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

Product Identifier

Material Name: Trimebutine Maleate Film-coated Tablets
Trade Name: Debridat; Modulon; Trimebutine Pfizer
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as gastric motility regulator and/or

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

Other Hazards
Australian Hazard Classification (NOHSC):


Note:
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings 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>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trimebutine maleate</td>
<td>34140-59-5</td>
<td>251-845-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>50</td>
</tr>
</tbody>
</table>
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Tartaric acid</td>
<td>87-69-4</td>
<td>201-766-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</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.

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: No data available

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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: No data available

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
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. Clean up 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 thoroughly after handling. 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 drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Trimebutine maleate
Pfizer OEL TWA-8 Hr: 1000µg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Silicon dioxide, colloidal NF

<table>
<thead>
<tr>
<th>Country/Standard</th>
<th>TWA/MAK</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.3 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td></td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>German (DFG) - MAK</td>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td></td>
<td>6 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td></td>
<td>20 mppcf Listed</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td></td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.3 mg/m³</td>
</tr>
</tbody>
</table>

Magnesium stearate

ACGIH Threshold Limit Value (TWA) | 10 mg/m³
Lithuania OEL - TWA | 5 mg/m³
Sweden OEL - TWAs | 5 mg/m³

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

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

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Name</td>
<td>Trimebutine Maleate Film-coated Tablets</td>
</tr>
<tr>
<td>Physical State</td>
<td>Film-coated tablets</td>
</tr>
<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>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting/Freezing Point °C</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point °C</td>
<td>No data available.</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Trimebutine maleate</td>
</tr>
</tbody>
</table>

Color: White
Odor Threshold: No data available.
Molecular Weight: Mixture

Revision date: 03-Nov-2014
Material Name: Trimebutine Maleate Film-coated Tablets
Page 4 of 9
Version: 2.0
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Lactose Monohydrate
No data available

Tartaric acid
No data available

Magnesium stearate
No data available

Water, purified
No data available

Film coating
No data available

Sodium starch glycolate
No data available

Starch, pregelatinized
No data available

Hydroxypropyl methylcellulose
No data available

Silicon dioxide, colloidal NF
No data available

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

Polymerization: Will not occur

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: None known
  Products:

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
11. TOXICOLOGICAL INFORMATION

Short Term: Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use. Based on its pharmacologic properties, exposure to this compound may cause effects on the gastrointestinal system.

Known Clinical Effects: Adverse effects associated with therapeutic use of trimebutine are infrequent and include skin rash, sleepiness, headache, vomiting, and dizziness.

Acute Toxicity: (Species, Route, End Point, Dose)

- **Trimebutine maleate**
  - Rat Oral LD50 > 5000 mg/kg
  - Mouse Oral LD50 3230 mg/kg
  - Rat IP LD50 365 mg/kg

- **Lactose Monohydrate**
  - Rat Oral LD50 29700 mg/kg

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

- **Hydroxypropyl methylcellulose**
  - Rat Oral LD50 > 10,000 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.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

- **Trimebutine maleate**
  - Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL No effects at maximum dose
  - Reproductive & Fertility Rabbit Oral 1000 mg/kg/day NOAEL No effects at maximum dose

- **Lactose Monohydrate**
  - In Vitro Bacterial Mutagenicity (Ames) Negative

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

Silicon dioxide, colloidal NF

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Film coating

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

#### Sodium starch glycolate

- 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: Not Listed

#### Tartaric acid

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>231-545-4</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>209-150-3</td>
</tr>
<tr>
<td>Water, purified</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>231-791-2</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>209-150-3</td>
</tr>
<tr>
<td>Water, purified</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>231-791-2</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Trimebutine Maleate Film-coated Tablets
Revision date: 03-Nov-2014

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS)</td>
<td>Present</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 03-Nov-2014
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet