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SECTION 1 - IDENTIFICATION

Product Identification:

RenThyroid ™ (Thyroid Tablets, USP) 15 mg, 14 count bottle	NDC 64950-170-14
RenThyroid ™ (Thyroid Tablets, USP) 15 mg, 90 count bottle	NDC 64950-170-09
RenThyroid ™ (Thyroid Tablets, USP) 15 mg, 100 count bottle	NDC 64950-170-01
RenThyroid ™ (Thyroid Tablets, USP) 30 mg, 14 count bottle	NDC 64950-171-14
RenThyroid ™ (Thyroid Tablets, USP) 30 mg, 90 count bottle	NDC 64950-171-09
RenThyroid ™ (Thyroid Tablets, USP) 30 mg, 100 count bottle	NDC 64950-171-01
RenThyroid ™ (Thyroid Tablets, USP) 45 mg, 14 count bottle	NDC 64950-179-14
RenThyroid ™ (Thyroid Tablets, USP) 45 mg, 90 count bottle	NDC 64950-179-09
RenThyroid ™ (Thyroid Tablets, USP) 45 mg, 100 count bottle	NDC 64950-179-01
RenThyroid ™ (Thyroid Tablets, USP) 60 mg, 14 count bottle	NDC 64950-172-14
RenThyroid ™ (Thyroid Tablets, USP) 60 mg, 90 count bottle	NDC 64950-172-09
RenThyroid ™ (Thyroid Tablets, USP) 60 mg, 100 count bottle	NDC 64950-172-01
RenThyroid ™ (Thyroid Tablets, USP) 75 mg, 14 count bottle	NDC 64950-180-14
RenThyroid ™ (Thyroid Tablets, USP) 75 mg, 90 count bottle	NDC 64950-180-09
RenThyroid ™ (Thyroid Tablets, USP) 75 mg, 100 count bottle	NDC 64950-180-01
RenThyroid ™ (Thyroid Tablets, USP) 90 mg, 14 count bottle	NDC 64950-173-14
RenThyroid ™ (Thyroid Tablets, USP) 90 mg, 90 count bottle	NDC 64950-173-09
RenThyroid ™ (Thyroid Tablets, USP) 90 mg, 100 count bottle	NDC 64950-173-01
RenThyroid ™ (Thyroid Tablets, USP) 120 mg, 14 count bottle	NDC 64950-174-14
RenThyroid ™ (Thyroid Tablets, USP) 120 mg, 90 count bottle	NDC 64950-174-09
RenThyroid ™ (Thyroid Tablets, USP) 120 mg, 100 count bottle	NDC 64950-174-01
RenThyroid ™ (Thyroid Tablets, USP) 180 mg, 14 count bottle	NDC 64950-175-14
RenThyroid ™ (Thyroid Tablets, USP) 180 mg, 90 count bottle	NDC 64950-175-09
RenThyroid ™ (Thyroid Tablets, USP) 180 mg, 100 count bottle	NDC 64950-175-01

Product Name: RenThyroid™ Thyroid Tablet USP

Recommended use: RenThyroid™ Thyroid Tablets USP is recommended to be used as replacement or supplemental therapy in patients with hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. This category includes cretinism, myxedema, and ordinary hypothyroidism in patients of any age, or state (including pregnancy); primary hypothyroidism resulting

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from functional deficiency, primary atrophy, partial or total absence of thyroid gland, or the effects of surgery, radiation, or drugs, with or without the presence of goiter; and secondary (pituitary), or tertiary (hypothalamic) hypothyroidism.

RenThyroid™ Thyroid Tablets USP is also used as pituitary TSH suppressants, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter, and in the management of thyroid cancer.

Restrictions: RenThyroid™ Thyroid Tablets USP is generally contraindicated for patients with hypersensitivity to its ingredients, patients with diagnosed but as yet uncorrected adrenal cortical insufficiency, myocardial infarction, or hypertension. There is no well-documented evidence, however, of true allergic or idiosyncratic reactions to thyroid hormone. Thyroid hormones, either alone or with other therapeutic agents, should not be used for the treatment of obesity, weight loss, or to treat infertility unless it is caused by low thyroid hormone levels.

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

Telephone number: (610) 782-9780 ext.*100
Fax number: (610) 782-9781

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The product RenThyroid™ Thyroid 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 ingredients (API), Thyroid Powder, which have Levothyroxine (T_4) and Liothyronine (T_3), and not for the tablet product itself.

Physical hazards:	Not classified
Health hazards:	Sensitization - Respiratory Category 1B Eye Irritant Category 2 Skin Corrosion/Irritant Category 2
Environmental hazards:	Not classified

Signal Word: Warning

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Hazard Statement: This is a pharmaceutical product designed to be prescribed by a licensed health care professional. RenThyroid™ product is non-hazardous in accordance with international standards for workplace safety and OSHA. The active ingredient Thyroid Powder may cause eyes, skin, or respiratory tract irritation, may be harmful if absorbed through skin, if inhaled, or if swallowed.

