SAFETY DATA SHEETS

This SDS packet was issued with item:

078036595

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078036579 078036587

FORT DODGE®

Material Safety Data Sheet

Torbutrol Tablets

WW MSDS No. 40-6325

Section 1. Product and Company Identification

Manufactured/ Supplied by	Fort Dodge Animal Health 800 5th Street NW P.O. Box 518 Fort Dodge, IA 50501 Phone: 515-955-4600 Fax: 515-955-9149
Product Trade Name	Torbutrol Tablets
Common Name	Not applicable.
Synonyms	Butorphanol tartrate tablets
Chemical Formula	Mixture.
Chemical Family	Not available.
Material Uses	Pharmaceutical industry: Analgesic.
Packaging	Plastic bottles.
Formula Type	(TB) Tablet.

Date of Preparation	18 January 2002
Product No.	40-6325
Formula No.	Not available.
CAS No.	Mixture.
U.N. No.	Not applicable.
EINECS No.	Mixture.

In Case of Emergency	515-955-6033

Section 2. Composition - Information on Ingredients

Name of Ingredients	CAS No.	Conc.	EU Symbol	R Phrase
1) Butorphanol Tartrate 2) Inert Ingredients	58786-99-5	0.2-2 98-99.8	T Not controlled.	R25 Not controlled.

Section 3. Hazards Identification - Summary of Primary Effects and Critical Hazards

Acute Health Effects	Significant adverse health effects are associated with chronic high level exposures.
Chronic Health Effects	Potential organ systems affected are: Central Nervous System (CNS). Adverse effects could include: Can cause dizziness, light headedness, headache, nausea, and blurred vision.
Environmental Hazards	No known significant effects or critical hazards.

Section 4. First Aid Measures - (by medical responders using "Universal Precautions")

Eye Contact	Flush eyes with plenty of water for 15 minutes, occasionally lifting upper and lower eyelids. (Check person for contact lenses and remove if present.) If redness or irritation persists have eyes examined by doctor immediately.
Skin Contact	Flush skin with plenty of soap and water for at least 15 minutes (remove all contaminated clothing and shoes). Get medical attention if symptoms persist.
Inhalation	No specific treatment, treat symptomaticaly. If breathing is difficult give oxygen, if respiratory arrest occurs provide artificial respiration and seek immediate medical assistance.
Ingestion	No specific treatment, treat symptomatically. Call medical doctor or poison control center immediately if large quantities are ingested.
Notes to Medical Doctor	Direct treatment at control of symptoms.

Continued on Next Page

Section 5. Fire-Fighting Measures

Extinguishing Media and Instructions	Follow your company's procedures. Use an extinguishing agent suitable for the surrounding class of fire.
Special Exposure Hazards	In certain Fire conditions, traces of other toxic gases may be emitted.
Special Fire Fighting Protective Equipment	Qualified persons wearing full fire-fighting suits and approved/certified self-contained breathing apparatus.

Section 6. Accidental Release Measures

Small Spill Guidelines	Put on appropriate personal protective equipment (see Section 8). Use a tool to scoop up and put into appropriate labeled waste container.
Large Spill Guidelines	Initiate company's spill response procedures immediately. Keep people out of area. Put on appropriate personal protective equipment (see Section 8).
Environmental Precautions	No special measures are typically indicated.

Section 7. Handling and Storage

Handling (ventilation and fire prevention)	Avoid contact with eyes, skin, and clothing. Avoid generating or breathing product aerosol. Wash after handling.
Storage (conditions and limitations)	Store tightly closed in original container. Keep containers in a well ventilated, secure location.

Section 8. Exposure Controls and Personal Protection - (normal and intended use)

Exposure Guidelines

Component	REG. Limit	OSHA (PEL)	ACGIH (TLV®)	Company Guideline
No hazardous ingredients				

Engineering Design and Control Measures	General ventilation is typically sufficient to keep airborne levels below established values. Provide eye wash and quick drench shower close to work station. Clean, appropriately launder, or dispose of all potentially contaminated work clothing, foot wear, and protective equipment after use.
Protective Clothing	
Eyes	Safety glasses, goggles or face shield where product aerosol or splash potential exists.
Skin	Lab coat.
Hands	Gloves, Chemical resistant.
Respiratory	Respirator selection must be based on anticipated exposure levels, product hazards, and the safe working limits of the selected respirator. A respirator is not needed under normal and intended conditions of product use.

Section 9. Physical and Chemical Properties

Physical State and Appearance	Solid. (Solid.)	Odor	Not available.
Molecular Weight	Mixture.	Color	Not available.
Boiling Point	Not applicable.	pH	Not available.
Melting/Freezing Point	Not available.		
Density/Bulk Density	Not available.		
Vapor Pressure	Not applicable.		

Continued on Next Page

Vapor Density	Not applicable.
Viscosity	Not applicable.
Partition Coefficient	Not applicable.
Solubility	Torbutrol Tablets: Soluble in cold water.
Flash Point	Not available.
Autoignition Point	Not available.
Explosion Limits	Not applicable.
Dust Explosivity	Not available.

Section 10. Stability and Reactivity

Conditions to Avoid and Incompatibility	This product is not expected to present any unusual stability or reactivity concerns for emergency response personnel.
Decomposition Products	These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...).

Section 11. Toxicological Information

Acute Effects

Component	Test	Result	Route	Species
1) Butorphanol Tartrate	LD50	315 mg/kg	oral	Rat
	LD50	395 mg/kg	oral	Mouse
	LD50	>50 mg/kg	oral	Dog

Eye Contact	Moderately irritating (USA). Irritating (EU).
Skin Contact	Moderatately irritating (USA). Irritating (EU).
Inhalation	Not available.
Ingestion	Toxic if swallowed.

