



# SAFETY DATA SHEET

according to Regulation (EU) 2015/830

Page 1/11

## ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name	ThyroKare™ (levothyroxine sodium tablets), USP
Product code	09100, 09101, 09102, 09103, 09104, 09105, 09106,
Product code	09107, 09108, 09109, 09110, 09111, 09112, 09113, 09114, 09115, 09125, 09126.
Registration No.	NADA 141-539.

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Description	For animal use only. Permitted for use only by and under the supervision of licensed veterinarians.
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#### 1.3. Details of the supplier of the safety data sheet

Company	Neogen Corporation
Address	620 Lesher Place Lansing MI 48912 USA
Web	www.neogen.com
Telephone	517-372-9200/800-234-5333
Email	SDS@neogen.com

#### 1.4. Emergency telephone number

	24 hours: Medical: 1-800-498-5743 (U.S. and Canada) or 1-651-523-0318 (international) Spill/CHEMTREC: 1-800-424-9300 (U.S. and Canada) or 1-703-527-3887 (international)
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#### Further information

	Manufactured By:. Neogen Corporation 944 Nandino Blvd. Lexington, KY 40511-1205 U.S.A.
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### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Based on available data, this product is not classified as hazardous.
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#### 2.2. Label elements

Hazard Statement	No Significant Hazard
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#### 2.3. Other hazards

Other hazards	Combustible dusts: May form combustible dust concentrations in air. Contains material(s) which may be harmful if swallowed. Dust may be irritating if inhaled.
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## ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01**SECTION 3: Composition/information on ingredients****3.2. Mixtures****EC 1272/2008**

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification
Microcrystalline cellulose (Cellulose)		9004-34-6	232-674-9		60 - 70%	
Levothyroxine sodium, USP		25416-65-3	685-634-1		0.1 - 1%	STOT SE 1: H370; STOT RE 1: H372;

**Description**

Concentrations listed are not product specifications.

**Further information**

Full text of Hazard Statements listed in this Section is provided in Section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures**

<b>Inhalation</b>	Move the exposed person to fresh air. If breathing is difficult give oxygen. If breathing stops, provide artificial respiration. Seek medical attention if irritation or symptoms persist.
<b>Eye contact</b>	Rinse immediately with plenty of water. Contact lenses should be removed. Seek medical attention if irritation or symptoms persist.
<b>Skin contact</b>	Remove contaminated clothing. Wash with soap and water. Seek medical attention if irritation or symptoms persist.
<b>Ingestion</b>	Do not induce vomiting unless told to do so by the poison control center or doctor. Rinse mouth thoroughly. Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

**4.2. Most important symptoms and effects, both acute and delayed**

<b>Inhalation</b>	Dust may be irritating if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Eye contact</b>	May cause irritation to eyes.
<b>Skin contact</b>	May cause irritation to skin.
<b>Ingestion</b>	Ingestion may cause nausea and vomiting.

**4.3. Indication of any immediate medical attention and special treatment needed**

Remove the affected person from the source of contamination immediately. Transfer to hospital if there are burns or symptoms of poisoning. Seek medical attention if irritation or symptoms persist. If medical advice is needed, have product container or label at hand.

**SECTION 5: Firefighting measures****5.1. Extinguishing media**

Use extinguishing media appropriate to the surrounding fire conditions.

**5.2. Special hazards arising from the substance or mixture**

Combustible dusts: May form combustible dust concentrations in air. Avoid formation of dust. Do not allow undiluted product to be released to ground water, water course or sewage system.

**5.3. Advice for firefighters**

Do not breathe dust or vapour. Wear suitable respiratory equipment when necessary.

# ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Avoid formation of dust. Use as appropriate: Protective equipment, Protective clothing. Ensure adequate ventilation of the working area. Avoid prolonged or repeated exposure.

### 6.2. Environmental precautions

Prevent further spillage if safe. Clean spillage area thoroughly with plenty of water. Do not flush into surface water. Do not let product contaminate subsoil.

