



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 11

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



Appearance Tablet	Physical state Solid	Odor Strong
Chemical Name Levothyroxine	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).	
Liothyronine		
Chemical Name Levothyroxine	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.	
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.	

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
- P201 - Obtain special instructions before use
- 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, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
MICROCRYSTALLINE CELLULO(AVICEL PH102)	9004-34-6	232-674-9	60 - 100*
Levothyroxine	51-48-9	200-101-1	5 - 10*
ADVANTIA HS244981CR31	13463-67-7	236-675-5	1 - 5*
Liothyronine	6893-02-3	229-999-3	1 - 5*
CALCIUM STEARATE NF	1592-23-0	216-472-8	1 - 5*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

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**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m ³)
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 5 mg/m ³ (vacated) STEL: 10 mg/m ³	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust TWA: 1 mg/m ³	N/A
Levothyroxine 51-48-9	N/A	N/A	N/A	0.3
ADVANTIA HS244981CR31 13463-67-7	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust (vacated) TWA: 10 mg/m ³ total dust	IDLH: 5000 mg/m ³	N/A
Liothyronine 6893-02-3	N/A	N/A	N/A	.05
CALCIUM STEARATE NF 1592-23-0	TWA: 10 mg/m ³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m ³ respirable particulate matter except stearates of toxic metals	N/A	N/A	N/A

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

Physical state	Solid	Appearance	Tablet
Color	No information available	Odor	Strong
Odor threshold	No information available		

<u>Property</u>	<u>Values</u>
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available

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**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
Levothyroxine	10000 mg/kg (mice)	N/A	N/A
ADVANTIA HS244981CR31	> 10000 mg/kg (Rat)	N/A	N/A
CALCIUM STEARATE NF	> 10 g/kg (Rat)	N/A	N/A

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Levothyroxine	Not Suspected of being a Mutagen.	No information available.	No information available.	It distributes into breast milk in at very low concentrations that are not considered harmful to a nursing infant.
Liothyronine	No information available.	No information available.	Not suspected of being a	Although only minimal

			reproductive hazard.	amounts of thyroid hormones are distributed into milk, thyroid agents should be used with caution in nursing women.
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Chemical Name	STOT - single exposure	STOT - repeated exposure
Levothyroxine	No information available.	Thyroid.
Liothyronine	No information available.	Thyroid.

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

Other adverse effects 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/NDL - 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).

Chemical Name	ACGIH	IARC	NTP	OSHA
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	-	Group 1	Known	X
ADVANTIA HS244981CR31 13463-67-7	-	Group 2B	-	X

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)
 X - 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

Chemical Name	California Proposition 65
ADVANTIA HS244981CR31 - 13463-67-7	Carcinogen

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	X	X	X
ADVANTIA HS244981CR31 13463-67-7	X	X	X

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