



## **SAFETY DATA SHEET**

### **Thyquidity® (Levothyroxine Sodium) Oral Solution**

Version: OL-THY-01

Updated Jul 21, 2025

#### **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

##### **1.1 Product Identifier**

Trade Name Thyquidity® (Levothyroxine Sodium) Oral Solution

CAS Number (API) 25416-65-3

EC Number (API) 200-221-4

NDA Number 214047

##### **1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available

Application of the substance/the mixture: Approved pharmaceutical product for the treatment of conditions related to thyroid hormone deficiency

##### **1.3 Details of the supplier of the safety data sheet**

Supplier

Oliva Therapeutics, LLC

45 N. Broad St #504

Ridgewood, NJ 07450

Further information available from

Oliva Therapeutics, LLC

E-Mail: [olivasafety@olivatherapeutics.com](mailto:olivasafety@olivatherapeutics.com)

Tel: +1 (877) 200 - 6088

**1.4 Emergency telephone number: +1 (877) 200-6088**

#### **SECTION 2: Hazards Identification**

##### **2.1 Classification of the substance or mixture**

Classification according to 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)  
The active pharmaceutical ingredient is not considered hazardous according to OSHA standards

## 2.2 Labeling Elements

Labeling according to OSHA HCS (29 CFR 1910.1200) - Not applicable

Hazard pictograms - Not applicable

Signal Word -Not applicable

Hazard statements - Not applicable

Results of PBT and vPvB Assessment

PBT Not applicable

vPvB Not applicable

Determination of endocrine disrupting properties: Not applicable

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

API CAS No. Description

25416-65-3 - Levothyroxine Sodium Hydrate

API Identification Number

200-221-4

## SECTION 4: First Aid Measures

### 4.1 Description of first aid measures

#### General Information

Personal protection for first aider

Immediately remove any clothing soiled by the product

Remove breathing equipment only after contaminated clothing has been completely removed

In case of irregular breathing or respiratory arrest provide artificial respiration

#### After Inhalation

Supply fresh air or oxygen; call for doctor

In case of unconsciousness, place patient stably in side position for transportation

#### After Skin Contact

Immediately wash with water and soap and rinse thoroughly

If skin irritation continues, consult a doctor

#### After Swallowing

Rinse mouth

Do not induce vomiting, call for medical help immediately

### 4.2 Most important symptoms and effects, both acute and delayed

Restlessness  
Diarrhea  
Fever  
Tachycardia  
Coma

#### **4.3 Indication of any immediate medical attention and special treatment needed**

A specific antidote is not available  
Therefore a symptomatic therapy is to be introduced

### **SECTION 5: Firefighting measures**

#### **5.1 Extinguishing media**

##### **Suitable extinguishing agents:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
For safety reasons unsuitable extinguishing agents: Water with full jet

#### **5.2 Special hazards arising from the substance or mixture**

##### **During heating or in case of fire poisonous gases are produced.**

In case of fire, the following can be released:

Nitrogen oxides (NO<sub>x</sub>)  
Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)  
Hydrogen iodide (HI)

#### **5.3 Advice for firefighters**

##### **Protective equipment:**

Do not inhale explosion gases or combustion gases.  
Wear self-contained respiratory protective device.  
Wear fully protective suit.  
Additional information  
Collect contaminated fire fighting water separately. It must not enter the sewage system

### **SECTION 6: Accidental release measures**

#### **6.1 Personal precautions, protective equipment and emergency procedures**

Keep away from ignition sources.  
Avoid formation of dust.  
Wear protective clothing.  
Use respiratory protective device against the effects of fumes/dust/aerosol.

#### **6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.**

#### **6.3 Methods and material for containment and cleaning up:**

Pick up mechanically.  
Send for recovery or disposal in suitable receptacles.  
Clean the affected area carefully; suitable cleaners are:  
Warm water and cleansing agent  
Dispose contaminated material as waste according to section 13.

#### **6.4 Reference to other sections**

See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### **SECTION 7: Handling and Storage**

#### **7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.  
Open and handle receptacle with care.  
Prevent formation of dust.  
Information about fire - and explosion protection:  
Dust can combine with air to form an explosive mixture.  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.

#### **7.2 Conditions for safe storage, including any incompatibilities**

##### **Storage:**

Requirements to be met by storerooms and receptacles: No special requirements.  
Information about storage in one common storage facility:  
Do not store together with acids.  
Do not store together with alkalis (caustic solutions).  
Further information about storage conditions:  
Protect from humidity and water.  
Avoid contact with air / oxygen.  
Protect from exposure to the light.

#### **7.3 Specific end use(s) No further relevant information available.**

### **SECTION 8: Exposure controls/personal protection**

#### **8.1 Control parameters**

Ingredients with limit values that require monitoring at the workplace: Not required.

