

Methotrexate

Version: 6.3

Revision Date: 22.01.2025

SDS Number: 100000000335

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

1.1 Product identifier

Trade name : Methotrexate

REACH Registration Number : NA

CAS-No. : 59-05-2

EC-No. : 200-413-8

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.
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.
Carcinogenicity, Category 2	H351: Suspected of causing cancer.
Specific target organ toxicity - single exposure, Category 3, Respiratory system	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:

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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	59-05-2 200-413-8		Acute toxicity estimate Acute oral toxicity: 135 mg/kg

Other information : No data available

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 plenty of 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 | : | If swallowed perform a gastric lavage and administer activated charcoal.
Specific antidote: Calciumfolinate (Leucovorin)
In case of decreased leukocytes: 6 - 12 mg, if large overdose occurs up to 75 mg, calciumfolinate iv or im, followed by 6 - 12 mg every 6 hours for 4 doses or more. |
|-----------|---|---|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|--------------------------------|---|---|
| Suitable extinguishing media | : | Carbon dioxide (CO2)
Foam
Powder
Water |
| Unsuitable extinguishing media | : | Do not use powerful water injection. |

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.
Dust may form explosive mixtures with air. |
| Hazardous combustion products | : | No data available |

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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

Further information : No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment as required.
Access of extra people to the spill area must be prevented.
Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
Do not get in eyes, on skin, or on clothing.
Avoid dust formation.
Eliminate all ignition sources if safe to do so.

6.2 Environmental precautions

Environmental precautions : Do not put into water system, drain or soil.

6.3 Methods and material for containment and cleaning up

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

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

7.2 Conditions for safe storage, including any incompatibilities

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

Further information on storage conditions : Keep container tightly closed.
Store in a well ventilated place.
Keep cool.
Protect from sunlight.
See incompatible materials in section 10.5.

7.3 Specific end use(s)

Specific use(s) : No information identified.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures : 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 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 : No data available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form : powder

Physical state : solid

Color : From yellow to brownish orange.

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

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Flash point	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Self-Accelerating decomposition temperature (SADT)	:	No data available
pH	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available
Solubility(ies)		
Water solubility	:	insoluble
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

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SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable when stored and handled according to instructions of use.
Substance is sensitive to light.
hygroscopic

10.3 Possibility of hazardous reactions

Hazardous reactions : No data available

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 toxicity estimate: 135 mg/kg
Method: ATE value derived from LD50/LC50 value

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

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

Skin corrosion/irritation

Skin corrosion/irritation : Causes skin irritation.

No data available

Serious eye damage/eye irritation

Serious eye damage/eye irritation : Causes serious eye irritation.

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No data available

Respiratory or skin sensitization

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

Germ cell mutagenicity

Germ cell mutagenicity : May cause genetic defects.

Genotoxicity in vitro : No data available

Genotoxicity in vivo : No data available

Carcinogenicity

Carcinogenicity : IARC Group 3: Not classifiable as to its carcinogenicity to humans

No data available

Reproductive toxicity

Reproductive toxicity : May damage the unborn child.

Effects on fertility : No data available

Effects on fetal development : No data available

STOT-single exposure

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

STOT-repeated exposure

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

Repeated dose toxicity

No data available

Aspiration toxicity

Aspiration Toxicity Hazard : Based on available data, the classification criteria are not met.

No data available

11.2 Information on other hazards

Endocrine disrupting properties

No data available

Experience with human exposure

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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

No data available

Other Health Hazards

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 effects, neurotoxic reactions and anaphylaxis.

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

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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

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

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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
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)

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

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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

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
Muta.	: Germ cell mutagenicity
Repr.	: Reproductive toxicity
Eye Irrit.	: Eye irritation
Skin Irrit.	: Skin irritation
Carc.	: Carcinogenicity
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

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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
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

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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 added, deleted or revised : Updated section / sections:
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.