Commission Regulation (EU) 2020/878



Levothyroxine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.14	28.09.2024	1130731-00021	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	e safety data sheet	
Company	: MSD	

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
Reproductive toxicity, Category 2

Specific target organ toxicity - repeated exposure, Category 1

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



born child.

H226: Flammable liquid and vapour.

longed or repeated exposure.

H361: Suspected of damaging fertility or the un-

H372: Causes damage to organs through pro-

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



Levothyroxine Formulation

Version 3.14	Revision Date: 28.09.2024	SDS Nun 1130731-	
Signal word		: Dange	r
Hazard statements		: H226 H361 H372	Flammable liquid and vapour. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.
Precautionary statements		: Preve	ntion:
Frecautionary statements		P201 P210 P233 P264 P280	Obtain special instructions before use. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Wash skin thoroughly after handling. Wear protective gloves/ protective clothing/ eye protection/ face protection.
		Respo P308 -	

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



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

Levothyroxine Formulation

		SDS Number: 1130731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016		
			limit Eye Irrit. 2; H319 >= 50 %		
levoth	iyroxine sodium	55-03-8 200-221-4	Acute Tox. 2; H300 Repr. 2; H361 STOT RE 1; H372 (Thyroid, Cardio- vascular system, Central nervous sys- tem) 	>= 0.1 - < 1	

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

SECTION 4: First aid measures

I.1 Description of first aid measures						
General advice	 In the case of accident or if you feel unwell, seek m vice immediately. When symptoms persist or in all cases of doubt see advice. 					
Protection of first-aiders	: First Aid responders should pay attention to self-pro and use the recommended personal protective equ when the potential for exposure exists (see section	pment				
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 of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 	and plenty				
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persi	sts.				
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.					



Levothyroxine Formulation

Commission Regulation (EU) 2020/878

Version 3.14	Revision Date: 28.09.2024		0S Number: 30731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016		
4.2 Most im	portant symptoms a	nd e	effects, both acute	e and delayed		
Risks :			Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.			
4.3 Indication	on of any immediate	med	lical attention and	d special treatment needed		
Treatm	ent	:	Treat symptomatically and supportively.			
SECTION	5: Firefighting meas	sur	es			
5.1 Extingu	ishing 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 mi	xture		
· · · · · · · ·		:	Do not use a solid water stream as it may scatter and sprea fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to heal			
Hazardous combustion prod- : ucts		:	Carbon oxides			
5.3 Advice	for firefighters					
	protective equipment	:		e, wear self-contained breathing apparatus. tective equipment.		
Specific ods	c extinguishing meth-	:	cumstances and Use water spray Remove undama so.	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do		
SECTION	6: Accidental releas		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 pro-
	tective equipment recommendations (see section 8).

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



Levothyroxine Formulation

Version 3.14	Revision Date: 28.09.2024	SDS Number: 1130731-00021	Date of last issue: 06.04.2024 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 of barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. 			
6.3 Method	Is and material for co	ntainment and clean	ing up		
Methods for cleaning up :		Soak up with ine Suppress (knock spray jet. For large spills, ment to keep ma be pumped, stor Clean up remain bent. Local or nationa posal of this mat employed in the mine which regu Sections 13 and	bls should be used. ert absorbent material. (c down) gases/vapours/mists with a water provide dyking or other appropriate contain- aterial from spreading. If dyked material can e recovered material in appropriate container. ing materials from spill with suitable absor- l regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding 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 equip- ment.
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 as- sessment 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.



