SAFETY DATA SHEET

Levothyroxine Formulation

SECTION 1. IDENTIFICATION

Product name : Levothyroxine Formulation
Other means of identification : No data available

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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 and face protection.
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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 attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and 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>Mixtures</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>levothyroxine sodium</td>
<td>55-03-8</td>
<td>&gt;= 0.1 - &lt; 1 *</td>
</tr>
</tbody>
</table>

# Voluntarily-disclosed non-hazardous substance
* Actual concentration or concentration range is withheld as a trade secret

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

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : High volume water jet

Specific hazards during firefighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapors may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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 spillages 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.

**Conditions for safe storage**: Keep in properly labeled containers. Store locked up. Keep tightly closed. 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>
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</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>TWA</td>
<td>1,000 ppm</td>
<td>CA AB OEL</td>
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</table>
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<table>
<thead>
<tr>
<th>55-03-8</th>
<th>1.880 mg/m³</th>
<th>1,000 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>STEL</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA EV</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td>1,880 mg/m³</td>
<td></td>
</tr>
<tr>
<td>levotyroxine sodium</td>
<td>TWA</td>
<td>0.1 µg/m³ (OEB 5)</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>1 µg/100 cm²</td>
</tr>
</tbody>
</table>

**Engineering measures**
- Use explosion-proof electrical, ventilating and lighting equipment.
- 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.

**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.

**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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
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<tr>
<td>Color</td>
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<td>Odor</td>
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<tr>
<td>pH</td>
<td>9.7 - 10.7</td>
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<td>Melting point/freezing point</td>
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<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
<td>44 °C</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
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<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
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<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
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<tr>
<td>Vapor pressure</td>
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<td>Relative vapor density</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Density</td>
<td>1.05 g/cm³</td>
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<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
<td>soluble</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
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<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
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<tr>
<td>Viscosity</td>
<td></td>
</tr>
</tbody>
</table>
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:
- Flammable liquid and vapor.
  - 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 administration)

LD50 (Rat): 20 mg/kg
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
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Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo:
Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

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 (Chron-}: NOEC (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 9 d
ic toxicity)
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
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.3</td>
<td>10/10/2020</td>
<td>1130650-00010</td>
<td>09/13/2019</td>
<td>11/30/2016</td>
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</table>

- **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

#### TDG
- **UN number**: UN 1170
- **Proper shipping name**: ETHANOL SOLUTION
- **Class**: 3
- **Packing group**: III
- **Labels**: 3
- **ERG Code**: 127
- **Marine pollutant**: no

#### 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

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)
- **CA AB OEL**: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
- **CA BC OEL**: Canada. British Columbia OEL
- **CA QC OEL**: Québec. Regulation respecting occupational health and safe-
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Levothyroxine Formulation

Version | Revision Date: | SDS Number: | Date of last issue: | Date of first issue:
--- | --- | --- | --- | ---
4.3 | 10/10/2020 | 1130650-00010 | 09/13/2019 | 11/30/2016

ty, Schedule 1, Part 1: Permissible exposure values for airborne contaminants

ACGIH / STEL : Short-term exposure limit
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / STEL : short-term exposure limit
CA QC OEL / TWAEO : Time-weighted average exposure value

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date : 10/10/2020
Date format : mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific
context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

CA / Z8