### 6.3. Methods and material for containment and cleaning up

Avoid formation of dust. Clean spillage area thoroughly with plenty of water. Do not contaminate water by cleaning of equipment or disposal of wastes.

### 6.4. Reference to other sections

See Section(s) 2, 8, and 13 for further information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Adopt best Manual Handling considerations when handling, carrying and dispensing. Avoid contact with eyes. Do not eat, drink or smoke in areas where this product is used or stored. Ensure adequate ventilation of the working area. Do not contaminate water by cleaning of equipment or disposal of wastes. Use as appropriate: Protective clothing.  
Read the entire label and follow all use directions, restrictions, and precautions.

### 7.2. Conditions for safe storage, including any incompatibilities

Store at temperatures between 20 °C and 25 °C.  
Store in original sealed container away from food or feed. Keep container tightly closed. Do not contaminate water, food, or feed by storage or disposal. Follow label instructions.

### 7.3. Specific end use(s)

See Section(s) 1.2 for further information.

### Further information

Refer to product label and/or package insert for additional information.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1. Exposure Limit Values


# ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

## 8.1.1. Exposure Limit Values

Microcrystalline cellulose (Cellulose (pure) respirable)	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m3: 4
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m3: -
	WEL 8-hr limit mg/m3 total inhalable dust: -	WEL 15 min limit mg/m3 total inhalable dust: -
	WEL 8-hr limit mg/m3 total respirable dust: -	WEL 15 min limit mg/m3 total respirable dust: -
Microcrystalline cellulose (Cellulose)	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m3: -
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m3: -
	WEL 8-hr limit mg/m3 total inhalable dust: 10	WEL 15 min limit mg/m3 total inhalable dust: 20
	WEL 8-hr limit mg/m3 total respirable dust: -	WEL 15 min limit mg/m3 total respirable dust: -

## 8.2. Exposure controls

	
8.2.1. Appropriate engineering controls	Not normally required.
8.2.2. Individual protection measures	Use as appropriate: Protective equipment.
Eye / face protection	Not normally required.
Skin protection - Handprotection	Use as appropriate: Chemical resistant gloves. Wash the outside of gloves before removing them.
Skin protection - Other	Use as appropriate: Protective clothing. Wash contaminated clothing, separately from other laundry, with detergent and water before reuse.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.
Occupational exposure controls	Exposure above the recommended occupational exposure limit (OEL) may cause adverse health effects. Protect clothing from contact with the product. Provide chemical shower. Provide eye wash station.

## Further information

	Refer to product label for additional PPE requirements and recommendations. Follow label instructions.
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## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

## ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

## 9.1. Information on basic physical and chemical properties

<b>Appearance</b>	Tablet
<b>Colour</b>	Various
<b>Odour</b>	Odourless/Slight
<b>Flammability (solid, gas)</b>	Combustible dust
<b>Vapour pressure</b>	No data available
<b>Vapour density</b>	No data available
<b>Relative density</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Odour threshold</b>	No data available
<b>pH</b>	No data available
<b>Melting point</b>	No data available
<b>Freezing Point</b>	No data available
<b>Initial boiling point</b>	No data available
<b>Flash point</b>	No data available
<b>Evaporation rate</b>	No data available
<b>Explosive properties</b>	No data available
<b>Oxidising properties</b>	No data available
<b>Viscosity</b>	Not applicable.
<b>Solubility</b>	Soluble in water

## 9.2. Other information

<b>Conductivity</b>	No data available
<b>Benzene Content</b>	No data available
<b>Lead content</b>	No data available
<b>VOC (Volatile organic compounds)</b>	No data available
<b>Surface tension</b>	Not applicable.
<b>Gas group</b>	Not applicable.

## Further information

	Color-coded and potency-embossed tablets: 0.1mg, Yellow. 0.2mg, Pink. 0.3mg, Green. 0.4mg, Light pink. 0.5mg, White. 0.6mg, Dark blue, Violet. 0.7mg, Orange, Pink. 0.8mg, Light blue. 1.0mg, Beige.
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## SECTION 10: Stability and reactivity

## 10.1. Reactivity

	Stable under normal conditions.
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## 10.2. Chemical stability

	Stable under normal conditions.
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## ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

## 10.3. Possibility of hazardous reactions

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

## 10.4. Conditions to avoid

Avoid formation of dust. Avoid sparks, flames, heat and sources of ignition. Protect from moisture.

