



SECTION 1: IDENTIFICATION

1.1 Product identifier

Product name:	Forthyron® flavoured tablets (containing 200µg, 400µg, 600µg or 800µg levothyroxine sodium)
Synonyms:	THYFORON, or CANITROID
Proper Shipping name:	Not Available
Other means of identification:	None

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

Recommended uses:	For the treatment of hypothyroidism in dogs.
Uses advised against:	Not for human use. Do not use in dogs suffering from uncorrected adrenal insufficiency. Do not use in cases of known hypersensitivity to levothyroxine sodium. Pregnant women should handle the product with caution. This product contains a high concentration of L-thyroxine sodium and may present a risk to humans, in particular children, if ingested.

1.3 Details of the supplier of the substance or mixture

Registered company name:	Eurovet Animal Health BV
Address:	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel The Netherlands
Telephone:	+31 (0) 497 544 300
Fax:	+31 (0) 497 544 302
Email:	Not available
Website:	www.dechra.com

1.4 Emergency Telephone Numbers

	+31 (0) 497 544 300 Office Hours.8.30-17.00
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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their



amendments. Not classified as Dangerous Goods for transport purposes.	
DSD Classification (EU):	Not Available
DPD Classification (EU)¹:	Not Available
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	H315 - Skin Corrosion/Irritation Category 2, H319 - Eye Irritation Category 2, H335 - Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), H413 - Chronic Aquatic Hazard Category 4
2.2 Label Elements	
Signal Word:	Warning
Hazard Statement(s):	
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H413	May cause long lasting harmful effects to aquatic life
Additional Statement(s):	
EUH208	Contains levothyroxine sodium. May cause an allergic reaction.
Precautionary Statement(s) Prevention:	
P273	Avoid release to the environment
Not applicable	
Precautionary Statement(s) Response:	
Not applicable	
Precautionary Statement(s) Storage:	
P405	Store locked up
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/containers in accordance with local regulations
Not applicable	
2.3 Other Hazard Information	
REACH - Art.57-59: The mixture contains no substances of highly hazardous substances (SVHC) on the date of printing the SDS.	



SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 55-03-8 2. 200-2214 3. Not available 4. Not available	0.13	Levothyroxine Sodium	Acute toxicity (dermal) Category 4, Acute toxicity (Inhalation) Category 4, Skin sensitizer Category 1, Acute aquatic hazard Category 1, Chronic aquatic hazard Category 1; H312, H332, H317, H410, EUH066 ¹
1. 2. 3. 4.	Proprietary	Other ingredients	Not Applicable

Legend: 1. Classified by Chemwatch; 2. Classification drawn from EC Directive 67/548/EEC - Annex I

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, remove the patient from the contaminated area. Other measures are usually unnecessary.
Ingestion:	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, immediately give a glass of water. Seek medical advice and show the package leaflet or the label to the medical practitioner.



	This product contains a high concentration of L-thyroxine sodium and may present a risk to humans, in particular children, if ingested.
4.2 Most important symptoms and effects, both acute and delayed	
See Section 11	
4.3 Indication of immediate medical attention and special treatment needed	
Not applicable	
SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Select extinguishing media suitable for surrounding area.
Unsuitable:	There is no restriction on the type of extinguisher which may be used.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert the Fire Brigade and tell them the location and nature of the hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses.
Fire / explosion hazard:	Not flammable. Not considered a significant fire risk, however containers may burn. May emit poisonous fumes- Carbon monoxide(CO), Carbon dioxide (CO ₂), Phosphorus oxides (PO _x)
SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8	
6.2 Environmental Precautions	
See section 8	
6.3 Methods and material for containment and cleaning up	
Spills are unlikely due to the nature of the product and how it is packaged	
Minor Spills:	Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment.



Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them the location and nature of the hazard. Control personal contact with the substance, by using protective equipment. Prevent, by any means available, spillage from entering drains or water course.
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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	Do not eat, drink or smoke when using the product. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children.

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	10 Tablets per blister, 5 or 25 blisters per carton Do not store above 25°C.
Storage incompatibility:	Not Applicable

7.3 Specific end uses

Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

DERIVED NO EFFECT LEVEL - DNEL

Not Available

PREDICTED NO EFFECT LEVEL - PNEC

Not Available


OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA:

Source	Ingredient	Material Name	TWA	STEL	Peak	Notes
Not Applicable						

EMERGENCY LIMITS:

Ingredient	Material	TEEL-1	TEEL-2	TEEL-3
Not Applicable				

	Name			
Not Applicable				
Ingredient		Original IDLH		Revised IDLH
L-thyroxine, sodium salt		Not Available		Not Available
8.2 Exposure controls				
Appropriate engineering controls:		The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.		
Personal protection:				
Eye and face protection:		Safety glasses with side shields / chemical goggles		
Skin protection:		See hand protection below		
Hands/ feet protection:		No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves		
Body protection:		Wear appropriate clothing		
Other protection:		No special equipment needed when handling small quantities		
Thermal hazards:		Not applicable		
Respiratory protection:		Not applicable		
8.3 Environmental exposure controls				
See Section 12				



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Forthyron: off-white round tablet with brown spots, quadrisect with side scores
 Levothyroxine Sodium: almost white, slightly hygroscopic, crystalline powder
Container: Forthyron is packaged in a blister Aluminium/PVC
Physical state: Solid
Odour: Not available
Odour Threshold: Not available
pH (as supplied):
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Solubility in water and solvents (mg/l): Levothyroxine Sodium: Very slightly soluble in water; slightly soluble in alcohol
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Levothyroxine Sodium: 799
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information
 Not Available

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is considered stable. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	See Section 7.
10.4 Conditions to avoid:	See Section 7.



10.5 Incompatible materials:	See section 7.	
10.6 Hazardous decomposition:	See Section 5.	
SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	Dust may cause irritation. Good hygiene requires that exposure is minimized and appropriate safety measures are taken when handling.	
Ingestion:	This product contains a high concentration of L-thyroxine sodium and may present a risk to humans, in particular children, if ingested.	
Skin contact:	This product may irritate skin upon contact. Good hygiene requires that exposure is minimized.	
Eye contact:	This product may cause eye irritation and damage in some persons.	
Chronic:	Prolonged exposure to the product is not expected to cause chronic effects harmful to health (in accordance with EC standards based on animal models). The adverse effects of levothyroxine are generally associated with excessive dosage and correspond to symptoms of hyperthyroidism.	
Forthyron® flavoured:	Acute toxicity	Irritation
	Not Available	Not Available
Levothyroxine Sodium:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : >10000 mg / kg ¹	Not available
<i>1.* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances</i>		
Skin corrosion/ irritation:		
Not Applicable		
Serious eye damage/ irritation:		
Not Applicable		
Respiratory or skin sensitization:		
Not Applicable		
Germ cell mutagenicity:		
Not Applicable		
Carcinogenicity:		
Not Applicable		



Reproductive toxicity:
Not Applicable
STOT – single exposure:
Not Applicable
STOT–repeated exposure:
Not Applicable
Aspiration hazard:
Not Applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Levothyroxine Sodium	Not Available	Not Available	Not Available	Not Available	Not Available

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Levothyroxine Sodium	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
Levothyroxine Sodium	MEDIUM (LogKOW = 4.1227)

12.4 Mobility in Soil

Ingredient	Mobility
Levothyroxine Sodium	LOW (KOC = 11270)



12.5 Results of PBT and vPvB assessment	
Not Available	
12.6 Other adverse effects	
Not Available	
SECTION 13: DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
Product / packaging disposal:	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p>
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available



SECTION 14: TRANSPORT INFORMATION

Labels required:

Marine pollutant: NO

Hazchem: Not Applicable

Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1 UN Number N/a

14.2 UN Proper Shipping Name N/a

14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a

14.4 Packing group N/a

14.5 Environmental hazards N/a

14.6 Special precautions for user	Special provisions	N/a
	Limited quantity	N/a

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code N/a

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1 UN Number N/a

14.2 UN Proper Shipping Name N/a

14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a

14.4 Packing group N/a

14.5 Environmental hazards N/a

14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a



	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		



14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
14.6 Special precautions for user	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

SECTION 15: REGULATORY INFORMATION

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

LEVOTHYROXINE SODIUM (55-03-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

European Customs Inventory Chemical Substances (ECICS) (English)
 European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Levothyroxine Sodium	55-03-8	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	STOT RE 2	GHS08, Wng	H373



1	Repr. 2, STOT RE 1	GHS08, Dgr	H361, H372
1	Acute Tox. 4, Acute Tox. 3	GHS07, Wng	H302, H312, H332
Harmonization Code 1 = The most prevalent classification.			

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (Levothyroxine Sodium)
Canada - NDSL	N
China - IECSC	N (Levothyroxine Sodium)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N
Korea - KECI	N (Levothyroxine Sodium)
New Zealand - NZIoC	N (Levothyroxine Sodium)
Philippines - PICCS	N (Levothyroxine Sodium)
USA - TSCA	Y
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

Full text Risk and Hazard codes:

H302	Harmful if swallowed
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H332	Harmful by inhalation.
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic organisms, with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life

Ingredients with multiple CAS numbers:

Name	CAS Number
Levothyroxine Sodium	55-03-8, 6106-07-6, 25416-65-3

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices



Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average

PC – STEL: Permissible Concentration-Short Term Exposure Limit

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

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