Levothyroxine Formulation

Version 3.14	Revision Date: 28.09.2024	SDS Number: 1130731-00021	Date of last issue: 06.04.2024 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 Condit	ions for safe storage,	including any inc	ompatibilities	
Requirements for storage areas and containers		tightly closed. accordance w	erly labelled containers. Store locked up. Keep Keep in a cool, well-ventilated place. Store in ith the particular national regulations. Keep at and sources of ignition.	
Advice	e on common storage	Strong oxidizi Self-reactive s Organic perox Flammable sc Pyrophoric liq Pyrophoric so Self-heating s Substances a flammable ga Explosives Gases	substances and mixtures kides blids uids lids ubstances and mixtures nd mixtures, which in contact with water, emit	

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	OELV - 15 min (STEL)	1,000 ppm	IE OEL
levothyroxine sodi- um	55-03-8	TWA	0.1 μg/m3 (OEB 5)	Internal
		Wipe limit	1 µg/100 cm ²	Internal

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

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



Levothyroxine Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
3.14		1130731-00021	Date of first issue: 30.11.2016

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Ethanol	Workers	Inhalation	Long-term systemic effects	380 mg/m3
	Workers	Skin contact	Long-term systemic effects	267 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m3

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 n	
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3.6 mg/kg dry
	weigh	
	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 flam- mable, which may impact the selection of hand protection.
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, dis- posable suits) to avoid exposed skin surfaces.



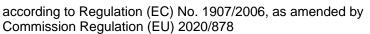
Levothyroxine Formulation

Version 3.14	Revision Date: 28.09.2024	SDS Number: 1130731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016
Resp	iratory protection	contaminate : If adequate I sure assessi ommended g	iate degowning techniques to remove potentially d clothing. ocal exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- guidelines, use respiratory protection. hould conform to I.S. EN 14387
Fi	lter type		articulates 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
рН	:	9.7 - 10.7
Viscosity Viscosity, kinematic	:	No data available
Solubility(ies) Water solubility	:	soluble
Partition coefficient: n-	:	Not applicable





Levothyroxine Formulation

Versior 3.14	n Revision Date: 28.09.2024	SDS Number: 1130731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016		
oc	stanol/water				
Va	apour pressure	: No data available			
Re	elative density	: No data availa	able		
Density		: 1.05 g/cm ³			
Re	elative vapour density	: No data availa	able		
Pa	article characteristics Particle size	: Not applicable			
9.2 Otł	ner information				
E>	cplosives	: Not explosive			
O	xidizing properties	: The substance	e or mixture is not classified as oxidizing.		
E١	aporation rate	: No data availa	able		

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.

SECTION 11: Toxicological information

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

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion



Levothyroxine Formulation

Versio 3.14	on	Revision Date: 28.09.2024		9S Number: 30731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016
				Eye contact	
4	Acute	toxicity			
1	Not cla	ssified based on availa	ble	information.	
F	Produc	<u>st:</u>			
ŀ	Acute o	oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method	
<u>(</u>	Compo	onents:			
E	Ethanc	ol:			
ŀ	Acute c	oral toxicity	:	LD50 (Rat): 10,47 Method: OECD T	
ļ	Acute i	nhalation toxicity	:	LC50 (Rat, male) Exposure time: 4 Test atmosphere:	h
ŀ	Acute o	dermal toxicity	:	LD50 (Rabbit): >	15,800 mg/kg
ŀ	evoth	roxine sodium:			
	-	oral toxicity	:	TDLo (Humans):	10 mg/kg
				TDLo (Dog): 10 m	ng/kg
				LD50 (Rat): > 1,0	00 mg/kg
ŀ	Acute o	lermal toxicity	:	LD50 (Rat): > 50	mg/kg
		oxicity (other routes of stration)	:	LD50 (Rat): 20 m Application Route	
				LD50 (Rat): 50 m Application Route	

Skin corrosion/irritation

Not classified based on available information.

Components:

Ethanol:

Species Method	-	Rabbit OECD Test Guideline 404
		No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ethanol:

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



Levothyroxine Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
3.14		1130731-00021	Date of first issue: 30.11.2016
Specie Metho Result	d	: Rabbit : OECD Test Gui : Irritation to eyes	deline 405 s, 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:

:	Mouse ear swelling test (MEST)
:	Skin contact
:	Mouse
:	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:

