



SAFETY DATA SHEET

Revision date 18-Jun-2025

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Methotrexate Injection, USP (Hospira, Inc.)
Product Code(s) PZ03148
Trade Name: Not applicable
Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as Antineoplastic

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

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

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Germ cell mutagenicity

Category 2 - (H341)

Reproductive toxicity

Category 1A - (H360D)

Specific target organ toxicity (repeated exposure)

Category 1 - (H372)

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

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Not applicable

2.2. Label elements



Signal word

Hazard statements

Danger

H360D - May damage the unborn child

H341 - Suspected of causing genetic defects

H372 - Causes damage to organs through prolonged or repeated exposure; liver, bone marrow.

Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

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

P260 - Do not breathe mist

P264 - Wash skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P280 - Wear protective gloves and protective clothing

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P405 - Store locked up

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

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				[CLP]			
Methotrexate (CAS #: 59-05-2)	2.5		200-413-8	Acute Tox.3 (H301) STOT RE.1 (H372) Repr.1A (H360D) Muta.2 (H341)	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Methotrexate 59-05-2	135	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No.

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1907/2006 (REACH), Article 59).

Additional information

+ Substance with a Union workplace exposure limit

* Proprietary

** to adjust pH

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO ₂ , alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
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Hazardous combustion products	Formation of toxic gases is possible during heating or fire.
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Explosion data

Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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Section 6: ACCIDENTAL RELEASE MEASURES

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6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Avoid breathing vapors or mists. Avoid contact with skin, eyes or 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.
General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product. Antineoplastic.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Methotrexate

Pfizer OEL TWA-8 Hr: 2 µg/m³

Methotrexate

Poland

TWA-NDS: 0.001 mg/m³; inhalable fraction

Sk

Russia

MAC: 0.1 mg/m³

SODIUM CHLORIDE

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Latvia	TWA: 5 mg/m ³ ;
Russia	MAC: 5 mg/m ³
Sodium hydroxide	
ACGIH OEL (Ceiling)	2 mg/m ³
ACGIH TLV	Ceiling: 2 mg/m ³
Austria	TWA-TMW: 2 mg/m ³ ; inhalable fraction
	STEL-KZGW: 4 mg/m ³ (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m ³ ; alkaline aerosols
Czech Republic	1 mg/m ³
	Ceiling: 2 mg/m ³
Denmark	Ceiling: 2 mg/m ³ ;
Estonia	TWA: 1 mg/m ³ ;
	STEL: 2 mg/m ³ ;
Finland	Ceiling: 2 mg/m ³ ;
France	2 mg/m ³
Hungary	TWA-AK: 1 mg/m ³ ;
	STEL-CK: 2 mg/m ³ ;
Ireland	STEL: 2 mg/m ³ ;
Ceiling Limit Value	2 mg/m ³
Latvia	TWA: 0.5 mg/m ³ ;
Poland	TWA-NDS: 0.5 mg/m ³ ;
	STEL-NDSch: 1 mg/m ³ ;
Romania	TWA: 1 mg/m ³ ;
	STEL: 3 mg/m ³ ;
Slovakia	TWA: 2 mg/m ³ ;
Spain	STEL (VLA-EC): 2 mg/m ³ ;
Switzerland	TWA-MAK: 2 mg/m ³ ; inhalable dust
	STEL-KZGW: 2 mg/m ³ ; inhalable dust
OSHA PEL	TWA: 2 mg/m ³
	(vacated) Ceiling: 2 mg/m ³
United Kingdom	STEL: 2 mg/m ³ ;
+ Hydrochloric Acid	
ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	TWA-TMW: 5 ppm;
	TWA-TMW: 8 mg/m ³ ;
	STEL-KZGW: 10 ppm (8 X 5 min);
	STEL-KZGW: 15 mg/m ³ (8 X 5 min);
Bulgaria	TWA: 5 ppm;
	TWA: 8.0 mg/m ³ ;
	STEL: 10 ppm;
	STEL: 15.0 mg/m ³ ;
Czech Republic	8 mg/m ³
	Ceiling: 15 mg/m ³
Denmark	STEL: 5 ppm;
	STEL: 8 mg/m ³ ;
Estonia	TWA: 5 ppm;
	TWA: 8 mg/m ³ ;
	STEL: 10 ppm;
	STEL: 15 mg/m ³ ;
European Union	TWA: 5 ppm;
	TWA: 8 mg/m ³ ;
	STEL: 10 ppm;
	STEL: 15 mg/m ³ ;
Finland	STEL: 5 ppm;
	STEL: 7.6 mg/m ³ ;
Germany DFG	TWA-MAK: 2 ppm; I(2);
	TWA-MAK: 3.0 mg/m ³ ; I(2);

