

Levothyroxine Formulation

Version 2.15 Revision Date: 05.12.2023 SDS Number: 1130664-00018 Date of last issue: 30.09.2023
Date of first issue: 30.11.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Levothyroxine Formulation

Other means of identification : Leventa (A010426)

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive
Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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.

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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. 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

| Chemical name | CAS-No. | Concentration (% w/w) |
|----------------------|---------|-----------------------|
| Ethanol# | 64-17-5 | >= 10 -< 20 |
| levothyroxine sodium | 55-03-8 | >= 0.1 -< 1 |

Voluntarily-disclosed substance

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.

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| 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. |

5. FIREFIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | High volume water jet |
| Specific hazards during fire-fighting | : | 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

| | | |
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| 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). |
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- 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/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.
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not breathe mist or vapours.
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 labelled containers.
Store locked up.
Keep tightly closed.

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Materials to avoid : Keep in a cool, well-ventilated place.
 Store in accordance with the particular national regulations.
 Keep away from heat and sources of ignition.
 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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|----------------------|---------|-------------------------------|--|----------|
| Ethanol | 64-17-5 | PEL (long term) | 1,000 ppm 1,880 mg/m ³ | SG OEL |
| | | STEL | 1,000 ppm | ACGIH |
| levothyroxine sodium | 55-03-8 | TWA | 0.1 µg/m ³ (OEB 5) | Internal |
| | | Wipe limit | 1 µg/100 cm ² | Internal |

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 vapour type
 Hand protection

Material : Chemical-resistant gloves

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| 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

| | | |
|---|---|-------------------|
| Appearance | : | Aqueous solution |
| Colour | : | colourless |
| Odour | : | slight |
| Odour 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 | : | No data available |

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flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour 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

Auto-ignition 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

10. STABILITY AND REACTIVITY

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|------------------------------------|---|
| Reactivity | : Not classified as a reactivity hazard. |
| Chemical stability | : Stable under normal conditions. |
| Possibility of hazardous reactions | : Flammable liquid and vapour. 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 |
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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

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

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

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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.

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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 (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- : log Pow: -0.35

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octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

- Waste from residues : Do not dispose of waste into sewer.
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
Environmentally hazardous : no

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
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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****Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.**

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Ethanol
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 05.12.2023

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / STEL : Short-term exposure limit
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

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AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; IECSC - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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.

SG / EN