1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Chemical Name Armour Thyroid

Other means of identification
Product Code FG00055
Synonyms Thyroid Tablets

Recommended use of the chemical and restrictions on use
Recommended Use Pituitary TSH suppressant, Hypothyroidism

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.

Details of the supplier of the safety data sheet
Manufacturer Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address SDS@Allergan.com

Emergency telephone number Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification
OSHA Regulatory Status This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Carcinogenicity Category 2
Effects on or via lactation Yes
Specific target organ toxicity (repeated exposure) Category 1

Label elements

Emergency Overview

Danger

Hazard statements
H351 - Suspected of causing cancer
H362 - May cause harm to breast-fed children
H372 - Causes damage to organs through prolonged or repeated exposure
Precautionary statements
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P405 - Store locked up
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P263 - Avoid contact during pregnancy/while nursing
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container to an approved waste disposal plant

Other Information
Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, they can be considered hazardous.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>60 - 100*</td>
</tr>
<tr>
<td>Levothyroxine</td>
<td>51-48-9</td>
<td>200-101-1</td>
<td>5 - 10*</td>
</tr>
<tr>
<td>ADVANTIA HS244981CR31</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>1 - 5*</td>
</tr>
<tr>
<td>Liothyronine</td>
<td>6893-02-3</td>
<td>229-999-3</td>
<td>1 - 5*</td>
</tr>
<tr>
<td>CALCIUM STEARATE NF</td>
<td>1592-23-0</td>
<td>216-472-8</td>
<td>1 - 5*</td>
</tr>
</tbody>
</table>

Appearance Tablet

Physical state Solid

Odor Strong

Symptoms
The most common adverse effects seen with this product use correspond to symptoms of hyperthyroidism. These effects include fatigue, weight loss, fever, sweating, headache, restlessness/anxiety, tremors, muscle weakness, insomnia, tachycardia, palpitations, arrhythmias, changes in blood pressure, chest pain, shortness of breath.

The most frequently reported adverse effects associated with liothyronine use were arrhythmia and tachycardia (JHP, 2008). Adverse effects seen with slight overdosage correspond with symptoms of hyperthyroidism (King, 2006). These effects include headache, irritability, nervousness, tremor, sweating, increased bowel motility, and menstrual irregularities. Chest pain, heart attack, and congestive heart failure may be induced or aggravated. Shock may also develop. The onset of symptoms related to liothyronine overdose occurs within 12-24 hours after exposure (MEDITEXT, 2010).

Medical Conditions Aggravated by Exposure
Thyroid hormone preparations are generally contraindicated in patients with diagnosed but as yet uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis, and apparent hypersensitivity to any of their active or extraneous constituents.

Physical state

Odor

Strong
4. FIRST AID MEASURES

First aid measures

Eye contact
Rinse immediately with plenty of water and seek medical advice.

Skin Contact
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation
Remove to fresh air.

Ingestion
Consult a physician if necessary.

Chemical Name
Levothyroxine

Note to physicians
Thyroid hormone preparations are generally contraindicated in patients with diagnosed but as yet uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis, and apparent hypersensitivity to any of their active or extraneous constituents. Treatment is aimed at reducing gastrointestinal absorption of the drugs and counteracting central and peripheral effects, mainly those of increased sympathetic activity. Vomiting may be induced initially if further gastrointestinal absorption can reasonable be prevented and barring contraindications such as coma, convulsions, or loss of gagging reflex. Treatment is symptomatic and supportive. Oxygen may be administered and ventilation maintained. Cardiac glycosides may be indicated if congestive heart failure develops. Antiadrenergic agents, particularly propranolol, have been used advantageously in the treatment of increased sympathetic activity.

Liothyronine
Thyroid hormone preparations are generally contraindicated in patients with diagnosed but as yet uncorrected adrenal cortical insufficiency, untreated thyrotoxicosis, and apparent hypersensitivity to any of their active or extraneous constituents. Treatment is aimed at reducing gastrointestinal absorption of the drugs and counteracting central and peripheral effects, mainly those of increased sympathetic activity. Vomiting may be induced initially if further gastrointestinal absorption can reasonable be prevented and barring contraindications such as coma, convulsions, or loss of gagging reflex. Treatment is symptomatic and supportive. Oxygen may be administered and ventilation maintained. Cardiac glycosides may be indicated if congestive heart failure develops. Antiadrenergic agents, particularly propranolol, have been used advantageously in the treatment of increased sympathetic activity.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data
Sensitivity to Mechanical Impact
Not impact sensitive.

Sensitivity to Static Discharge
Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions
See Section 12 for additional ecological information.

Methods for containment
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling
Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions
Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials
None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction (vacated) TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³</td>
<td>TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust TWA: 1 mg/m³</td>
<td>N/A</td>
</tr>
<tr>
<td>Levothyroxine 51-48-9</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.3</td>
</tr>
<tr>
<td>ADVANTIA HS244861CR31 13463-67-7</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust (vacated) TWA: 10 mg/m³ total dust</td>
<td>IDLH: 5000 mg/m³</td>
<td>N/A</td>
</tr>
<tr>
<td>Liothyronine 6893-02-3</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>.05</td>
</tr>
<tr>
<td>CALCIUM STEARATE NF 1592-23-0</td>
<td>TWA: 10 mg/m³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m³ respirable particulate matter except stearates of toxic metals</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

NIOSH IDLH Immediately Dangerous to Life or Health

Other Information
Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls
Engineering Controls

The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.

