MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Celiprolol Hydrochloride Tablets

Trade Name: SELECTROL(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for high blood pressure (hypertension), angina pectoris.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Celiprolol Hydrochloride	57470-78-7	260-752-2	200 mg ***
Magnesium stearate	557-04-0	209-150-3	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Titanium dioxide	13463-67-7	236-675-5	*

Ingredient	CAS Number	EU EINECS List	%
Croscarmellose sodium	74811-65-7	Not listed	*
Polyethylene glycol	25322-68-3	Not listed	*
Hypromellose	9004-65-3	Not listed	*
Polysorbate 80	9005-65-6	Not listed	*
Mannitol	69-65-8	200-711-8	*

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White tablets
Signal Word: WARNING

Statement of Hazard: Antihypertensive drug: has blood pressure-lowering properties

Additional Hazard Information:
Short Term: May cause eye and skin irritation.
Long Term: Animal studies indicate that this material may cause adverse effects on the the developing fetus.

Known Clinical Effects: Clinical use of this drug has caused fatigue, headache, dizziness, dilation of pupils, dry eyes, ringing of the ears, sleep disturbances, convulsion, troubled breathing, decrease in blood pressure (hypotension), decreased heart rate (bradycardia), vasodilation, impaired heart conduction (atrioventricular block).

EU Indication of danger: Not classified

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 eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation or unusual symptoms occur even if they are delayed.

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: May burn emitting oxides of: chlorine. carbon and nitrogen

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

Fire / Explosion Hazards: Not applicable

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, skin, and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	

Microcrystalline cellulose

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

Titanium dioxide

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

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary.

Personal Protective Equipment:

Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	Not required for the normal use of this product. 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:	Tablet	**Color:**	White
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: Not determined
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)

Mannitol
Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Hypromellose
Rat Oral LD50 > 10,000 mg/kg

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

Polysorbate 80
Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25 g/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Celiprolol Hydrochloride
Rat Oral LD 50 3836 mg/kg
Mouse Oral LD 50 2029 mg/kg

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

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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

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

Celiprolol Hydrochloride
12 Month(s) Dog Oral 10 mg/kg/day NOAEL
2 Year(s) Rat Oral 18 grams NOAEL

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

Celiprolol Hydrochloride
Reproductive & Fertility Rat 320 mg/kg/day NOAEL Fertility
Embryo / Fetal Development Rat 320 mg/kg/day NOAEL Fetotoxicity, Not Teratogenic
Embryo / Fetal Development Rat Oral 600 mg/kg/day LOAEL Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development Rabbit Oral 540 mg/kg/day LOAEL Maternal Toxicity, Fetotoxicity

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

Celiprolol Hydrochloride
Bacterial Mutagenicity (Ames) Negative
Mammalian Cell Mutagenicity Negative

Carcinogen Status: See below

Titanium dioxide
IARC: Group 2B
OSHA: Present

12. ECOLOGICAL INFORMATION

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

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
Antihypertensive drug: has blood pressure-lowering properties

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Celiprolol Hydrochloride
EU EINECS List 260-752-2

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

Croscarmellose sodium
Australia (AICS): Present

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

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

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

Polysorbate 80
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Titanium dioxide
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 236-675-5

Mannitol
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-711-8

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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