MATERIAL SAFETY DATA SHEET

Updated on 2016-02-25

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

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Material Name: Methimazole Tablets

Chemical Family: Not determined

Intended Use: Pharmaceutical product used for Hyperthyroidism

2.HAZARDS IDENTIFICATION

Appearance: White tablets

Statement of Hazard: H360D - May damage the unborn child

Additional Hazard Information:

Short Term: No data available

Known Clinical Effects: This compound can cross the placenta in pregnant women. Can induce cretinism and goiter in the developing fetus. Adverse effects associated with therapeutic use include decrease in platelets and red/white blood cells (pancytopenia), decreased white blood cells (leukopenia),thrombocytopenia, inflammation of the liver (hepatitis), changes in liver function, effects on the thyroid, headache, skin rash, hives, redness and swelling of the skin (urticaria), loss of hair, nausea, vomiting, loss of taste.

EU Indication of danger: Toxic to reproduction: Category 1

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3.COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Methimazole	60-56-0	200-482-4	Repr. Cat.1;R61	5-10
Potato starch	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Talc	14807-96-6	238-877-9	Not Listed	*
Lactose monohydrate	64044-51-5	Not Listed	Not Listed	*

Additional Information: *Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO_2, extinguishing powder, foam, or water.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7.HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Potato starch

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL – TWA	10 mg/m^3
Bulgaria OEL – TWA	10 mg/m^3
Czech Republic OEL – TWA	4.0 mg/m^3
Greece OEL-TWA	10 mg/m^3
	5 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	4 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	4 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3

Talc

ACGIH Threshold Limit Value (TWA)	2 mg/m^3
Australia TWA	2.5 mg/m^3
Austria OEL-MAKs	2 mg/m^3
Belgium OEL – TWA	2 mg/m^3
Bulgaria OEL – TWA	1.0 fiber/cm^3
	6.0 mg/m^3
	3.0 mg/m^3
Czech Republic OEL – TWA	2.0 mg/m^3
Denmark OEL - TWA	0.3 fiber/cm^3
Finland OEL - TWA	0.5 fiber/cm^3
Greece OEL-TWA	10 mg/m^3
	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	10 mg/m^3
	0.8 mg/m^3
Lithuania OEL - TWA	2 mg/m^3
	1 mg/m^3
Netherlands OEL - TWA	0.25 mg/m^3
OSHA - Final PELS – Table Z-3 Mineral D:	20 mppcf
Poland OEL-TWA	4.0 mg/m^3
	1.0 mg/m^3
Portugal OEL - TWA	2 mg/m^3
Romania OEL-TWA	2 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
	10 mg/m^3
Slovenia OEL-TWA	2 mg/m^3
Spain OEL - TWA	2 mg/m^3
Sweden OEL-TWAs	2 mg/m^3
	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL – TWA	5 mg/m^3
Sweden OEL – TWAs	5 mg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categorieswhen the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given isbased upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomesavailable.

Methimazole

Pfizer Occupational Exposure Band (OEB):	OEB 3 (control exposure to the range of >10ug/m^3 to < 100ug/m^3)
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom ofthe OEB range.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablets **Color:** White

Molecular Formula: Mixture **Molecular Weight:** Mixture

Partition Coefficient: (Method, pH, Endpoint, Value)

Methimazole

Predicted 7.4 Log D -2.743

10.STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11.TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Talc

Rat	Oral	LD50	>	1600	mg/kg
Rabbit	Dermal	LD50	>	2000	mg/kg

Magnesium stearate

Rat	Oral	LD50	>	2000	mg/kg
Rat	Inhalation	LC50	>	2000	mg/m^3

Methimazole

Rat Oral LD 50 2250 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Methimazole

Embryo / Fetal Development	Rat	Oral	50 mg/kg/day	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rabbit	No route specified	Dose not specified		Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Methimazole

In Vitro Chromosome Aberration Positive

In Vivo Negative

11.TOXICOLOGICAL INFORMATION

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Methimazole

2 Year(s) Rat Oral 0.5 mg/kg/day NOAEL Thyroid, Tumors

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12.ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Methimazole

Methimazole Predicted 7.4 Log D -2.743

13.DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14.TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15.REGULATORY INFORMATION

EU Indication of danger: Toxic to reproduction: Category 1

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Methimazole

California Proposition 65	Developmental toxicity initial date 7/1/90
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

15.REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-482-4

Potato starch

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Sodium starch glycolate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Lactose monohydrate

Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present

Talc

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

16.OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Toxic to reproduction: Category 1

R61 - May cause harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information

Prepared by: Product Stewardship Hazard Communication

Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet