



MATERIAL SAFETY DATA SHEET

Revision date: 09-Jan-2008

Version: 2.0

Page 1 of 7

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

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Material Name: Benzphetamine Hydrochloride Tablets

Trade Name:	Didrex Tablets
Chemical Family:	Sympathomimetic amine
Intended Use:	Pharmaceutical product used for weight control.

2. HAZARDS IDENTIFICATION

Appearance: Peach Tablet
Signal Word: DANGER

Statement of Hazard: Toxic if swallowed.

Additional Hazard Information:
Known Clinical Effects:

Adverse reactions are related to CNS stimulatory effects, such as nervousness, insomnia, dizziness, headaches, increased blood pressure, and irregular heartbeat. Adverse reactions are dose-related and may be severe at higher doses. Other less common effects include allergic reaction, skin reaction and loss of libido. Drugs of this class may cause symptoms of dependence/withdrawal; may be secreted in human breast milk. Additionally, effects on developing fetus may occur.

EU Indication of danger: Harmful

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

MATERIAL SAFETY DATA SHEET

Material Name: Benzphetamine Hydrochloride Tablets
Revision date: 09-Jan-2008

Page 2 of 7
Version: 2.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Benzphetamine Hydrochloride	5411-22-3	226-489-2	T;R25	16.95
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Calcium stearate	1592-23-0	216-472-8	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Povidone	9003-39-8	Not listed	Not Listed	*
Sorbitol	6706-59-8	Not listed	Not Listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	Not Listed	*
Erythrosine Sodium	49746-10-3	Not listed	Not Listed	*
Lactose Monohydrate	64044-51-5	Not listed	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

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.
- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** No data available
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** No data available

6. ACCIDENTAL RELEASE MEASURES

MATERIAL SAFETY DATA SHEET

Material Name: Benzphetamine Hydrochloride Tablets
Revision date: 09-Jan-2008

Page 3 of 7
Version: 2.0

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:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided.
Storage Conditions:	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
Storage Temperature:	20-25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Benzphetamine Hydrochloride

Pfizer OEL TWA-8 Hr: 90µg/m³

Corn Starch

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Bulgaria OEL - TWA = 10.0 mg/m³ TWA
Czech Republic OEL - TWA = 4.0 mg/m³ TWA
Greece OEL - TWA = 10 mg/m³ TWA
Ireland OEL - TWAs = 5 mg/m³ TWA
Ireland OEL - TWAs = 10 mg/m³ TWA
OSHA - Final PELs - TWAs: = 4 mg/m³ TWA
OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
OSHA - Final PELs - TWAs: = 5 mg/m³ TWA
Portugal OEL - TWA = 10 mg/m³ TWA
Spain OEL - TWA = 10 mg/m³ VLA-ED

Calcium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
Lithuania OEL - TWA = 3 mg/m³ IPRV
Portugal OEL - TWA = 10 mg/m³ TWA does not include stearates of toxic metals
Spain OEL - TWA = 10 mg/m³ VLA-ED not including stearates of toxic metals
Sweden OEL - TWAs = 5 mg/m³ LLV

MATERIAL SAFETY DATA SHEET

Material Name: Benzphetamine Hydrochloride Tablets
Revision date: 09-Jan-2008

Page 4 of 7
Version: 2.0

Refer to available public information for specific member state Occupational Exposure Limits. 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. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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:	Tablet	Color:	Peach
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: No data available
Incompatible Materials: No data available

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)

Benzphetamine Hydrochloride

Rat Oral LD 50 160 mg/kg
Mouse Oral LD 50 227 mg/kg
Mouse Intraperitoneal LD 50 102 mg/kg

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

Povidone

Rat Oral LD50 100 g/kg

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

MATERIAL SAFETY DATA SHEET

Material Name: Benzphetamine Hydrochloride Tablets
Revision date: 09-Jan-2008

Page 5 of 7
Version: 2.0

Povidone
IARC: Group 3

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. Member State specific and Community specific provisions must be considered.

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:
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

OSHA Label:
DANGER
Toxic if swallowed.

Canada - WHMIS: Classifications

WHMIS hazard class:
D1b toxic materials

MATERIAL SAFETY DATA SHEET

Material Name: Benzphetamine Hydrochloride Tablets
Revision date: 09-Jan-2008

Page 6 of 7
Version: 2.0



Benzphetamine Hydrochloride California Proposition 65	developmental toxicity, initial date 4/1/90
Drug Enforcement Administration: EU EINECS/ELINCS List	Schedule III 226-489-2
Povidone Inventory - United States TSCA - Sect. 8(b) Australia (AICS):	XU Present
Corn Starch Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	XU Present Present 232-679-6
Calcium stearate Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	Present Present Present 216-472-8
FD&C yellow No.6 aluminum lake Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	Present Present 239-888-1
Erythrosine Sodium Australia (AICS):	Present
Lactose Monohydrate Australia (AICS):	Present

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R25 - Toxic if swallowed.

Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by:

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MATERIAL SAFETY DATA SHEET

Material Name: Benzphetamine Hydrochloride Tablets
Revision date: 09-Jan-2008

Page 7 of 7
Version: 2.0

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet