



KIMYAGARAN
Emrooz
Chemical Industries Co.

Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Metformin Hydrochloride

Product Description: Active Pharmaceutical Ingredients
(API)

CAS No.: 1115-70-4

Product Formulation: C₄H₁₂ClN₅

Common Names: Metformin HCl

Chemical Family: Active Pharmaceutical Ingredients (API)

Manufacturer: Kimyagaran Emrooz Chemical Industries Co.

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2. HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

Classification according to Regulation (EC) No 1272/2008

Acute toxicity, Oral (Category 4), H302

2.2 Label Elements

Labelling according Regulation (EC) No 1272/2008



Signal word

Warning

Hazard statement(s)

H302 Harmful if swallowed

Precautionary statement(s)

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

Supplemental Hazard statement

None

Reduced Labeling (<= 125 ml)



Signal word

Warning

Hazard statement

None

Precautionary statement(s)

None

Supplemental Hazard statement

None

2.3 Other Hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. COMPOSITION

Chemical Name	Wt. %	CAS No.
Metformin HCl	Min. 99.9	1115-70-4

4. FIRST AID MEASURES

4.1 General advice: Consult a physician. Show this material safety data sheet to the doctor in attendance 20 minutes.

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact: Wash off with soap and plenty of water. Consult a physician.

In case of eye contact: Flush eyes with water as precaution.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. FIRE-FIGHTING MEASURES

1. Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or Carbon Dioxide

2. Special hazards arising from the substance or mixture : Carbon Oxides, Nitrogen Oxides (NO_x), Hydrogen Chloride gas combustible.

3. Advice for firefighters: Wear self-contained breathing apparatus for firefighting if necessary.

4. Further Information: No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions:

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up:

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep insuitable, closed containers for disposal.

6.4 Reference to other sections:

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling:

Advice on safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.

Advice on protection against fire and explosion

Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities:

Storage conditions

Keep container tightly closed in a dry and well-ventilated place. Store in cool place.

7.3 Specific and use(s):

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure Controls

Personal protective equipment

Eye/Face protection: Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU)2016/425 and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11

mmBreak through time: 480

min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile

rubber

Minimum layer thickness: 0,11

mmBreak through time: 480

min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail

sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the EC approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body protection: Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection: For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EUEN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of Environmental Exposure: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form: solid

Color: white

Odor: odorless

Odor threshold: no data available

pH: 6.7 (at 10 g/L at 20°C)

Melting Point / Freezing point: 225 °C

Initial Boiling Point and Boiling range: Decomposition Below Boiling Point

Flash Point: no data available

Evaporation rate: no data available

Flammability (Solid/Gas): no data available

Upper/Lower flammability or explosive limits: no data available

Vapor pressure: <0.00001 hPa at 20°C – OECD Test Guideline 104

Vapor density: no data available

Relative density: no data available

Water solubility: 350 g/L at 20°C

Partition coefficient (n-Octanol /Water): log Pow: -3.5 at 20°C – OECD Test Guideline 107 – Bioaccumulation is not expected.

Autoignition temperature: >400 °C – Relative self-ignition temperature for solids

Decomposition temperature: >230 °C

Explosive properties: no data available

Oxidizing properties: no data available

Surface tension: 73mN/m at 20°C– OECD Test Guideline 115

10. STABILITY AND REACTIVITY

Reactivity

No data available

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

No data available

Conditions to avoid

No data available

Incompatible materials

Strong oxidizing agents

Hazardous decomposition products

In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - male and female - 1.770 mg/kg (OECD Test Guideline 401)

LD50 Dermal - Rat - > 500 mg/kgRemarks: (External MSDS)

Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation

(Draize Test)

Serious eye damage/eye irritation

Eyes - Rabbit

Result: No eye irritation (OECD Test Guideline 405)

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Test Type: Ames test

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Result: negative

Test Type: Mutagenicity (mammal cell test):

Test system: Mouse lymphoma test

Metabolic activation: with and without metabolic activation

Result: negative

Test Type: Mutagenicity (mammal cell test): chromosome aberration.

Test system: Human lymphocytes

Metabolic activation: with and without metabolic activation

Result: negative

Test Type: In vivo micronucleus test

Species: Mouse

Cell type: Bone marrow

Application Route: Oral

Result: negative

Carcinogenicity

No data available

Reproductive toxicity

Reproductive toxicity- Rat

No data available

Developmental Toxicity- Rabbit

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

Repeated dose toxicity - No data available

RTECS: DU1800000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

No data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish: NOEC – Lepomis Macrochirus (Bluegill snfish) - > 932 mg/l – 96 h (OECD test guideline 203)

Toxicity to daphnia and other aquatic invertebrates: EC50 – Daphnia magna (water flea) – 64 mg/l – 48 h (OECD test guideline 202)

Toxicity to algae: EC50 – Desmodesmus subspicatus (green algae) – >320 mg/l – 72 h (OECD test guideline 201)

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects

Harmful to aquatic life.

Discharge into the environment must be avoided

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

UN number

ADR/RID: -

IMDG: -

IATA: -

UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

Packaging group

ADR/RID: -

IMDG: -

IATA: -

Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

Special precautions for user**Further information**

Not classified as dangerous in the meaning of transport regulations

15. Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture**

This material safety data sheet complies with the requirements of regulation (EC) No. 1907/2006.

National legislation

Seveso III: Directive 2012/18/EU of : not applicable
the European Parliament and of the
Council on the control of major-accident
hazards involving dangerous substances

Chemical safety assessment

For this product a chemical safety assessment was not carried out.

16. OTHER INFORMATION

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.

Caution

The information contained in this Material Safety Data Sheet (MSDS) is believed to be correct since it was obtained from sources we believe are reliable. However no representation, guarantees or warranties of any kind are made as to its accuracy, suitability for particular applications, hazards connected with the use of the material, or the results to be obtained from the use thereof. User assumes all risks and liability of any use, processing or handling of any material, variations in methods, conditions and equipment used to store, handle, or process the material and hazards connected with the use of the material are solely the responsibility of the user and remain at his sole discretion.
