

and Labelling of Chemicals (GHS) - Sixth revised edition

Version: 1.0 Creation Date: Aug 20, 2018 Revision Date: Aug 20, 2018

# 1.Identification

# **1.1 GHS Product identifier**

Product name isoniazide

# 1.2 Other means of identification

Product number PRD3931 Other names HIA

# 1.3 Recommended use of the chemical and restrictions on use

For industry use only. **Identified uses** 

Uses advised against no data available

# 1.4 Supplier's details

Company Acros PharmaTech Limited

HongKong: Unit 3A-8,12/F,Kaiser Centre,No.18 Centre Street,Sai Ying Pun,HongKong Address Mainland: Suite 920, Changwu Road 888, Changzhou, Jiangsu, China Telephone 86(519)85265509

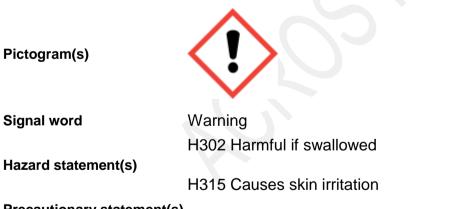
# 2.Hazard identification

# 2.1 Classification of the substance or mixture

Acute toxicity - Oral, Category 4

Skin irritation, Category 2

# 2.2 GHS label elements, including precautionary statements



**Precautionary statement(s)** 

P264 Wash ... thoroughly after handling.

Prevention P270 Do not eat, drink or smoke when using this product.

> P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/...if you feel unwell.

P330 Rinse mouth.

Response

P302+P352 IF ON SKIN: Wash with plenty of water/...

P321 Specific treatment (see ... on this label).



# ACROS PHARMA SAFETY DATA SHEET

According to Globally Harmonized System of Classification

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P332+P313 If skin irritation occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before reuse.

Storage

Disposal P501 Dispose of contents/container to ...

none

### 2.3 Other hazards which do not result in classification

none

# 3. Composition/information on ingredients

# 3.1 Substances

Chemical name Common names and synonymsCAS numberEC numberConcentrationisoniazideisoniazide54-85-3none≥98%

# 4.First-aid measures

# 4.1 Description of necessary first-aid measures

### **General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

Fresh air, rest.

#### In case of skin contact

Remove contaminated clothes. Rinse and then wash skin with water and soap.

#### In case of eye contact

First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then refer for medical attention.

### If swallowed

Rinse mouth. Give a slurry of activated charcoal in water to drink. Refer for medical attention .

### 4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound include irritation of the skin, peripheral nerve sensory changes, somnolence, anorexia, sweating, respiratory depression, urine changes and toxic psychosis. Other symptoms include dizziness, paresthesias, fatal hepatitis, metabolic acidosis, convulsions and coma. It can cause headache, muscle twitching deafness, polyneuritis, paralysis and pyridoxine deficiency. It can also cause nausea, vomiting, atropinic signs such as mydriasis, brightly colored lights and other visual hallucinations, tachycardia, peripheral neuropathy, other central nervous system reactions, stupor, exhaustion, urinary retention, liver damage, bone marrow damage and death. Exposure may cause fatigue, weakness, malaise, toxic encephalopathy, optic neuritis, optic atrophy, memory impairment, epigastric distress, elevated serum transaminases (SGOT, SGPT), bilirubinemia, bilirubinuria, jaundice, agranulocytosis hemolytic anemia, sideroblastic anemia, aplastic anemia, thrombocytopenia, eosinophilia, fever, skin eruptions (morbilliform, maculopapular, purpuric or exfoliative), lymphadenopathy, vasculitis, pellagra, hyperglycemia, gynecomastia, rheumatic syndrome, systemic lupus erythematosus-like syndrome, blurred vision, respiratory distress, central nervous system depression, severe and intractable seizures and acetonuria. Exposure may also cause gastrointestinal effects, liver necrosis, slight euphoria, irritability, nervousness, insomnia, excessive dreaming and giddiness. Other symptoms include peripheral neuritis, burning of the feet, reduction of central vision and papilledema. Hyperreflexia, vertigo, ataxia, tinnitus, hepatic reactions, hypersensitivity reactions and lethargy may occur. Constipation, difficulty in starting urination, dryness of the mouth, mood-elevating effect and mental disturbances, ranging from minor personality changes to major mental derangements. This compound may also

