# SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: Methimazole Tablets**

**Trade Name:** TAPAZOLE
**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical product used for Hyperthyroidism

**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**

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

**Pfizer Ltd**
**Ramsgate Road**
**Sandwich, Kent**
**CT13 9NJ**
**United Kingdom**
**+00 44 (0)1304 616161**
**Emergency telephone number:**
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS - Classification**

Reproductive Toxicity: Category 1A

**EU Classification:**

EU Indication of danger: Toxic to reproduction: Category 1

EU Risk Phrases:

R61 - May cause harm to the unborn child.

**Label Elements**

**Signal Word:** Danger
**Hazard Statements:** H360D - May damage the unborn child

**Precautionary Statements:**
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up

**Other Hazards** No data available
**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.

**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

**Hazardous**

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|
| Methimazole | 60-56-0 | 200-482-4 | Repr. Cat.1;R61 | Repr.1A (H360D) | 5-10 |
| Corn Starch | 9005-25-8 | 232-679-6 | Not Listed | Not Listed | * |
| Starch, pregelatinized | 9005-25-8 | 232-679-6 | Not Listed | Not Listed | * |
| Magnesium stearate | 557-04-0 | 209-150-3 | Not Listed | Not Listed | * |
| Talc (non-asbestiform) | 14807-96-6 | 238-877-9 | Not Listed | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|
| Lactose NF, monohydrate | 64044-51-5 | Not Listed | Not Listed | Not Listed | * |

**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 R phrases and 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 fire fighting 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. 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 product used for Hyperthyroidism

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Corn Starch**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 10 mg/m$^3$ |
| **Australia TWA** | 10 mg/m$^3$ |
| **Belgium OEL - TWA** | 10 mg/m$^3$ |
| **Bulgaria OEL - TWA** | 10.0 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 4.0 mg/m$^3$ |
| **Greece OEL - TWA** | 10 mg/m$^3$<br>5 mg/m$^3$ |
| **Ireland OEL - TWAs** | 10 mg/m$^3$<br>4 mg/m$^3$ |
| **OSHA - Final PELS - TWAs:** | 15 mg/m$^3$ |
| **Portugal OEL - TWA** | 10 mg/m$^3$ |
| **Slovakia OEL - TWA** | 4 mg/m$^3$ |
| **Spain OEL - TWA** | 10 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 3 mg/m$^3$ |

**Starch, pregelatinized**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 10 mg/m$^3$ |
| **Australia TWA** | 10 mg/m$^3$ |
| **Belgium OEL - TWA** | 10 mg/m$^3$ |
| **Bulgaria OEL - TWA** | 10.0 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 4.0 mg/m$^3$ |
| **Greece OEL - TWA** | 10 mg/m$^3$<br>5 mg/m$^3$ |
| **Ireland OEL - TWAs** | 10 mg/m$^3$<br>4 mg/m$^3$ |
| **OSHA - Final PELS - TWAs:** | 15 mg/m$^3$ |
| **Portugal OEL - TWA** | 10 mg/m$^3$ |
| **Slovakia OEL - TWA** | 4 mg/m$^3$ |
| **Spain OEL - TWA** | 10 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 3 mg/m$^3$ |

**Magnesium stearate**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 10 mg/m$^3$ |
| **Lithuania OEL - TWA** | 5 mg/m$^3$ |
| **Sweden OEL - TWAs** | 5 mg/m$^3$ |

**Talc (non-asbestiform)**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 2 mg/m$^3$ |
| **Australia TWA** | 2.5 mg/m$^3$ |
| **Austria OEL - MAKs** | 2 mg/m$^3$ |
| **Belgium OEL - TWA** | 2 mg/m$^3$ |
| **Bulgaria OEL - TWA** | 1.0 fiber/cm3<br>6.0 mg/m$^3$<br>3.0 mg/m$^3$ |
| **Czech Republic OEL - TWA** | 2.0 mg/m$^3$ |
| **Denmark OEL - TWA** | 0.3 fiber/cm3 |
| **Finland OEL - TWA** | 0.5 fiber/cm3 |
| **Greece OEL - TWA** | 10 mg/m$^3$<br>2 mg/m$^3$ |
| **Hungary OEL - TWA** | 2 mg/m$^3$ |

