Section 8 for Exposure Controls/Personal Protection recommendations.

Most important symptoms and effects, both acute and delayed

See Sections 2 and 11.

Indication of immediate medical attention and special treatment needed, if necessary

Contains trimethobenzamide, a sedating antihistamine. Medical conditions aggravated by exposure: none known or reported. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.
### SECTION 5 - FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Extinguishing media</th>
<th>Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific hazards arising from the substance or mixture</td>
<td>No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, nitric and hydrochloric acid, and other nitrogen- and/or chlorine-containing compounds.</td>
</tr>
<tr>
<td>Flammability/Explosivity</td>
<td>No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.</td>
</tr>
<tr>
<td>Advice for firefighters</td>
<td>Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.</td>
</tr>
</tbody>
</table>

### SECTION 6 - ACCIDENTAL RELEASE MEASURES

| Personal precautions, protective equipment and emergency procedures | If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe mist/spray. |
| Environmental precautions | Do not empty into drains. Avoid release to the environment. |
| Methods and material for containment and cleaning up | If vials are crushed or broken, DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9). |
| Reference to other sections | See Sections 8 and 13 for more information. |

### SECTION 7 - HANDLING AND STORAGE

| Precautions for safe handling | If vials are opened, crushed or broken, follow recommendations for handling bulk formulated pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. |
| Conditions for safe storage including any incompatibilities | Store at controlled room temperature (25°C; 77°F) away from incompatible materials. Excursions are permitted to 15-30°C (59-86°F). Keep container upright. Discard unused portion. |
| Specific end use(s) | No information identified. |
SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note
Dispose of broken vials in a sharps container.

Control Parameters/Occupational Exposure Limit Values

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimethobenzamide HCl</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

Exposure/Engineering controls
None required for normal handling of packaged product. If handling bulk product or if vials are opened/crushed/broken: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling. High-energy operations should be done within an approved emission control or containment system.

Respiratory protection
None required for normal handling of packaged product. If handling bulk product or if vials are opened/crushed/broken: For routine handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.

Hand protection
None required for normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible.

Skin protection
Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Environmental Exposure Controls
Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

Other protective measures
Wash hands in the event of contact with this mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).
### SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Liquid in vials</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Clear; Colorless</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Odorless</td>
</tr>
<tr>
<td><strong>Odor threshold</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>Melting point/ freezing point</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Upper/lower flammability or explosive limits</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Vapor density</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
<td>Soluble in water</td>
</tr>
<tr>
<td><strong>Solvent solubility</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Partition coefficient</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><em>(n-octanol/water)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
<td>No information identified.</td>
</tr>
<tr>
<td><strong>Oxidizing properties</strong></td>
<td>No information identified.</td>
</tr>
</tbody>
</table>
### SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

**Other information**

- **Molecular weight**: Not applicable (Mixture)
- **Molecular formula**: Not applicable (Mixture)

### SECTION 10 - STABILITY AND REACTIVITY

**Reactivity**: No information identified.

**Chemical stability**: No information identified.

**Possibility of hazardous reactions**: No information identified.

**Conditions to avoid**: Avoid extreme temperatures.

**Incompatible materials**: Strong oxidizers.

**Hazardous decomposition products**: No information identified.

### SECTION 11 - TOXICOLOGICAL INFORMATION

**Note**: No toxicology data for the product/mixture were identified. The following data describe the active ingredient, other individual ingredients, where applicable.

**Information on toxicological effects**

**Route of entry**: May be absorbed by inhalation, skin contact and ingestion.

**Acute toxicity**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimethobenzamide HCl</td>
<td>LD$_{50}$</td>
<td>Oral</td>
<td>Rat</td>
<td>1600 mg/kg</td>
</tr>
</tbody>
</table>

**Irritation/Corrosion**: No data available.

**Sensitization**: No data available.

**STOT-single exposure**: No data available.

**STOT-repeated exposure/Repeat-dose toxicity**: No data available.

**Reproductive toxicity**: No data available.
SECTION 11 - TOXICOLOGICAL INFORMATION …continued

**Developmental toxicity**
An increased number of embryonic resorptions and/or stillborn pups was noted following administration (route not specified) of trimethobenzamide HCl to pregnant rats at doses ≥20 mg/kg/day. Similar increases in resorptions were reported following treatment of pregnant rabbits with 100 mg/kg/day.

**Genotoxicity**
No data available. Based on its mechanism of action, the genotoxic potential of trimethobenzamide HCl is low.

