



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.2

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

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

Material Name: Temazepam Hard Gelatin Capsules

Trade Name: Levaxol
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as sedative-hypnotic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Temazepam	846-50-4	212-688-1	5-10 mg***
Magnesium stearate	557-04-0	209-150-3	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Titanium dioxide	13463-67-7	236-675-5	*
Iron oxide	1309-37-1	215-168-2	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*
Erythrosine (CI 45430)	16423-68-0	240-474-8	*
Water	7732-18-5	231-791-2	*
Gelatin	9000-70-8	232-554-6	*

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: Capsules
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
May cause central nervous system effects
May cause harm to the unborn child.
May cause harm to breastfed babies.

Additional Hazard Information:
Short Term: May be harmful if swallowed. (based on components) .

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Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Use of this drug is habit forming. Addiction may occur.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include drowsiness, lethargy, dizziness, confusion, anxiety, state of intense good feeling (euphoria), clumsy motion of limbs/trunk (ataxia), weakness, lightheadedness, incoordination. Cases of severe overdose may lead to respiratory depression, coma.

EU Indication of danger: Harmful
Toxic to reproduction, Category 2

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

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

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. 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: 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.

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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. Minimize dust generation and accumulation. Use with adequate ventilation.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Temazepam

Pfizer OEL TWA-8 Hr: 0.08 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA
ACGIH Threshold Limit Value (TWA) = 2 mg/m³ TWA
Australia TWA = 2.5 mg/m³ TWA containing no asbestos fibers

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Iron oxide

OSHA - Final PELs - TWAs: = 10 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA
Australia TWA = 5 mg/m³ 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. General room ventilation is adequate unless the process generates dust, mist or fumes.

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Capsule	Color:	Yellow/orange
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

Temazepam

Rat	Oral	LD50	1833 mg/kg
Mouse	Oral	LD50	1963 mg/kg
Rabbit	Oral	LD50	> 2400 mg/kg

Lactose

Rat	Oral	LD50	> 10 g/kg
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Magnesium stearate

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

Talc (non-asbestiform)

Rat	Oral	LD50	> 1600 mg/kg
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Titanium dioxide

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

Erythrosine (CI 45430)

Rat	Oral	LD50	1840 mg/kg
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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 & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Temazepam

Peri-/Postnatal Development	Rat	Oral	60 mg/kg/day	LOAEL	Postnatal mortality
Embryo / Fetal Development	Rat	Oral	30 mg/kg/day	LOAEL	Embryotoxicity
Embryo / Fetal Development	Rabbit	Oral	40 mg/kg/day	LOAEL	Teratogenic

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

Temazepam

Direct DNA Damage Rat Hepatocyte Negative

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

Temazepam

18 Month(s) Mouse Oral 160 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Rat Oral 160 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: See below

Temazepam

IARC: Group 3

Talc (non-asbestiform)

IARC: Group 3

Titanium dioxide

IARC: Group 2B

OSHA: Present

Iron oxide

IARC: Group 3

Additional Information: Drugs of this class have caused adverse effect on breast feeding infants.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly 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 Symbol: T

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EU Indication of danger: Harmful
Toxic to reproduction, Category 2

EU Risk Phrases:
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May be harmful if swallowed.
May cause central nervous system effects
May cause harm to the unborn child.
May cause harm to breastfed babies.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials



Temazepam

California Proposition 65	developmental toxicity, initial date 4/1/90
Drug Enforcement Administration:	Schedule IV
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	212-688-1

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

Magnesium stearate

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

Talc (non-asbestiform)

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

Titanium dioxide

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5
Erythrosine (CI 45430)	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	240-474-8
Water	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2
Gelatin	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6
Iron oxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-168-2

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 7 - Handling and Storage. 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

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End of Safety Data Sheet