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **Ireland OEL - TWAs** | 10 mg/m$^3$ |
| | 0.8 mg/m$^3$ |
| **Lithuania OEL - TWA** | 2 mg/m$^3$ |
| | 1 mg/m$^3$ |
| **Netherlands OEL - TWA** | 0.25 mg/m$^3$ |
| **OSHA - Final PELs - Table Z-3 Mineral D:** | 20 mppcf |
| **Poland OEL - TWA** | 4.0 mg/m$^3$ |
| | 1.0 mg/m$^3$ |
| **Portugal OEL - TWA** | 2 mg/m$^3$ |
| **Romania OEL - TWA** | 2 mg/m$^3$ |
| **Slovakia OEL - TWA** | 2 mg/m$^3$ |
| | 10 mg/m$^3$ |
| **Slovenia OEL - TWA** | 2 mg/m$^3$ |
| **Spain OEL - TWA** | 2 mg/m$^3$ |
| **Sweden OEL - TWAs** | 2 mg/m$^3$ |
| | 1 mg/m$^3$ |
| **Switzerland OEL -TWAs** | 2 mg/m$^3$ |

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.

**Methimazole**

**Pfizer Occupational Exposure Band (OEB):** OEB 3 (control exposure to the range of 10ug/m$^3$ to < 100ug/m$^3$)

**Exposure Controls**

**Engineering Controls:** 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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|---|---|---|
| **Physical State:** | Tablet | **Color:** | White to off-white |
| **Odor:** | No data available. | **Odor Threshold:** | No data available. |
| **Molecular Formula:** | Mixture | **Molecular Weight:** | Mixture |

| | |
|---|---|
| **Solvent Solubility:** | No data available |
| **Water Solubility:** | No data available |
| **pH:** | No data available. |
| **Melting/Freezing Point (°C):** | No data available |
| **Boiling Point (°C):** | No data available. |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Lactose NF, monohydrate**
No data available
**Talc (non-asbestiform)**
No data available
**Magnesium stearate**
No data available
**Starch, pregelatinized**
No data available
**Corn Starch**
No data available
**Methimazole**
Predicted 7.4 Log D -2.743

**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

**Flammablity:**
- **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:** This compound can cross the placenta in pregnant women. Can induce cretinism and goiter in the developing fetus. Adverse effects associated with therapeutic use include decrease in platelets and red/white blood cells (pancytopenia), decreased white blood cells (leukopenia), thrombocytopenia, inflammation of the liver (hepatitis), changes in liver function, effects on the thyroid, headache, skin rash, hives, redness and swelling of the skin (urticaria), loss of hair, nausea, vomiting, loss of taste.

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

## 11. TOXICOLOGICAL INFORMATION

**Talc (non-asbestiform)**
Rat Oral LD50 > 1600 mg/kg

**Magnesium stearate**
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m$^3$

**Methimazole**
Rat Oral LD50 2250 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 & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Methimazole**
Embryo / Fetal Development Rat Oral50 mg/kg/day LOAEL Developmental toxicity
Embryo / Fetal Development Rabbit No route specified Dose not specified Not Teratogenic

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Methimazole**
*In Vitro* Chromosome Aberration Positive
*In Vivo* Negative

**Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Methimazole**
2 Year(s) Rat Oral 0.5 mg/kg/day NOAEL Thyroid, Tumors

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

**Talc (non-asbestiform)**
**IARC:** Group 3 (Not Classifiable)

**Methimazole**
**IARC:** Group 3 (Not Classifiable)

## 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:**
**Partition Coefficient: (Method, pH, Endpoint, Value)**
**Methimazole**
Predicted 7.4 Log D -2.743

**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:**
Class D, Division 2, Subdivision A

**Methimazole**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | developmental toxicity initial date 7/1/90 |
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **Standard for the Uniform Scheduling for Drugs and Poisons:** | Schedule 4 |
| **EU EINECS/ELINCS List** | 200-482-4 |

**Corn Starch**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |

## 15. REGULATORY INFORMATION

| | |
|---|---|
| **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 |

**Starch, pregelatinized**

| | |
|---|---|
| **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 |

**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 |

**Lactose NF, monohydrate**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | Not Listed |
| **California Proposition 65** | Not Listed |
| **Australia (AICS):** | Present |
| **REACH - Annex IV - Exemptions from the obligations of Register:** | Present |
| **EU EINECS/ELINCS List** | Not Listed |

**Talc (non-asbestiform)**

| | |
|---|---|
| **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** | 238-877-9 |

## 16. OTHER INFORMATION

**Text of R phrases and GHS Classification abbreviations mentioned in Section 3**

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Toxic to reproduction: Category 1

R61 - May cause harm to the unborn child.

**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 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

**Revision date:** 16-Apr-2015
Product Stewardship Hazard Communication
**Prepared by:** 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**