



## METHOTREXATE TABLETS

### SAFETY DATA SHEET

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations and according to the Hazardous Products Regulation (February 11, 2015).

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

##### **Product Identifier**

**Product Name:** Methotrexate Tablets

**Synonyms:** Methotrexate Tablets, USP; Methotrexate Tablets 2.5 mg

##### **Intended Use of the Product**

Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

##### **Name, Address, and Telephone of the Responsible Party**

Mylan N.V.  
Building 4  
Trident Place  
Mosquito Way  
Hatfield  
Hertfordshire  
AL10 9UL  
United Kingdom  
[www.mylan.com](http://www.mylan.com)  
+44 (0)1707 853000

##### **Emergency Telephone Number**

**Emergency Number** : For Hazardous Materials Incident  
Spill, Leak, Fire, Exposure, or Accident  
Call CHEMTREC (24 Hours)  
Worldwide +1 703-741-5970

For adverse health events call:  
+1 877-446-3679

#### 2. HAZARDS IDENTIFICATION

**Intended Use of the Product:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

*This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, it is exempt from labeling, as defined in the 29 CFR 1910.1200(b)(5)(iii) and in Canada's Hazardous Products Regulations.*

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

*This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii) and in Canada's Hazardous Products Regulations.*

#### 4. FIRST AID MEASURES

##### **Description of First-aid Measures**

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

**Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**Skin Contact:** Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**Eye Contact:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention (show the label where possible).

#### **Most Important Symptoms and Effects Both Acute and Delayed**

**General:** Please refer to the package insert for more detailed information. Common clinical side effects include: ulcerative stomatitis, leukopenia, nausea, dizziness, malaise, and abdominal distress.

**Inhalation:** May cause irritation to the respiratory tract.

**Skin Contact:** May cause mild skin irritation.

**Eye Contact:** May cause minor eye irritation.

**Ingestion:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** May damage fertility or the unborn child.

#### **Indication of Any Immediate Medical Attention and Special Treatment Needed**

If exposed or concerned, get medical advice and attention.

### **5. FIREFIGHTING MEASURES**

#### **Extinguishing Media**

**Suitable Extinguishing Media:** Not flammable. Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** None known.

#### **Special Hazards Arising From the Substance or Mixture**

**Fire Hazard:** Not flammable.

**Explosion Hazard:** Product is in pill form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

#### **Advice for Firefighters**

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers. Avoid raising dust.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Thermal decomposition generates: Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Sodium oxides.

**Other information:** Refer to Section 9 for flammability properties

### **6. ACCIDENTAL RELEASE MEASURES**

#### **Personal Precautions, Protective Equipment and Emergency Procedures**

**General Measures:** Avoid all eye and skin contact and do not breathe dust.

#### **For Non-Emergency Personnel**

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### **For Emergency Personnel**

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Avoid creating or spreading dust. Eliminate ignition sources. Evacuate unnecessary personnel. Stop leak if safe to do so. Ventilate area.

#### **Environmental Precautions**

Prevent entry to sewers and public waters.

#### **Methods and Materials for Containment and Cleaning Up**

**Methods for Cleaning Up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Vacuum must be fitted with HEPA filter to prevent release of particulates during clean-up.

#### **Reference to Other Sections**

See section 8, Exposure Controls and Personal Protection. See section 13, Disposal Considerations.

### **7. HANDLING AND STORAGE**

#### **Precautions for Safe Handling**

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

**Hygiene Measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

**Conditions for Safe Storage, Including Any Incompatibilities**

**Storage Conditions:** Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight. Protect from moisture.

**Specific End Use(s)**

Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control Parameters**

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), Canadian provincial governments.

**Exposure Controls**

**Appropriate Engineering Controls:** Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Materials for Protective Clothing:** Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

**Hand Protection:** Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

**Eye Protection:** In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

**Skin and Body Protection:** In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

**Respiratory Protection:** When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if found to be necessary.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on Basic Physical and Chemical Properties**

Physical state	: Solid
Appearance	: Orange, round, scored tablet
Odor and Odor threshold	: Not available
pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting/Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Upper and Lower flammable limit	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density/Specific gravity	: Not available
Solubility	: Not available
Log Pow/Log Kow	: Not available
Viscosity	: Not available
Explosive Properties	: Dust explosion hazard in air

**10. STABILITY AND REACTIVITY**

**Reactivity** Hazardous reactions will not occur under normal conditions.

**Chemical Stability** Stable under normal conditions.

**Possibility of Hazardous Reactions** Hazardous polymerization will not occur.

**Conditions to Avoid** Direct sunlight. Extremely high or low temperatures. Incompatible materials. Moisture. Avoid creating or spreading dust.

**Incompatible Materials** Strong oxidizers. Strong bases. Strong acids.

**Hazardous Decomposition Products** None known.

**11. TOXICOLOGICAL INFORMATION**

**Information on Toxicological Effects - Product**

**Acute Toxicity (Oral):** Not classified

**Acute Toxicity (Dermal):** Not classified  
**Acute Toxicity (Inhalation):** Not classified  
**LD50 and LC50 Data:** Not available  
**Skin Corrosion/Irritation:** Not classified  
**Eye Damage/Irritation:** Not classified  
**Respiratory or Skin Sensitization:** Not classified  
**Germ Cell Mutagenicity:** Not classified  
**Carcinogenicity:** Not classified  
**Specific Target Organ Toxicity (Repeated Exposure):** Not classified  
**Reproductive Toxicity:** May damage fertility or the unborn child.  
**Specific Target Organ Toxicity (Single Exposure):** Not classified  
**Aspiration Hazard:** Not classified  
**Information on Toxicological Effects - Ingredient(s)**  
**LD50 and LC50 Data:** Not applicable

**12. ECOLOGICAL INFORMATION**

**Toxicity**

**Ecology - General:** Not classified.

**Persistence and Degradability** Not available

**Bioaccumulative Potential** Not available

**13. DISPOSAL CONSIDERATIONS**

**Sewage Disposal Recommendations:** Do not empty into drains.

**Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

**14. TRANSPORT INFORMATION**

**In Accordance with DOT** Not regulated for transport

**In Accordance with IMDG** Not regulated for transport

**In Accordance with IATA** Not regulated for transport

**In Accordance with TDG** Not regulated for transport

**15. REGULATORY INFORMATION**

**US Federal Regulations**

This product does not appear on any US federal lists.

**US State Regulations**

This product does not appear on any US state lists.

**Canadian Regulations**

This product does not appear on any Canadian lists.

**16. OTHER INFORMATION**

**Revision Date** : 27 June 2016

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR).

*This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*