

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version 3.11 Revision Date: 05.12.2023 SDS Number: 1130735-00018 Date of last issue: 30.09.2023
Date of first issue: 30.11.2016

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

1.1 Product identifier

Trade name : Levothyroxine Formulation

Other means of identification : Leventa (A010426)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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	H226: Flammable liquid and vapour.
Reproductive toxicity, Category 2	H361: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version 3.11 Revision Date: 05.12.2023 SDS Number: 1130735-00018 Date of last issue: 30.09.2023
Date of first issue: 30.11.2016

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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319 _____ specific concentration limit	>= 10 - < 20

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version 3.11 Revision Date: 05.12.2023 SDS Number: 1130735-00018 Date of last issue: 30.09.2023
Date of first issue: 30.11.2016

		Eye Irrit. 2; H319 ≥ 50 %	
levothyroxine sodium	55-03-8 200-221-4	Acute Tox. 2; H300 Repr. 2; H361 STOT RE 1; H372 (Thyroid, Cardio-vascular system, Central nervous system) <hr/> specific concentra- tion limit Repr. 2; H361 > 0,01 % STOT RE 1; H372 > 0,01 %	≥ 0,1 - < 1

For explanation of abbreviations see section 16.
#: Voluntarily-disclosed substance

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 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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

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 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

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 (see section 7) and personal protective equipment recommendations (see section 8).

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

6.2 Environmental precautions

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.

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.
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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version 3.11 Revision Date: 05.12.2023 SDS Number: 1130735-00018 Date of last issue: 30.09.2023
Date of first issue: 30.11.2016

Hygiene measures : Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
: 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
Self-reactive substances and mixtures
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
Very acutely toxic substances and mixtures

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TWA	500 ppm 950 mg/m ³	FOR-2011-12-06-1358
levothyroxine sodium	55-03-8	TWA	0.1 µg/m ³ (OEB 5)	Internal
		Wipe limit	1 µg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version 3.11 Revision Date: 05.12.2023 SDS Number: 1130735-00018 Date of last issue: 30.09.2023
Date of first issue: 30.11.2016

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanol	Workers	Inhalation	Long-term systemic effects	950 mg/m ³
	Workers	Skin contact	Long-term systemic effects	343 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	206 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	87 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Ethanol	Fresh water	0,96 mg/l
	Freshwater - intermittent	2,75 mg/l
	Marine water	0,79 mg/l
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3,6 mg/kg dry weight (d.w.)
	Marine sediment	2,9 mg/kg dry weight (d.w.)
	Soil	0,63 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food

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.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Eye/face 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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

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. Equipment should conform to NS EN 14387
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

Physical state	:	Aqueous solution
Colour	:	colourless
Odour	:	slight
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	44 °C
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	9,7 - 10,7
Viscosity Viscosity, kinematic	:	No data available
Solubility(ies)	:	

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : 1,05 g/cm³

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version 3.11 Revision Date: 05.12.2023 SDS Number: 1130735-00018 Date of last issue: 30.09.2023
Date of first issue: 30.11.2016

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

Species: Mouse
Application Route: Ingestion
Result: negative

levothyroxine sodium:

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0,25 mg/kg body weight

Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 3 mg/kg body weight

Test Type: Development
Species: Rabbit
Result: No teratogenic effects

Test Type: Development
Species: Guinea pig
Result: No teratogenic effects

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs 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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

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)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

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- : log Pow: -0,35
octanol/water

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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.
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

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

14.1 UN number or ID number

ADN	:	UN 1170
ADR	:	UN 1170
RID	:	UN 1170
IMDG	:	UN 1170
IATA	:	UN 1170

14.2 UN proper shipping name

ADN	:	ETHANOL SOLUTION
ADR	:	ETHANOL SOLUTION
RID	:	ETHANOL SOLUTION
IMDG	:	ETHANOL SOLUTION
IATA	:	Ethanol solution

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 3	
ADR	: 3	
RID	: 3	
IMDG	: 3	
IATA	: 3	

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: F1
Hazard Identification Number	: 30
Labels	: 3
ADR	
Packing group	: III
Classification Code	: F1
Hazard Identification Number	: 30
Labels	: 3
Tunnel restriction code	: (D/E)
RID	

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

IMDG

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

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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

Substance(s) or mixture(s) are listed

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version 3.11 Revision Date: 05.12.2023 SDS Number: 1130735-00018 Date of last issue: 30.09.2023
Date of first issue: 30.11.2016

here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

P5c	FLAMMABLE LIQUIDS	Quantity 1 5.000 t	Quantity 2 50.000 t
-----	-------------------	-----------------------	------------------------

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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 lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H300 : Fatal if swallowed.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

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
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / : Long term exposure limit
TWA

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; 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; 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; 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; 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

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/>

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.11	05.12.2023	1130735-00018	Date of first issue: 30.11.2016

Classification of the mixture:

Flam. Liq. 3	H226
Repr. 2	H361
STOT RE 1	H372

Classification procedure:

Based on product data or assessment
Calculation method
Calculation method

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.

NO / EN