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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING
1.1. Product identifier

Trade name: Methotrexate
CAS-number: 59-05-2

Reach registration number: NA

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

The uses of the chemical: Active pharmaceutical ingredients
Classification of the economic activities (NACE): 212
Use categories (UC62): 41

1.3. Details of the supplier of the safety data sheet:

Manufacturer/importer: Fermion Oy
Street address: Koivu-Mankkaan tie 6 A
Post-office box: P.O. Box 28
Postcode: 02101 Espoo, Finland
Telephone number: +358 10 4261
Telefax: +358 9 452 1764
E-mail address: chemicalsafety@orion.fi
VAT Reg. No: FI18552129

1.4. Emergency telephone number

Poison Center: +358 9 471 977

SECTION 2: HAZARDS IDENTIFICATION
2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008	Acute Tox. 3 Muta. 1B Repr. 1B Eye Irrit. 2 Skin Irrit. 2 Carc. 2 STOT SE 3	H301, H340, H360D, H319, H315, H351, H335,
H Statements	Toxic if swallowed.	

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	May cause genetic defects. May damage the unborn child. Causes serious eye irritation. Causes skin irritation. Suspected of causing cancer. May cause respiratory irritation.
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2.2. Label elements

Hazard Pictograms



Signal word

Danger

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.

P Statements

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P305+P351+P338 IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
 P280 Wear protective gloves/protective clothing/eye protection.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P501 Dispose of contents according to national and local law.

2.3. Other hazards

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

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Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Methotrexate	59-05-2	200-413-8	NA

Other information

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions

Helpers should ensure their own protection.

Inhalation

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.

Skin contact

Remove/Take off immediately all contaminated clothing.
IF ON SKIN: Wash with soap and water.
Get medical advice/attention.

Eye contact

IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

Ingestion

Rinse mouth.
Do NOT induce vomiting.
Get medical advice/attention.

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

See section 11 for symptoms of exposure.

4.3. Indication of any immediate medical attention and special treatment needed

If swallowed perform a gastric lavage and administer activated charcoal.
Specific antidote: Calciumfolinate (Leucovorin)

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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: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

- Powder
- Carbon dioxide
- Foam
- Water

Unsuitable extinguishing media Do not use powerful water injection.

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of oxides of carbon and nitrogen during heating or fire.
Dust may form explosive mixtures with air.

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters Isolating breathing apparatus eg. compressed breathing apparatus and isolating protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.
Access of extra people to the spill area must be prevented.
Do not breathe dust/fume/gas/mist/vapours/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

Do not put into water system, drain or soil.

6.3. Methods and material for containment and cleaning up

Collect spilled powder without dusting into tight closed container.
Provide sufficient ventilation.

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6.4. Reference to other sections

See Section 8 and 13

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for 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

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)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values	-
DNELs	-
PNECs	-

8.2. Exposure controls

Appropriate engineering controls

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.

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.

Hand protection

Use protective gloves (e.g. nitrile or neopren gloves).

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Eye protection

Use protective goggles.

Skin protection

In dust making work use disposal overalls and extra throwaway sleeves.

Environmental exposure controls

Do not put into water system, drain or soil.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**Appearance**

Physical state	Powder
Colour	From yellow to brownish orange.
Odour	Odourless
Odour threshold	-

9.1. Information on basic physical and chemical properties

Melting point	182 - 189 °C
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Water solubility	Insoluble
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9.2. Other information

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SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

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10.2. Chemical stability

Stable when stored and handled according to instructions of use.

Substance is sensitive to light.

Hygroscopic.

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10.3. Possibility of hazardous reactions

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10.4. Conditions to avoid

Heat
Oxidising conditions

10.5. Incompatible materials

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 toxicological effects

Acute toxicity	Toxic if swallowed. LD50 = 135 mg/kg (rat, oral). LD50 = 146 mg/kg (mouse, oral).
Skin irritation and corrosion	Causes skin irritation.
Skin sensitization	Based on available data, the classification criteria are not met.
Serious eye damage and irritation	Causes serious eye irritation.
Respiratory irritation	Data not available.
Respiratory sensitization	Based on available data, the classification criteria are not met.
Carcinogenicity	IARC Group 3: Not classifiable as to its carcinogenicity to humans

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Germ cell mutagenicity

May cause genetic defects.

Reproductive toxicity

May damage the unborn child.

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Repeated dose toxicity

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.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Data not available.

Toxic effects on other organisms

Data not available.

12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Octanol-water partition coefficient Data not available.

Bioconcentration factor Data not available.

12.4. Mobility in soil

Data not available.

12.5. Results of PBT and vPvB assessment

Data not available.

12.6. Other adverse effects

Data not 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.

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SECTION 14: TRANSPORT INFORMATION
14.1. UN Number

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)

6.1

14.4. Packing group

III

14.5. Environmental hazard

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14.6. Special precautions for user

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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 substance or mixture

The product has not been fully tested.

15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION
Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be

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used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Fermion Oy shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the Safety Data Sheet

Information provided by the supplier

Information which has been added, deleted or revised

Updated section / sections:

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