Section 1. Identification

1.1 Substance Name: Atomoxetine Capsules USP

1.2 Chemical Name: Tomoxetine, Tomoxetine hydrochloride capsules , Tomoxetine hydrochloride formulation,

1.3 Relevant identified uses of the substance or mixture and uses advised against:
Use according to manufacturer's directions

1.4 Company Identification: Glenmark Pharmaceuticals Inc., USA
750 Corporate Drive

Mahwah, NJ 07430

1.6 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Chemwatch Hazard Ratings

		Min/Max
Flammability	**0**	
Toxicity	**2**	[redacted]
Body Contact	**3**	[redacted]
Reactivity	**1**	[redacted]
Chronic	**0**	

0 = Minimum

1 = Low
2 = Moderate
3 = High
4 = Extreme
Relevant risk statements are found in section 2

Classification

Acute Toxicity (Oral) Category 4, Serious Eye Damage Category 1, Acute Aquatic Hazard Category 1

*LIMITED EVIDENCE

2.2 Label elements:

2.3 Risk Phrase:

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

2.4 Safety Advice:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
P391	Collect spillage.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P501	Dispose of contents/container in accordance with local regulations.

2.5 Other hazards: Not Known

Section 3- Composition/Information on Ingredients

3.1 Substances

CHEMICAL NAME	CAS #	%
Atomoxetine Hydrochloride	82248-59-7	3-37
ingredients determined not to be hazardous [Mfr]	-	Proprietary

Section 4. First aid Measures

4.1 Inhalation:

- If fumes, aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

4.2 Skin: If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

4.3 Eyes: If this product comes in contact with the eyes:

- Immediately hold eyelids apart and flush the eye continuously with running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

4.4 Ingestion:

- For advice, contact a Poisons Information Centre or a doctor at once.
- Urgent hospital treatment is likely to be needed.
- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Transport to hospital or doctor without delay

4.5 Most important symptoms and effects, both acute and delayed
See Section 11

Indication of any immediate medical attention and special treatment needed
As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

BASIC TREATMENT

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema.
- Monitor and treat, where necessary, for shock.
- Anticipate seizures.

- **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

ADVANCED TREATMENT

- Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

Section 5. Fire-fighting Measures

5.1 General Information:

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves in the event of a fire.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.

5.2 Extinguishing Media:

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

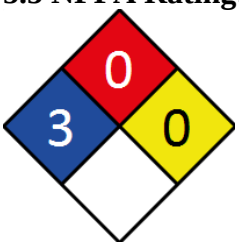
5.3 Fire/Explosion Hazard:

- Non combustible.
- Not considered a significant fire risk, however containers may burn.

May emit poisonous fumes. May emit corrosive fumes.

5.4 Fire Incompatibility: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

5.5 NFPA Rating:



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Section 6. Accidental Release Measures

6.1 General Information: Personal Protective Equipment advice is contained in Section 8 of the SDS.

6.2 Minor Spills:

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact with the substance, by using protective equipment.

6.3 Major Spills: Moderate hazard.

- CAUTION: Advise personnel in area.

- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.

Section 7. Handling and Storage

7.1 Handling:

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

7.2 Storage:

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.

7.3 Suitable Container:

- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

7.4 Storage incompatibility: Avoid reaction with oxidising agents

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Atomoxetine Hydrochloride Capsules [CAS 82248-59-7]	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Atomoxetine hydrochloride [CAS 82248-59-7]	Not Available	Not Available

MATERIAL DATA

It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.
At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.
NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.
Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable.

8.2 Exposure controls:

Appropriate engineering Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly

controls effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.
The basic types of engineering controls are:
Process controls which involve changing the way a job activity or process is done to reduce the risk.
Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.

Personal protection

Eye and face

- Safety glasses with side shields.

protection

- Chemical goggles.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.

Skin protection See Hand protection below

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene.
- nitrile rubber.
- butyl rubber.

Hands/feet protection

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care.

Body protection See Other protection below

Other protection

- Overalls.
- P.V.C. apron.
- Barrier cream.

Thermal hazards Not Available

Respiratory protection

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1	-	PAPR-P1
	Air-line*	-	-
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Solid
Appearance	:	odourless powder
Colour	:	White to off-white odourless powder
pH Value	:	Not Known
Vapor Pressure	:	Not Known
Vapor Density	:	Not Known
Evaporation Rate	:	Not Known
Other information		
Flash point	:	Not Known

Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Miscible
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron)	:	Not Known

9.2 Other Information: Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Not Known

10.2 Chemical stability:

- Unstable in the presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

10.3 Conditions to Avoid: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

10.4 Incompatibilities with Other Materials: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

10.5 Hazardous Decomposition Products:
May emit poisonous fumes. May emit corrosive fumes.

10.6 Hazardous Polymerization: Not Known

Section 11. Toxicological Information

11.1 Information on toxicological effects

Inhaled	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

Skin Contact	Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis. Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
Eye	When applied to the eye(s) of animals, the material produces severe ocular lesions which are present twenty-four hours or more after instillation.
Chronic	Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Atomoxetine Hydrochloride

Section 12. Ecological Information

12.1 Toxicity:

	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
Atomoxetine Hydrochloride Tablets and Capsules	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Very toxic to aquatic organisms.
Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.
Wastes resulting from use of the product must be disposed of on site or at approved waste sites.
DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability:

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

12.3 Bioaccumulative potential:

Ingredient	Bioaccumulation
	No Data available for all ingredients

12.4 Mobility in soil:

Ingredient	Mobility
	No Data available for all ingredients

12.5 Other: Not Known

Section 13. Disposal Considerations

13.1 Waste treatment methods

Product / Packaging disposal

- Recycle wherever possible or consult manufacturer for recycling options.
- Consult State Land Waste Management Authority for disposal.
- Bury residue in an authorised landfill.
- Recycle containers if possible, or dispose of in an authorised landfill.
- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- Where possible retain label warnings and SDS and observe all notices pertaining to the product.

Section 14. Transport Information

14. 1 Special precautions for user:

Labels Required

Marine Pollutant

Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

Section 15. Regulatory Information

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

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SECTION 311/312 HAZARD CATEGORIES

Immediate (acute) health hazard	Yes
Delayed (chronic) health hazard	No
Fire hazard	No
Pressure hazard	No
Reactivity hazard	No

US. EPA CERCLA HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES (40 CFR 302.4)

None Reported

State Regulations

US. CALIFORNIA PROPOSITION 65

None Reported

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	Y
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y

Section 16. Additional Information

Disclaimer:

The information provided in this 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 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.

Compiled By (R & D)	Approved by (EHS Head)
Sanjeev 18-05-2017	18/05/2017
Signature /Date	Signature /Date