MATERIAL SAFETY DATA SHEET

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

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CHEMTREC (24 hours): 1-800-424-9300

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Fesoterodine Fumarate Tablets

Trade Name: TOVIAZ
Synonyms: Fesoterodine Sustained Release (SR) Tablets
Chemical Family: Not determined
Intended Use: Pharmaceutical product for the treatment of overactive bladder

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Fesoterodine fumarate	286930-03-8	Not listed	1.2-2.5
Microcrystalline cellulose	9004-34-6	232-674-9	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*

Ingredient	CAS Number	EU EINECS List	%
Glycerol dibehenate	99880-64-5	Not listed	*
Xylitol	87-99-0	201-788-0	*
Hypromellose	9004-65-3	Not listed	*
Opadry blue	NOT ASSIGNED	Not listed	*
Lactose Monohydrate	64044-51-5	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Blue tablets
Signal Word: WARNING

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: May be harmful if swallowed. May cause eye irritation if tablets are crushed or broken . Not a skin sensitizer . Not a skin irritant . (based on components) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver and the developing fetus.
Known Clinical Effects: Adverse effects most commonly reported in clinical use include dry mouth constipation, upset stomach, dry eyes, urinary tract infection, abdominal pain, back pain, inflammation of the pharynx (pharyngitis), painful urination, and difficulty with urination.
EU Indication of danger: Not classified

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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Not determined

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 Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes . Use appropriate ventilation.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Fesoterodine fumarate

Pfizer OEL TWA-8 Hr:	35µg/m^3

Microcrystalline cellulose

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA
ACGIH Threshold Limit Value (TWA)	= 2 mg/m^3 TWA
Australia TWA	= 2.5 mg/m^3 TWA containing no asbestos fibers

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Not available

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Film-coated tablets	**Color:**	Light blue or Blue
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solubility: Highly soluble: Water

10. STABILITY AND REACTIVITY

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)

Fesoterodine fumarate
Rat Oral LD50 ~ 681 mg/kg
Mouse Oral LD50 ~ 316 mg/kg
Rat Intravenous NOAEL 10 mg/kg
Mouse Intravenous NOAEL 10 mg/kg

Hypromellose
Rat Oral LD50 > 10,000 mg/kg

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 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.

Irritation / Sensitization: (Study Type, Species, Severity)

Fesoterodine fumarate
Skin Sensitization - M & K Guinea Pig Negative
Eye Irritation Rabbit Irritant
Skin Irritation Rabbit Negative

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Fesoterodine fumarate
6 Month(s) Mouse Oral 25 mg/kg/day NOAEL None identified
13 Week(s) Rat Oral 5 mg/kg/day NOEL Liver
13 Week(s) Dog Oral 2.5 mg/kg/day NOAEL Cardiovascular system, Blood
9 Month(s) Dog Oral 2.5 mg/kg/day NOAEL Cardiovascular system, Gallbladder

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Fesoterodine fumarate
Fertility and Embryonic Development Mouse Oral 15 mg/kg/day NOAEL Negative
Embryo / Fetal Development Mouse Oral 15 mg/kg/day NOAEL Not Teratogenic, Embryotoxicity
Embryo / Fetal Development Rabbit Oral 9 mg/kg/day NOAEL Not Teratogenic, Embryotoxicity
Embryo / Fetal Development Rabbit Subcutaneous 4.5 mg/kg/day NOAEL No effects at maximum dose
Prenatal & Postnatal Development Mouse Oral 60 mg/kg/day NOAEL No effects at maximum dose

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

Fesoterodine fumarate
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Mouse Negative

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

Fesoterodine fumarate
2 Year(s) Mouse Oral 60 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Rat Oral 60 mg/kg/day NOAEL Not carcinogenic

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

Talc (non-asbestiform)
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided. The active ingredient in this formulation may be harmful to aquatic organisms. Long-term adverse effects to aquatic organisms are possible.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Fesoterodine fumarate
Scenedesmus subspicatus (Green Alga) OECD EC50 72 Hours 20 mg/L
Activated sludge OECD EC50 3 Hours > 1000 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
WARNING
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials
D2b toxic materials

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

Xylitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-788-0

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Talc (non-asbestiform)

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

Lactose Monohydrate

Australia (AICS):	Present

16. OTHER INFORMATION

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

End of Safety Data Sheet