US - OSHA SAFETY DATA SHEET

Issue Date 01-May-2015 **Revision Date** 23-Nov-2015 **Version** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Liothyronine Sodium Tablets, 5mcg, 25mcg, 50mcg

Other means of identification

Synonyms None known.

Recommended use of the chemical and restrictions on use

Recommended Use Synthetic hormonal agent.
Uses advised against Prescription use only.

Details of the supplier of the safety data sheet

Manufacturer Address
Mayne Pharma Inc.
1240 Sugg Parkway
Greenville, NC 27834

Emergency telephone number

Company Phone Number +1-252-752-3800
24 Hour Emergency Phone Number For Hazardous Materials [or Dangerous Goods] Incident
Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC Day or Night
Within USA and Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

Health Hazards
Not classified.

Physical hazards
Not classified.

OSHA Regulatory Status
Drugs when in solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

Label elements

Emergency Overview

Hazard statements

Appearance Tablet **Physical state** Solid **Odor** Not available.

Hazards not otherwise classified (HNOC)
Not classified.

Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows in this Safety Data Sheet (SDS).

Chemical Name	CAS No.	Weight-%
Microcrystalline Cellulose, NF	9004-34-6	80-90
Calcium Sulfate Dihydrate, NF	10101-41-4	<10
Talc	14807-96-6	1-5
Liothyronine Sodium, USP	55-06-1	<0.05

4. FIRST AID MEASURES

First aid measures

Eye contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-protection of the first aider Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms Not available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical
Not available.

Hazardous combustion products Not available.

Explosion data
Sensitivity to Mechanical Impact Not available.
Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation, especially in confined areas.

Environmental precautions

Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Microcrystalline Cellulose, NF 9004-34-6	TWA: 10 mg/m^3	TWA: 15 mg/m^3 total dust TWA: 5 mg/m^3 respirable fraction (vacated) TWA: 15 mg/m^3 total dust (vacated) TWA: 5 mg/m^3 respirable fraction (vacated) TWA: 5 mg/m^3 (vacated) STEL: 10 mg/m^3	TWA: 10 mg/m^3 total dust TWA: 5 mg/m^3 respirable dust TWA: 1 mg/m^3
Calcium Sulfate Dihydrate, NF 10101-41-4	TWA: 10 mg/m^3 inhalable fraction	-	-
Talc 14807-96-6	TWA: 2 mg/m^3 particulate matter containing no asbestos and <1% crystalline silica, respirable fraction	(vacated) TWA: 2 mg/m^3 respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more, use Quartz limit	IDLH: 1000 mg/m^3 TWA: 2 mg/m^3 containing no Asbestos and <1% Quartz respirable dust

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and body protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid		
Appearance	Tablet	**Odor**	Not available.
Color	Not available.	**Odor threshold**	Not available.

Property	**Values**	**Remarks**
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	

Autoignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

Other Information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity
Stable at normal conditions.

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid
Extremes of temperature and direct sunlight.

Incompatible materials
None known based on information supplied.

Hazardous Decomposition Products
None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation No data available.

Eye contact No data available.

Skin Contact No data available.

Ingestion No data available.

Acute toxicity Not available.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Microcrystalline Cellulose, NF 9004-34-6	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m^3 (Rat) 4 h	-
Liothyronine Sodium, USP 55-06-1	= 4500-7500 mg/kg (Rat)	-	-	-

Information on toxicological effects

Symptoms Not available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No data found.
Serious eye damage/eye irritation No data found.
Irritation No data found.
Sensitization No data found.
Germ cell mutagenicity No data found.
Carcinogenicity An apparent association between prolonged thyroid therapy and breast cancer has been reported but has not been confirmed. No long-term studies in animals have been performed to evaluate carcinogenic potential. Not listed by IARC, NTP or USOSHA.

Chemical Name	ACGIH	IARC	NTP	OSHA
Talc 14807-96-6		Group 3		

Reproductive toxicity No long-term studies in animals have been performed to evaluate impairment of fertility or effect on fetuses.
Developmental Toxicity Not available.
Teratogenicity Not available.
STOT - single exposure Not available.
STOT - repeated exposure Not available.
Chronic toxicity Not available.
Target Organ Effects Not available.
Aspiration hazard Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available.

97.47% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Talc 14807-96-6		100: 96 h Brachydanio rerio g/L LC50 semi-static		

Persistence and degradability
Not available.

Bioaccumulation
Not available.

Mobility
Not available.

Other adverse effects
Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and

regulations.

Contaminated packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number Not available.

14. TRANSPORT INFORMATION

DOT Not regulated.

TDG Not regulated.

MEX Not regulated.

ICAO (air) Not regulated.

IATA Not regulated.

IMDG Not regulated.

RID Not regulated.

ADR Not regulated.

ADN Not regulated.

15. REGULATORY INFORMATION

This product is a drug and as such is regulated under the US Food and Drug Administration (FDA).

International Inventories

TSCA	Does not comply.
DSL/NDSL	Does not comply.
EINECS/ELINCS	Does not comply.
ENCS	Does not comply.
IECSC	Does not comply.
KECL	Does not comply.
PICCS	Does not comply.
AICS	Complies.

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product 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.

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No

Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)
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).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product contains the following substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Microcrystalline Cellulose, NF 9004-34-6	X	X	X
Talc 14807-96-6	X	X	X

U.S. EPA Label Information
EPA Pesticide Registration Number Not available.

16. OTHER INFORMATION

Issue Date	01-May-2015
Revision Date	23-Nov-2015
Revision Note	Not available.

Disclaimer
Mayne Pharma Inc. considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use 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. Mayne Pharma Inc. shall not be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet