



# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Revision date: 06/11/2024 Supersedes version of: 03/04/2023 Version: 2.0

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

### 1.1. Product identifier

Product form : Substance

Substance name : Metixene hydrochloride
Chemical name : Metixene hydrochloride

CAS-No. : 7081-40-5 Product code : 201600584

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

### Relevant identified uses

Use of the substance/mixture : Scientific research and development

Technical testing and analysis For professional use only

Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

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

European Directorate for the Quality of Medicines & Healthcare

EDQM, Council of Europe 7, Allée Kastner, CS30026

F 67081 Strasbourg France

T +33(0)388412035, F +33(0)388412771

sds@edqm.eu, www.edqm.eu

### 1.4. Emergency telephone number

Emergency number : +33(0)390215608

# **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 4 H302 Hazardous to the aquatic environment – Acute Hazard, H400

Category 1

Hazardous to the aquatic environment – Chronic Hazard, H410

Category 1

Full text of H- and EUH-statements: see section 16

### Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Very toxic to aquatic life with long lasting effects.

### 2.2. Label elements

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

Hazard pictograms (CLP)





GHS07

GHS09

Signal word (CLP) : Warning

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Hazard statements (CLP) : H302 - Harmful if swallowed.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P301+P312 - IF SWALLOWED: Call a POISON CENTER if you feel unwell.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

No labelling required

### 2.3. Other hazards

Other information : Active substance (in pharmaceutical products).

Warning - substance not yet tested completely.

# **SECTION 3: Composition/information on ingredients**

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Metixene hydrochloride	CAS-No.: 7081-40-5	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500.00000 mg/kg) Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H- and EUH-statements: see section 16

## **SECTION 4: First aid measures**

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If

the person feels unwell : Get medical advice/attention.

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.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking

or redness persists.

First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth

to an unconscious person. Immediately call a POISON CENTER/doctor.

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

No additional information available

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

No additional information available

# **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry

powder. Extinguishing blanket.

Unsuitable extinguishing media : Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other

toxic gases. Toxic fumes may be released.

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### 5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

## **SECTION 6: Accidental release measures**

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

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

# 6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.

Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

### 6.4. Reference to other sections

See Section 13 for disposal information.

## **SECTION 7: Handling and storage**

## 7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not

be allowed out of the workplace. Wash hands before work breaks and after finishing work.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and

direct sunlight.

Packaging materials : Keep in original containers.

# 7.3. Specific end use(s)

No additional information available

## **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

### **Appropriate engineering controls**

### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

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### Personal protection equipment

### Eye and face protection

### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

## **Skin protection**

## Skin and body protection:

Wear suitable protective clothing. Laboratory use: Lab coat. (EN 13034)

#### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

### **Respiratory protection**

### Respiratory protection:

In case of dust formation use respirator with filter: P3

# **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Physical state : Solid

Colour : white, almost white. Appearance : Crystalline powder. Molecular mass : 363.95 g/mol Odour : Not available Odour threshold : Not available : ≈ 215 °C Melting point Freezing point : Not available Boiling point : Not available Flammability : Not available Lower explosion limit : Not applicable Upper explosion limit : Not applicable : Not applicable Flash point : Not applicable Auto-ignition temperature : Not available Decomposition temperature : Not available рΗ pH solution : Not available Viscosity, kinematic : Not applicable Solubility : Water: 33.3 - 100 g/l Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50°C : Not available Density : Not available Relative density : Not available Relative vapour density at 20°C : Not applicable Particle size : Not 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

No additional information available

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### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

## 10.6. Hazardous decomposition products

No additional information available

# **SECTION 11: Toxicological information**

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

Acute toxicity (oral) : Harmful if swallowed.

Acute toxicity (dermal) : Not classified (Lack of data)

Acute toxicity (inhalation) : Not classified (Lack of data)

### Metixene hydrochloride (7081-40-5)

LD50 oral rat > 300 − ≤ 2000 mg/kg (estimated value)

Skin corrosion/irritation : Not classified (Lack of data) Serious eye damage/irritation : Not classified (Lack of data) Respiratory or skin sensitisation : Not classified (Lack of data) Germ cell mutagenicity : Not classified (Lack of data) Carcinogenicity : Not classified (Lack of data) Reproductive toxicity : Not classified (Lack of data) STOT-single exposure : Not classified (Lack of data) : Not classified (Lack of data) STOT-repeated exposure

Aspiration hazard : Not classified (Technical impossibility to obtain the data)

### 11.2. Information on other hazards

No additional information available

# **SECTION 12: Ecological information**

# 12.1. Toxicity

Hazardous to the aquatic environment, short-term : Very toxic to aquatic life.

