



SAFETY DATA SHEET

1. Identification

Product identifier	Isoniazid	
Other means of identification		
Catalog number	1349706	
CAS number	54-85-3	
Synonyms	Isonicotinic acid hydrazide * INH	
Chemical name	4-Pyridinecarboxylic acid, hydrazide	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Skin corrosion/irritation	Category 2
	Specific target organ toxicity, repeated exposure	Category 2 (liver)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	Harmful if swallowed. Causes skin irritation. May cause damage to organs (liver) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves.
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. Get medical advice/attention if you feel unwell.
Storage	Not available.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Isoniazid	Isonicotinic acid hydrazide INH	54-85-3	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Liver damage. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Overdose treatment may include the following: Do NOT induce vomiting; seizures may occur following ingestion. Perform gastric lavage within 2 to 3 hours of ingestion; administer activated charcoal and a cathartic if seizures are controlled and the airway is protected. Administer intravenous pyridoxine in a gram-for-gram dose, equivalent to the amount of isoniazid ingested, as a 5% or 10% solution in water for injection over 30 to 60 minutes. If the amount of overdose is unknown, administer 5 gram doses every 5 to 30 minutes until seizures stop or consciousness is regained. Seizures may be controlled with diazepam, which acts synergistically with pyridoxine. Phenytoin should be used with caution, if at all, since isoniazid inhibits phenytoin metabolism. Thiopental may be effective in treating refractory seizures. Administer sodium bicarbonate carefully if pyridoxine and diazepam do not control seizure activity. Lactic acid accumulation produces an anion-gap metabolic acidosis within a few hours, which is often severe and refractory to treatment with sodium bicarbonate. Use caution against overcorrection and watch for hypokalemia or hyperkalemia. Supportive measures such as establishing intravenous lines, hydration, correction of electrolyte imbalance, oxygenation, and support of ventilatory function are essential. Significant amounts of isoniazid are removed from the blood by hemodialysis. Peritoneal dialysis is of limited benefit.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage	
Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Crystalline powder.
Color	Colorless. White.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	340.52 °F (171.4 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.

Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	0.000002 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Freely soluble.
Solubility (other)	Ether: Very slightly soluble. Chloroform: Slightly soluble. Ethanol: Sparingly soluble. High lipid solubility.
Partition coefficient (n-octanol/water)	-0.7
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Pyridine derivative.
Molecular formula	C6-H7-N3-O
Molecular weight	137.15 g/mol
pH in aqueous solution	6 - 7.5 (10% solution)

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong acids. Strong bases. Oxidizing agents. Peroxides. Phenols.
Hazardous decomposition products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Causes skin irritation.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Harmful if swallowed.
Symptoms related to the physical, chemical, and toxicological characteristics	Gastrointestinal disturbances. Dry mouth. Fever. Skin rash. Yellow eyes and/or skin. Dark urine. Weakness. Tiredness. Unsteadiness. Numbness, pain, tingling, or weakness in hands or feet. Behavior, mood, or mental changes. Hallucinations. Seizures. Convulsions.

Information on toxicological effects

Acute toxicity	Harmful if swallowed.
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Product	Species	Test Results
Isoniazid (CAS 54-85-3)		
<u>Acute</u>		
Oral		
LD50	Mouse	133 mg/kg
	Rat	1250 mg/kg
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	

Local effects

Draize Test: Skin irritation.
Result: Irritation
Species: Rabbit
Test Duration: 24 hours
Severity: Moderate

Respiratory or skin sensitization

Respiratory sensitization Knowledge about sensitization hazard is incomplete.

Skin sensitization Knowledge about sensitization hazard is incomplete.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Mutagenicity

Ames test (Salmonella typhimurium)
Result: Equivocal.
Dominant lethal test: in vivo.
Result: Negative.
Species: Mouse
Genotoxicity in vitro: rodent cells., (chromosomal aberration, sister chromatid exchange, DNA damage)
Result: Positive for chromosomal aberrations and sister chromatid exchange; negative for DNA damage.
Genotoxicity in vivo, (chromosomal aberration, sister chromatid exchange, DNA damage)
Result: Negative.
Species: Rodent
In vivo chromosome aberration: mammalian oocytes.
Result: Negative.
Mutagenicity, Gene conversion assay in yeast
Result: Negative.
Mutagenicity, In vivo sperm morphology tests in mice and rabbits
Result: Negative.
Mutagenicity, Induction of transformation in hamster embryo cells
Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.
Epidemiological studies have not shown a causal relationship between this material and cancer in humans.

0 - 0.03 % Carcinogenicity, administered orally in diet.
Result: No evidence of carcinogenicity.
Species: Rat
Test Duration: 87 weeks
0 - 83 mg/kg Carcinogenicity, administered subcutaneously one time per week.
Result: No evidence of carcinogenicity.
Species: Rat
Test Duration: 87 weeks
1.1 mg/day Carcinogenicity, administered orally 5 times per week.
Result: Increased incidence of lung tumors.
Species: Mouse
Test Duration: 25 months

IARC Monographs. Overall Evaluation of Carcinogenicity

Isoniazid (CAS 54-85-3) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete.
A review of limited human pregnancy data has not demonstrated an increase in adverse developmental effects.

Reproductivity

150 mg/kg/day Reproductivity and development studies
Result: Developmental toxicity but no teratogenicity.
Species: Mouse

Reproductivity

Reproductivity and development studies in chick embryos

Result: Single doses on different days of incubation produced anomalies.

Reproductivity and development studies, administered during gestation.

Result: Impairment of growth, development, behavior, and learning at doses three times the human dose but not at 1.5 times the human dose. No teratogenicity.

Species: Rat

Reproductivity and development studies, dose equivalent to human dose.

Result: No teratogenicity.

Species: Rabbit

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure May cause damage to organs (liver) through prolonged or repeated exposure.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this substance.

Bioaccumulative potential

Octanol/water partition coefficient log K_{ow}

-0.7 0.7

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Acute toxicity (any route of exposure)

Skin corrosion or irritation

Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations**California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	02-24-2006
Revision date	12-18-2018
Version #	04

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