Pictogram:

Precautionary Statement: This Safety Data Sheet (SDS) is written to provide environmental, health, and safety information for people handling this formulated product. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information, package insert product label, or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Hazards Not Otherwise Classified: None known.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

Chemical Identity	Other Names	CAS Number
Thyroid Powder	Thyroidin, Desiccated thyroid hormone	50809-32-0
Colloidal Silicon Dioxide	Silica, Dioxosilane, Cab-O-sil	7631-86-9
Mannitol	(L)-Mannitol, D-Mannitol, Diosmol	69-65-8
Microcrystalline Cellulose	Cephere, Avicel PH-101, Cellulose Gel	9004-34-6
Calcium Stearate	Stearic acid calcium salt, Aquacal	1592-23-0

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

SECTION 4 – FIRST AID MEASURES

Eye Contact: Not an expected route of exposure under normal conditions for the finished product. If not used as prescribed, flush eyes 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: Not an expected route of exposure under normal conditions for the finished product. If exposure happened, wash the skin with soap and large amount of water. Contact medical personnel if irritation persists.

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Ingestion: Do not use more than prescribed dose. Taking more medication will not improve the symptoms; rather they may cause poisoning or serious side-effects. If an overdose occurs, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician or a Poison Control Center (1-800-222-1222) immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Not an expected route of exposure under normal conditions for the finished product. If breathing is difficult, move to fresh air and seek medical attention immediately.

Symptoms or effects: Excessive doses of thyroid medicine result in a hypermetabolic state resembling the condition of endogenous origin, which may include fatigue, insomnia, tremors, weight loss, muscle weakness, tachycardia, palpitations, arrhythmias, changes in blood pressure, and shortness of breath. The onset of symptoms related overdose might occur within 12 to 24 hours after exposure.

Recommendations: RenThyroid™ is generally safe at recommended doses. Before start using the medicine, inform the doctor about current list of medications and over the counter products (vitamins, herbal supplements, etc.), also about allergies, pre-existing diseases, pregnancy, and current health conditions. Some health conditions and medications may make the patient more susceptible to the side-effects of the drug.

Take the medicine exactly as prescribed. Do not stop taking the medicine without talking with the doctor. Talk to the doctor about risk of side effects. Medicine dosage is based on patient condition. 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.

Note to Physician: RenThyroid™ contains Levothyroxine (T_4) and Liothyronine (T_3). Advice patients not to stop the medicine, increase the dose or dosing frequency without medical authorization because serious adverse events may occur. Before start treatment verify if the patient have diabetes, high blood pressure, heart failure or have had a heart attack, conditions that affect adrenal glands, or elderly or history of hypothyroidism. An ECG is highly recommended before start the treatment. Inform the patient that if missed a dose, to take skipped dose within 2 to 3 hours, and to take the medicine in the morning on an empty stomach at least half an hour before the first meal.

The use of RenThyroid™ should be evaluated if and when the patient has certain medical conditions or situations such as cardiovascular disease, hypertension, myocardial infarction, uncorrected adrenal failure, or untreated hyperthyroidism. Patients on thyroid hormone preparations and parents of children on thyroid therapy should be informed that replacement therapy is to be taken essentially for life, with the exception of cases of transient hypothyroidism, usually associated with thyroiditis, and in those patients receiving a therapeutic trial of the drug. Patients should immediately report during the course of therapy any signs or symptoms of thyroid hormone toxicity, e.g., chest pain, increased pulse rate, palpitations, excessive sweating, heat intolerance, nervousness, or any other unusual event.

In case of concomitant diabetes mellitus, the daily dosage of antidiabetic medication may need readjustment as thyroid hormone replacement is achieved. If thyroid medication is stopped, a downward readjustment of the dosage of insulin or oral hypoglycemic agent may be necessary to

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avoid hypoglycemia. At all times, close monitoring of urinary glucose levels is mandatory in such patients. In case of concomitant oral anticoagulant therapy, the prothrombin time should be measured frequently to determine if the dosage of oral anticoagulants is to be readjusted. Instruct patients to discontinue biotin or any biotin-containing supplements for at least 2 days before thyroid function testing is conducted. Partial loss of hair may be experienced by children in the first few months of thyroid therapy, but this is usually a transient phenomenon and later recovery is usually the rule.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media — Use Water, Dry chemical, CO_2 or any material appropriate for fire in the surrounding area. No Unsuitable extinguishing media known.

Specific hazards arising from the mixture: — Formation of irritating, corrosive and/or toxic gases is possible during a fire. (Refer to Section 10). No direct explosion hazard from the finish product.

Advice to the firefighters: — As in any fire, wear self-contained breathing apparatus pressure demand, NIOSH approved or equivalent, for the firefighting and full protective gear and clothing.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

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

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: — Prevent material from flush/entering sewer, or public waters. Isolate area around spill as specified by site procedures.

Clean Up Procedures: — Collect spill with broom and scoop, and place it in a clearly labeled compatible container for waste. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Decontaminate the area with water. Notify the manager for instructions on how to dispose the material Dispose according to applicable regulations (Refer to section 13).