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cause skin rash, urticaria, arthritic symptoms such as back pain, bilateral proximal interphalangeal joint involvement, arthralgia of the knees, elbows and wrists and "shoulder-hand" syndrome; separation of ideas and reality, florid psychosis, loss of self-control, excessive sedation, incoordination and methemoglobinemia. ACUTE/CHRONIC HAZARDS: This compound is an irritant of the skin, eyes, mucous membranes and upper respiratory tract. It is harmful by ingestion, inhalation and skin absorption. When heated to decomposition it emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, ammonia and partially oxidized hydrocarbons.

# 4.3 Indication of immediate medical attention and special treatment needed, if necessary

Emergency and supportive measures; 1. Maintain an open airway and assist ventilation if necessary. 2. Treat coma, seizures, and metabolic acidosis if they occur. Administer diazepam, 0.1-0.2 mg/kg IV, for treatment of seizures.

# 5.Fire-fighting measures

# 5.1 Extinguishing media

### Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. A water spray may also be used.

# 5.2 Specific hazards arising from the chemical

This chemical is combustible.

# 5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

### 6.Accidental release measures

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

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

### 6.2 Environmental precautions

Sweep spilled substance into covered sealable containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder. Then store and dispose of according to local regulations. Personal protection: P2 filter respirator for harmful particles.

### 6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal. Sweep up and shovel. Keep in suitable, closed containers for disposal.

# 7.Handling and storage

#### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use.Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

# 7.2 Conditions for safe storage, including any incompatibilities

Cool. Well closed. Store below 40°C (104°C), preferably between 15 and 30°C (59 and 86 deg F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container. Protect from freezing. NOTE: Crystallization may occur at low temperatures. Upon warming to room temperature, the crystals will redissolve.

#### 8. Exposure controls/personal protection



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# 8.1 Control parameters

### **Occupational Exposure limit values**

no data available

### **Biological limit values**

no data available

# 8.2 Appropriate engineering controls

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

# 8.3 Individual protection measures, such as personal protective equipment (PPE)

# **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

Wear impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. 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 EU Directive 89/686/EEC and the standard EN 374 derived from it.

### **Respiratory protection**

Wear dust mask when handling large quantities.

**Thermal hazards** 

no data available

# 9. Physical and chemical properties

Physical state	white crystalline powder		
Colour	COLORLESS OR WHITE CRYSTALS, OR A WHITE, CRYSTALLINE POWDER		
Odour	no data available		
Melting point/ freezing point	-8°C(lit.)		
Boiling point or initial boiling point and boiling range 212°C(lit.)			

in a fire.

Flammability	Combustible. Gives off irritating or toxic fumes (or gases) in
Lower and upper explosion limit / flammability limit	no data available
Flash point	75°C(lit.)
Auto-ignition temperature	no data available
Decomposition temperature	no data available
рН	pH of a 1% aqueous solution 5.5 to 6.5
Kinematic viscosity	no data available
Solubility	In water:14 g/100 mL (25 °C)
Partition coefficient n-octanol/water (log value)	no data available
Vapour pressure	Negligible
Density and/or relative density	1.244g/cm3
Relative vapour density	no data available



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**Particle characteristics** 

no data available

### **10.Stability and reactivity**

### **10.1 Reactivity**

no data available

# **10.2 Chemical stability**

STABLE AT ROOM TEMP FOR MORE THAN 14 DAYS IN AQ SOLN AND MORE THAN 6 WK WHEN STORED AT ABOUT 4 DEG C.