(acute)

Hazardous to the aquatic environment, long-term : Very toxic to aquatic life with long lasting effects.

(chronic)

## 12.2. Persistence and degradability

## Metixene hydrochloride (7081-40-5)

Persistence and degradability Rapidly degradable

### 12.3. Bioaccumulative potential

No additional information available

## 12.4. Mobility in soil

No additional information available

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# 12.5. Results of PBT and vPvB assessment

No additional information available

## 12.6. Endocrine disrupting properties

No additional information available

# 12.7. Other adverse effects

No additional information available

# **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

No additional information available

# **SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
14.3. Transport hazard class(es)		
9	9	9
		2
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

# 14.6. Special precautions for user

## **Overland transport**

Classification code (ADR) : M7

Special provisions (ADR) : 274, 335, 375, 601

Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1

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Packing instructions (ADR) : P002, IBC08, LP02, R001

Special packing provisions (ADR) : PP12, B3 Mixed packing provisions (ADR) : MP10

Portable tank and bulk container instructions (ADR) : T1, BK1, BK2, BK3

Portable tank and bulk container special provisions : TF

(ADR)

Tank code (ADR) : SGAV, LGBV

Vehicle for tank carriage : AT
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V13
Special provisions for carriage - Bulk (ADR) : VC1, VC2
Special provisions for carriage - Loading, unloading : CV13

and handling (ADR)

Hazard identification number (Kemler No.) : 90

Orange plates :

90 3077

Tunnel restriction code (ADR)

### Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969

Limited quantities (IMDG) : 5 kg
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : LP02, P002
Special packing provisions (IMDG) : PP12
IBC packing instructions (IMDG) : IBC08
IBC special provisions (IMDG) : B3

Tank instructions (IMDG) : BK1, BK2, BK3, T1

Tank special provisions (IMDG) : TP33
Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW23

### Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y956
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 956
PCA max net quantity (IATA) : 400kg
CAO packing instructions (IATA) : 956
CAO max net quantity (IATA) : 400kg

Special provisions (IATA) : A97, A158, A179, A197, A215

ERG code (IATA) : 9L

## 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

# **SECTION 15: Regulatory information**

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

### **EU-Regulations**

### **REACH Annex XVII (Restriction List)**

Not listed on REACH Annex XVII

# **REACH Annex XIV (Authorisation List)**

Not listed on REACH Annex XIV (Authorisation List)

### **REACH Candidate List (SVHC)**

Not listed on the REACH Candidate List

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### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

## Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

# **Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### **Drug Precursors Regulation (273/2004)**

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

# 15.2. Chemical safety assessment

No additional information available

## **SECTION 16: Other information**

Indication of changes	5	
Section	Changed item	Comments
	Revision date	Added
	Supersedes version of	Added
1.1	CAS-No.	Added
1.1	Name	Modified
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	S-phrases	Added
2.2	R-phrases	Added
2.2	Hazard statements (CLP)	Modified
2.2	Hazard pictograms (CLP)	Modified
2.2	Precautionary statements (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after eye contact	Modified
4.1	First-aid measures after inhalation	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after ingestion	Added
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Fire hazard	Removed
5.2	Hazardous decomposition products in case of fire	Added

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Indication of changes		
Section	Changed item	Comments
5.3	Firefighting instructions	Modified
5.3	Protection during firefighting	Added
6.1	Emergency procedures	Modified
6.1	Protective equipment	Added
6.1	General measures	Added
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Hygiene measures	Added
7.1	Precautions for safe handling	Added
7.2	Storage conditions	Added
7.2	Packaging materials	Added
7.3	Specific end uses	Removed
8.2	Skin and body protection	Modified
8.2	Hand protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Eye protection	Added
8.2	Respiratory protection	Added
9	Colour	Added
9	Melting point	Added
9	Solubility in water	Added
9	Molecular mass	Added
9	Appearance	Modified
10.1	Reactivity	Removed
10.3	Possibility of hazardous reactions	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	ATE CLP (oral)	Modified
11.1	LD50 oral rat	Modified
14	Transport information	Modified

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H302	Harmful if swallowed.
H400	Very toxic to aquatic life.

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Full text of H- and EUF	I-statements:
H410	Very toxic to aquatic life with long lasting effects.

Safety Data Sheet (SDS), EU

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