

Product Name: Synthroid Tablets
Issued: Feb-25-2016



SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Synthroid Tablets

Synonyms: Synthroid, Tablets; Levothyroxine Sodium Tablets; Sodium Levothyroxine Tablets

Trade name: Synthroid

List Number: 3727; 4341; 4552; 5182; 6594; 6624; 7068; 7069; 7070; 7148; 7149; 9296; 10118; 10119; 10120; 10121; 10122; 10123; 10124; 10125; 10126; 10127; 10129; 10130; 10523; 10524

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

Recommended use: Pharmaceuticals

1.3. Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4. Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Reproductive toxicity Category 2

Classification according to EU Directives 67/548/EEC or 1999/45/EC

2.2. Label elements

Product Name:
Issued:

Synthroid Tablets
Feb-25-2016



Signal Word: Warning

Hazard Statements: H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- P308 + P313 - IF exposed or concerned: Get medical advice/attention
- P405 - Store locked up
- P501 - Dispose of contents/container to an approved waste disposal plant

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

| Chemical Name | Weight-% | EINECS/ELINCS Number | EEC Classification | EU - GHS Substance Classification | REACH Reg. No |
|--|----------|----------------------|--------------------|---|-------------------|
| Sucrose 57-50-1 | 30-60 | Present | | Not Hazardous* | No data available |
| Lactose 63-42-3 | 30-60 | Present | | Not Hazardous* | No data available |
| Talc, Nonasbestos Containing 14807-96-6 | 1-10 | Present | | Not Hazardous* | No data available |
| Acacia | 1-5 | NA | | Not Hazardous* | No data available |
| Magnesium Stearate 557-04-0 | 0.1-1 | Present | | Not Hazardous* | No data available |
| Levothyroxine Sodium 55-03-8 | 0.01-1 | Present | | Repro Cat 2 (H361) STOT RE Cat 1 (H372) | No data available |

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Product Name: Synthroid Tablets
Issued: Feb-25-2016

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms No signs and symptoms from occupational exposure are known. Reported to cause the following: headaches, fast heart rate, increased blood pressure, nausea, diarrhea, sweating, low blood sugar, gastrointestinal upset. Clinical overdose may result in the following: abnormal thyroid function.

Medical Conditions Aggravated by Exposure No medical conditions aggravated by occupational exposure are known. Data suggest any pre-existing ailments in the following organs: cardiovascular system, gastrointestinal system, thyroid. Hypersensitivity to the material and/or similar materials. Concurrent use of medications.

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

Notes To Physician: Treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3. Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

Product Name: Synthroid Tablets
Issued: Feb-25-2016

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid breathing dust.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

| Chemical Name | Employee Exposure Limit | Skin Notation |
|--|--------------------------------|----------------------|
| Sucrose 57-50-1 | Not applicable | None |
| Lactose 63-42-3 | Not applicable | None |
| Talc, Nonasbestos Containing 14807-96-6 | Not applicable | None |
| Acacia | Not applicable | None |
| Magnesium Stearate 557-04-0 | Not applicable | None |
| Levothyroxine Sodium 55-03-8 | 3 mcg/m ³ TWA | None |

| Chemical Name | ACGIH TLV | France | German MAK | Ireland | Italy |
|--|---|---------------------------|-------------------|--|--------------|
| Sucrose 57-50-1 | 10 mg/m ³ TWA | TWA: 10 mg/m ³ | | 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) | |
| Lactose 63-42-3 | 10 mg/m ³ total dust, 3 mg/m ³ respirable dust | | | | |
| Talc, Nonasbestos Containing 14807-96-6 | 2 mg/m ³ TWA | | | 30 mg/m ³ (STEL) 2.4 mg/m ³ (STEL) 10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA) | |
| Magnesium Stearate 557-04-0 | 10 mg/m ³ total dust | | | | |

| Chemical Name | The Netherlands | Spain | Switzerland | UK OEL/MEL |
|--|------------------------------|----------------------------|---------------------------|---|
| Sucrose 57-50-1 | | 10 mg/m ³ (TWA) | | 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) |
| Talc, Nonasbestos Containing 14807-96-6 | 0.25 mg/m ³ (TWA) | 2 mg/m ³ (TWA) | 2 mg/m ³ (TWA) | 3 mg/m ³ (STEL) 1 mg/m ³ (TWA) |

8.2. Exposure controls

Product Name: Synthroid Tablets
Issued: Feb-25-2016

Engineering Controls: No special provisions are required under normal product use conditions. Handle product formulation inside a process enclosure.