### 10.3 Possibility of hazardous reactions

ISONIAZID is incompatible with chloral, aldehydes, iodine, hypochlorites and ferric salts. It is also incompatible with oxidizers. It may react with sugars and ketones. It can react as a weak acid or a weak base. It can be decomposed by oxidative and reductive reactions.

### 10.4 Conditions to avoid

no data available

# **10.5 Incompatible materials**

no data available

### **10.6 Hazardous decomposition products**

When heated to decomposition it emits toxic fumes of /nitrogen oxides/.

# 11.Toxicological information

#### Acute toxicity

- Oral: LD50 Rat oral 650 mg/kg •
- Inhalation: no data available
- Dermal: no data available

#### Skin corrosion/irritation

no data available

### Serious eye damage/irritation

no data available

#### **Respiratory or skin sensitization**

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

Inadequate evidence of carcinogenicity in humans. Limited evidence of carcinogenicity in animals. OVERALL EVALUATION: Group 3: The agent is not classifiable as to its carcinogenicity to humans.

**Reproductive toxicity** 



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no data available

#### STOT-single exposure

no data available

#### STOT-repeated exposure

no data available

#### Aspiration hazard

no data available

# **12.Ecological information**

#### **12.1 Toxicity**

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available •
- Toxicity to microorganisms: no data available •

### 12.2 Persistence and degradability

no data available

### 12.3 Bioaccumulative potential

no data available

# 12.4 Mobility in soil

no data available

#### 12.5 Other adverse effects

no data available

#### **13.Disposal considerations**

### **13.1 Disposal methods**

#### Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

#### **Contaminated packaging**

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

# **14.Transport information**

# 14.1 UN Number

ADR/RID: Not dangerous goods. IMDG: Not dangerous goods. IATA: Not dangerous goods.

# 14.2 UN Proper Shipping Name



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ADR/RID: unknown IMDG: unknown IATA: unknown

# 14.3 Transport hazard class(es)

ADR/RID: Not dangerous goods. IMDG: Not dangerous goods. IATA: Not dangerous goods.

# 14.4 Packing group, if applicable

ADR/RID: Not dangerous goods. IMDG: Not dangerous goods. IATA: Not dangerous goods.

# **14.5 Environmental hazards**

ADR/RID: no IMDG: no IATA: no

# 14.6 Special precautions for user

no data available

# 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

# **15.Regulatory information**

# 15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number	
isoniazide	isoniazide	54-85-3	none	
European Inventor	Listed.			
EC Inventory			Listed.	
United States Toxic Substances Control Act (TSCA) Inventory			Listed.	
China Catalog of Hazardous chemicals 2015			Not Listed.	
New Zealand Inven	Listed.			
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Listed.	
Vietnam National C	Chemical Inventory		Not Listed.	
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC) Listed.				

### **16.Other information**

Abbreviations and acronyms

- CAS: Chemical Abstracts Service ٠
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road •
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail •
- IMDG: International Maritime Dangerous Goods ٠
- IATA: International Air Transportation Association •
- TWA: Time Weighted Average ٠
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50% •
- LD50: Lethal Dose 50% •
- EC50: Effective Concentration 50% •

#### References

IPCS - The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home



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- HSDB Hazardous Substances Data Bank, website: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm
- IARC International Agency for Research on Cancer, website: http://www.iarc.fr/
- eChemPortal The Global Portal to Information on Chemical Substances by OECD, website: ٠ http://www.echemportal.org/echemportal/index?pageID=0&request\_locale=en
- CAMEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple ٠
- ChemIDplus, website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
- ٠ ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: http://www.phmsa.dot.gov/hazmat/library/erg
- Germany GESTIS-database on hazard substance, website: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp •
- ECHA European Chemicals Agency, website: https://echa.europa.eu/ •

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