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



Levothyroxine Formulation

Versior 3.14	-	vision Date: .09.2024	-	S Number: 30731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016
Ef	ffects on f	ertility	:	Test Type: Two-ge Species: Mouse Application Route: Result: negative	eneration reproduction toxicity study
le	vothyrox	ine sodium:			
Effects on foetal develop- ment : Test Type: Develor Species: Rat Application Route Developmental To Test Type: Develor Species: Mouse Application Route Developmental To Test Type: Develor Species: Rabbit Result: No teratoo Test Type: Develor Species: Rabbit Result: No teratoo		Oral xicity: LOAEL: 0.25 mg/kg body weight pment Oral xicity: NOAEL: 3 mg/kg body weight pment enic effects pment ig			
	eproducti [,] essment	ve toxicity - As-	:	Result: No teratog Suspected of dam	enic effects aging the unborn child.
S	TOT - sin	gle exposure ed based on availa	ble	nformation.	
S	TOT - rep	eated exposure			
Ca	auses dai	mage to organs three	oug	h prolonged or repe	eated exposure.
<u>C</u>	omponer	<u>nts:</u>			
Та	e vothyrox arget Orga ssessmer		:		ascular system, Central nervous system o organs through prolonged or repeated
Re	epeated	dose toxicity			
<u>C</u>	omponer	<u>nts:</u>			
Et	thanol:				
N L Ap	pecies OAEL OAEL pplication xposure ti			Rat 1,730 mg/kg 3,200 mg/kg Ingestion 90 Days	

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: 06.04.2024
3.14	28.09.2024	1130731-00021	Date of first issue: 30.11.2016

Aspiration toxicity

Not classified based on available information.

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)): 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 microorganisms	:	EC50 (Protozoa): 5,800 mg/l Exposure time: 4 h
Toxicity to fish (Chronic tox- icity)	:	NOEC: >= 79 mg/l Exposure time: 100 d Species: Oryzias latipes (Japanese medaka)
Toxicity to daphnia and other	:	NOEC: 9.6 mg/l



Levothyroxine Formulation

Version 3.14	Revision Date: 28.09.2024	SDS Number: 1130731-0002				
aquat ic tox	tic invertebrates (Chron- icity)		Exposure time: 9 d Species: Daphnia magna (Water flea)			
12.2 Pers	istence and degradabil	ity				
Com	ponents:					
Etha i Biode	nol: egradability		adily biodegradable. ation: 84 % time: 20 d			
12.3 Bioa	ccumulative potential					
Com	ponents:					
	nol: ion coefficient: n- ıol/water	: log Pow: -	0.35			
	i lity in soil ata available					
12.5 Resu	llts of PBT and vPvB as	ssessment				
<u>Prod</u> Asse	<u>uct:</u> ssment	to be eithe	ance/mixture contains no components considered or persistent, bioaccumulative and toxic (PBT), or stent and very bioaccumulative (vPvB) at levels of gher.			
12.6 Endo	ocrine disrupting prope	erties				
<u>Prod</u>	uct:					
Asse	ssment	ered to ha REACH A (EU) 2017	ance/mixture does not contain components consid- ve endocrine disrupting properties according to rticle 57(f) or Commission Delegated regulation /2100 or Commission Regulation (EU) 2018/605 at .1% or higher.			
	r adverse effects ata available					
SECTION	N 13: Disposal consid	lerations				
12 4 14/	a traatmant mathada					
Produ	te treatment methods uct	According are not pre	f in accordance with local regulations. to the European Waste Catalogue, Waste Codes oduct specific, but application specific.			

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.



Levothyroxine Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
3.14		1130731-00021	Date of first issue: 30.11.2016
Conta	aminated packaging	: Empty contained dling site for re Empty contained Do not pressur pose such cont of ignition. The	e of waste into sewer. ers should be taken to an approved waste han- cycling or disposal. ers retain residue and can be dangerous. ize, cut, weld, braze, solder, drill, grind, or ex- tainers to heat, flame, sparks, or other sources y may explode and cause injury and/or death. e 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
ΙΑΤΑ	:	UN 1170

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

Packing group Classification Code

Labels

Hazard Identification Number :

		Class	Subsidiary risks
ADN	:	3	
ADR	:	3	
RID	:	3	
IMDG	:	3	
ΙΑΤΑ	:	3	
14.4 Packing group			
ADN Packing group Classification Code Hazard Identification Number Labels	•	III F1 30 3	
ADR			