Respiratory Protection: Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Not needed during typical product use conditions. Wear impervious gloves when handling the bulk formulation.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|----------------------|
| Appearance: | Tablet |
| Odor: | Odor not determined. |
| Odor Threshold: | Not determined |
| pH: | Not determined |
| Boiling Pt. @ 760 mm Hg (°C): | Not determined |
| Melting/Freezing Point (°C): | Not determined |
| Flash Point (°C): | Not determined |
| Evaporation Rate at 20°C: | Not determined |
| Flammability (Solid): | Not determined |
| Lower Explosive Limit: | Not determined |
| Upper Explosive Limit: | Not determined |
| Vapor Pressure (mm Hg): | Not determined |
| Vapor Density (Air = 1): | Not determined |
| Specific Gravity: | Not determined |
| Solubility(ies): | Not determined |
| Partition coefficient: n-octanol/water | Not determined |
| Autoignition Temp. (°C): | 360-380 |
| Decomposition temperature (°C): | Not determined |
| Viscosity (centipoise): | Not determined |
| Explosion Severity: | Not determined |
| Oxidizer Properties: | Not determined |

9.2. Other information

| | |
|--|-----|
| Maximum Pressure Rise (bar): | 7.8 |
| Max. rate of pressure rise (bar/sec): | 383 |
| Kst Value (bar.m/s): | 104 |

Product Name: Synthroid Tablets
Issued: Feb-25-2016

Min. Ignition Energy-Cloud (mJ): 50-100
Min. Ignition Temp.-Layer (°C): 150

SECTION 10: Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined

10.4. Conditions to avoid

Not determined

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Not determined
Inhalation: Not determined

Acute Toxicity - Oral: Data for component (s) given below:

| Chemical Name | Acute Test | Value | Units | Species |
|---------------------------------|------------|--------|-------|---------|
| Sucrose 57-50-1 | LD50 > | 29,700 | mg/kg | Rats |
| Lactose 63-42-3 | LD50 > | 10000 | mg/kg | Rats |
| Levothyroxine Sodium 55-03-8 | LD50 > | 10,000 | mg/kg | Rats |

Acute Toxicity - Dermal: Not determined

Acute Toxicity - Inhalation: Data for component (s) given below:

| Chemical Name | Test | Value | Units | Species |
|--------------------------------|---------|-------|----------------------------|---------|
| Magnesium Stearate 557-04-0 | LC 50 > | 2000 | mg/m ³ , 1 hour | Rats |

Other Toxicology Data: Data for component (s) given below:

Product Name: Synthroid Tablets
Issued: Feb-25-2016

| Chemical Name | Test Type | Value | Units | Species | Comments |
|---------------------------------|-------------|-------|-------|---------|----------|
| Levothyroxine Sodium 55-03-8 | LD50 (ip) = | 20 | mg/kg | Rats | None |
| | LD50 (sc) = | 50 | mg/kg | | |

Corrosivity Not determined

Dermal Irritation: Not determined

Eye irritation Not determined

Sensitization Not determined

Toxicokinetics/Metabolism: Not determined

Target Organ Effects Clinical dose is less than (<) 10 mg/day. In clinical use, target organs include: thyroid, endocrine system.

| Chemical Name | Target Organs: | Species | Dosage | Units | Route | Duration |
|---------------------------------|----------------|---------|--------|--------|-------|---------------------------|
| Levothyroxine Sodium 55-03-8 | Thyroid | Rats | 200 | mcg/kg | Oral | Variable exposure periods |
| | | Rabbits | | | | |

Reproductive Effects In animals adverse reproductive effects include: fetal abnormalities. maternal toxicity, reduced fetal growth, fetal toxicity.

| Chemical Name | Species | Dosage | Units | Route | Duration |
|---------------------------------|---------|--------|--------|-------|------------------|
| Levothyroxine Sodium 55-03-8 | Rats | 120 | mcg/kg | Oral | During Gestation |
| | Rabbits | | | | |

Carcinogenicity Data for component (s) given below:

| Chemical Name | Site of Tumors | Species | Dosage | Route | Units | Duration |
|--|----------------|---------|--------|------------|-----------------------------|----------|
| Talc, Nonasbestos Containing 14807-96-6 | Lungs | Rats | 18 | Inhalation | mg/m ³ , 6 hours | 2 years |
| | | | | | | |

