



# 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 TABLETTEN \* LEVOTHYROXINE SODIUM, FORMULATED PRODUCT

**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.

**Recommended restrictions** No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: msds@gsk.com  
Website: www.gsk.com  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

**Classified hazards**

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

**Label elements**

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

**Hazard(s) not otherwise classified (HNOC)**

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

## 3. Composition/information on ingredients

**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
MICROCRYSTALLINE CELLULOSE	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	9004-34-6	< 95
STARCH	ARROWROOT STARCH * CORN STARCH * POTATO STARCH * RICE STARCH	9005-25-8	< 5
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	< 1
TALC	TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE	14807-96-6	< 1

Material name: ELTROXIN TABLETS

127747 Version #: 06 Revision date: 10-30-2014 Issue date: 10-30-2014

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Chemical name	Common name and synonyms	CAS number	%
SODIUM LEVOTHYROXINE PENTAHYDRATE	L-THYROXINE, SODIUM SALT, PENTAHYDRATE * L-TYROSINE, O-(4-HYDROXY-3,5-DIIODOPHENYL)-3,5-D IIDO-, SODIUM SALT, PENTAHYDRATE * O-(4-HYDROXY-3,5-DIIODOPHENYL)-3,5-D IIDO-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	6106-07-6	< = 0.02

Other components below reportable levels

< 1

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. 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 center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</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>Indication of immediate medical attention and special treatment needed</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 center.
<b>General information</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.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	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>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</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 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
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**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/personal protection

### Occupational exposure limits

#### GSK

Components	Type	Value	Note
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 5	SKIN REPRODUCTIVE HAZARD

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
STARCH (CAS 9005-25-8)	PEL	15 mg/m3 5 mg/m3 15 mg/m3	Total dust. Respirable fraction. Total dust.

#### US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
TALC (CAS 14807-96-6)	TWA	0.3 mg/m3 0.1 mg/m3 20 mppcf 2.4 mppcf	Total dust. Respirable. Respirable.

#### 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.

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
STARCH (CAS 9005-25-8)	TWA	10 mg/m3 5 mg/m3 10 mg/m3	Total Respirable. Total
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

### Biological limit values

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

### Exposure guidelines

#### Appropriate engineering controls

General ventilation normally adequate.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

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

<b>Skin protection</b>	
<b>Hand protection</b>	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.
<b>Other</b>	Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	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>Vapor pressure</b>	Not available.
<b>Vapor 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 oxidizing 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 likely 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 the physical, chemical and toxicological characteristics</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.
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### Information on toxicological effects

<b>Acute toxicity</b>	Health injuries are not known or expected under normal use. May be harmful if swallowed.
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Components	Species	Test Results
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
<i>Oral</i>		
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.
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#### Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE	0
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<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.
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#### Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days
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### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Not available.
<b>Skin sensitization</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.
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<b>Carcinogenicity</b>	Health injuries are not known or expected under normal use.
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#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

<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.
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#### Reproductivity

SODIUM LEVOTHYROXINE PENTAHYDRATE	Embryo-foetal development Result: Cranial malformations Species: Mouse Embryo-foetal development Result: Hormonal effects Species: Rabbit
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**Reproductivity**

SODIUM LEVOTHYROXINE PENTAHYDRATE

Embryo-foetal development  
Result: Urogenital abnormalities  
Species: Rat**Specific target organ toxicity - single exposure** May cause damage to organs by ingestion.

SODIUM LEVOTHYROXINE PENTAHYDRATE

Clinical use  
Species: Human  
Organ: cardiovascular system; central nervous system**Specific target organ toxicity - repeated exposure** See effects of single exposure.**Aspiration hazard** Not available.**Chronic effects** Prolonged inhalation may be harmful.**Further information** 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>		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i> ) 130 mg/l, 96 hours
SODIUM LEVOTHYROXINE PENTAHYDRATE (CAS 6106-07-6)		
<i>Chronic</i>		
	NOEC	0.16 µg/l, 28 days , <i>Rana rugosa</i>
TALC (CAS 14807-96-6)		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	EC50	Zebra fish (Adult <i>Brachydanio rerio</i> ) > 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-soil)**

MAGNESIUM STEARATE 50 %, 13 days

**Bioaccumulative potential****Bioconcentration factor (BCF)**

MAGNESIUM STEARATE &gt; 9999 Estimated

**Mobility in soil****Adsorption****Soil/sediment sorption - log Koc**

MAGNESIUM STEARATE 5.86 Estimated

**Mobility in general** Not available.**Other adverse effects** Not available.

### 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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.
<b>Contaminated packaging</b>	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

<b>DOT</b>	Not regulated as a dangerous good.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

### 15. Regulatory information

#### US federal regulations

<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>SARA 304 Emergency release notification</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**  
Not regulated.

#### Other federal regulations

<b>Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List</b>	Not regulated.
<b>Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)</b>	Not regulated.
<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.

#### US state regulations

**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**  
Not listed.

**US. Massachusetts RTK - Substance List**

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)  
 STARCH (CAS 9005-25-8)  
 TALC (CAS 14807-96-6)

**US. New Jersey Worker and Community Right-to-Know Act**

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)  
 TALC (CAS 14807-96-6)

**US. Pennsylvania Worker and Community Right-to-Know Law**

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)  
 STARCH (CAS 9005-25-8)  
 TALC (CAS 14807-96-6)

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**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, including date of preparation or last revision**

<b>Issue date</b>	10-30-2014
<b>Revision date</b>	10-30-2014
<b>Version #</b>	06
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 2 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 Flammability: 0 Instability: 0
<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: Business Units Composition / Information on Ingredients: Ingredients Regulatory Information: United States GHS: Classification