

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

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METOCLOPRAMIDI HYDROCHLORIDUM MONOHYDRICUM

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Metoclopramide hydrochloride monohydrate Metoclopramidi hydrochloridum monohydricum Metoclopramide hydrochloride monohydraat Métoclopramide (chlorhydrate de) monohydraté Metoclopramidhydrochloride-Monohydrat
N° CAS:	54143-57-6
N° EC:	641-713-2

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
STOT SE 3	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention
Irritant

Hazard statements:
H302 Harmful if swallowed.

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H335	May cause respiratory irritation.
Precautionary statements:	
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P501	Dispose of this substance and its container at a special or hazardous waste collection point in accordance with local, regional, national and/or international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Metoclopramide hydrochloride monohydrate
IUPAC name:	4-Amino-5-chlor-N- [2-(diethylamino)ethyl]-2- methoxybenzamid hydrochloride monohydrate
Synonyms:	Reglan Metoclopramide hydrochloride hydrate Metoclopramide HCl monohydrate
N° CAS:	54143-57-6
N° EC:	641-713-2
Molecular Formula:	$C_{14}H_{23}Cl_2N_3O_2 \cdot H_2O$
Content:	99.0 per cent to 101.0 per cent (anhydrous substance)

3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.

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After ingestion: If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Irritation effects: This product contains substances that cause irritation to the skin and eyes, or when inhaled. Local contact with irritating substances may make the area of contact more prone to absorb harmful substances such as allergens.

4.3 Indication of any immediate medical attention and special treatment needed

If eye irritation persists, contact a doctor.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.
Neighbouring fires (containers exposed to fire): Water spray or fog.

Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

If the product is exposed to high temperatures, as in the case of fire, carbon oxides are produced. The fire will result in thick, black smoke. Exposure to these catabolic products can damage health. Firefighters should wear appropriate protective equipment. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-fighting water to run into sewers and other watercourses.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8.
Avoid breathing vapours. Ensure adequate ventilation.

For emergency responders

For exposure control and personal protective measures, see section 8.
Avoid breathing vapours. Ensure adequate ventilation.

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6.2 Environmental precautions

Prevent product from entering ground water and/or sewage system.

6.3 Methods and material for containment and cleaning up

Sweep up spills carefully. Use water sprays or ventilated evacuation systems to avoid dust. Cleaning should be carried out as far as possible using normal cleaning agents. Solvents should be avoided. Use sand, sawdust, earth, vermiculite, diatomaceous earth to contain and collect non-combustible absorbent materials and place in containers for disposal in accordance with local legislation.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Avoid contact with eyes and skin. Do not smoke, eat or drink during handling. Wash hands and exposed skin after handling.

Personal protection:

Not available.

Technical protective measures:

Avoid formation of dust and aerosols. Adequate extraction should be provided where dust is formed.

Handling:

Do not smoke, eat or drink during handling. Wash hands and exposed skin after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

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

Storage – away from:

Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

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Individual protection measures

Eye/face protection:	Protective face shields and safety goggles according to EN166.
Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.
Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder or crystals
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	about 183 °C, with decomposition
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in ethanol (96 per cent), sparingly soluble in methylene chloride.
Solubility in water:	Very soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.

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Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 354.27 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

Flames, heat or sparks.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (rat, LD₅₀): 750 mg/kg

Acute oral toxicity (mouse, LD₅₀): 280 mg/kg

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: No component of this product is identified as a probable, possible or confirmed human carcinogen at levels greater than or equal to 0.1%.

Reproductive toxicity: Not available.

Summary of evaluation of the

CMR properties:

STOT-single exposure: Not available.

STOT-repeated exposure: Prolonged or repeated ingestion may affect the respiratory tract.

Aspiration Hazard: Not available.

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Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Not available.
Skin contact: Not available.
Inhalation: May cause respiratory irritation.
Ingestion: Harmful if swallowed.
Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

The substance does not meet the criteria to be identified as a PBT or vPvB according to Annex XIII of the REACH Regulation.

12.6 Other adverse effects

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Contaminated container: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), It is not dangerous in transport.
IATA/ICAO (Air) :

14.2 UN proper shipping name

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ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.6 Special precautions for user

It is not dangerous in transport.

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

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant

Risk phrases:

R22 Harmful if swallowed.

R37 Irritating to respiratory system.

Safety phrases:

S7/9 Keep container tightly closed and in a well-ventilated place.

S20/21 When using do not eat, drink or smoke.

S51 Use only in well-ventilated areas.

S56 Dispose of this material and its container at hazardous or special waste collection point.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

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ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department
FAC SECUNDUM ARTEM NV

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