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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 a Room Temperature at 20°C to 25°C (68°F to 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 is no exposure limits for the RenThyroid™ Thyroid Tablet product. The exposure limits listed below are for the active ingredient Thyroid Powder, which have Levothyroxine (T_4) and Liothyronine (T_3), and not for the RenThyroid™ Thyroid Tablet product itself.

OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	0.02 µg/m^3
Acceptable Daily Exposure (ADE):	0.1 µg/m^3
5 Band System Exposure Classification:	Category 5 Extremely High
ACGIH Threshold Limit Values (TLVs):	
Short Term Exposure Limits (STEL) – 15 min:	Not Available
Time Weight Average (TWA) – 8 Hours:	Not Available
NIOSH Immediately Dangerous to Life or Health (IDLH):	Not Listed

Engineering Controls: Not required for the normal use of this product.

Personal Protective Measures:

Respiratory protection:	None required when handling this product. If it found to be necessary, wear a mask or an appropriate NIOSH approved respirator.
Eye protection:	None required when handling this product. If it found to be necessary, wear safety glasses or goggles if unnecessary eye contact is possible.

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Protective gloves:	Not required under normal conditions of use. Chemical compatible when needed.
Skin and body protection:	Not required under normal conditions of use.
Hygiene measures:	Wash hands, forearms and face thoroughly after handling chemical 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	Color: Light brown to brown	
Odor:	Strong porcine odor	Density:	Not Available
Boiling Point:	Not Applicable	Melting Point:	Not Applicable
Solubility:	Water, Alcohol	Viscosity:	Not Applicable
Specific Gravity:	Not Applicable	Conductivity:	Not Available

Chemical Properties:

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

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

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Hazardous decomposition products: None known

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Oral, Ingestion

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

General effects: It may cause fatigue, palpitations, changes in appetite and weight, heat intolerance, excessive sweating.

Sensitization: None known.

Mutagenic effects: Not suspected of being a Mutagen. Mutagenicity studies have not been conducted with the product; however, published information might be available for the individual active ingredients of the product.

Reproductive toxicity: Not suspected of being a reproductive hazard. Fertility and reproductive studies have not been conducted with the product; however, published information should be available for the individual active ingredients of the product.

Fetotoxic / Teratogenic Effects: There are no available data when the product is used in pregnant women to inform a drug-associated risk for adverse developmental outcomes.

Effects on or via lactation: RenThyroid™ Thyroid Tablets active ingredient, Thyroid Powder, have Levothyroxine (T_4) and Liothyronine (T_3), which distributes into breast milk in at very low concentrations that are not considered harmful to a nursing infant. Although only minimal amounts of Thyroid hormones are distributed into milk, Thyroid agents should be used with caution in nursing women.

Specific target organ toxicity (STOT):

Single exposure:	No data available
Repeated exposure:	Thyroid Gland Category 2
Prolonged exposure:	Thyroid Gland Category 2

Toxicity (LD50):

Toxicity studies have not been conducted with RenThyroid™ Thyroid Tablets USP. The toxicity information listed below is for the active ingredient Thyroid Powder, which have Levothyroxine (T_4) and Liothyronine (T_3), and not for the tablet product itself.

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The amount of a material, given all at once, which causes the death of 50% (one half) of a group of test animals, is known as Lethal Dose (LD_{50}). There are no toxicity studies that determine the LD_{50} for the RenThyroid™ Thyroid Tablets USP active ingredient Thyroid Powder.

Adverse Reactions / Side Effects: Adverse reactions other than those indicative of hyperthyroidism because of therapeutic overdosage, either initially or during the maintenance period, are rare.

Carcinogenicity: Carcinogenicity studies have not been conducted with the product RenThyroid™ Thyroid Tablets USP; however, published information might be available for the individual active ingredients or related active ingredients. RenThyroid™ Thyroid Tablets USP is not listed as a carcinogen by OSHA.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects):

No information or Ecotoxicity studies have been conducted or are currently available on the environmental impact of RenThyroid™ Thyroid Tablets USP product. All releases to soil and aquatic environments should be avoided.

Persistence and Degradability: No data available.

Bioaccumulation: No data available.

Leaching studies: No data available.

Other adverse effects: Product not classified as environmentally hazardous. No major effects to aquatic organisms are expected, however; is recommended avoid environmental releases.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers in accordance with the Food and Drug Administration (FDA) guidelines and the federal, state or local requirements.

Waste Disposal Methods: Dispose of waste in accordance with Environmental Protection Agency (EPA) guidelines and 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 Regulated.

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).

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

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

SARA 311/312 Hazard Categories: Not Listed

SARA 313 Toxic Chemical Release Inventory (TRI):

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA) is known as SARA 313. This product, as supplied, does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

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):

Chemical Identity	CAS Number
Colloidal Silicon Dioxide	7631-86-9
Mannitol	69-65-8
Microcrystalline Cellulose	9004-34-6
Calcium Stearate	1592-23-0

There may be specific reporting requirements at the local, regional, state, or national level pertaining to releases of this material.

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SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Mar/26/25, New SDS

Revision Date: N/A

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