Powder Handling

Isolator or direct connection with appropriate contained transfer device, and WIP for cleaning (Taped cuffs), disposable or launderable coveralls (Category III equivalent), and booties

Solutions/Suspensions and coated tablet handling (no powders or aerosols)

Not Applicable

Packaging (uncoated tablets, hot side work)

Appropriate contained transfer device WIP/CIP for the hopper (if possible), and contained ventilated filler

Laboratory Powder Handling or aerosol generation

VBSE, BSC or Glove Box

Personal Decontamination Procedure/Controls

Required

Unless, In controlled containment: Recommended.

Individual protection measures, such as personal protective equipment

PPE

The following high level PPE requirements assume Engineering Controls that reduce exposure below the limit are not in place. More specific requirements may apply

Powder Handling

PAPR with full hooded top with max APF and HEPA filter or supplied air, gloves

Solutions/Suspensions and coated tablet handling (no powders or aerosols)

Gloves, long sleeved GMP clothing and safety equipment for the area

Packaging (uncoated tablets, hot side work)

During cleaning and hopper filler operator - PAPR with full hooded head top with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III equivalent), and booties 1/2 mask, gloves, long sleeved GMP clothing and safety equipment for the area

Laboratory Powder Handling or aerosol generation

Minimum lab PPE gloves No controls-controlled area, min lab PPE, gloves and appropriately fitted 1/2 mask for powders

Eye/face protection

No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection

During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection

Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No information available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>pH</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor</td>
<td>Strong</td>
</tr>
</tbody>
</table>
Flash point  No information available
Evaporation rate  No information available
Flammability (solid, gas)  No information available
Flammability Limit in Air
   Upper flammability limit:  No information available
   Lower flammability limit:  No information available
Vapor pressure  No information available
Vapor density  No information available
Specific Gravity  No information available
Water solubility  No information available
Solubility in other solvents  No information available
Partition coefficient  No information available
Autoignition temperature  No information available
Decomposition temperature  No information available
Explosive properties  No information available
Oxidizing properties  No information available

Other Information
Molecular weight  No information available
VOC Content (%)  No information available
Density  No information available
Bulk density  No information available

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.
Possibility of Hazardous Reactions
None under normal processing.
Conditions to avoid
Aerosol formation.
Incompatible materials
None known based on information supplied.
Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50 (mg/kg)</th>
<th>Dermal LD50 (mg/kg)</th>
<th>Inhalation LD50 (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE</td>
<td>&gt; 5 kg (Rat)</td>
<td>&gt; 2 kg (Rabbit)</td>
<td>&gt; 5800 mg/m³ (Rat 4 h)</td>
</tr>
<tr>
<td>CELLULO(avicel PH102)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levothyroxine</td>
<td>10000 mg/kg (mice)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>ADVANTA HS24981CR31</td>
<td>&gt; 10000 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>CALCIUM STEARATE NF</td>
<td>&gt; 10 g/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levothyroxine</td>
<td>Not Suspected of being a Mutagen.</td>
<td>No information available.</td>
<td>No information available.</td>
<td>It distributes into breast milk in at very low concentrations that are not considered harmful to a nursing infant.</td>
</tr>
<tr>
<td>Liothyronine</td>
<td>No information available.</td>
<td>No information available.</td>
<td>Not suspected of being a</td>
<td>Although only minimal</td>
</tr>
</tbody>
</table>
reproductive hazard. Amounts of thyroid hormones are distributed into milk, thyroid agents should be used with caution in nursing women.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>STOT - single exposure</th>
<th>STOT - repeated exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levothyroxine</td>
<td>No information available.</td>
<td>Thyroid.</td>
</tr>
<tr>
<td>Liothyronine</td>
<td>No information available.</td>
<td>Thyroid.</td>
</tr>
</tbody>
</table>

**Target Organ Effects**
Eyes, lungs, Respiratory system, Skin, Thyroid.

**Numerical measures of toxicity - Product Information**
The following values are calculated based on chapter 3.1 of the GHS document.

- ATEmix (oral): 6323 mg/kg
- ATEmix (dermal): 2860 mg/kg
- ATEmix (inhalation-dust/mist): 8.3 mg/l

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**
No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes**
Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging**
Do not reuse container. Dispose of contents/containers in accordance with local regulations.

**14. TRANSPORT INFORMATION**

- **DOT**: Not regulated
- **TDG**: Not regulated
- **ICAO (air)**: Not regulated
- **IATA**: Not regulated
- **IMDG**: Not regulated
- **ADR**: Not regulated
- **ADN**: Not regulated

**15. REGULATORY INFORMATION**

**International Inventories**
- **TSCA**: Not Listed
- **DSL/NDSL**: Not Listed
- **EINECS/ELINCS**: Not Listed
Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

Carcinogenicity
The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVICEL PH102 9004-34-6</td>
<td>-</td>
<td>Group 1</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>ADVANTIA HS244981CR31</td>
<td>-</td>
<td>Group 2B</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

IARC (International Agency for Research on Cancer)
- Group 2B - Possibly Carcinogenic to Humans
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
- Present

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories
- Acute health hazard: No
- Chronic Health Hazard: No
- Fire hazard: No
- Sudden release of pressure hazard: No
- Reactive Hazard: No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVANTIA HS244981CR31 - 13463-67-7</td>
<td>Carcinogen</td>
</tr>
</tbody>
</table>

U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICROCRYSTALLINE CELLULO AVICE PH102</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>9004-34-6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADVANTIA HS244981CR31 13463-67-7</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Revision Date 02-Oct-2018
Revision Note No information available
Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet