

# Metformin hydrochloride

## Safety Data Sheet

**629693**

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)

2015/830

Issue date: 07/09/2012

Revision date 22/12/2020

Supersedes 17/05/2017

Version: 3.0

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

### 1.1. Product identifier

Product form : Substance  
 Substance name : Metformin hydrochloride  
 IUPAC name : 1,1-Dimethylbiguanide hydrochloride  
 EC-No. : 214-230-6  
 CAS-No. : 1115-70-4  
 Product code : 629693  
 Formula : C<sub>4</sub>H<sub>11</sub>N<sub>5</sub> · HCL  
 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  
 Industrial/Professional use spec : For professional use only  
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

#### 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 - The Netherlands  
 T +31(0)23-5319093  
[farma@ducheffa.nl](mailto:farma@ducheffa.nl) - [www.duchefa-farma.com](http://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)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

## 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

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Skin corrosion/irritation, Category 2H315

Serious eye damage/eye irritation, Category 2H319

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] Extra labelling to displayExtra classification(s) to display

Hazard pictograms (CLP):



GHS07

Signal word (CLP): Warning

Hazard statements (CLP):

H302 - Harmful if swallowed.

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

Precautionary statements (CLP):

P280 - Wear eye protection, face protection, protective clothing, protective gloves.

P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

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]
Metformin hydrochloride	(CAS-No.) 1115-70-4 (EC-No.) 214-230-6	100	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319

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 general	: If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	: Remove victim to fresh air Obtain medical attention if breathing difficulty persists.
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 if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water If eye irritation persists, take medical advice.
First-aid measures after ingestion	: Rinse mouth. Never give anything by mouth to an unconscious person Seek medical advice.

#### 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	: Water spray dry chemical powder, alcohol-resistant foam, carbon dioxide (CO <sub>2</sub> ).
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	: hydrogen chloride Nitrogen oxides Carbon oxides (CO, CO <sub>2</sub> ).
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#### 5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Wear self-contained breathing apparatus, rubber boots and thick rubber gloves.

### SECTION 6: Accidental release measures

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

##### 6.1.1. For non-emergency personnel

Protective equipment	: Use the personal protective equipment as indicated in chapter 8.
Emergency procedures	: Ensure adequate air ventilation. Avoid raising dust. Only qualified personnel equipped with suitable protective equipment may intervene.

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

**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**

For containment : Stop leak if safe to do so. Sweeping or shovelling without dust for disposal.

Methods for cleaning up : Hose down area with water.

**6.4. Reference to other sections**

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

**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.

Storage temperature : 15 - 25 °C

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

Pharmaceutical industry.

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

No additional information available

**8.2. Exposure controls****Appropriate engineering controls:**

Handle in accordance with good industrial hygiene and safety practice.

**Hand protection:**

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

**Eye protection:**

Safety glasses (to European standard EN 166 or equivalent)

**Skin and body protection:**

Protective clothing (with elasticated cuffs and closed neck)

**Respiratory protection:**

Dustmask with filtertype P2

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline solid.
Molecular mass	: 165.6 g/mol
Colour	: White to off-white.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: No data available
pH solution	: 1 % in H <sub>2</sub> O
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 223 - 226 °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	: Soluble in water.
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.

### 10.3. Possibility of hazardous reactions

None under normal conditions.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

## 10.6. Hazardous decomposition products

In case of fire see chapter 5.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed.

Metformin hydrochloride (1115-70-4)	
LD50 oral rat	1000 mg/kg
LD50 oral	350 mg/kg rabbit

Skin corrosion/irritation : Causes skin irritation.  
Serious eye damage/irritation : Causes serious eye irritation.  
Respiratory or skin sensitisation : Not classified  
Germ cell mutagenicity : Not classified  
Carcinogenicity : Not classified

Reproductive toxicity : Not classified  
STOT-single exposure : Not classified  
STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : The product has not been tested.

Metformin hydrochloride (1115-70-4)	
EC50 Daphnia 1	52 mg/l 48 h

### 12.2. Persistence and degradability

Metformin hydrochloride (1115-70-4)	
Persistence and degradability	Biodegradability in water: no data available.

### 12.3. Bioaccumulative potential

Metformin hydrochloride (1115-70-4)	
Bioaccumulative potential	No bioaccumulation data 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.  
Product/Packaging disposal : Dispose in a safe manner in accordance with local/national recommendations regulations.

**SECTION 14: Transport information**

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

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

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

No data available

**- 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

Metformin hydrochloride is not on the REACH Candidate List

Metformin hydrochloride 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

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

## SECTION 16: Other information

Indication of changes:

1		Modified	change of logo
2.2		Removed	H317 + H411
4.2	Symptoms/effects	Removed	
7.2	Storage temperature	Added	

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
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

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. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

SDS EU (REACH Annex II) duchefa nieuwe logo

*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.*