

ISONIAZIDUM

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

1.1 PRODUCT IDENTIFIER

Product name:	EN:	Isoniazide
	LAT:	Isoniazidum
	NL:	Isoniazide
	FR:	Isoniazide
	DE:	Isoniazid
N° CAS:		54-85-3
N° EC:		200-214-6

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE/MIXTURE AND USES ADVISED AGAINST

Identified uses:	Active Pharmaceutical Ingredient.
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1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk 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 Antifigcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antifigcentrum.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
Skin Irrit. 2	H315

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning

Hazard statements:

H302	Harmful if swallowed.
H315	Causes skin irritation.

Precautionary statements:

P264	Wash hands [and ...] thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.

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P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P317	IF SWALLOWED: Get medical help.
P302+P352	IF ON SKIN: wash with plenty of water.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P332+P317	If skin irritation occurs: Get medical help.
P362+P364	Take off immediately all contaminated clothing and wash it before reuse.
P501	Dispose of this substance and its container to a special or hazardous waste collection point in accordance with local, regional, national and/or international regulations.

Additional applicable label elements:



2.3 OTHER HAZARDS

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Product name:	Isoniazide
IUPAC name:	pyridine-4-carbohydrazide
Synonyms:	Isonicotinic acid hydrazide Isonicotinohydrazide Isoniazide Nydrazid 4-Pyridinecarboxylic acid, hydrazide
N° CAS:	54-85-3
N° EC:	200-214-6
Molecular Formula:	C ₆ H ₇ N ₃ O
Content:	99.0 per cent to 101.0 per cent (dried substance)

3.2 MIXTURES

Not applicable.

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:	Remove 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

The most important known symptoms and effects are described on the label (see section 2.2) and/or under heading 11.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

In cases of doubt, or when symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water fog.
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

In case of fire, fumes harmful to health may be produced.

5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires: Cool containers with water to prevent decomposition of product and development of health hazards. Always use full fire protection. Collect water from entering 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

Avoid dust formation by spraying the product with water if there are no contraindications. In case of airborne dust, wear respiratory protection.

FOR EMERGENCY RESPONDERS

Avoid dust formation by spraying the product with water if there are no contraindications. In case of airborne dust, wear respiratory protection.

6.2 ENVIRONMENTAL PRECAUTIONS

Prevent product from entering sewers, surface water, groundwater and neighbouring areas.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

The contaminated area must be cleaned immediately with a suitable decontaminant. Pour the decontaminant on the debris and leave it for several days until no reaction occurs, in an unsealed container.

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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:	Smoking, eating and drinking must be prohibited in the application area. Never use pressure to empty the containers; they are not pressure-resistant containers. Keep the product in containers made of material identical to the original.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Comply with occupational health and safety legislation.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store in a cool, well-ventilated and dry place. Keep container tightly closed.
Storage – away from:	Store away from heat, flames, sparks and other sources of ignition.

7.3 SPECIFIC END USE(S)

Active Pharmaceutical Ingredient.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

The product does NOT contain substances with Occupational Exposure Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 EXPOSURE CONTROLS

APPROPRIATE ENGINEERING CONTROL

Since the use of appropriate technical measures must 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 visco-elastic tray.

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

INDIVIDUAL PROTECTION MEASURES

Eye/face protection:	Protective face shields and safety goggles according to EN 165, EN 166, EN 167, EN 168.
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 standards EN 374-1, EN 374-2, EN 374-3, EN 420.

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Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 149). 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 colourless crystals.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	6.0 - 8.0 (5% in water, 20°C)
Melting/freezing point:	170 - 174 °C
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:	Sparingly soluble in ethanol (96 per cent), practically insoluble in heptane.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 OTHER INFORMATION

Molecular weight: 137.14 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

No special conditions. Stable under recommended handling and storage conditions (see section 7).

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10.2 CHEMICAL STABILITY

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

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Under normal conditions of use and storage no dangerous reactions are expected.

10.4 CONDITIONS TO AVOID

None in particular. However, the usual precautions should be taken against chemicals.

10.5 INCOMPATIBLE MATERIALS

Keep away from oxidising agents and strongly alkaline or acidic materials to avoid exothermic reactions.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

It is not decomposed if it is used for its intended purpose.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity:	Acute oral toxicity (LD ₅₀ , rat): 500 mg/kg
Skin corrosion/irritation:	Causes skin irritation.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 ADDITIONAL INFORMATION ON POTENTIAL ADVERSE HUMAN HEALTH EFFECTS AND SYMPTOMS

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

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.

12.1 TOXICITY

Not available.

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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

Not available.

12.6 OTHER ADVERSE EFFECTS

Avoid release to the environment.

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 packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

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

The product is classified according to the hazardous materials conventions.

14.1 UN NUMBER

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

14.2 UN PROPER SHIPPING NAME

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

14.3 TRANSPORT HAZARD CLASS(ES)

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

14.4 PACKING GROUP

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

14.5 ENVIRONMENTAL HAZARDS

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

14.6 SPECIAL PRECAUTIONS FOR USER

It is not dangerous in transport.

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14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

Not applicable.

14.8 ADDITIONAL TRANSPORT INFORMATION

Not available.

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.

R38 Irritating to skin.

Safety phrases:

S27 Take off immediately all contaminated clothing.

S28 After contact with skin, wash immediately with plenty of water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

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

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/>

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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

Magis-Pharma NV
info@magis-pharma.be