**Carcinogenicity**
No data available. Based on its mechanism of action, the carcinogenic potential of trimethobenzamide HCl is low. None of the components present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

**Aspiration hazard**
No data available.

**Human health data**
See Section 2 - "Other hazards"

SECTION 12 - ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Compound</th>
<th>Type</th>
<th>Species</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trimethobenzamide HCl</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

**Persistence and Degradability**
No data identified.

**Bioaccumulative potential**
No data identified.

**Mobility in soil**
No data identified.

**Results of PBT and vPvB assessment**
Not performed.

**Other adverse effects**
No data identified.

**Note**
The environmental characteristics of this mixture have not been fully investigated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

**Waste treatment methods**
Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
### SECTION 14 - TRANSPORT INFORMATION

<table>
<thead>
<tr>
<th><strong>Transport</strong></th>
<th>Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN number</strong></td>
<td>None assigned.</td>
</tr>
<tr>
<td><strong>UN proper shipping name</strong></td>
<td>None assigned.</td>
</tr>
<tr>
<td><strong>Transport hazard classes and packing group</strong></td>
<td>None assigned.</td>
</tr>
<tr>
<td><strong>Environmental hazards</strong></td>
<td>Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.</td>
</tr>
<tr>
<td><strong>Special precautions for users</strong></td>
<td>Avoid release to the environment.</td>
</tr>
<tr>
<td><strong>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</strong></td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

### SECTION 15 - REGULATORY INFORMATION

<table>
<thead>
<tr>
<th><strong>Safety, health and environmental regulations/legislation specific for the substance or mixture</strong></th>
<th>This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local/regional authorities for more information.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical safety assessment</strong></td>
<td>Not conducted.</td>
</tr>
<tr>
<td><strong>OSHA Hazardous</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>WHMIS classification</strong></td>
<td>Not required. Drugs are not subject to WHMIS. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.</td>
</tr>
<tr>
<td><strong>TSCA status</strong></td>
<td>Drugs are exempt from TSCA.</td>
</tr>
<tr>
<td><strong>SARA section 313</strong></td>
<td>Not listed.</td>
</tr>
<tr>
<td><strong>California proposition 65</strong></td>
<td>Not listed.</td>
</tr>
<tr>
<td><strong>Additional information</strong></td>
<td>No other information identified.</td>
</tr>
</tbody>
</table>
### Full text of R phrases and EU Classifications

- **Xn** - Harmful. 
- **R22** - Harmful if swallowed.

### Full text of H phrases, P phrases and GHS classification

- **ATO4** - Acute Toxicity (Oral) Category 4. 
- **H302** - Harmful if swallowed.

### Sources of data

Information from published literature and internal company data.

### Abbreviations

- **ACGIH** - American Conference of Governmental Industrial Hygienists; 
- **ADR/RID** - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; 
- **AIHA** - American Industrial Hygiene Association; 
- **CAS#** - Chemical Abstract Services Number; 
- **CLP** - Classification, Labelling, and Packaging of Substances and Mixtures; 
- **DNEL** - Derived No Effect Level; 
- **DOT** - Department of Transportation; 
- **EINECS** - European Inventory of New and Existing Chemical Substances; 
- **ELINCS** - European List of Notified Chemical Substances; 
- **EU** - European Union; 
- **GHS** - Globally Harmonized System of Classification and Labeling of Chemicals; 
- **IARC** - International Agency for Research on Cancer; 
- **IDLH** - Immediately Dangerous to Life or Health; 
- **IATA** - International Air Transport Association; 
- **IMDG** - International Maritime Dangerous Goods; 
- **LOEL** - Lowest Observed Effect Level; 
- **LOAEL** - Lowest Observed Adverse Effect Level; 
- **NIOSH** - The National Institute for Occupational Safety and Health; 
- **NOEL** - No Observed Effect Level; 
- **NOAEL** - No Observed Adverse Effect Level; 
- **NTP** - National Toxicology Program; 
- **OEL** - Occupational Exposure Limit; 
- **OSHA** - Occupational Safety and Health Administration; 
- **PNEC** - Predicted No Effect Concentration; 
- **SARA** - Superfund Amendments and Reauthorization Act; 
- **STEL** - Short Term Exposure Limit; 
- **TDG** - Transportation of Dangerous Goods; 
- **TSCA** - Toxic Substances Control Act; 
- **TWA** - Time Weighted Average; 
- **WHMIS** - Workplace Hazardous Materials Information System

### Revisions

This is the first version of this SDS.

### Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.