



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

Page 1 of 6

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

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

Material Name: Clotiazepam Tablets

Trade Name: CLOZANI®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antianxiety agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Microcrystalline cellulose	9004-34-6	232-674-9	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Magnesium stearate	557-04-0	209-150-3	*
Clotiazepam	33671-46-4	251-627-3	5 or 10 mg***

Ingredient	CAS Number	EU EINECS List	%
Lactose Monohydrate	64044-51-5	Not listed	*
Opadry blue	NOT ASSIGNED	Not listed	*
Carboxy methylcellulose calcium	9050-04-8	Not listed	*

Additional Information: *** per tablet/capsule/lozenge/suppository
* Proprietary

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: May be harmful if swallowed.
May cause central nervous system effects.

Additional Hazard Information:

Short Term: May be harmful if swallowed. (based on animal data)
Known Clinical Effects: Commonly reported adverse effects seen during the use of clotiazepam include drowsiness, sedation, fatigue, dizziness, vertigo, insomnia, and muscle weakness.
EU Indication of danger: Harmful

EU Hazard Symbols:

MATERIAL SAFETY DATA SHEET

Material Name: Clotiazepam Tablets
Revision date: 02-Jan-2007

Page 2 of 6
Version: 1.1



EU Risk Phrases:

R22 - Harmful if swallowed.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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 eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
- Skin Contact:** Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.
- Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
- Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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.
- Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
- 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.

MATERIAL SAFETY DATA SHEET

Material Name: Clotiazepam Tablets
Revision date: 02-Jan-2007

Page 3 of 6
Version: 1.1

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Magnesium stearate

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

Clotiazepam

Pfizer OEL TWA-8 Hr: 0.06 mg/m³
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.

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:	Tablets	Color:	Blue
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use. This material discolors upon exposure to light.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.
Polymerization: Will not occur

MATERIAL SAFETY DATA SHEET

Material Name: Clotiazepam Tablets
Revision date: 02-Jan-2007

Page 4 of 6
Version: 1.1

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)

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Clotiazepam

Rat Oral LD50 1461 mg/kg
Mouse Oral LD50 636 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)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Talc (non-asbestiform)

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

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

MATERIAL SAFETY DATA SHEET

Material Name: Clotiazepam Tablets
Revision date: 02-Jan-2007

Page 5 of 6
Version: 1.1

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful
EU Risk Phrases: R22 - Harmful if swallowed.
EU Safety Phrases: S22 - Do not breathe dust.

OSHA Label:
WARNING
May be harmful if swallowed.
May cause central nervous system effects.

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.

Lactose Monohydrate	
Australia (AICS):	Present
Microcrystalline cellulose	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9
Talc (non-asbestiform)	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3
Clotiazepam	
Drug Enforcement Administration:	Schedule IV
EU EINECS List	251-627-3

MATERIAL SAFETY DATA SHEET

Material Name: Clotiazepam Tablets
Revision date: 02-Jan-2007

Page 6 of 6
Version: 1.1

Carboxy methylcellulose calcium

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

XU

Present

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet