



MATERIAL SAFETY DATA SHEET

Revision date: 29-Mar-2012

Version: 2.0

Page 1 of 7

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Methotrexate Solution for Injection

Trade Name:	Methoblastin; Maxtrex; Methotrexat; Lantarel; Trexan
Chemical Family:	Mixture
Intended Use:	Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Clear yellow solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: May be absorbed through the skin and cause systemic effects. May be harmful if swallowed. (based on components) .

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. The use of this drug during pregnancy has resulted in birth defects.

Known Clinical Effects: Adverse effects associated with therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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

Hazardous

MATERIAL SAFETY DATA SHEET

Material Name: Methotrexate Solution for Injection
Revision date: 29-Mar-2012

Page 2 of 7
Version: 2.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Methotrexate	59-05-2	200-413-8	Mut. Cat.3;R68 Repr. Cat.1;R61 T;R25	0.25
Sodium hydroxide	1310-73-2	215-185-5	C;R35	###

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary
as required.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

MATERIAL SAFETY DATA SHEET

Material Name: Methotrexate Solution for Injection
Revision date: 29-Mar-2012

Page 3 of 7
Version: 2.0

Measures for Environmental Protections:

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

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

General Handling:

Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Wash thoroughly after handling. Avoid open handling.

Storage Conditions:

Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Methotrexate

Pfizer OEL TWA-8 Hr: 2 µg/m³

Sodium chloride

Latvia OEL - TWA 5 mg/m³

Lithuania OEL - TWA 5 mg/m³

Sodium hydroxide

ACGIH Ceiling Threshold Limit: 2 mg/m³

Australia PEAK 2 mg/m³

Austria OEL - MAKs 2 mg/m³

Bulgaria OEL - TWA 2.0 mg/m³

Czech Republic OEL - TWA 1 mg/m³

Estonia OEL - TWA 1 mg/m³

France OEL - TWA 2 mg/m³

Greece OEL - TWA 2 mg/m³

Hungary OEL - TWA 2 mg/m³

Japan - OELs - Ceilings 2 mg/m³

Latvia OEL - TWA 0.5 mg/m³

OSHA - Final PELs - TWAs: 2 mg/m³

Poland OEL - TWA 0.5 mg/m³

Slovakia OEL - TWA 2 mg/m³

Slovenia OEL - TWA 2 mg/m³

Sweden OEL - TWAs 1 mg/m³

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Methotrexate Solution for Injection
Revision date: 29-Mar-2012

Page 4 of 7
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Physical State:	Solution	Color:	Clear Yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Methotrexate

Rat	Oral	LD50	135 mg/kg
Rat	Sub-tenon injection (eye)	LD50	6 mg/kg
Rat	Intravenous	LD50	14 mg/kg
Mouse	Oral	LD50	146 mg/kg
Not Specified	Inhalation	LC50	> 188 ug/m ³

Sodium chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Sodium hydroxide

Mouse	IP	LD50	40 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)

Sodium chloride

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Sodium hydroxide

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

MATERIAL SAFETY DATA SHEET

Material Name: Methotrexate Solution for Injection
Revision date: 29-Mar-2012

Page 5 of 7
Version: 2.0

11. TOXICOLOGICAL INFORMATION

Methotrexate

4 Week(s)	Rat	Oral	5.6 mg/kg	LOAEL	Bone marrow, Liver
6 Week(s)	Rat	Oral	4.2 mg/kg	LOAEL	Bone Marrow, Liver

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

Methotrexate

Embryo / Fetal Development	Mouse	Oral	10 mg/kg/day	NOAEL	Not teratogenic
Embryo / Fetal Development	Mouse	Oral	25-50 mg/kg/day	LOAEL	Teratogenic
Embryo / Fetal Development	Monkey	Intravenous	30 mg/kg/day	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rat	Intraperitoneal	5 mg/kg	LOAEL	Fetotoxicity

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

Methotrexate

<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Positive
<i>In Vitro</i> Sister Chromatid Exchange	Mouse	Positive
Unscheduled DNA Synthesis	Human Lymphocytes	Positive
<i>In Vivo</i> Micronucleus	Mouse	Positive

Carcinogen Status:

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

Methotrexate

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Methotrexate Solution for Injection
Revision date: 29-Mar-2012

Page 6 of 7
Version: 2.0

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

D2a very toxic materials



Methotrexate

California Proposition 65	developmental toxicity initial date 1/1/89
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	200-413-8

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Water for Injection

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	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

MATERIAL SAFETY DATA SHEET

Material Name: Methotrexate Solution for Injection
Revision date: 29-Mar-2012

Page 7 of 7
Version: 2.0

R25 - Toxic if swallowed.
R35 - Causes severe burns.
R60 - May impair fertility.
R68 - Possible risks of irreversible effects.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: 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.

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