



METHOTREXATE INJECTION SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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

Product Identifier

Product name: Methotrexate Injection

Synonyms: Methotrexate Injection, USP; Methotrexate Injection (25 mg/ml)

Intended Use of the Product

Pharmaceutical. Antineoplastic, Antimetabolite Agent. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party

Supplier:

Mylan N.V.
Building 4, Trident Place
Mosquito Way
Hatfield,
Hertfordshire
AL10 9UL, United Kingdom
+44 (0)1707 853000

www.mylan.com

Contact e-mail:

SDScontact@Mylan.com

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 reporting adverse health events, call:
+1 877-446-3679

2. HAZARDS IDENTIFICATION

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Patients/Consumers: 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.

Classification of the Substance or Mixture

Classification (GHS-US)

Muta. 2 H341

Repr. 1A H360

Label Elements

GHS-US labeling

Hazard pictograms (GHS-US)



Signal word (GHS-US)

: Danger

Hazard statements (GHS-US)

: H341 - Suspected of causing genetic defects
H360 - May damage fertility or the unborn child

Precautionary statements (GHS-US)

: P202 - Do not handle until all safety precautions have been read and understood.

P280 - Wear eye protection, face protection, protective gloves, protective clothing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Methotrexate	(CAS No) 59-05-2	2.5	Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Muta. 2, H341 Repr. 1A, H360

Additional Information: sodium hydroxide and hydrochloric acid have been added for pH adjustment.
Full text of H-phrases: see section 16

4. FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.

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.

Inhalation: None expected under normal conditions of use.

Skin Contact: Causes skin irritation.

Eye Contact: Causes serious eye irritation.

Ingestion: Ingestion is likely to be harmful or have adverse effects.

Injection: Common clinical side effects include: headache, nausea, vomiting. Bone marrow, liver, and kidney toxicities.

Chronic symptoms: Suspected of causing genetic defects, 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. In the event of accidental injection, go immediately to the nearest emergency room.

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 not explosive.

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.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides.

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.

Personal Precautions, Protective Equipment and Emergency Procedures

General measures: Avoid all eye and skin contact and do not breathe vapor and mist.

For Non-Emergency Personnel

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

Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equip cleanup crew with proper protection.

Emergency procedures: Evacuate unnecessary personnel. Stop leak if safe to do so.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods and Material 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.

Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

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 vapor or mist. 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.

Special rules on packaging: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Specific End Use(s)

Pharmaceutical. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.

Control Parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

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.

Personal protective equipment: 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 respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical state	: Liquid
Appearance	: Not available
Odor	: Not available
Odor threshold	: Not available

pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting point/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
Explosion data - sensitivity to mechanical impact	: Not available
Explosion data - sensitivity to static discharge	: Not available

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 Strong oxidizers. Strong bases. Strong acids.

Hazardous Decomposition Products Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Not classified.

LD50 and LC50 Data: Not available.

Skin Corrosion/Irritation: Not classified.

Serious Eye Damage/Irritation: Not classified.

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Suspected of causing genetic defects.

Teratogenicity: Not available.

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:

Methotrexate (59-05-2)	
LD50 oral rat	135 - 225 mg/kg
ATE CLP (oral)	135.000 mg/kg
Methotrexate (59-05-2)	
IARC group	3

12. ECOLOGICAL INFORMATION

Toxicity

Not available

Persistence and Degradability

Not available

Bioaccumulative Potential

Not available

13. DISPOSAL CONSIDERATIONS

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.

Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number

Not regulated for transport

UN Proper Shipping Name

Not regulated for transport

15. REGULATORY INFORMATION**US Federal Regulations****Methotrexate Injection**

SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard
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US State Regulations**Methotrexate (59-05-2)**

U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.
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Methotrexate (59-05-2)

RTK - U.S. - Massachusetts - Right To Know List

Canadian Regulations**Methotrexate Injection**

WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects
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**Methotrexate (59-05-2)**

Listed on Non-Domestic Substances List (NDSL)

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

16. OTHER INFORMATION

- Revision date** : 31 August 2016
- Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
- Other information** : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Muta. 2	Germ cell mutagenicity Category 2
Repr. 1A	Reproductive toxicity Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
H301	Toxic if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H341	Suspected of causing genetic defects
H360	May damage fertility or the unborn child

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department
Phone Number: 304-599-2595

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.

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