## 10.5. Incompatible materials

No data available.

## 10.6. Hazardous decomposition products

Carbon oxides.

## SECTION 11: Toxicological information

## 11.1. Information on toxicological effects

Acute toxicity	Based on available data, the classification criteria are not met. However, this product does contain substance(s) that are classified as hazardous. For more information, see Section 3.
Skin corrosion/irritation	May cause irritation to skin.
Serious eye damage/irritation	May cause irritation to eyes.
Respiratory or skin sensitisation	May cause allergic reactions in susceptible people.
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	No components at >0,01% are listed in the American Conference of Governmental Industrial Hygienists (ACGIH) Guide to Occupational Exposure Values. Listed by the International Agency for Research on Cancer (IARC) as a group 3 substance: evidence does not support the substance as a human carcinogen, [Brilliant blue FCF, disodium salt, CAS No. 3844-45-9]. No components at >0,01% are listed in the National Toxicology Program (NTP) Report on Carcinogens. Not listed in the OSHA standard 1910.1003 Carcinogens.
Reproductive toxicity	No teratogenic effects reported.
STOT-single exposure	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
STOT-repeated exposure	Based on available data, the classification criteria are not met. However, this product does contain substance(s) that are classified as hazardous. For more information, see Section 3.
Aspiration hazard	No Significant Hazard.
Repeated or prolonged exposure	Avoid prolonged or repeated exposure. Exposure above the recommended occupational exposure limit (OEL) may cause adverse health effects. Delayed appearance of the complaints and development of hypersensitivity (difficult breathing, coughing, asthma) are possible.

## 11.1.2. Mixtures

See Section(s) 3 for further information.

## 11.1.3. Hazard Information

See Section(s) 2 and 3 for further information.

## 11.1.4. Toxicological Information

No data available

## 11.1.5. Hazard Class

See Section(s) 2 and 14 for further information.

## 11.1.6. Classification Criteria

Based on the Globally Harmonised System (GHS) considerations for the classification of mixtures.

# ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

## 11.1.6. Classification Criteria

See Section 15 for regulatory citations.

## 11.1.7. Information on likely routes of exposure

Ingestion. Inhalation. Skin contact. Eye contact.

## 11.1.8. Symptoms related to the physical, chemical and toxicological characteristics

See Section(s) 4.2 for further information.

## 11.1.9. Delayed and immediate effects as well as chronic effects from short and long-term exposure

See Section(s) 4.2 for further information.

## 11.1.10. Interactive effects

No data available.

## 11.1.11. Absence of specific data

<1% of this mixture consists of ingredients of unknown acute toxicity.

## 11.1.12. Mixture versus substance information

See Section(s) 3 for further information.

## 11.1.13. Other information

Permitted for use only by and under the supervision of licensed veterinarians.

## SECTION 12: Ecological information

### 12.1. Toxicity

No data available

### 12.2. Persistence and degradability

No data is available on this product.

### 12.3. Bioaccumulative potential

No data is available on this product.

### Partition coefficient

ThyroKare™ (levothyroxine sodium tablets), USP No data available

### 12.4. Mobility in soil

No data is available on this product.

### 12.5. Results of PBT and vPvB assessment

No data is available on this product.

### 12.6. Other adverse effects

Specific test data for the substance or mixture is not available.

### Further information

Keep out of lakes, ponds, or streams.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Dispose of in compliance with all local and national regulations. Follow label instructions.

## ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

## Disposal methods

Do not contaminate water by cleaning of equipment or disposal of wastes. Do not flush into surface water. Dispose of in compliance with all local and national regulations.

