

Methotrexate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 25/05/2012 Revision date: 27/02/2017

1034537

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Methotrexate
IUPAC name : (2S)-2-[[4-[[[2,4-Diaminopteridin-6-yl)methyl]methylamino]benzoyl]amino]pentanedioic acid
EC No : 200-413-8
CAS No : 59-05-2
Product code : 1034537
Formula : C₂₀H₂₂N₈O₅
Synonyms : Amethopterin, MTX
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 3

H301

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Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Germ cell mutagenicity, Category 1B	H340
Carcinogenicity, Category 2	H351
Reproductive toxicity, Category 1B	H360

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS06

GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H340 - May cause genetic defects
H351 - Suspected of causing cancer
H360 - May damage fertility or the unborn child

Precautionary statements (CLP)

: P201 - Obtain special instructions before use
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P308+P313 - IF exposed or concerned: Get medical advice/attention

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Methotrexate	(CAS No) 59-05-2 (EC No) 200-413-8	97 - 102	Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Muta. 1B, H340 Carc. 2, H351 Repr. 1B, H360

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures**4.1. Description of first aid measures**

- First-aid measures after inhalation : Remove victim to fresh air. Seek medical attention immediately.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention immediately.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Seek medical attention immediately.
- First-aid measures after ingestion : Give water to drink. Never give anything by mouth to an unconscious person. Seek medical attention immediately.

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

- Symptoms/injuries : Weakening of the immune system. Cardiac and blood circulation effects. Irritation to eyes, skin and respiratory tract. Exposure may produce an allergic reaction. Can affect blood cell formation. Gastrointestinal complaints. Nausea. Vomiting. Damage to kidneys and liver.

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

Antidote : calcium folinate. On ingestion : Give activated charcoal.

SECTION 5: Fire-fighting measures**5.1. Extinguishing media**

- Suitable extinguishing media : Carbon dioxide. Dry powder. Foam. Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides.
- Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****6.1.1. For non-emergency personnel**

- Emergency procedures : Ensure adequate air ventilation. Avoid raising dust. Evacuate area.

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment. Wear respiratory protection.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Sodium hypochlorite solution.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from moisture. Protect from sunlight.

Maximum storage period : 5 year

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

Methotrexate (59-05-2)		
United Kingdom	WEL STEL (mg/m ³)	0.002 mg/m ³

8.2. Exposure controls**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck). Chemical resistant apron

Respiratory protection:

Dust production: dust mask with filter type P3

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 454.4 g/mol
Colour	: Yellow. orange.
Odour	: odourless.
Odour threshold	: No data available
pH	: 8.5 - 8.8
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 185 - 204 °C
Freezing point	: No data available
Boiling point	: No data available

Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Insoluble in water. Soluble in : Aqueous solution of alkaline agents.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions. May decompose on contact with moist air or water.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

heat. Moisture. Light (daylight).

10.5. Incompatible materials

Strong oxidizers. Strong bases.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Toxic if swallowed.

Methotrexate (59-05-2)	
LD50 oral rat	135 mg/kg

Skin corrosion/irritation	: Causes skin irritation. pH: 8.5 - 8.8
Serious eye damage/irritation	: Causes serious eye irritation. pH: 8.5 - 8.8
Respiratory or skin sensitisation	: Not classified

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Germ cell mutagenicity	: May cause genetic defects.
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information**12.1. Toxicity**

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available


SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	6.1
	Not applicable
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

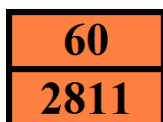
14.6. Special precautions for user**- Overland transport**

Classification code (ADR) : T2

Excepted quantities (ADR) : E1

Hazard identification number (Kemler No.) : 60

Orange plates :



Tunnel restriction code (ADR) : E

EAC code : 2X

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Methotrexate is not on the REACH Candidate List

Methotrexate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

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CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
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Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Supplier.

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Carc. 2	Carcinogenicity, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Muta. 1B	Germ cell mutagenicity, Category 1B
Repr. 1B	Reproductive toxicity, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H301	Toxic if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H340	May cause genetic defects
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child

SDS EU (REACH Annex II) Version 2017

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product