



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** ELTROXIN TABLETS

**Other means of identification**

**Synonyms**

ELTROXIN TABLETS 50 MCG \* ELTROXIN TABLETS 100 MCG \* DEXNON COMPRIMIDOS \* OROXINE TABLETS \* THEVIER TABLETTE \* LEVOTHYROXINE SODIUM, FORMULATED PRODUCT

**Recommended use of the chemical and restrictions on use**

**Recommended use** Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Restrictions on use** No other uses are advised.

**Details of manufacturer or importer**

**Manufacturer**

GlaxoSmithKline Australia  
1061 Mountain Highway  
Melbourne, Victoria 3155  
Australia  
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS  
(available 24hrs/7days: multi-language response)  
Australia Toll Free +(61) 2 9037 2994  
International Toll Call +(1) 703 527 3887

## 2. Hazard(s) identification

**Classification of the hazardous chemical**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Label elements, including precautionary statements**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

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

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

**Mixture**

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
MICROCRYSTALLINE CELLULOSE	9004-34-6	< 95
AVICEL PH MICROCRYSTALLINE CELLULOSE		
ALPHA-CELLULOSE		
AVICEL PH101		
AVICEL PH102		
AVICEL PH103		
AVICEL PH105		
AVICEL PH112		
AVICEL PH200		
CELLULOSE (8CI9CI)		
CELLULOSE CRYSTALLINE		
CELLULOSE, FOOD GRADE		
CRYSTALLINE CELLULOSE		

Starch	9005-25-8	< 5
ARROWROOT STARCH		
CORN STARCH		
POTATO STARCH		
RICE STARCH		
MAGNESIUM STEARATE	557-04-0	< 1
STEARIC ACID, MAGNESIUM SALT		
MAGNESIUM DISTEARATE		
DIBASIC MAGNESIUM STEARATE		
MAGNESIUM DISTEARATE, PURE		
Talc	14807-96-6	< 1
TALCUM, NON-ASBESTOS FORM		
Talc		
HYDROUS MAGNESIUM SILICATE		
SODIUM LEVOTHYROXINE PENTAHYDRATE	6106-07-6	< = 0.02
L-THYROXINE, SODIUM SALT, PENTAHYDRATE		
L-TYROSINE, O-(4-HYDROXY-3,5-DIIODOPHENYL)-3,5-DIIODO-, SODIUM SALT, PENTAHYDRATE		
O-(4-HYDROXY-3,5-DIIODOPHENYL)-3,5-DIIODO-L-TYROSINE, SODIUM SALT, PENTAHYDRATE		
L-3-(4-(4-HYDROXY-3,5-DIIODOPHENOXY)-3,5-DIIODOPHENYL)-ALANINE, MONOSODIUM SALT, PENTAHYDRATE		
L-THRYOXINE SODIUM SALT		
L-3,3',5,5'-TETRAIODOTHYRONINE, SODIUM SALT		
GR 37743A		
Other components below reportable levels		< 1

#### 4. First-aid measures

##### Description of necessary first aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.
<b>Personal protection for first-aid responders</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
<b>Symptoms caused by exposure</b>	None known. The following adverse effects have been noted with therapeutic use of this material: headache; flushing; fever; sweating; weight loss; restlessness; increased heart rate; menstrual irregularities.
<b>Medical attention and special treatment</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

#### 5. Fire-fighting measures

##### Extinguishing media

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.

**Specific hazards arising from the chemical** During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for fire fighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Hazchem Code</b>	Not available.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

**Methods and materials for containment and cleaning up** Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

## 7. Handling and storage

**Precautions for safe handling** Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities** Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls and personal protection

**Control parameters** Follow standard monitoring procedures.

### Occupational exposure limits

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>	<b>Note</b>
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1	
SODIUM LEVOTHYROXINE PENTAHYDRATE (CAS 6106-07-6)	8 HR TWA	0.2 mcg/m3	
	OHC	5	skin
		5	Reproductive hazard

### Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

<b>Components</b>	<b>Type</b>	<b>Value</b>	<b>Form</b>
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	Inhalable fibers.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	Inhalable dust.
Talc (CAS 14807-96-6)	TWA	2.5 mg/m3	

### Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

<b>Components</b>	<b>Type</b>	<b>Value</b>	<b>Form</b>
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inspirable dust.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	Inspirable dust.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	Inspirable dust.
Talc (CAS 14807-96-6)	TWA	2.5 mg/m3	

**US. ACGIH Threshold Limit Values**

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
Starch (CAS 9005-25-8)	TWA	10 mg/m3	
Talc (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.

**UK. EH40 Workplace Exposure Limits (WELs)**

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	STEL	20 mg/m3	Inhalable dust.
	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.
Starch (CAS 9005-25-8)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable
Talc (CAS 14807-96-6)	TWA	1 mg/m3	Respirable dust.

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Exposure guidelines****Appropriate engineering controls**

General ventilation normally adequate.

**Individual protection measures, for example personal protective equipment (PPE)****Eye/face protection**

If contact is likely, safety glasses with side shields are recommended.

**Skin protection****Hand protection**

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

**Other**

Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection**

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

**9. Physical and chemical properties****Appearance****Physical state**

Solid.

**Form**

Tablet.

**Colour**

Not available.

**Odour**

Not available.

**Odour threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

**Evaporation rate**

Not available.

**Flammability (solid, gas)**

Not available.

## Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on possible routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate the skin. Pharmacological effects may occur following skin absorption.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Symptoms related to exposure</b>	None known. The following adverse effects have been noted with therapeutic use of this material: headache; flushing; fever; sweating; weight loss; restlessness; increased heart rate; menstrual irregularities.

<b>Acute toxicity</b>	Health injuries are not known or expected under normal use. May be harmful if swallowed.
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<b>Components</b>	<b>Species</b>	<b>Test results</b>
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg

Components	Species	Test results
Oral LD50	Rat	> 2000 mg/kg
* Estimates for product may be based on additional component data not shown.		
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use. Prolonged skin contact may cause temporary irritation.	
<b>Irritation Corrosion - Skin: P.I.I. value</b>		
MAGNESIUM STEARATE	0	
<b>Serious eye damage/irritation</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.	
<b>Eye / Kay and Calandra class - Intact</b>		
MAGNESIUM STEARATE	4	
	Recovery Period: 2 days	
<b>Respiratory or skin sensitisation</b>		
<b>Respiratory sensitisation</b>	Not available.	
<b>Skin sensitisation</b>	Health injuries are not known or expected under normal use.	
<b>Germ cell mutagenicity</b>	Health injuries are not known or expected under normal use.	
<b>Carcinogenicity</b>	Health injuries are not known or expected under normal use.	
<b>ACGIH Carcinogens</b>		
MAGNESIUM STEARATE (CAS 557-04-0)	A4 Not classifiable as a human carcinogen.	
Starch (CAS 9005-25-8)	A4 Not classifiable as a human carcinogen.	
Talc (CAS 14807-96-6)	A4 Not classifiable as a human carcinogen.	
<b>Reproductive toxicity</b>	Health injuries are not known or expected under normal use. Contains components which have been classified as: Possible risk of toxicity in developing human offspring.	
<b>Specific target organ toxicity - single exposure</b>	May cause damage to organs by ingestion.	
SODIUM LEVOTHYROXINE PENTAHYDRATE	Clinical use Species: Human Organ: cardiovascular system; central nervous system	
<b>Specific target organ toxicity - repeated exposure</b>	See effects of single exposure.	
<b>Aspiration hazard</b>	Not available.	
<b>Other information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.	

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components	Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Aquatic</b>		
<b>Acute</b>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)
		130 mg/l, 96 hours
SODIUM LEVOTHYROXINE PENTAHYDRATE (CAS 6106-07-6)		
<b>Chronic</b>		
	NOEC	
		0.16 µg/l, 28 days , Rana rugosa
Talc (CAS 14807-96-6)		
<b>Aquatic</b>		
<b>Acute</b>		
Fish	EC50	Zebra fish (Adult Brachydanio rerio)
		> 100 g/l, 24 hours Static renewal test

\* Estimates for product may be based on additional component data not shown.

### Persistence and degradability

#### Photolysis

##### Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

##### UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

#### Biodegradability

##### Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD

##### Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE 95 %, 22 days Sturm test

##### Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

#### Bioaccumulative potential

##### Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

**Mobility in soil** No data available for this product.

#### Adsorption

##### Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

**Mobility in general** Not available.

**Other adverse effects** Not available.

### 13. Disposal considerations

**Disposal methods** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**Residual waste** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### ADG

Not regulated as dangerous goods.

#### RID

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

#### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not available.

### 15. Regulatory information

#### Safety, health and environmental regulations

**National regulations** This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

##### Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

##### Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

##### Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix D**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix E**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix F**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix G**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix H**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix I**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix J**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix K**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 2**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 3**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 4**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 5**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 6**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 7**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 8**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 9**

Poisons schedule number not allocated.

**High Volume Industrial Chemicals (HVIC)**

Talc (CAS 14807-96-6)

100000 - 999999 TONNES See the regulation for additional information.

**Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)**

Not listed.

**National Pollutant Inventory (NPI) substance reporting list**

Not listed.

**Prohibited Carcinogenic Substances**

Not regulated.

**Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)**

Not listed.

**Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)**

Not listed.

**Restricted Carcinogenic Substances**

Not regulated.

**International regulations**

**Stockholm Convention**

Not applicable.

**Rotterdam Convention**

Not applicable.

**Kyoto protocol**

Not applicable.

**Montreal Protocol**

Not applicable.



**Basel Convention**

Not applicable.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information**

<b>Issue date</b>	30-October-2014
<b>Revision date</b>	30-October-2014
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
<b>Revision Information</b>	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Regulatory Information: United States GHS: Classification