## Disposal of packaging

Nonrefillable container. Do not reuse or refill this container.  
If empty: Do not reuse this container. Place in trash or offer for recycling, if available.  
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

## Further information

Refer to product label and/or package insert for additional information. Follow label instructions.

## SECTION 14: Transport information

## 14.1. UN number

The product is not classified as dangerous for carriage.

## 14.2. UN proper shipping name

The product is not classified as dangerous for carriage.

## 14.3. Transport hazard class(es)

The product is not classified as dangerous for carriage.

## 14.4. Packing group

The product is not classified as dangerous for carriage.

## 14.5. Environmental hazards

The product is not classified as dangerous for carriage.

## 14.6. Special precautions for user

The product is not classified as dangerous for carriage.

## 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

The product is not classified as dangerous for carriage.

## SECTION 15: Regulatory information

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

<b>Regulations</b>	1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
<b>Chemical Inventories/Right-to-Know Lists:</b>	<p>--International--</p> <p>Basel Convention (Hazardous Waste): Not applicable.</p> <p>Chemical Weapons Convention (OPCW): This product contains no hazardous substances at or above published reporting levels.</p> <p>Kyoto Protocol Greenhouse Gases: This product contains no hazardous substances at or above published reporting levels.</p> <p>Mercosur Agreement: Not applicable.</p> <p>Montreal Protocol: This product contains no hazardous substances at or above published reporting levels.</p> <p>The Rotterdam Convention: This product contains no hazardous substances at or above published reporting levels.</p> <p>The Stockholm Convention: This product contains no hazardous substances at or above published reporting levels.</p> <p>--Asia and the ASEAN Nations--</p>



# ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

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

Catalog of Hazardous Chemicals (China): This product contains no hazardous substances at or above published reporting levels.

Regulation of Minister of Trade of the Republic of Indonesia, Number 75, Year 2014, regarding The Second Amendment of Minister of Trade, Number 44, Year 2009, Regarding Provision, Distribution, and Control of Hazardous Substances: This product contains no hazardous substances at or above published reporting levels.

Air Pollution Control Law (Japan): This product contains no hazardous substances at or above published reporting levels.

Chemical Substances Control Law (Japan): This product contains no hazardous substances at or above published reporting levels.

Industrial Safety and Health Act, Dangerous Substances (Japan): This product contains no hazardous substances at or above published reporting levels.

Poisonous and Deleterious Substances Act (Japan): This product contains no hazardous substances at or above published reporting levels.

Soil Contamination Countermeasures Act (Japan): This product contains no hazardous substances at or above published reporting levels.

Water Pollution Control Law (Japan): This product contains no hazardous substances at or above published reporting levels.

Chemical Substances Subject to Permission (Korea): This product contains no hazardous substances at or above published reporting levels.

Restricted or Prohibited Substances (Korea): This product contains no hazardous substances at or above published reporting levels.

Use and Standards of Exposure of Chemicals Hazardous to Health (USECHH), Regulation 2000 (Malaysia): Schedule I exposure standard, [Cellulose, CAS No. 9004-34-6 (dust)].

Philippine Inventory of Chemicals and Chemical Substances (PICCS): Toxic Substances and Hazardous and Nuclear Wastes Control Act (RA6969):, All ingredients listed or exempt., No restrictions.

Taiwan Toxic and Concerned Chemical Substances Control Act (TCCSCA): This product contains no hazardous substances at or above published reporting levels.

Hazardous Substances Act (Thailand): This product contains no hazardous substances at or above published reporting levels.

Law on Chemicals (Vietnam): This product contains no hazardous substances at or above published reporting levels.

--Australia and New Zealand--.

Australian Dangerous Goods Code: Not applicable.

Australian Inventory of Chemical Substances (AICS): All ingredients listed or exempt., No restrictions.

New Zealand Inventory of Chemicals (NZIoC): All ingredients listed or exempt., No restrictions.

--European Union (EU) and the United Kingdom (UK)--.

Authorisation List (Annex XIV of REACH): This material contains no reportable components.

Annex XVII for REACH: This product contains no hazardous substances at or above published reporting levels, No restrictions.

