



Resonance Specialties Limited

MATERIAL SAFETY DATA SHEET

Isoniazid

1. IDENTIFICATION :

Common Name: Isoniazid

2. COMPOSITION AND INFORMATION ON INGREDIENTS

Formula: C₆H₇N₃O

Synonym: Isonicotinic acid hydrazide; INH

Chemical Name: 4-Pyridinecarboxylic acid, hydrazide

CAS: 54-85-3

RTECS Number: NS1751850

Chemical Family: Pyridine derivative

Therapeutic Category: Antibacterial (tuberculostatic)

Composition: Pure Material

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW - Irritant.

Adverse Effects: Adverse effects may include loss of appetite; nausea; vomiting; unusual tiredness or weakness; hepatitis (dark urine yellow eyes or skin); clumsiness;

unsteadiness; numbness, tingling, burning, or pain in hands or feet; diarrhea; and stomach pain. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Symptoms of overdose include severe nausea and vomiting, dizziness, slurred speech, lethargy, disorientation, exaggerated reflexes, seizures, and coma. It may take up to 2 hours following acute overdose for symptoms to occur.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation and liver damage.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism, and impaired liver or kidney function.

Cross Sensitivity: Persons sensitive to ethionamide, pyrazinamide, niacin (nicotinic acid), or other chemically related medications may be sensitive to this material also.

Target Organs: Central nervous system

4. FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: Causes irritation. Avoid contact. Wash with copious quantities of soap and water.

Ingestion: May cause irritation and toxicity. Flush out mouth with water. Material is readily absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Overdose treatment should be symptomatic and supportive and 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. [USP DI 2006]

5. FIRE FIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

6. ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

7. HANDLING AND STORAGE

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. Wash thoroughly after handling.

Storage: Store in tight, light-resistant 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

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Appearance and Odor: Colorless or white crystals or white crystalline powder; odorless

Odor Threshold: n/f

pH: 6 - 7.5 (10% solution)

Melting Range: 170 - 173° C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Freely soluble

Fat Solubility: n/f

Other Solubility: Sparingly soluble in alcohol; slightly soluble in chloroform; very slightly soluble in ether.

Partition Coefficient: n-octanol/water: - 0.70

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₆H₇N₃O

Molecular Weight: 137.14

10. STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to light, moisture, and air.

Incompatibilities: Oxidizing agents, strong acids, and strong bases

Decomposition Products: When heated to decomposition material emits toxic fumes of NO_x and NH₃. Emits toxic fumes under fire Conditions Stable? Yes Hazardous Polymerization? No.

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD₅₀: 1250 mg/kg

Oral Mouse: LD50: 133 mg/kg

Other Toxicity Data:

Oral Dog: LD50: 50 mg/kg

Oral Guinea Pig: LD50: 255 mg/kg

Oral Rabbit: LD50: 250 mg/kg

11. TOXICOLOGICAL INFORMATION

Irritancy Data: Rabbit/Skin: moderate

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: NTP: No IARC: No OSHA: No

Other Carcinogenicity Data: This material is not classifiable as to its carcinogenicity in humans. Isoniazid has been shown to cause lung tumors in a number of strains of mice. There is no conclusive evidence of cancer risk associated with isoniazid therapy in humans.

Mutagenicity Data: Isoniazid did not induce lethal mutations in mice, or chromosomal aberrations, sister chromatid exchanges, or DNA damage in rodents treated in vivo. In cultured rodent cells, isoniazid induced chromosomal aberrations and sister chromatid exchanges, but not DNA damage. It also did not induce transformation of Syrian hamster embryo cells or gene conversion in yeast. This material was mutagenic to *Salmonella typhimurium*.

Reproductive and Developmental Effects: Pregnancy studies in rats and rabbits have shown that isoniazid may cause embryo death and it was shown to produce developmental toxicity, including increases in the percentage of dead or resorbed fetuses, in mice that were administered doses up to 150 mg/kg/day.

Isoniazid has not been shown to cause birth defects in mice, rats, or rabbits. There have been reports of increased rates of congenital abnormalities in children whose mothers received isoniazid during pregnancy; however, it is not known if the abnormalities were due to isoniazid, other drugs being used, or the disease being treated. Isoniazid is thought to decrease the amount of available vitamin B6, which may account for the adverse reproductive effects.

12. ECOLOGICAL INFORMATION

Ecological Information: n/f

13. DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

14. TRANSPORTATION INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

15. REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: EINECS: 200-214-6

Hazard Code: T

Risk Phrases: R46, R23/24/25, R36/37/38

Safety Phrases: S45, S46, S22, S36/37/38

16. ADDITIONAL INFORMATION

MSDS Creation **Date:** 07/18/1996

MSDS Revision **Date:** 08/18/2007

The information above is believed to be accurate and represents the best information currently available to us. However we take no warranty of merchantability or any other warranty express or implied with respect to such information and we assume no liability resulting from the use. Users should make the own investigation to determine the suitability of information for there particular purposes. In no way shall be company be liable for any claim losses or damages of any third party of for lost profit or a special indirect incidental consequential or exemplary damages howsoever arising. Even if the company has been advised of the possibility of such damages.