SAFETY DATA SHEET
Levothyroxine Formulation

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

1.1 Product identifier
   Trade name : Levothyroxine Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             20 Spartan Road
             1619 Spartan, South Africa
   Telephone : +27119239300
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Flammable liquids, Category 3
   Reproductive toxicity, Category 2
   Specific target organ toxicity - repeated exposure, Category 1
   Classification (EC) No 1272/2008)
   H226: Flammable liquid and vapour.
   H361: Suspected of damaging fertility or the unborn child.
   H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   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 through prolonged or repeated exposure.
Precautionary statements:

**Prevention:**
P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Levothyroxine sodium

**2.3 Other hazards**

Vapours may form explosive mixture with air.

---

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>603-002-00-5</td>
<td>Flam. Liq.2; H225 Eye Irrit.2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Levothyroxine sodium</td>
<td>55-03-8</td>
<td>200-221-4</td>
<td></td>
<td>Acute Tox.2; H300 Repr.2; H361 STOT RE1; H372</td>
<td>&gt;= 0,1 - &lt; 1</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

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### SECTION 4: First aid measures

#### 4.1 Description of 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.

**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).

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

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

4.3 Indication of any immediate medical attention and special treatment needed
Treatment:
Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media:
High volume water jet

5.2 Special hazards arising from the substance or mixture
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

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

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation. If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof 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.

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers:
Keep in properly labelled 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.

Advice on common storage:
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

7.3 Specific end use(s)
Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>TWA OEL-RL</td>
<td>1.000 ppm 1.900 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td></td>
<td></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>
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</table>
Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>343 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>206 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>114 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>87 mg/kg bw/day</td>
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</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Fresh water</td>
<td>0.96 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.79 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>2.75 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>580 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.6 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>2.9 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.63 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>720 mg/kg food</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

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.

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.

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.

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 (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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>
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<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>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>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
**Explosive properties**: Not explosive

**Oxidizing properties**: The substance or mixture is not classified as oxidizing.

### 9.2 Other information

- **Flammability (liquids)**: Not applicable
- **Particle size**: Not applicable

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

- **Hazardous reactions**: Flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

- **Conditions to avoid**: Heat, flames and sparks.

#### 10.5 Incompatible materials

- **Materials to avoid**: Oxidizing agents, Acids

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

- **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
- 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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs 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, Cardio-vascular system, Central nervous system
Symptoms: Palpitation, hypotension, Tremors, Headache, increase in appetite, Sweating, Vomiting, Diarrhoea, Fever, nervousness, weight loss

SECTION 12: Ecological information

12.1 Toxicity

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 microorganisms: EC50 (Pseudomonas putida): 6.500 mg/l Exposure time: 16 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 9,6 mg/l Exposure time: 9 d Species: Daphnia magna (Water flea)

### 12.2 Persistence and degradability

**Components:**

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

### 12.3 Bioaccumulative potential

**Components:**

- **Ethanol:**
  - Partition coefficient: n-octanol/water: log Pow: -0,35

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

- **Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **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.
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SECTION 14: Transport information

14.1 UN number

<table>
<thead>
<tr>
<th>Country</th>
<th>UN number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 1170</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 1170</td>
</tr>
<tr>
<td>RID</td>
<td>UN 1170</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 1170</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 1170</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>Country</th>
<th>UN proper shipping name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>ETHANOL SOLUTION</td>
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<td>ADR</td>
<td>ETHANOL SOLUTION</td>
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<tr>
<td>IMDG</td>
<td>ETHANOL SOLUTION</td>
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<tr>
<td>IATA</td>
<td>Ethanol solution</td>
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14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>Country</th>
<th>Transport hazard class(es)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>3</td>
</tr>
<tr>
<td>ADR</td>
<td>3</td>
</tr>
<tr>
<td>RID</td>
<td>3</td>
</tr>
<tr>
<td>IMDG</td>
<td>3</td>
</tr>
<tr>
<td>IATA</td>
<td>3</td>
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</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>Country</th>
<th>Packing group</th>
<th>Classification Code</th>
<th>Hazard Identification Number</th>
<th>Labels</th>
<th>Tunnel restriction code</th>
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<tbody>
<tr>
<td>ADN</td>
<td>III</td>
<td>F1</td>
<td>30</td>
<td>3</td>
<td>(D/E)</td>
</tr>
<tr>
<td>ADR</td>
<td>III</td>
<td>F1</td>
<td>30</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>III</td>
<td>F1</td>
<td>30</td>
<td>3</td>
<td>(D/E)</td>
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<tr>
<td>IMDG</td>
<td>III</td>
<td>F1</td>
<td>30</td>
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<table>
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<tr>
<td>RID</td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td></td>
</tr>
</tbody>
</table>
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IATA (Cargo)
Packing instruction (cargo aircraft): 366
Packing instruction (LQ): Y344
Packing group: III
Labels: Flammable Liquids

IATA (Passenger)
Packing instruction (passenger aircraft): 355
Packing instruction (LQ): Y344
Packing group: III
Labels: Flammable Liquids

14.5 Environmental hazards

ADN
Environmentally hazardous: no

ADR
Environmentally hazardous: no

RID
Environmentally hazardous: no

IMDG
Marine pollutant: no

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:

AICS: not determined

DSL: not determined

IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical
# SAFETY DATA SHEET

## Levothyroxine Formulation

<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>
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</thead>
</table>

### Full text of H-statements

- **H225**: Highly flammable liquid and vapour.
- **H300**: Fatal if swallowed.
- **H319**: Causes serious eye irritation.
- **H361**: Suspected of damaging fertility or the unborn child.
- **H372**: Causes damage to organs through prolonged or repeated exposure.

### Full text of other abbreviations

- **Acute Tox.**: Acute toxicity
- **Eye Irrit.**: Eye irritation
- **Flam. Liq.**: Flammable liquids
- **Repr.**: Reproductive toxicity
- **STOT RE**: Specific target organ toxicity - repeated exposure
- **ZA OEL**: South Africa, Hazardous Chemical Substances Regulations, Occupational Exposure Limits
- **ZA OEL / TWA OEL-RL**: Long term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IESCC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information
SAFETY DATA SHEET

Levothyroxine Formulation

Version: 3.2
Revision Date: 13.09.2019
SDS Number: 1130666-00009
Date of last issue: 24.04.2019
Date of first issue: 30.11.2016

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

Classification of the mixture:

<table>
<thead>
<tr>
<th>Flam. Liq.</th>
<th>H226</th>
<th>Based on product data or assessment</th>
</tr>
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<tbody>
<tr>
<td>Repr. 2</td>
<td>H361</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

ZA / EN