

Levothyroxine Formulation

Versior 5.0	Revision Date: 28.09.2024		S Number: 30649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016		
SECTIO	SECTION 1. IDENTIFICATION					
Pr	Product identifier		Levothyroxine Formulation			
Ot	ner means of identification	:	Leventa (A01042	26)		
Ма	nufacturer or supplier's	deta	ils			
Co	mpany	:	MSD			
Ad	dress	:	Rua Coronel Ber Cruzeiro - Sao P	nto Soares, 530 Paulo - Brazil CEP 12730-340		
Те	lephone	:	908-740-4000			
En	nergency telephone	:	1-908-423-6000			
E-	mail address	:	EHSDATASTEW	/ARD@msd.com		
Re	commended use of the c	hem	ical and restriction	ons on use		
	commended use strictions on use	:	Veterinary produ Not applicable	ict		

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accord Flammable liquids	lan :	ce with ABNT NBR 14725 Standard Category 3
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure	:	Category 1 (Thyroid, Cardio-vascular system, Central nervous system)
GHS label elements in accore	dar	nce with ABNT NBR 14725 Standard
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: P201 Obtain special instructions before use.



Version 5.0	Revision Date: 28.09.2024	SDS Number: 1130649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016
		and other ignit P233 Keep co P264 Wash sk P270 Do not e	ray from heat, hot surfaces, sparks, open flames ion sources. No smoking. Intainer tightly closed. in thoroughly after handling. at, drink or smoke when using this product. Detective gloves/ protective clothing/ eye protec- ection.
		ly all contamin	- P353 IF ON SKIN (or hair): Take off immediate- ated clothing. Rinse skin with water. F exposed or concerned: Get medical advice/
		Storage: P405 Store loc	sked up.
Othe	r hazards which do r	not result in classifica	tion

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Ethanol#	64-17-5	Flam. Liq., 2 Eye Irrit., 2A	>= 10 -< 20
levothyroxine sodium	55-03-8	Acute Tox. (Oral), 2 Repr., 2 STOT RE, (Thyroid, Cardio-vascular sys- tem, Central nervous system), 1	>= 0,1 -< 1

Voluntarily-disclosed substance

SECTION 4. FIRST AID MEASURES

:	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, remove to fresh air.
	Get medical attention.
:	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.
:	Flush eyes with water as a precaution.
	Get medical attention if irritation develops and persists.
	:



Vers 5.0	ion	Revision Date: 28.09.2024		0S Number: 30649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016
	and effe delayed Protect	nportant symptoms ects, both acute and	:	Get medical atten Rinse mouth thor Suspected of dam Causes damage t exposure. First Aid responde and use the recor when the potentia	NOT induce vomiting. tion. bughly with water. haging fertility or the unborn child. to organs through prolonged or repeated ers should pay attention to self-protection, nmended personal protective equipment al for exposure exists (see section 8). cally and supportively.
SEC	TION 5	. FIRE-FIGHTING ME	ASL	IRES	
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
	Unsuita media	ble extinguishing	:	High volume wate	er jet
	Specific fighting	c hazards during fire	:	fire. Flash back possik Vapors may form	d water stream as it may scatter and spread ble over considerable distance. explosive mixtures with air. bustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	Carbon oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special for fire-	protective equipment fighters	:		e, wear self-contained breathing apparatus. tective 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.



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05.12.2023
5.0	28.09.2024	1130649-00019	Date of first issue: 30.11.2016
	ods and materials for inment and cleaning up	Soak up with ine Suppress (knock jet. For large spills, j containment to k can be pumped, container. Clean up remain absorbent. Local or national disposal of this r employed in the determine which Sections 13 and	ols should be used. ert absorbent material. (down) gases/vapors/mists with a water spray provide diking or other appropriate seep material from spreading. If diked material store recovered material in appropriate ning materials from spill with suitable I regulations may apply to releases and material, as well as those materials and items cleanup of releases. You will need to regulations are applicable. 15 of this SDS provide information regarding 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
Hygiene measures	:	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.
Conditions for safe storage	:	Keep in properly labeled containers.



Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 05.12.2023
5.0		1130649-00019	Date of first issue: 30.11.2016
Materi	als to avoid	Store in accorda Keep away from Do not store with Strong oxidizing Self-reactive sub Organic peroxide Flammable solid Pyrophoric liquic Pyrophoric solid Self-heating sub Substances and flammable gases Explosives Gases	ed. vell-ventilated place. nce with the particular national regulations. heat and sources of ignition. the following product types: agents ostances and mixtures es s s s stances and mixtures mixtures which in contact with water emit

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Ethanol	64-17-5	LT	780 ppm 1.480 mg/m ³	BR OEL
	Further infor	mation: Degree c	of harmfulness: minim	um
		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	

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.



Version 5.0	Revision Date: 28.09.2024		DS Number: 30649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016
	er type protection	:	Combined particu	lates and organic vapor type
Ма	terial	:	Chemical-resista	nt gloves
Re	marks	:		gloving. Take note that the product is may impact the selection of hand
Eye pı	rotection	:	Wear safety glass If the work enviro mists or aerosols Wear a faceshield	ses with side shields or goggles. nment or activity involves dusty conditions, , wear the appropriate goggles. d or other full face protection if there is a et contact to the face with dusts, mists, or
Skin a	nd body protection	:	Work uniform or I Additional body g task being perform disposable suits)	arments should be used based upon the med (e.g., sleevelets, apron, gauntlets, to avoid exposed skin surfaces. degowning techniques to remove potentially

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	Aqueous solution
Color	:	colorless
Odor	:	slight
Odor Threshold	:	No data available
рН	:	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



Levothyroxine Formulation

Versi 5.0	ion	Revision Date: 28.09.2024		S Number: 30649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016
I	Relative	e vapor density	:	No data available	
i	Relative	e density	:	No data available	9
I	Density	,	:	1,05 g/cm ³	
:	Solubili Wat	ty(ies) er solubility	:	soluble	
		n coefficient: n-	:	Not applicable	
	octanol Autoign	ition temperature	:	No data available	2
I	Decom	position temperature	:	No data available	2
,	Viscosi Visc	ty osity, kinematic	:	No data available	
I	Explosi	ve properties	:	Not explosive	
(Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Particle Particle	characteristics size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Flammable liquid and vapor. Vapors may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials	:	Heat, flames and sparks. Oxidizing agents Acids
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	
exposure		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



Vers 5.0	ion	Revision Date: 28.09.2024		9S Number: 30649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016
	<u>Compc</u>	onents:			
	Ethano	ol:			
	Acute c	oral toxicity	:	LD50 (Rat): 10.47 Method: OECD Te	0 0
	Acute ii	nhalation toxicity	:	LC50 (Rat, male): Exposure time: 4 Test atmosphere:	n
	Acute c	lermal toxicity	:	LD50 (Rabbit): > 1	15.800 mg/kg
	levothy	/roxine sodium:			
	Acute c	oral toxicity	:	TDLo (Humans): 7	I0 mg/kg
				TDLo (Dog): 10 m	g/kg
				LD50 (Rat): > 1.00	00 mg/kg
	Acute c	lermal toxicity	:	LD50 (Rat): > 50 r	ng/kg
		oxicity (other routes of stration)	:	LD50 (Rat): 20 mg Application Route	
				LD50 (Rat): 50 mg Application Route	
	1				

Skin corrosion/irritation

Not classified based on available information.

Components:

Ethanol:

Species Method Result	RabbitOECD Test Guideline 404No skin irritation
-----------------------------	---

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ethanol:

Species : Result : Method :	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.



Levothyroxine Formulation

ersion .0	Revision Date: 28.09.2024		9S Number: 30649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016
•	iratory sensitization lassified based on ava	ilable	information.	
Com	ponents:			
Etha	-			
Test Route	Type es of exposure	:	Mouse ear swell Skin contact	ing test (MEST)
Spec Resu	ies	:	Mouse negative	
	n cell mutagenicity lassified based on ava	ilable	information.	
	ponents:			
Ethai	nol:			
Geno	toxicity in vitro	:		erial reverse mutation assay (AMES) Test Guideline 471
				ro mammalian cell gene mutation test Test Guideline 476
			Test Type: Chro Result: negative	mosome aberration test in vitro
Geno	toxicity in vivo	:	Test Type: Mam cytogenetic assa Species: Rat Application Rout	
			Result: negative	
Carci	i nogenicity lassified based on ava	ilable	information.	
-	oductive toxicity ected of damaging fert	tility or	the unborn child.	
Com	ponents:			
Ethai	nol:			
Effec	ts on fertility	:	Test Type: Two- Species: Mouse Application Rout Result: negative	te: Ingestion

levothyroxine sodium:

Н

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



Version 5.0	Revision Date: 28.09.2024		Number: 649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016
Repro	oductive toxicity - As- nent	S A D T S R T S R	est Type: Devel pecies: Rabbit esult: No terato est Type: Devel pecies: Guinea esult: No terato	e: Oral oxicity: NOAEL: 3 mg/kg body weight opment genic effects. opment pig
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:

:	Rat
:	1.730 mg/kg
:	3.200 mg/kg
:	Ingestion
:	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,



Levothyroxine Formulation

ersion .0	Revision Date: 28.09.2024		S Number: 30649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016
II			nervousness, we	eight loss
ECTION	12. ECOLOGICAL INFO	DRN	IATION	
Ecote	oxicity			
Com	ponents:			
Ethai	nol:			
Toxic	ity to fish	:	LC50 (Pimephale Exposure time: 9	es promelas (fathead minnow)): 14.200 mg/l 96 h
	ity to daphnia and other tic invertebrates	:	EC50 (Ceriodap Exposure time: 4	hnia dubia (water flea)): 5.012 mg/l I8 h
Toxic plants	ity to algae/aquatic S	:	ErC50 (Chlorella Exposure time: 7	i vulgaris (Fresh water algae)): 275 mg/l 72 h
			EC10 (Chlorella Exposure time: 7	vulgaris (Fresh water algae)): 11,5 mg/l 72 h
Toxic icity)	ity to fish (Chronic tox-	:	NOEC (Oryzias Exposure time: 1	latipes (Japanese medaka)): >= 79 mg/l 00 d
aquat	tic invertebrates (Chron-	:	NOEC (Daphnia Exposure time: 9	magna (Water flea)): 9,6 mg/l d
ic tox Toxic	ity to microorganisms	:	EC50 (Protozoa) Exposure time: 4	
II Persi	stence and degradabili	ity		
Com	ponents:			
Ethai	nol:			
	egradability	:	Result: Readily b Biodegradation: Exposure time: 2	84 %
Bioa	ccumulative potential			
Com	ponents:			
Ethai	nol:			
	ion coefficient: n- ol/water	:	log Pow: -0,35	
	lity in soil ata available			
	r adverse effects ata available			



Version	Revision Date:	SDS Number:	Date of last issue: 05.12.2023
5.0	28.09.2024	1130649-00019	Date of first issue: 30.11.2016

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		
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 (passen- ger aircraft)	:	355
3 ,		
IMDG-Code UN number		UN 1170
	-	ETHANOL SOLUTION
Proper shipping name	:	3
Packing group	:	5 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

ANTT	
UN number	: UN 1170
Proper shipping name	: ETHANOL SOLUTION
Class Packing group	: 3
Packing group	: 111



Version 5.0	Revision Date: 28.09.2024	SDS Number: 1130649-00019	Date of last issue: 05.12.2023 Date of first issue: 30.11.2016			
Labe	els ard Identification Numbe	: 3 er : 30				
Spe	cial precautions for us	ser				
base She	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.					
SECTION	N 15. REGULATORY IN	FORMATION				
Safe mixt		mental regulations/le	egislation specific for the substance or			
	National List of Carcinogenic Agents for Humans - : Not applicable (LINACH)					
	Brazil. List of chemicals controlled by the Federal : Ethanol Police					
The	ingredients of this pro	oduct are reported in	the following inventories:			
AICS	• •	: not determined	-			
DSL		: not determined				
IECS	SC	: not determined				

SECTION 16. OTHER INFORMATION

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

Further information

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

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 other abbreviations

	USA. ACGIH Threshold Limit Values (TLV) Brazil. NR 15 - Unhealthy activities and operations
	Short-term exposure limit Up to 48 hours /week

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



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05.12.2023
5.0	28.09.2024	1130649-00019	Date of first issue: 30.11.2016

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 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.

BR / Z8