SAFETY DATA SHEET
Levothyroxine Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Levothyroxine Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

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 vapour.
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/ sparks/ open flames/ hot surfaces.
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Version 2.6  Revision Date: 2020/03/23  SDS Number: 1130656-00009  Date of last issue: 2019/09/13  Date of first issue: 2016/11/30

No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P260 Do not breathe mist or vapours.
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/ shower.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

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

Other hazards which do not result in classification
Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<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;= 0.01 - &lt; 1</td>
</tr>
</tbody>
</table>

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 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:
- 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.

5. FIREFIGHTING 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.
- Vapours 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 firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Remove all sources of ignition.
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- 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/vapours/mists with a water
spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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.

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.

Advice on safe handling : Avoid inhalation of vapour or mist. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. 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 and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.


Materials to avoid : Do not store with the following product types: Self-reactive substances and mixtures Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Poisonous gases Explosives
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>NAB</td>
<td>1,000 ppm</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Adopted in Year 1996, Upper respiratory tract irritation</td>
<td></td>
</tr>
<tr>
<td>Ethanol</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></td>
<td>Wipe limit 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.

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 vapour type

Hand protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>colourless</td>
</tr>
<tr>
<td>Odour</td>
<td>slight</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>9.7 - 10.7</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>44 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.05 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
   Vapours 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.

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: > 2,000 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: vapour

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
- Method: OECD Test Guideline 405
- Result: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Ethanol:
- Test Type: Local lymph node assay (LLNA)
- Exposure routes: 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
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</tbody>
</table>

Result: negative

- **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 foetal 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, Diarrhoea, Fever, nervousness, weight loss

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-
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 

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. 

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
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**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.

**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.

### 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
- **Hazardous substances that must be registered**: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
- **Hazardous substances approved for use**: Ethanol
- **Prohibited substances**: Not applicable
- **Restricted substances**: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
- **Type of Hazardous Materials Restricted to Import, Distribution and Supervision**: Not applicable

**The components of this product are reported in the following inventories:**
- **AICS**: not determined
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16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / STEL: Short-term exposure limit
ID OEL / NAB: Long term exposure limit

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.

ID / EN