1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier
Material Name: Tigan (trimethobenzamide hydrochloride) Capsules
Trade Name: TIGAN
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used for nausea and vomiting (antiemetic)

Details of the Supplier of the Safety Data Sheet
Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Acute Oral Toxicity: Category 4

Label Elements
Signal Word: Warning
Hazard Statements: H302 - Harmful if swallowed

Precautionary Statements:
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with all local and national regulations

PZ02185
SAFETY DATA SHEET

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

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimethobenzamide hydrochloride</td>
<td>554-92-7</td>
<td>209-075-6</td>
<td>Acute Tox.4 (H302)</td>
<td>65-70</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hard gelatin capsules</td>
<td>MIXTURE</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures
Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: 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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed
Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None
5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product used for nausea and vomiting (antiemetic)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Magnesium stearate
- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 5 mg/m³

Corn Starch
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Australia TWA: 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). 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.

Hands:
Impervious gloves (e.g. Nitrile, etc.) are 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.)

Eyes:
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.)

Skin:
Impervious 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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Capsule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>Color:</td>
<td>Purple</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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.

Trimethobenzamide hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Physical State: Capsule
Color: Purple
Odor: No data available.
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture
Solvent Solubility: No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available.
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available.
Vapor Pressure (kPa): No data available.
Vapor Density (g/ml): No data available.
Relative Density: No data available.
Viscosity: No data available.

Flammability:
  Autoignition Temperature (Solid) (°C): No data available.
  Flammability (Solids): No data available.
  Flash Point (Liquid) (°C): No data available.
  Upper Explosive Limits (Liquid) (% by Vol.): No data available.
  Lower Explosive Limits (Liquid) (% by Vol.): No data available.

10. STABILITY AND REACTIVITY

Reactivity: No data available.
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available.
  Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
  Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
  Hazardous Decomposition Products: No data available.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
  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 drowsiness, hypersensitivity reactions, decrease in blood pressure (hypotension), convulsion, headache, disorientation, blurred vision, dizziness, diarrhea, tremors, slurred speech, paranoia, anxiety.
  Acute Toxicity: (Species, Route, End Point, Dose)
SAFETY DATA SHEET

Material Name: Tigan (trimethobenzamide hydrochloride) Capsules
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11. TOXICOLOGICAL INFORMATION

Magnesium stearate
 Rat Oral LD50 > 2000 mg/kg
 Rat Inhalation LC50 > 2000 mg/m³

Trimethobenzamide hydrochloride
 Mouse Oral LD50 1600 mg/kg

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)

Trimethobenzamide hydrochloride
 Skin Irritation Rabbit Non-irritating
 Eye Irritation Rabbit Moderate
 Skin Sensitization - Beuhler Guinea Pig Negative

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

Trimethobenzamide hydrochloride
 Embryo / Fetal Development Rat Oral 20 mg/kg/day LOAEL Not teratogenic, Embryotoxicity
 Embryo / Fetal Development Rabbit Oral 100 mg/kg/day LOAEL Not Teratogenic, Embryotoxicity

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

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 waste water 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.
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.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Trimethobenzamide hydrochloride
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   EU EINECS/ELINCS List: 209-075-6

Lactose NF, monohydrate
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   Australia (AICS): Present
   EU EINECS/ELINCS List: Not Listed

Magnesium stearate
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   EU EINECS/ELINCS List: 209-150-3

Hard gelatin capsules
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   EU EINECS/ELINCS List: Not Listed

Corn Starch
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   REACH - Annex IV - Exemptions from the obligations of Register: Present
   EU EINECS/ELINCS List: 232-679-6
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Data Sources:
Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.
Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 16 - Other
Information. Updated Section 3 - Composition / Information on Ingredients.

Revision date: 29-Nov-2018
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet