

Methotrexate, disodium salt

Version: 5.4

Revision Date: 22.01.2025

SDS Number: 100000000742

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Methotrexate, disodium salt

REACH Registration Number : -

CAS-No. : 7413-34-5

EC-No. : 231-022-0

Unique Formula Identifier : -

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

Use of the Sub-
stance/Mixture : Active pharmaceutical ingredients

Recommended restrictions
on use : No data available

1.3 Details of the supplier of the safety data sheet

Company : Fermion Oy

Street address : Koivu-Mankkaan tie 6 A

Post-office box: : P.O. Box 28

Postcode : 02101 Espoo, Finland

Telephone : +358 10 4261

E-mail address of person
responsible for the SDS : chemicalsafety@orion.fi

VAT Reg. No: : FI18552129

1.4 Emergency telephone number

Poison Center : +358 800 147111
+358 9 471 977

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 3	H301: Toxic if swallowed.
Carcinogenicity, Category 2	H351: Suspected of causing cancer.
Germ cell mutagenicity, Category 1B	H340: May cause genetic defects.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin irritation, Category 2	H315: Causes skin irritation.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.

For explanation of abbreviations see section 16.

2.2 Label elements

Labeling (REGULATION (EC) No 1272/2008)

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Hazard pictograms :  

Signal Word : Danger

Hazard Statements

H301	Toxic if swallowed.
H351	Suspected of causing cancer.
H340	May cause genetic defects.
H360D	May damage the unborn child.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.

Precautionary Statements

General:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P305 + P351 + P333 IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P501 Dispose of contents according to national and local law.

2.3 Other hazards

Other hazards	: No data available
PBT	: No data available
vPvB	: No data available
Endocrine disrupting properties	: Ecological information: No data available Toxicological information: No data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	CAS-No. EC-No. Registration-No	Concentration (% w/w)	M-Factor, SCL, ATE
Methotrexate, disodium salt	7413-34-5 231-022-0		

Other information : -

3.2 Mixtures

Not applicable

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SECTION 4: First aid measures

4.1 Description of first-aid measures

- | | | |
|-------------------------|---|---|
| General advice | : | Helpers should ensure their own protection. |
| If inhaled | : | IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
If appropriate, give artificial respiration or oxygen.
Get medical advice/attention. |
| In case of skin contact | : | Remove/ Take off immediately all contaminated clothing.
IF ON SKIN: Wash with soap and water.
Get medical advice/attention. |
| In case of eye contact | : | IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention. |
| If swallowed | : | Rinse mouth.
Do NOT induce vomiting.
Get medical advice/attention. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|----------|---|--|
| Symptoms | : | See section 11 for symptoms of exposure. |
| Risks | : | No data available |

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|-------------------|
| Treatment | : | No data available |
|-----------|---|-------------------|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|------------------------------|---|--|
| Suitable extinguishing media | : | Carbon dioxide (CO ₂)
Foam
Water
Powder |
|------------------------------|---|--|

- | | | |
|--------------------------------|---|-------------------|
| Unsuitable extinguishing media | : | No data available |
|--------------------------------|---|-------------------|

5.2 Special hazards arising from the substance or mixture

- | | | |
|---------------------------------------|---|---|
| Specific hazards during fire fighting | : | May emit toxic fumes of oxides of carbon and nitrogen during heating or fire. |
| Hazardous combustion products | : | No data available |

5.3 Advice for firefighters

- | | | |
|--|---|---|
| Special protective equipment for fire-fighters | : | Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing. |
| Specific extinguishing methods | : | No data available |

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Further information : No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Access of extra people to the spill area must be prevented.

6.2 Environmental precautions

Environmental precautions : Data not available.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Collect spilled powder without dusting into tight closed container.

6.4 Reference to other sections

See Section 8 and 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : All exposure must be avoided.
Do not get in eyes, on skin, or on clothing.
Handle in well-ventilated space.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Store in a well ventilated place.
Keep container tightly closed.
Keep cool.
Protect from sunlight.
Store at normal storing temperature.
See incompatible materials in section 10.5.

Packaging material : Suitable material: No data available
Unsuitable material: No data available

7.3 Specific end use(s)

Specific use(s) : No information identified.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures : Wash up thoroughly after handling.
All exposure must be avoided.
Avoid contact during pregnancy/while nursing.
Handle in closed systems or use an efficient local exhaust if dust, vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal

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protective equipment.

Personal protective equipment

- Respiratory protection : In open handling use respirator (P3) with a minimum protection factor of 200.
See standard working procedures/instructions or department's instructions for more detailed protection measures.
- Eye/face protection : Use protective goggles.
- Hand protection
Remarks : Use protective gloves (e.g. nitrile or neopren gloves).
- Skin and body protection : In dust making work use disposal overalls and extra throwaway sleeves.
- Protective measures : No data available

Environmental exposure controls

- Air : Do not put into water system, drain or soil.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Form : powder
- Physical state : solid
- Color : yellow
- Odor : odorless
- Odor Threshold : No data available
- Melting point/range : 182 - 189 °C
- Boiling point/boiling range : No data available
- Flammability : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Flash point : No data available
- Autoignition temperature : No data available
- Decomposition temperature : No data available
- Self-Accelerating decomposition temperature (SADT) : No data available

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pH : 8,1
Concentration: 1 % w/V

Viscosity
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Flow time : No data available

Solubility(ies)
Water solubility : soluble

Solubility in other solvents : No data available

Dissolution Rate : No data available

Partition coefficient: n-octanol/water : No data available

Dispersion Stability : No data available

Vapor pressure : No data available

Relative density : No data available

Density : No data available

Bulk density : No data available

Relative vapor density : No data available

Dissociation constant : No data available

Particle characteristics : No data available

9.2 Other information

Self-ignition : No data available

Hygroscopic properties : No data available

Henry's Constant : No data available

Further information : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under normal conditions.

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10.3 Possibility of hazardous reactions

Hazardous reactions : Not expected to occur.

10.4 Conditions to avoid

Conditions to avoid : Heat.
Oxidizing conditions

10.5 Incompatible materials

Materials to avoid : Oxidants
Strong acids

10.6 Hazardous decomposition products

May emit toxic fumes of oxides of carbon and nitrogen during heating or fire.

SECTION 11: Toxicological information

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

Acute toxicity

Health hazard information : Toxic if swallowed.

Acute oral toxicity : LD50 (Rat): 135 mg/kg
LD50 (Mouse): 146 mg/kg

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : No data available

Skin corrosion/irritation

Result : Causes skin irritation.

Serious eye damage/eye irritation

Result : Causes serious eye irritation.

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Genotoxicity in vitro : May cause genetic defects.

Genotoxicity in vivo : No data available

Carcinogenicity

Result : Suspected of causing cancer.

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Reproductive toxicity

Effects on fertility : No data available

Effects on fetal development : May damage the unborn child.

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Repeated dose toxicity

Remarks : The most common toxic effects are on the gastrointestinal tract and bone marrow. The symptoms include ulceration of mouth, nausea vomiting and diarrhea, leucopenia, thrombocytopenia and anaemia. There are reports of hepatotoxicity, teratogenic and carcinogenic effects, neurotoxic reactions and anaphylaxis.

Aspiration toxicity

No data available

11.2 Information on other hazards

Endocrine disrupting properties

No data available

Experience with human exposure

General Information : No data available

Inhalation : No data available

Skin contact : No data available

Eye contact : No data available

Ingestion : No data available

Toxicology, Metabolism, Distribution

Remarks : No data available

Neurological effects

Remarks : No data available

Further information

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Remarks : May cause respiratory irritation.

Other Health Hazards

No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : No data available

Toxicity to daphnia and other aquatic invertebrates : No data available

Toxicity to algae/aquatic plants : No data available

Toxicity to fish (Chronic toxicity) : No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : No data available

Toxicity to microorganisms : No data available

Toxicity to soil dwelling organisms : No data available

Plant toxicity : No data available

Sediment toxicity : No data available

Toxicity to terrestrial organisms : No data available

Ecotoxicology Assessment

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

Toxicity Data on Soil : No data available

Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

Biodegradability : No data available

Biochemical Oxygen Demand (BOD) : No data available

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Chemical Oxygen Demand (COD)	:	No data available
BOD/COD	:	No data available
ThOD	:	No data available
BOD/ThOD	:	No data available
Dissolved organic carbon (DOC)	:	No data available
Physico-chemical removability	:	No data available
Stability in water	:	No data available
Impact on Sewage Treatment	:	No data available
Photodegradation	:	No data available

12.3 Bioaccumulative potential

Bioaccumulation	:	No data available
Partition coefficient: n-octanol/water	:	No data available

12.4 Mobility in soil

Mobility	:	No data available
Distribution among environmental compartments	:	No data available
Stability in soil	:	No data available

12.5 Results of PBT and vPvB assessment

Assessment	:	No data available
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12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

Environmental fate and pathways	:	No data available
Adsorbed organic bound halogens (AOX)	:	No data available
Ozone-Depletion Potential	:	No data available

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Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

SECTION 14: Transport information

14.1 UN number

ADR/RID: UN 2811

IMDG: UN 2811

IATA: UN 2811

14.2 UN proper shipping name

TOXIC SOLID, ORGANIC, N.O.S. (methotrexate, disodium salt)

14.3 Transport hazard class(es) (ADR/RID, IMDG, ICAO/IATA)

ADR/RID: 6.1

IMDG: 6.1

IATA: 6.1

14.4 Packing group

ADR/RID: III

IMDG: III

IATA: III

14.5 Environmental hazards

ADR/RID: -

IMDG: -

IATA: -

14.6 Special precautions for user

Tunnel restriction code : No data available

Further information for transport : No data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable

SECTION 15: Regulatory information

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

The product has not been fully tested.

15.2 Chemical Safety Assessment

No

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SECTION 16: Other information

Full text of H-Statements

H301	Toxic if swallowed.
H351	Suspected of causing cancer.
H340	May cause genetic defects.
H360D	May damage the unborn child.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Carc.	:	Carcinogenicity
Muta.	:	Germ cell mutagenicity
Repr.	:	Reproductive toxicity
Eye Irrit.	:	Eye irritation
Skin Irrit.	:	Skin irritation
STOT SE	:	Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

AIIC - Australian Inventory of Industrial Chemicals

ASTM - American Society for the Testing of Materials

bw - Body weight

CLP - Classification Labelling Packaging Regulation

Regulation (EC) No 1272/2008

CMR - Carcinogen, Mutagen or Reproductive Toxicant

DIN - Standard of the German Institute for Standardisation

DSL - Domestic Substances List (Canada)

ECHA - European Chemicals Agency

EC-Number - European Community number

ECx - Concentration associated with x% response

ELx - Loading rate associated with x% response

EmS - Emergency Schedule

ENCS - Existing and New Chemical Substances (Japan)

ErCx - Concentration associated with x% growth rate response

GHS - Globally Harmonized System

GLP - Good Laboratory Practice

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC50 - Half maximal inhibitory concentration

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ICAO - International Civil Aviation Organization
IECSC - Inventory of Existing Chemical Substances in China
IMDG - International Maritime Dangerous Goods
IMO - International Maritime Organization
ISHL - Industrial Safety and Health Law (Japan)
ISO - International Organisation for Standardization
KECI - Korea Existing Chemicals Inventory
LC50 - Lethal Concentration to 50 % of a test population
LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)
MARPOL - International Convention for the Prevention of Pollution from Ships
n.o.s. - Not Otherwise Specified
NO(A)EC - No Observed (Adverse) Effect Concentration
NO(A)EL - No Observed (Adverse) Effect Level
NOELR - No Observable Effect Loading Rate
NZIoC - New Zealand Inventory of Chemicals
OECD - Organization for Economic Co-operation and Development
OPPTS - Office of Chemical Safety and Pollution Prevention
PBT - Persistent, Bioaccumulative and Toxic substance
PICCS - Philippines Inventory of Chemicals and Chemical Substances (Q)SAR - (Quantitative) Structure Activity Relationship
REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RID - Regulations concerning the International Carriage of Dangerous Goods by Rail
SADT - Self-Accelerating Decomposition Temperature
SDS - Safety Data Sheet
SVHC - substance of very high concern
TCSI - Taiwan Chemical Substance Inventory
TECI - Thailand Existing Chemicals Inventory
TRGS - Technical Rule for Hazardous Substances
TSCA - Toxic Substances Control Act (United States)
UN - United Nations
vPvB - Very Persistent and Very Bioaccumulative

Further information

Other information : No data available

Sources of key data used to compile the Material Safety Data Sheet : Information provided by the supplier

Information which has been : Updated section / sections:

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