: III : F1

: 3

30

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



Levothyroxine Formulation

Versio 3.14	on	Revision Date: 28.09.2024	-	OS Number: 30731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016
Г	Tunnel	restriction code	:	(D/E)	
F C F	Classif	g group ication Code I Identification Number	:	III F1 30 3	
F	IMDG Packing Labels EmS C	g group ode	:	III 3 F-E, S-D	
F a F F	Packin aircraft Packin	Cargo) g instruction (cargo) g instruction (LQ) g group	: : :	366 Y344 III Flammable Liquid	ls
F G F F	Packin ger airc Packin	Passenger) g instruction (passen- craft) g instruction (LQ) g group	::	355 Y344 III Flammable Liquid	ls
14.5 I	Enviro	onmental hazards			
	ADN Enviror	nmentally hazardous	:	no	
	ADR Enviror	nmentally hazardous	:	no	
	RID Enviror	nmentally hazardous	:	no	
-	IMDG Marine	pollutant	:	no	
14.6 \$	Specia	al precautions for use	er		
t S	based Sheet.	upon the properties of	the catio	unpackaged mater	r informational purposes only, and solely ial as it is described within this Safety Data ode of transportation, package sizes, and var-

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, Conditions of restriction for the following entries should be considered:

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



Levothyroxine Formulation

Version 3.14	Revision Date: 28.09.2024	SDS Number: 1130731-00021		f last issue: 06.04.2 f first issue: 30.11.2	
mixtures and articles (Annex XVII)				Number on list 3	
				here according to in the regulation, use/purpose or the restriction. Please tions in correspondetermine wheth	mixture(s) are listed o their appearance irrespective of their ne conditions of the e refer to the condi- nding Regulation to er an entry is appli- ing on the market or
	CH - Candidate List of S cern for Authorisation (A		h :	Not applicable	
	ulation (EC) on substand		one :	Not applicable	
Regu	ulation (EU) 2019/1021 (recast)	on persistent organic po	ollu- :	Not applicable	
Regu ment	ulation (EU) No 649/201 and the Council conce ingerous chemicals			Not applicable	
REA	CH - List of substances ex XIV)	subject to authorisatior	n :	Not applicable	
Seve	eso III: Directive 2012/18 r-accident hazards invo			t and of the Counc	

		Quantity 1	Quantity 2
P5c	FLAMMABLE LIQUIDS	5,000 t	50,000 t

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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.

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



Levothyroxine Formulation

Version 3.14	Revision Date: 28.09.2024		DS Number: 30731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016	
	xt of H-Statements				
H225		:		liquid and vapour.	
H300		:	Fatal if swallowed		
H319		:	Causes serious e	ye irritation.	
H361		:	Suspected of dam	naging fertility or the unborn child.	
H372		:	Causes damage to organs through prolonged or repeated exposure.		
Full te	xt of other abbreviati	ons			
Acute	Tox.	:	Acute toxicity		
Eye Irr	it.	:	Eye irritation		
Flam. I	Liq.	:	Flammable liquids		
Repr.	•	:	Reproductive toxicity		
STOT	RE	:	Specific target organ toxicity - repeated exposure		
IE OEL	-	:	Ireland. List of Ch	emical Agents and Carcinogens with Occu- E Limit Values - Code of Practice, Schedule 1	
IE OEL (STEL)	_ / OELV - 15 min)	:	Occupational exp od)	osure limit value (15-minute reference peri-	

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative



Levothyroxine Formulation

Version 3.14	Revision Date: 28.09.2024	SDS Number: 1130731-00021	Date of last issue: 06.04.2024 Date of first issue: 30.11.2016
Furth	er information		
	ces of key data used to ile the Safety Data t		cal data, data from raw material SDSs, OECD search results and European Chemicals Agen- europa.eu/
Class	sification of the mixtu	re:	Classification procedure:
Flam.	Liq. 3	H226	Based on product data or assessment
Repr.	2	H361	Calculation method
STOT	RE 1	H372	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.

IE / EN