

Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Levothyroxine Formulation

Other means of identification : Leventa (A010426)

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 3

Reproductive toxicity : Category 2

Specific target organ toxicity

- repeated exposure

Category 1 (Thyroid, Cardio-vascular system, Central nervous

system)

GHS label elements

Hazard pictograms





Signal Word : Danger

Hazard Statements : H226 Flammable liquid and vapor.

H361 Suspected of damaging fertility or the unborn child. H372 Causes damage to organs (Thyroid, Cardio-vascular system, Central nervous system) through prolonged or repeated

exposure.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P210 Keep away from heat, hot surfaces, sparks, open flames

and other ignition sources. No smoking. P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.



Levothyroxine Formulation

Version Revision Date: SDS Number: Date of last issue: 05.12.2023 4.11 28.09.2024 1130661-00018 Date of first issue: 30.11.2016

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately

all contaminated clothing. Rinse skin with water.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

Vapors may form explosive mixture with air.

SECTION 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

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

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. 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

Protection of first-aiders

In case of eye contact

Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated

exposure.

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).



Levothyroxine Formulation

 Version
 Revision Date:
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 4.11
 28.09.2024
 1130661-00018
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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 fire

fighting

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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency 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



Levothyroxine Formulation

 Version
 Revision Date:
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 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

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 equip-

ment.

Advice on safe handling : Do not breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Non-sparking tools should be used. Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Keep away from heat and sources of ignition.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides



Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

Flammable solids Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Substances and mixtures which in contact with water emit

flammable gases

Explosives Gases

Very acutely toxic substances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	VLE-CT	1,000 ppm	NOM-010- STPS-2014
		STEL	1,000 ppm	ACGIH
levothyroxine sodium	55-03-8	TWA	0.1 μg/m3 (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.

Combined particulates and organic vapor type

Filter type

Material

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,



Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Color : colorless

Odor : slight

Odor Threshold : No data available

pH : 9.7 - 10.7

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : 44 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.05 g/cm³

Solubility(ies)

Water solubility : soluble

Partition coefficient: n- : Not applicable



Levothyroxine Formulation

SDS Number: Date of last issue: 05.12.2023 Version Revision Date: 4.11 28.09.2024 1130661-00018 Date of first issue: 30.11.2016

octanol/water

Autoignition temperature No data available

Decomposition temperature No data available

Viscosity

No data available Viscosity, kinematic

Explosive properties Not explosive

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

Particle characteristics

Particle size Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Flammable liquid and vapor.

Possibility of hazardous reac-

tions

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 toxicity estimate: > 5,000 mg/kg Acute oral toxicity

Method: Calculation method

Components:

Ethanol:

Acute oral toxicity LD50 (Rat): 10,470 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity LC50 (Rat, male): 116.9 mg/l

Exposure time: 4 h



Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

Test atmosphere: vapor

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

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 : Mouse ear swelling test (MEST)

Routes of exposure : Skin contact
Species : Mouse
Result : negative



Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

Germ cell mutagenicity

Not classified based on available information.

Components:

Ethanol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: Ingestion

Result: negative

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.



Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

Test Type: Development Species: Guinea pig

Result: No teratogenic effects.

Reproductive toxicity - As-

sessment

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 : 1,730 mg/kg LOAEL : 3,200 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:



Levothyroxine Formulation

Version Revision Date: SDS Number: Date of last issue: 05.12.2023 4.11 28.09.2024 1130661-00018 Date of first issue: 30.11.2016

LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l Toxicity to fish

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 5,012 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 fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l

Exposure time: 100 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 9.6 mg/l

Exposure time: 9 d

Toxicity to microorganisms EC50 (Protozoa): 5,800 mg/l

Exposure time: 4 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 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



Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

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
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 : 366

aircraft)

Packing instruction (passen- : 355

ger aircraft)

IMDG-Code

UN number : UN 1170

Proper shipping name : ETHANOL SOLUTION

Class : 3
Packing group : III
Labels : 3
EmS Code : F-E, S-D

Marine pollutant : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

UN number : UN 1170

Proper shipping name : ETHANOL SOLUTION

Class : 3
Packing group : III
Labels : 3

Special precautions for user

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



Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for

producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA, ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

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

CT

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 Substanc-



Levothyroxine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 4.11
 28.09.2024
 1130661-00018
 Date of first issue: 30.11.2016

es; (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

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

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

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

MX / Z8