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	Peak: 4 ppm; Peak: 6 mg/m ³ ; TWA-AGW; 2 ppm (exposure factor 2); TWA-AGW; 3 mg/m ³ (exposure factor 2); TWA-AK: 8 mg/m ³ ; TWA-AK: 5 ppm; STEL-CK: 165 mg/m ³ ; STEL-CK: 10 ppm; TWA: 8 mg/m ³ ; TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m ³ ; TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Germany TRGS	2 ppm
Hungary	3.0 mg/m ³
Ireland	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Italy MDLPS	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Ceiling Limit Value	2 ppm
Latvia	3.0 mg/m ³
Netherlands	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Poland	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Romania	TWA-NDS: 5 mg/m ³ ; STEL-NDSch: 10 mg/m ³ ;
Russia	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Slovakia	MAC: 5 mg/m ³
Spain	TWA: 5 ppm; TWA: 8.0 mg/m ³ ; Ceiling: 15 mg/m ³ ;
Switzerland	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m ³ ; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m ³ ;
U.S. - OSHA - Final PELs - Ceiling Limits	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m ³ ; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m ³ ;
OSHA PEL	5 ppm
United Kingdom	7 mg/m ³
	Ceiling: 5 ppm
	Ceiling: 7 mg/m ³
	(vacated) Ceiling: 5 ppm
	(vacated) Ceiling: 7 mg/m ³
	TWA: 1 ppm; gas and aerosol mist
	TWA: 2 mg/m ³ ; gas and aerosol mist
	STEL: 5 ppm; gas and aerosol mist
	STEL: 8 mg/m ³ ; gas and aerosol mist

Pfizer Occupational Exposure Band (OEB) Statement:

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,

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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.

SODIUM CHLORIDE

Pfizer Occupational Exposure
Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Chemical name	Oral	Dermal	Inhalation
SODIUM CHLORIDE 7647-14-5	-	295.52 mg/kg bw/day [4] [6] 295.52 mg/kg bw/day [4] [7]	2068.62 mg/m ³ [4] [6] 2068.62 mg/m ³ [4] [7]

Chemical name	Oral	Dermal	Inhalation
SODIUM CHLORIDE 7647-14-5	126.65 mg/kg bw/day [4] [6] 126.65 mg/kg bw/day [4] [7]	126.65 mg/kg bw/day [4] [6] 126.65 mg/kg bw/day [4] [7]	443.28 mg/m ³ [4] [6] 443.28 mg/m ³ [4] [7]

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
SODIUM CHLORIDE 7647-14-5	5 mg/L	-	-	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
SODIUM CHLORIDE 7647-14-5	-	-	500 mg/L	4.86 mg/kg soil dw	-

8.2. 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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

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Skin and body protection	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).
Thermal hazards	No information available.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Solution
Physical state	Liquid
Color	Clear Yellow
Odor	No information available.
Odor threshold	No information available

Property	Values
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

Methotrexate

Predicted 7.4 Log D -5.22

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

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9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Short term May be absorbed through the skin and cause systemic effects.

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

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.

Acute toxicity Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitization Based on available data, the classification criteria are not met.

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure. Classification is based on mixture calculation methods based on component data.

Reproductive toxicity May damage the unborn child. Classification is based on mixture calculation methods based on component data.

Germ cell mutagenicity Suspected of causing genetic defects. Classification is based on mixture calculation methods based on component data.

Carcinogenicity Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

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

Methotrexate

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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/m³

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Methotrexate	= 135 mg/kg (Rat)	-	-
SODIUM CHLORIDE	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

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

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

+ Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

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

Methotrexate

4 Week(s) Rat Oral 0.1 mg/kg LOAEL Bone marrow, Liver
6 Week(s) Rat Oral 4.2 mg/kg LOAEL Bone Marrow, Liver
2 Week(s) Rat Inhalation 1.27 mg/kg/day LOAEL Gastrointestinal system, Lungs

Reproduction & Development Toxicity: (Duration, 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 1 mg/kg/day NOAEL Developmental toxicity
Embryo / Fetal Development Rat Intraperitoneal 0.1 mg/kg LOAEL Fetotoxicity
Embryo / Fetal Development Rabbit Intravenous, Intraperitoneal 4.8 mg/kg/day NOAEL Developmental toxicity, Fetotoxicity, Maternal Toxicity

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

Methotrexate

In Vitro Chromosome Aberration Human Lymphocytes Positive
In Vitro Sister Chromatid Exchange Mouse Positive

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Unscheduled DNA Synthesis Human Lymphocytes Positive
In Vivo Micronucleus Mouse Positive
+ Hydrochloric Acid
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Methotrexate

2 Year(s) Mouse Oral 10 mg/kg/day NOAEL Equivocal
2 Year(s) Hamster Oral, in feed 20 mg/kg/day NOAEL Not carcinogenic

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

Methotrexate

IARC Group 3

+ Hydrochloric Acid

IARC Group 3

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

Methotrexate

Predicted 7.4 Log D -5.22

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

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Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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 wastewater 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.

Section 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.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

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CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Developmental
TSCA	Present
EINECS	200-413-8
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4
SODIUM CHLORIDE	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present
Sodium hydroxide	
CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6
+ Hydrochloric Acid	
CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Methotrexate 59-05-2	-	-	Development Category 1A Fertility Category 2

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

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Major Accidents Ordinance SR 814.012

Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Methotrexate 59-05-2	75	-
Sodium hydroxide 1310-73-2	75	-
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants

Not applicable

Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algicides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

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15.2. Chemical safety assessment

Chemical Safety Report

No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H301 - Toxic if swallowed H331 - Toxic if inhaled H314 - Causes severe skin burns and eye damage H360D - May damage the unborn child H341 - Suspected of causing genetic defects H372 - Causes damage to organs through prolonged or repeated exposure

Data Sources:

Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reason for revision

Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage.
Updated Section 11 - Toxicology Information.

Revision date

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Prepared By

Pfizer Global Environment, Health, and Safety

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