

# Methotrexate

## Safety Data Sheet

according to Regulation (EU) 2015/830

Date of issue: 08/07/2011      Revision date 16/03/2018  
Supersedes 05/08/2011

**M0130**

Version: 2.0

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

#### 1.1. Product identifier

Product form : Substance  
Trade 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 : M0130  
Formula : C<sub>20</sub>H<sub>22</sub>N<sub>8</sub>O<sub>5</sub>  
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 : Professional use  
Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.  
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 Biochemie B.V.  
A. Hofmanweg 71  
2031 BH Haarlem - The Netherlands  
T +31(0)23-5319093 - F +31(0)23-5318027  
[info@duchefa.nl](mailto:info@duchefa.nl)

#### 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)

Organisation/Company	Address	Comment
World Health Organization world directory of poison centres	<a href="http://apps.who.int/poisoncentres/">http://apps.who.int/poisoncentres/</a>	Consult website for a local poison centre

### 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  
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 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	%
Methotrexate	(CAS-No.) 59-05-2 (EC-No.) 200-413-8	100

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/effects : 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: Firefighting 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. [In case of inadequate ventilation] 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.  
 Store at room temperature.

Maximum storage period : 5 year

#### 7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

<b>Methotrexate (59-05-2)</b>		
United Kingdom	WEL STEL (mg/m <sup>3</sup> )	0,002 mg/m <sup>3</sup>

#### 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)**

<b>Methotrexate (59-05-2)</b>	
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
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
Other information	: See actual entry in RTECS for complete information: MA1225000.

## 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

Additional information : Prevent entry to sewers and public waters. Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.  
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

### SECTION 14: Transport information

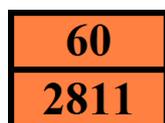
In accordance with ADR / IATA / IMDG

ADR	IMDG	IATA
<b>14.1. UN number</b>		
2811	2811	2811
<b>14.2. UN proper shipping name</b>		
TOXIC SOLID, ORGANIC, N.O.S. (contains Methotrexate)	TOXIC SOLID, ORGANIC, N.O.S. (contains Methotrexate)	Toxic solid, organic, n.o.s. (contains Methotrexate)
<b>Transport document description</b>		
UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (contains Methotrexate), 6.1, III, (E)	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (contains Methotrexate), 6.1, III	UN 2811 Toxic solid, organic, n.o.s. (contains Methotrexate), 6.1, III
<b>14.3. Transport hazard class(es)</b>		
6.1	6.1	6.1
		
<b>14.4. Packing group</b>		
III	III	III
<b>14.5. Environmental hazards</b>		
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No
No supplementary information available		

#### 14.6. Special precautions for user

##### . Overland transport

Classification code (ADR) : T2  
 Special provisions (ADR) : 274, 614  
 Limited quantities (ADR) : 5kg  
 Excepted quantities (ADR) : E1  
 Transport category (ADR) : 2  
 Special provisions for carriage -  
 Operation (ADR) : S9  
 Hazard identification number (Kemler  
 No.) : 60  
 Orange plates :



Tunnel restriction code (ADR) : E  
 EAC code : 2X

##### - Transport by sea

Special provisions (IMDG) : 223, 274  
 EmS-No. (Fire) : F-A  
 EmS-No. (Spillage) : S-A  
 Stowage category (IMDG) : A  
 Properties and observations (IMDG) : Toxic if swallowed, by skin contact or by inhalation.

**- Air transport**

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y645
PCA limited quantity max net quantity (IATA)	: 10kg
PCA packing instructions (IATA)	: 670
PCA max net quantity (IATA)	: 100kg
CAO packing instructions (IATA)	: 677
CAO max net quantity (IATA)	: 200kg
Special provisions (IATA)	: A3, A5
ERG code (IATA)	: 6L

**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****Germany**

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

**Netherlands**

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : Methotrexate is listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : Methotrexate is listed

**Denmark**

Recommendations Danish Regulation : Young people below the age of 18 years are not allowed to use the product  
Pregnant/breastfeeding women working with the product must not be in direct contact with the product  
The requirements from the Danish Working Environment Authorities regarding work with carcinogens must be followed during use and disposal

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes:

1.1	IUPAC name	Added	
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:

ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

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 Biochemicals version 2018

*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*