SAFETY DATA SHEET
Levothyroxine Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Levothyroxine Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 3
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 1 (Thyroid, Cardio-vascular system, Central nervous system)

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H226 Flammable liquid and vapor.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (Thyroid, Cardio-vascular system, Central nervous system) through prolonged or repeated exposure.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately...
all contaminated clothing. Rinse skin with water.  
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:  
P405 Store locked up.

Disposal:  
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards  
Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ethanol#</td>
</tr>
<tr>
<td></td>
<td>levothyroxine sodium</td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
</tr>
<tr>
<td>levothyroxine sodium</td>
<td>55-03-8</td>
</tr>
</tbody>
</table>

# Voluntarily-disclosed non-hazardous substance

SECTION 4. FIRST AID MEASURES

General advice:  
In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:  
If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact:  
In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact:  
Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed:  
If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:  
Suspected of damaging fertility or the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders:  
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:  
Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES
### SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**
- Remove all sources of ignition.
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spills cannot be contained.

**Methods and materials for containment and cleaning up**
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapors/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling: Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage: Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Keep away from heat and sources of ignition.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
Explosives
Gases
## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>VLE-CT</td>
<td>1,000 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>levothyroxine sodium</td>
<td>55-03-8</td>
<td>TWA</td>
<td>0.1 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

### Engineering measures

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Use explosion-proof electrical, ventilating and lighting equipment.

### Personal protective equipment

#### Respiratory protection

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapor type

Hand protection:

Material: Chemical-resistant gloves

Remarks: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

#### Eye protection

Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

#### Skin and body protection

Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: liquid
- **Color**: colorless
- **Odor**: slight
- **Odor Threshold**: No data available
- **pH**: 9.7 - 10.7
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: 44 °C
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Relative density**: No data available
- **Density**: 1.05 g/cm³
- **Solubility(ies)**
  - **Water solubility**: soluble
- **Partition coefficient: n-octanol/water**: Not applicable
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- Vapors may form explosive mixture with air.
- Can react with strong oxidizing agents.

Conditions to avoid:
- Heat, flames and sparks.
Incompatible materials:
- Oxidizing agents
- Acids

Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Ethanol:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapor

Levothyroxine sodium:
Acute oral toxicity: TDLo (Humans): 10 mg/kg
TDLo (Dog): 10 mg/kg
LD50 (Rat): > 1,000 mg/kg

Acute dermal toxicity: LD50 (Rat): > 50 mg/kg

Acute toxicity (other routes of exposure): LD50 (Rat): 20 mg/kg
SAFETY DATA SHEET
Levothyroxine Formulation

Version 4.4 Revision Date: 09.04.2021 SDS Number: 1130661-00011 Date of last issue: 10.10.2020 Date of first issue: 30.11.2016

administration) Application Route: Intraperitoneal
LD50 (Rat): 50 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation
Not classified based on available information.

Components:
Ethanol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Ethanol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Ethanol:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
Ethanol:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test Result: negative
Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Suspected of damaging fertility or the unborn child.

Components:

Ethanol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

levothyroxine sodium:
Effects on fetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.25 mg/kg body weight

Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 3 mg/kg body weight

Test Type: Development
Species: Rabbit
Result: No teratogenic effects.

Test Type: Development
Species: Guinea pig
Result: No teratogenic effects.

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (Thyroid, Cardio-vascular system, Central nervous system) through prolonged or repeated exposure.

Components:

levothyroxine sodium:
Target Organs : Thyroid, Cardio-vascular system, Central nervous system
Assessment : Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

Components:

Ethanol:
Species: Rat
NOAEL: 1,280 mg/kg
LOAEL: 3,156 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
levothyroxine sodium:
Ingestion: Target Organs: Thyroid
Target Organs: Cardio-vascular system
Target Organs: Central nervous system
Symptoms: Palpitation, hypotension, Tremors, Headache,
increase in appetite, Sweating, Vomiting, Diarrhea, Fever,
nervousness, weight loss

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ethanol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
Exposure time: 72 h
EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 9.6 mg/l
Exposure time: 9 d

Toxicity to microorganisms: EC50 (Pseudomonas putida): 6,500 mg/l
Exposure time: 16 h
Persistence and degradability

Components:

Ethanol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Bioaccumulative potential

Components:

Ethanol:
Partition coefficient: n-octanol/water: log Pow: -0.35

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 1170
Proper shipping name: ETHANOL SOLUTION
Class: 3
Packing group: III
Labels: 3

IATA-DGR
UN/ID No.: UN 1170
Proper shipping name: Ethanol solution
Class: 3
Packing group: III
Labels: Flammable Liquids
Packing instruction (cargo aircraft): 366
Packing instruction (passenger aircraft) : 355

**IMDG-Code**

UN number : UN 1170
Proper shipping name : ETHANOL SOLUTION
Class : 3
Packing group : III
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : no

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**Domestic regulation**

**NOM-002-SCT**
UN number : UN 1170
Proper shipping name : ETHANOL SOLUTION
Class : 3
Packing group : III
Labels : 3

**Special precautions for user**
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

**SECTION 15. REGULATORY INFORMATION**

**Safety, health and environmental regulations/legislation specific for the substance or mixture**
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

**The ingredients of this product are reported in the following inventories:**
AICS : not determined
DSL : not determined
IECSC : not determined

**SECTION 16. OTHER INFORMATION**

**Full text of other abbreviations**
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / STEL : Short-term exposure limit
SAFETY DATA SHEET

Levothyroxine Formulation

Version 4.4
Revision Date: 09.04.2021
SDS Number: 1130661-00011
Date of last issue: 10.10.2020
Date of first issue: 30.11.2016

NOM-010-STPS-2014 / VLE-CT: Short term exposure limit value

Sources of key data used to compile the Material Safety Data Sheet:
- Revision Date: 09.04.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8