SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Isoniazid Tablets USP, 100 mg, 100 Ct Bottles	NDC 64950-216-10
Isoniazid Tablets USP, 300 mg, 30 Ct Bottles	NDC 64950-217-03
Isoniazid Tablets USP, 300 mg, 100 Ct Bottles	NDC 64950-217-10

Product Name: Isoniazid Tablets USP

Recommended use: Isoniazid tablets USP is an antibacterial that is recommended for all forms of tuberculosis in which organisms are susceptible.

It's also recommended as preventive therapy, regardless of age, for persons with human immunodeficiency virus (HIV) infection, recent converters, persons in contact with newly diagnosed infectious tuberculosis, persons with chest radiographs that show fibrotic lesions likely to represent old healed tuberculosis, intravenous drug users known to be HI seronegative, and persons with medical conditions that have been reported to increase the risk of tuberculosis.

Restrictions: Do not use this product by itself to treat tuberculosis. Resistance develops rapidly when Isoniazid monotherapy is administered. Active tuberculosis must be treated with multiple concomitant anti-tuberculosis medications to prevent the emergence of Isoniazid drug resistance. Single-drug treatment of active tuberculosis with Isoniazid or any other medication is inadequate therapy.

Manufacturer Name:
Manufacturer Address:
Patheon Pharma Services Inc.
111 Consumers Drive
Whitby, Ontario L1N 5Z5, Canada

Telephone number: (919) 226-3200

Distributor Name:
Distributor Address:
Genus Lifesciences Inc.
514 N. 12th Street
Allentown, PA 18102

Telephone number: (610) 782-9780

Fax number: (610) 782-9781

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SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The product Isoniazid Tablets USP is a non-hazardous pharmaceutical mixture and does not meet OSHA's Hazard Communication Standard (HCS) 2012, 29CFR 1910.1200 and OSHA's Globally Harmonized System (GHS) hazard criteria. As per OSHA section 1910.1200(b)(6)(vii), "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient; drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment" are exempt. The GHS hazards listed below are for the active product ingredient (API), Isoniazid USP, and not for the Tablet product itself.

Physical hazards:	Not classified
Health hazards:	Oral Acute Toxicity Category 4 Reproductive Toxicity Category 2 Skin Irritant Category 2
Environmental hazards:	Aquatic environment Acute Category 3 Aquatic environment Long Term Category 3

Signal Word: Warning

Hazard Statement: This compound is an irritant of the skin, eyes, mucous membranes and upper respiratory tract. It is harmful by ingestion, inhalation and skin absorption. For the finished product, many side effects have been reported after ingestion of therapeutic doses, including drug-induced hepatitis. Should any person while using this product observe any adverse health effects, they should seek medical treatment immediately. The risk of hepatitis is increased with daily consumption of alcohol

Pictogram:

Precautionary Statement: Severe and sometimes fatal hepatitis associated with Isoniazid therapy has been reported and may occur or may develop even after many months of treatment. Therefore, patients given isoniazid should be carefully monitored and interviewed at monthly intervals. The risk of developing hepatitis is age related. Preventive treatment should be deferred in persons with acute hepatic diseases.

Hazards Not Otherwise Classified: None known.

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SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

Chemical Identity	Other Names	CAS Number
Colloidal Silicon Dioxide	Silica, Aerosil	7631-86-9
Crospovidone USP	Polyplasdone XL	9003-39-8
Hydrogenated Vegetable Oil NF	Mixed vegetable oil	68334-28-1
Isoniazid USP	Isonex, Ftivazide	54-85-3
Microcrystalline Cellulose NF	Alphacel, Avicel	9004-34-6
Pregelatanized Starch NF	Corn Starch	9005-25-8
Talc USP	Agalite, Asbestine	14807-96-6

* Chemical exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 – FIRST AID MEASURES

Eye Contact: As a finished product is not an expected route of exposure. If contact suspected, flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention if irritation or discomfort persists.

Skin Contact: Wash with soap and large amount of water. Contact medical personnel if irritation persists.

Ingestion: This product is intended for ingestion. If an overdose, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician immediately.

Inhalation: As a finished product is not an expected route of exposure. If breathing is difficult, move to fresh air and seek medical attention.

Symptoms or effects: Isoniazid overdose produces symptoms within 30 minutes to 3 hours after ingestion. The most frequent reactions are those affecting the nervous system and the liver. Among the early manifestations are nausea, vomiting, dizziness, slurring of speech, blurring of vision, and visual hallucinations (including bright colors and strange designs).

Recommendations: Immediate medical attention is required if an overdose is suspected. Call a Poison Control Center (1-800-222-1222) or 911 if you feel unwell. No action shall be taken involving any personal risk or without suitable training. If needed and if possible, give artificial respiration and/or CPR. Administer activated charcoal as slurry.

Note to Physician: Inform patients or their caregivers to discontinue Isoniazid and contact a healthcare provider immediately if serious reactions occur. With marked overdose, respiratory distress and CNS depression, progressing rapidly from stupor to profound coma, are to be expected, along with

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severe, intractable seizures. Severe metabolic acidosis, acetonuria and hyperglycemia are typical laboratory findings. Untreated or inadequately treated cases of gross Isoniazid overdose, 80 mg/kg to 150 mg/kg, can cause neurotoxicity6 and terminate fatally, but good response has been reported in most patients brought under adequate treatment within the first few hours after drug ingestion. Therefore patients given isoniazid should be carefully monitored and interviewed at monthly intervals.

Patients with tuberculosis who have hepatitis attributed to Isoniazid should be given appropriate treatment with alternative drugs. If isoniazid must be reinstituted, it should be reinstituted only after symptoms and laboratory abnormalities have cleared. The drug should be restarted in very small and gradually increasing doses and should be withdrawn immediately if there is any indication of recurrent liver involvement.

Patients should be instructed to immediately report signs or symptoms consistent with liver damage or other adverse effects. These include any of the following: unexplained anorexia, nausea, vomiting, dark urine, icterus, rash, persistent paresthesias of the hands and feet, persistent fatigue, weakness or fever of greater than 3 days duration and/or abdominal tenderness, especially right upper quadrant discomfort. If these symptoms appear or if signs suggestive of hepatic damage are detected, isoniazid should be discontinued promptly, since continued use of the drug in these cases has been reported to cause a more severe form of liver damage.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media — Use Water spray, Dry chemical, CO_2, Halon or any material appropriate for fire in the surrounding area. Do not use water jet as an extinguisher, as this might spread the fire.

Specific hazards arising from the mixture: — None known for the finished product, but the active ingredient is combustible and when heated to decomposition it emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, ammonia and partially oxidized hydrocarbons. (Refer to section 10)

Advice to the firefighters: — Wear appropriate protective clothing and equipment, including self-contained breathing apparatus.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions: — No action shall be taken involving any personal risk or without suitable training. Clean the spill if is safe to do so. Minimize exposure. Keep unnecessary personnel away. Do not touch or walk through spilled material.

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Protective Equipment: Safety Glasses or goggles, gloves, protecting clothes. (Refer to section 8)

Emergency procedures: Evacuate the area. Keep unnecessary personnel away. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Containment Precautions: Isolate area around spill as specified by site procedures.

Clean Up Procedures: Use suitable absorbent material. Collect the material in a compatible container. Dispose according to applicable regulations (Refer to section 13). Decontaminate with water.

SECTION 7 – HANDLING AND STORAGE

Precaution for safe handling: Observe safe industrial practices. No special handling requirements for normal use of this material. Dispense content with a child resistant closure and in a tight, light-resistant container as defined in the USP/NF.

Conditions for safe storage: Store in original container at 25°C (77°F). Protect from Moisture and Light. Keep container tightly closed. Keep out of reach of children. Do not use if seal under cap is missing or broken. For more information follow directions in product packaging.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There are no exposure limits for the Isoniazid Tablets USP product. The exposure limits listed below are for the Active Product Ingredient (API) Isoniazid and not for the finished Tablet product itself.

OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	Not Available
ACGIH Threshold Limit Values (TLVs):	
Short Term Exposure Limits (STEL) – 15 min:	Not Available
Time Weight Average (TWA) – 8 Hours:	Not Available

Engineering Controls: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations are available and accessible in areas

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where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Clean work areas routinely to prevent accumulation of product as appropriate.

Personal Protective Measures:

Respiratory protection:	Not required under normal conditions of use for finished product. If it found to be necessary, wear a mask or an appropriate NIOSH approved respirator.
Eye protection:	Not required under normal conditions of use for finished product. If it found to be necessary, wear safety glasses or goggles as appropriate for the task.
Protective gloves:	Not required under normal conditions of use for finished product. If it found to be necessary, wear chemical compatible gloves.
Skin and body protection:	Not required under normal conditions of use for finished product. During manufacture or other similar industrial operations, wear the necessary protection for the process.
Hygiene measures:	Wash hands, wrist, forearms and face thoroughly after handling chemicals and products, before eating, and at the end of working period. Contaminated work clothing should not be allowed out of the workplace. Wash clothing before reusing.
Other personal protection:	None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Round Tablet	Odor:	None
Density:	Not Available	Boiling Point:	Not available
Color:	White	Solubility:	Water, Alcohol
Viscosity:	Not Available	Specific Gravity:	Not Available
Evaporation Rate:	Not Available	Conductivity:	Not Available

Chemical Properties:

pH:	Not Available	Flash Point:	Not Available
Reactivity:	Refer to section 10	Toxicity:	Refer to section 11

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SECTION 10 – STABILITY AND REACTIVITY

Reactivity: None expected under normal conditions of use.

Chemical stability: Stable under normal conditions of use.

Other:

Conditions to avoid: Moisture, light, and heat.

Incompatible materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products: None known

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Ingestion and skin.

Delayed, immediate and chronic effects for short and long term exposure:

General effects: Common side effects might include dark urine, loss of appetite, clumsiness, tiredness or weakness, nausea or vomiting, diarrhea, stomach pain, numbness, tingling, burning, or pain in hands and feet.

Sensitization: No known significant effects.

Mutagenic effects: No known significant effects or critical hazards.

Reproductive toxicity: No known significant effects.

Fetotoxic / Teratogenic Effects: No known significant effects or critical hazards.

Specific Target Organ Toxicity (STOT):

Single exposure: Nervous System Category 1

Repeated exposure: Nervous System, Liver, and Blood Category 1

Toxicity (LD50):

Toxicity studies have not been conducted with the Isoniazid Tablets USP product. The exposure limits listed below are for the active product ingredient (API) Isoniazid and not for the finished Tablet product itself.

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Oral LD_{50} Rat:	1250 mg/kg	Intraperitoneal LD_{50} Rat:	335 mg/kg
Subcutaneous LD_{50} Rat:	329 mg/kg	Intravenous LD_{50} Rat:	365 mg/kg
Intramuscular LD_{50} Rat:	400 mg/kg	Oral LD_{50} Mouse:	133 mg/kg
Intraperitoneal LD_{50} Mouse:	100 mg/kg	Subcutaneous LD_{50} Mouse:	125 mg/kg
Intravenous LD_{50} Mouse:	149 mg/kg	Intramuscular LD_{50} Mouse:	137 mg/kg

Symptoms / Adverse Reactions: Isoniazid Tablets may cause rash, abnormal liver function tests, hepatitis, peripheral neuropathy, mild central nervous system (CNS) effects.

Carcinogenicity: Product not listed as a carcinogen by OSHA.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects): Ecotoxicity studies have not been conducted with the Isoniazid Tablets USP product.

Persistence and Degradability: Not Available

Bioaccumulation: Not Available

Leaching studies: Not Available

Other adverse effects: Not Available. It is highly recommended to avoid environmental releases.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers in accordance with the federal, state or local regulatory requirements.

Waste Disposal Methods: Dispose all the product waste in accordance with the federal, state or local regulatory requirements.

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Special Precautions: Discard away from children's reach. Releases to the sewer should be avoided.

SECTION 14 – TRANSPORT INFORMATION

USDOT - Department of Transportation:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under USDOT.

ICAO - International Civil Aviation Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under ICAO.

IATA - International Air Transport Association:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IATA.

IMDG/IMO - International Maritime Dangerous Goods / International Maritime Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IMDG/IMO.

Special Precautions: None Known

SECTION 15 – REGULATORY INFORMATION

Drug Enforcement Administration (DEA): Not Listed as Controlled Substances.

Food and Drug Administration (FDA): Approved prescription medication.

Occupational Safety and Health Administration (OSHA):

GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

SARA 302/304 Extreme Hazardous Substances (EHS): Not Listed

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SARA 311/312 Hazard Categories: Immediate Hazard – No
Delayed Hazard – No
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard – No

SARA 313 Toxic Chemical Release Inventory (TRI): Not Regulated

Resource Conservation and Recovery Act (RCRA): No Code Applicable

Clean Water Act (CWA):

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Clean Air Act (CAA):

This product does not contain any chemicals listed under Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

Environmental Response Compensation and Liability Act (CERCLA):

Not applicable for the product. This product, as supplied, do not contains substances regulated as hazardous substances under CERCLA (40 CFR 302). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Toxic Substances Control Act (TSCA):

Not applicable for the product. The following ingredients are included on the TSCA inventory 8(b):

Ingredient	CAS Number
Colloidal Silicon Dioxide	7631-86-9
Crospovidone	9003-39-8
Hydrogenated Vegetable Oil	68334-28-1
Isoniazid	54-85-3
Microcrystalline Cellulose	9004-34-6
Pregelatanized Starch	9005-25-8
Talc	14807-96-6

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SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Aug/09/24, New SDS

Revision Date: N/A

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

Signature Manifest

Document Number: WP-0793 **Revision:** 1
Title: SDS Isoniazid Tablets USP - 64950
Effective Date: 27 Aug 2024

All dates and times are in Eastern Time.

SDS Isoniazid Tablets USP - 64950

Department Approval

Name/Signature	Title	Date	Meaning/Reason
July Ortiz (JORTIZ)		27 Aug 2024, 09:14:48 AM	Approved

Regulatory Affairs Approval

Name/Signature	Title	Date	Meaning/Reason
Demeitrius Sawickij (DSAWICKIJ)		27 Aug 2024, 11:02:21 AM	Approved

Quality Assurance Approval

Name/Signature	Title	Date	Meaning/Reason
Rama Chitirala (RCHITIRALA)	Vice President of Quality Assurance	27 Aug 2024, 12:19:58 PM	Approved