

# **Levothyroxine Formulation**

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

 3.12
 28.09.2024
 1130720-00019
 Date of first issue: 30.11.2016

#### **SECTION 1. IDENTIFICATION**

Product name : Levothyroxine Formulation

Other means of identification : Leventa (A010426)

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

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 repeat-

ed exposure.

Precautionary Statements : Prevention:



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P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

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

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

P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

ly 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

disposal plant.

#### Other hazards which do not result in classification

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

<sup>#</sup> 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

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.



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Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and Suspected of damaging fertility or the unborn child.

exposure.

delayed

Notes to physician

Causes damage to organs through prolonged or repeated

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).

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

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-

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

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, protec- : tive 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.



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Methods and materials for containment and cleaning up

Non-sparking tools should be used. Soak up with inert absorbent material.

Suppress (knock down) gases/vapors/mists with a water spray

jet.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Use explosion-proof electrical, ventilating and lighting 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.

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 Flammable solids Pyrophoric liquids



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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	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Ethanol	64-17-5	CMP	1.000 ppm	AR OEL	
	Further information: A4 - Not classifiable as a human carcinogen				
		STEL	1.000 ppm	ACGIH	
levothyroxine sodium	55-03-8	TWA	0.1 µg/m3 (OEB	Internal	
			5)		
		Wipe limit	1 μg/100 cm <sup>2</sup>	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 vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is

flammable, which may impact the selection of hand

protection.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a



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potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

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

use of administrative controls.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

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



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Relative density : No data available

Density : 1,05 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition 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 characteristics

Particle size : Not applicable

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Flammable liquid and vapor.
Vapors may form explosive mixture with air.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Acids

Hazardous decomposition

products

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

## **Components:**

**Ethanol:** 



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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
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.



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#### Components:

**Ethanol:** 

Test Type : Mouse ear swelling test (MEST)

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

## Germ cell mutagenicity

Not classified based on available information.

## **Components:**

**Ethanol:** 

Genotoxicity in vitro : Test Type: 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



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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 - 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



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#### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

#### **Components:**

**Ethanol:** 

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14.200 mg/l

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



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#### **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

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 Ш Labels 3 Environmentally hazardous nο

**IATA-DGR** 

UN/ID No. **UN 1170** 

Proper shipping name Ethanol solution

Class 3 Packing group Ш

Labels Flammable Liquids

366

Packing instruction (cargo

aircraft)

Packing instruction (passen-355

ger aircraft)

**IMDG-Code** 

**UN** number UN 1170

Proper shipping name **ETHANOL SOLUTION** 

Class Packing group Ш Labels 3 **EmS Code** F-E, S-D Marine pollutant

#### 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.



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#### **SECTION 15. REGULATORY INFORMATION**

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

Argentina. Carcinogenic Substances and Agents

Not applicable

Ethanol

Registry.

Control of precursors and essential chemicals for the

preparation of drugs.

Sodium hydrogencarbonate

#### 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

**Further information** 

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet

cy, http://echa.europa.eu/

#### Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV) AR OEL Argentina. Occupational Exposure Limits

ACGIH / STEL Short-term exposure limit AR OEL / CMP TLV (Threshold Limit Value)

AllC - 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



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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.

AR / Z8