#### **8.2 Exposure controls**

Appropriate engineering controls No further data; see section 7.  
Individual protection measures, such as personal protective equipment  
General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Do not eat, drink, smoke or sniff while working.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

Respiratory protection:

Short term filter device:

Filter P3

#### **Hand protection**

Check protective gloves prior to each use for their proper condition.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves: Rubber gloves

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**Eye/face protection:** Safety glasses

**Body protection:** Protective work clothing

## **Section 9: Physical and chemical properties**

### **9.1 Information on basic physical and chemical properties**

**Appearance** Clear, colorless solution

**Odor** No data available

**Odor Threshold** No data available

**Molecular Weight** 798.85 g/mol (Levothyroxine Sodium)

**Chemical Formula** C<sub>15</sub>H<sub>10</sub>I<sub>4</sub>NNaO<sub>4</sub> (Levothyroxine Sodium)

**pH (1% aqueous solution)** 5.2 – 5.7

**Freezing | Melting Point** No data available

**Boiling Point Range** No data available

**Evaporation Rate** No data available

**Flammability (solid, gas)** Not applicable

**Flash Point** No data available

**Autoignition Temperature** No data available

#### **Decomposition**

**Temperature** No data available

**Lower Explosive Limit (LEL)** No data available

**Upper Explosive Limit (UEL)** No data available

**Vapor Pressure** No data available

**Vapor Density** No data available

**Specific Gravity** No data available

**Density** No data available

**Viscosity** No data available

**Solubility in Water** Slightly soluble  
**Partition Coefficient (noctanol/water)** No data available  
**Oxidizing Properties** Not applicable  
**Explosive Properties** Not applicable  
**Volatiles by Weight @ 21 °C** No data available

## SECTION 10: Stability and reactivity

**10.1 Reactivity** No further relevant information available.

### 10.2 Chemical stability

Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

### 10.3 Possibility of hazardous reactions

As the product is supplied it is not capable of dust explosion; however enrichment with fine dust causes risk of dust explosion.

Ø **10.4 Conditions to avoid** No further relevant information available.

### 10.5 Incompatible materials:

Alkaline solutions

Acids

Oxidizing agent

**10.6 Hazardous decomposition products:** No dangerous decomposition products known

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

Oral LD50 10,000 mg/kg (rat)

Skin corrosion/irritation Not known.

Serious eye damage/irritation May cause eye irritation.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

**11.2 Information on other hazards**

Endocrine disrupting properties Substance is not listed.

**SECTION 12: Ecological information****12.1 Toxicity**

Aquatic toxicity: No further relevant information available.

**12.2 Persistence and degradability** No further relevant information available.

**12.3 Bioaccumulative potential**

Due to the distribution coefficient n-octanol/water an accumulation in organisms is possible.

**12.4 Mobility in soil** No further relevant information available.

**12.5 Results of PBT and vPvB assessment**

PBT: Not applicable.

vPvB: Not applicable.

**12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

**12.7 Other adverse effects**

Additional ecological information:

General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities

Danger to drinking water if even extremely small quantities leak into the ground

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Recommendation Must be specially treated adhering to official regulations.

Uncleaned packaging:

Recommendation:

Disposal must be made according to official regulations.

Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning

**SECTION 14: Transport Information****14.1 UN number or ID number**

ADR, ADN, IMDG, IATA                      Void

**14.2 UN proper shipping name**

ADR, ADN, IMDG, IATA	Void
<b>14.3 Transport hazard class(es)</b>	
ADR, ADN, IMDG, IATA	
Class	Void
<b>14.4 Packing group</b>	
ADR, IMDG, IATA	Void
<b>14.5 Environmental hazards:</b>	
	Not applicable
<b>14.6 Special precautions for user</b>	
	Not applicable
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	
	Not applicable
<b>Transport/Additional information:</b> Not dangerous according to the above specifications.	
<b>UN "Model Regulation":</b>	
	Void

#### SECTION 15: Regulatory Information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
**29 CFR 1910.119, OSHA's Process Safety Management (PSM) standard**

**Named dangerous substances - ANNEX A** Substance is not listed.

**Restriction of the use of certain hazardous substances in electrical and electronic equipment** – Not applicable

REGULATION OSHA Process Safety Management (PSM) of Highly Hazardous Chemicals (29 CFR 1910.119)

Explosive precursor

Substance is not listed.

Regulation (EC) No 273/2004 on drug precursors Substance is not listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Substance is not listed.

**National regulations:**

Information about limitation of use:

Employment restrictions concerning pregnant and lactating women must be observed.

**15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

#### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship