



SAFETY DATA SHEET

Isoniazid Oral Solution, USP (50mg/5mL)

SDS DATE: 30-Sep-2015

SECTION 1: IDENTIFICATION

PRODUCT NAME: Isoniazid Oral Solution, USP (50mg/5mL)

SYNONYMS: Isonicotinic Acid Hydrazide

NDC Number: 46287-009-01

MANUFACTURER: CMP Pharma, Inc.

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Farmville, NC 27828

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CHEMTREC PHONE: 1-908-859-2151

OTHER CALLS: 1-252-753-7111

CHEMICAL NAME (for active ingredient): Isonicotinylhydrazide

CHEMICAL FAMILY (for active ingredient): Amide

CHEMICAL FORMULA (for active ingredient): C₆H₇N₃O

PRODUCT USE: Antimycobacterial

SECTION 2: HAZARD(S) IDENTIFICATION

PHYSICAL HAZARDS: Not classified.

HEALTH HAZARDS: Oral toxicity Category 4

SIGNAL WORD: Warning

HAZARD STATEMENT: May be harmful if swallowed. May cause allergic skin reactions. May cause hepatic disorder.

HAZARD SYMBOLS:



PRECAUTIONARY STATEMENTS:

Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Do not eat, drink, or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace.

If exposure occurs: Get medical advice/attention.

HAZARDS NOT OTHERWISE CLASSIFIED: None classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<u>INGREDIENT:</u>	<u>CAS NO.</u>	<u>Amount</u>
Isoniazid	54-85-3	1%
Sorbitol Solution USP	50-70-4	99%



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SECTION 4: FIRST AID MEASURES

- EYE CONTACT:** Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.
- SKIN CONTACT:** Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.
- INGESTION:** Rinse mouth with water. If conscious, give victim one or two glasses of water to dilute the drug. Seek medical attention immediately.
- INHALATION:** If breathing is difficult, remove to fresh air. Watch for signs of respiratory insufficiency and assist ventilations if needed. Monitor for pulmonary edema and treat if necessary. Seek medical attention immediately.

MOST IMPORTANT SYMPTOMS/EFFECTS

ACUTE OR DELAYED:

None classified

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

This product should only be given to patients by medical professionals educated in the therapy intended for this product. Treat any symptoms and eliminate exposure.

SECTION 5: FIRE-FIGHTING MEASURES

- SUITABLE EXTINGUISHING MEDIA:** Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
- UNSUITABLE EXTINGUISHING MEDIA:** None known.
- UNUSUAL FIRE AND EXPLOSION HAZARDS:** Hazardous decomposition products may be formed under fire conditions.
- SPECIAL FIRE FIGHTING PROCEDURES:** Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- PERSONAL PRECAUTIONS:** Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Minimize the generation of aerosols. Remove all sources of heat and ignition.
- METHODS/MATERIALS USED FOR CONTAINMENT & CLEANING:** Use an inert absorbent material to remove and collect spillage. Minimize the generation of aerosols. Dampen remaining residue with water, then clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

SECTION 7: HANDLING AND STORAGE

- HANDLING PRECAUTIONS:** 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. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts, shoes, and any other items that cannot be decontaminated.



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STORAGE PRECAUTIONS: When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. In case of insufficient ventilation, wear suitable respiratory protection. Keep this drug out of the reach of children.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	HSE WEL (TWA)
Isoniazid	N/A	N/A	N/A	N/A
Sorbitol Solution USP	N/A	N/A	N/A	N/A

ENGINEERING CONTROLS: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

EYE PROTECTION: Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

SKIN PROTECTION: Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

RESPIRATORY PROTECTION: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ODOR: This product is a clear, orange viscous liquid with an orange aroma.

FLASH POINT:	Not established.	% VOLATILE:	Not established.
AUTOIGNITION TEMP:	Not established.	VISCOSITY:	Not established.
BOILING POINT:	Not established.	pH:	Not established.
MELTING POINT:	Not established.	Octanol/H2O PART. COEFFICIENT:	Not established.
VAPOR PRESSURE (mmHg):	Not established.	POUR POINT:	Not established.
EVAPORATION RATE (H2O = 1):	Not established.	% SOLUBILITY IN WATER:	Not established.
VAPOR DENSITY (AIR = 1):	Not established.	SPECIFIC GRAVITY (H2O = 1):	Not established.
LOWER FLAMMABILITY LIMIT:	Not established.	UPPER FLAMMABILITY LIMIT:	Not established.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY: Oxidizing agents.

CHEMICAL STABILITY: Material is stable under normal conditions.

POSSIBILITY OF HAZARDOUS REACTIONS: No dangerous reaction known under conditions of normal use.



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- CONDITIONS TO AVOID:** Avoid heat and flame.
- INCOMPATIBLE MATERIALS:** Acids, caustics, and other chemicals that could affect its performance should be avoided.
- HAZARDOUS DECOMPOSITION PRODUCTS:** Under fire conditions, thermal decomposition may generate irritating and/or toxic fumes or gases (i.e. carbon oxides).

SECTION 11: TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE:

- INGESTION:** In an occupational setting, ingestion of this product is unlikely. Ingestion may cause irritation.
- INHALATION:** Although unlikely due to product form, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon exposure to fresh air.
- SKIN CONTACT:** Non irritating.
- EYE CONTACT:** Avoid contact with eyes. May cause irritation of the eyes.

SIGNS AND SYMPTOMS OF OVEREXPOSURE:

Possible irritation to nose and throat if inhaled or ingested.

CHRONIC EFFECTS:

May include possible hypersensitivity, fever, gastrointestinal discomfort, anorexia, headache, and hepatic disorder.

ACUTE TOXICITY VALUES: LD 50 for Isoniazid active ingredient (oral, rat) = 0.3-2 g/kg

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

WASTE DISPOSAL CONTAINERS:

Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

SECTION 15: REGULATORY INFORMATION

This product is in conformance with the GHS Standard.



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SECTION 16: OTHER INFORMATION

NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) RATINGS:

Health: 1

Flammability: 0

Reactivity: 0

Other: 0

CREATION DATE:

30Sep2015

REVISION DATE:

N/A

DISCLAIMER:

CMP Pharma, Inc. believes that the information contained in this Safety Data Sheet (SDS) is accurate, and while it is provided in good faith, it is without warranty of any kind, express or implied.

The information contained herein is designated only as guidance for safe handling and storage of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment, should handle all chemicals. CMP Pharma, Inc. shall not be held liable for any loss, injury, or damage from contact with the product.