Article 95 of the Biocidal Products Regulation (BPR): Not applicable.

--North America--.

Domestic/Non-Domestic Substances Lists (DSL/NDSL): All ingredients listed or exempt., No restrictions.

Toxic Substances Control Act (TSCA): All ingredients listed or exempt.

Massachusetts Right-to-Know Hazardous Substance List: This product contains no hazardous substances at or above published reporting levels.

New Jersey Worker and Community Right to Know Act: This product contains no hazardous

# ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

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

	<p>substances at or above published reporting levels.</p> <p>Pennsylvania Right to Know Law: Cellulose, CAS No. 9004-34-6.</p> <p>Rhode Island Right-to-Know General Law: This product contains no hazardous substances at or above published reporting levels.</p> <p>California Proposition 65: This product does not contain reportable substances at &gt;0,0001% concentration.</p>
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### Further information

<b>Additional Regulating Authority:</b>	Approved by the Food and Drug Administration (FDA). The labeling requirements of the Federal Food, Drug, and Cosmetic Act differ from the classification criteria and hazard information required for safety data sheets and for workplace labels under the OSHA Hazard Communication Standard 29 CFR 1910.1200. Following is the hazard information as required on the drug label..
<b>Label Precautions</b>	<p>User Safety Warnings:.</p> <p>Not for human use. Keep out of reach of children. In case of accidental ingestion, seek medical advice immediately and show the product label to the physician. Wash hands after handling the product.</p> <p>Animal Safety Warnings:.</p> <p>Keep away from children, domestic animals, and pets.</p>

## SECTION 16: Other information

### Other information

<b>Acronyms</b>	<p>ADR/RID: European Agreements Concerning the International Carriage of Dangerous Goods by Rail (RID) and by Road (ADR).</p> <p>CAS No.: Chemical Abstracts Service.</p> <p>CLASS: Classification, Labelling, and Safety Data Sheet of Hazardous Chemicals Regulation 2013 (Malaysia).</p> <p>FIFRA: U.S. Federal Insecticide, Fungicide, and Rodenticide Act.</p> <p>GHS: Globally Harmonized System.</p> <p>HCS 2012: U.S. Hazard Communication Standard (2012 revision).</p> <p>IATA: International Air Transport Association.</p> <p>ICAO: International Civil Aviation Organisation.</p> <p>IMDG: International Maritime Dangerous Goods.</p> <p>LD: Lethal dose.</p> <p>OEL: Occupational exposure limit.</p> <p>OSHA: U.S. Occupational Safety and Health Administration.</p> <p>PEL: Permissible Exposure Limit.</p> <p>REACH: Registration, Evaluation, Authorisation, and Restriction of Chemicals.</p> <p>STOT: Specific Target Organ Toxicity.</p> <p>SVHC: Substance of very high concern.</p> <p>US DOT: United States Department of Transportation.</p> <p>VOC: Volatile Organic Compound.</p> <p>WEL: Workplace Exposure Limit.</p>
<b>Text of Hazard Statements in Section 3</b>	<p>STOT SE 1: H370 - Causes damage to organs .</p> <p>STOT RE 1: H372 - Causes damage to organs through prolonged or repeated exposure .</p>

### Further information

	<p>DISCLAIMER: The information and recommendations set forth herein ("Information") are presented in good faith and believed to be correct as of the date issued. No representation is made regarding the completeness or accuracy of the Information. Further, because of the many factors that affect the use of this product, the Information is supplied upon the condition that the person(s) receiving it</p>
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# ThyroKare™ (levothyroxine sodium tablets), USP

Revision 0  
Revision date 2021-03-01

## Further information

will make their own determination regarding its suitability for their own unique purpose(s), prior to use.

Except as expressly stated herein, NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COURSE OF PERFORMANCE, USAGE OF TRADE, OR RESULTS TO BE OBTAINED BY USE OF THIS PRODUCT are made with respect to this product or use of this product. The product covered is furnished "as is" and only subject to the warranties herein provided, no liability is assumed resulting from the use of this product.