Mutagenicity: Data for component (s) given below:

| Chemical Name | Micronucleus Assay | Ames Test: | Mouse Lymphoma Assay | Chromosomal Abbr. Assay |
|--------------------------------|--------------------|------------|----------------------|-------------------------|
| Magnesium Stearate 557-04-0 | No Data. | Negative | No Data. | No Data. |

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

SECTION 12: Ecological information

12.1. Toxicity

Not determined

12.2. Persistence and degradability

Not determined

12.3. Bioaccumulative potential

Not determined

Product Name: Synthroid Tablets
Issued: Feb-25-2016

12.4. Mobility in soil

Not determined

12.5. Results of PBT and vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

SECTION 14: Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

14.1. UN number Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special provisions: Not applicable
14.7. Transport in bulk Not applicable
according to Annex II of
MARPOL 73/78 and the IBC
Code:

SECTION 15: Regulatory information

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

International Inventories

| Chemical Name | EINECS/ ELINCS | TSCA | DSL | NDSL | PICCS |
|--|----------------|------|-----|------------|-------|
| Sucrose 57-50-1 | Present | X | X | Not listed | X |
| Lactose 63-42-3 | Present | X | X | Not listed | X |
| Talc, Nonasbestos Containing 14807-96-6 | Present | X | X | Not listed | X |

Product Name: Synthroid Tablets
Issued: Feb-25-2016

| | | | | | |
|---------------------------------|---------|---|---|------------|---|
| Acacia | - | - | - | Not listed | - |
| Magnesium Stearate 557-04-0 | Present | X | X | Not listed | X |
| Levothyroxine Sodium 55-03-8 | Present | X | - | X | - |

| Chemical Name | ENCS | ISHL | IECSC | AICS | KECL | New Zealand |
|--|---------|---------|-------|------|---------|-------------|
| Sucrose 57-50-1 | - | Present | X | X | Present | |
| Lactose 63-42-3 | - | Present | X | X | Present | |
| Talc, Nonasbestos Containing 14807-96-6 | Present | - | X | X | Present | |
| Acacia | - | - | - | - | - | |
| Magnesium Stearate 557-04-0 | Present | - | X | X | Present | |
| Levothyroxine Sodium 55-03-8 | Present | Present | - | X | - | |

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

| Chemical Name | Weight-% | NTP: | IARC: | ACGIH: |
|------------------------------|----------|------------|------------|---|
| Sucrose | 30-60 | Not listed | Not listed | A4 - Not Classifiable as a Human Carcinogen |
| Lactose | 30-60 | Not listed | Not listed | Not listed |
| Talc, Nonasbestos Containing | 1-10 | Not listed | Not listed | A4 - Not Classifiable as a Human Carcinogen (containing no asbestos fibers) |
| Acacia | 1-5 | Not listed | Not listed | Not listed |
| Magnesium Stearate | 0.1-1 | Not listed | Not listed | Not listed |
| Levothyroxine Sodium | 0.01-1 | Not listed | Not listed | Not listed |

SARA 313 Information

| Chemical Name | Weight-% | SARA 313 Chemical: | CERCLA RQ/SARA EHS RQ (lbs): | SARA EHS TPQ (lbs): |
|------------------------------|----------|--------------------|------------------------------|---------------------|
| Sucrose | 30-60 | No | Not applicable | Not applicable |
| Lactose | 30-60 | No | Not applicable | Not applicable |
| Talc, Nonasbestos Containing | 1-10 | No | Not applicable | Not applicable |
| Acacia | 1-5 | No | Not applicable | Not applicable |
| Magnesium Stearate | 0.1-1 | No | Not applicable | Not applicable |
| Levothyroxine Sodium | 0.01-1 | No | Not applicable | Not applicable |

Immediate Health: No

Delayed Health: No

Fire: No

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

Product Name: Synthroid Tablets
Issued: Feb-25-2016

WHMIS Hazard Class Exempt

NFPA Rating:
Health: 0
Fire: 1
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

| |
|--------------------------------------|
| SECTION 16: Other information |
|--------------------------------------|

Full text of H-Statements referred to under sections 2 and 3

H361 - Suspected of damaging fertility or the unborn child if inhaled

H372 - Causes damage to organs (a,b,c) through prolonged or repeated exposure if inhaled

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Supersedes the SDS dated: May-28-2011

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