Chronic Effects

Target Organs	Potential organ systems affected are: Central Nervous System (CNS).
Adverse Effects Statements	Adverse effects could include: Can cause dizziness, light headedness, headache, nausea, and blurred vision..
Sensitization	Not available.
Carcinogenic Effects	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH.
Mutagenic Effects	Not mutagenic in a standard battery of genetic toxicological tests.
Teratogenic Effects	Specific teratogenic effects noted in animal tests. No human evidence of teratogenic effects.
Reproductive Effects	No evidence of human reproductive effects.
Other Effects	Not available.

Continued on Next Page

Section 12. Ecological Information

Environmental Fate Not available.

Environmental Hazards No known significant effects or critical hazards.

Ecotoxicity

Component	Species	Period	Result
No hazardous ingredients			

Other Not available.

Section 13. Disposal Considerations

Waste Handling and Disposal Avoid disposal, make attempts to use product completely in accordance with intended use. Incinerate unwanted products and waste materials.

Note: The waste generator must be informed of and follow all applicable rules and regulations for the handling and disposal of waste.

Section 14. Transport Information

Proper Shipping Name, Primary Class, UNNA Number, Pakaging Group Not controlled.

ADR/RID Classification (Road and Rail Transport) Not controlled.

ADNR Classification (Inland Waterways) Not controlled.

IMO/IMDG Class (Maritime Transport) Not controlled.

ICAO/IATA (Air Transport) Not controlled.

CEFIC Tremcard Not available.

III Kemler Not available.

U.S.A. DOT Class Not controlled.

RQ Not applicable.

Packaging Intructions Not available.

Section 15. Regulatory Information and Warning Labels

(R) Risk Phrases R22- Harmful if ingested.

[Xi] Irritant.
[Xn] Hrmful if ingested.

(S) Safety Phrases S41- In case of fire and/or explosion do not breathe fumes.

Germany water endangerment: Torbutrol Tablets (FDAH), Class 3 (Self-Assigned)

NOTE: This product has been classified in accordance with applicable country-specific regulations.

Continued on Next Page

Section 16. Other Key Information

Other Considerations See product label and package insert for additional information.
Not available.

19 January 2002 **Responsible for MSDS:** Global Engineering, Environmental and Safety

Fort Dodge Animal Health -- within American Home Products Corporation

Notice to Reader

** This symbol indicates information which has changed from the previous MSDS.*

The information provided in this MSDS is based on current knowledge, however, this does not constitute a warranty by the Company for that information. The product user is responsible for the appropriate and intended handling, use, and disposal of this product in accordance with label or package precautions and this information. All materials may present unknown hazards and should be used with caution.

MSDSs available in multiple languages

MATERIAL SAFETY DATA SHEET

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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288
Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Butorphanol Tartrate Tablets

Trade Name: TORBUTROL
Chemical Family: Opioid analgesic
Intended Use: Veterinary product used as opioid analgesic

2. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: DANGER

Statement of Hazard:
May damage the unborn child.
May cause harm to breastfed babies.

Additional Hazard Information:
Short Term: Harmful if swallowed (based on animal data) .
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

EU Indication of danger: Toxic to Reproduction: Category 2

EU Hazard Symbols:

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

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Butorphanol tartrate	58786-99-5	261-443-5	Xn;R22 Repr.Cat.2;R61 R64	0.2-2.0

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Inert ingredients	NOT ASSIGNED	Not Listed	Not Listed	*

Additional Information: 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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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: 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). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Butorphanol tartrate

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of >1ug/m^3 to <10ug/m^3)

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	**Color:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical 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 active ingredient

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

Butorphanol tartrate
Rat Oral LD50 315 mg/kg

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

Butorphanol tartrate
Reproductive & Fertility Rat Oral 2.5 mg/kg/day NOAEL Fertility
Embryo / Fetal Development Rat Oral Dose not specified NOAEL Not Teratogenic
Reproductive & Fertility Rat Subcutaneous 1 mg/kg/day LOAEL Fetal mortality

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

Butorphanol tartrate
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
Unscheduled DNA Synthesis Human fibroblast cells Negative

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

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

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction: Category 2

EU Risk Phrases:

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:
DANGER
May damage the unborn child.
May cause harm to breastfed babies.

Canada - WHMIS: Classifications

WHMIS hazard class:
D1b toxic materials
D2a very toxic materials

Butorphanol tartrate
EU EINECS/ELINCS List 261-443-5

15. REGULATORY INFORMATION

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

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.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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

SAFETY DATA SHEET

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

Product Identifier

Material Name: Butorphanol Tartrate Tablets

Trade Name: TORBUTROL
Chemical Family: Opioid analgesic

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as opioid analgesic
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: VMIPSrecords@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Tablet

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B
Reproductive Toxicity: Effects on or via lactation

EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 2

EU Symbol: T
EU Risk Phrases:
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

Label Elements

Signal Word: Danger
Hazard Statements: H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P263 - Avoid contact during pregnancy/while nursing
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: May be harmful if swallowed.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Butorphanol tartrate	58786-99-5	261-443-5	Xn;R22 Repr.Cat.2;R61 R64	Acute Tox. 4 (H302) Repr. 1B (H360D) Lact. (H362)	1, 5 and 10 mg/tablet

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Inert ingredients	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. For one or more ingredients, the chemical identity has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe 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). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Butorphanol tartrate

Zoetis OEB OEB 4 (control exposure to the range of 1ug/m^3 to <10ug/m^3)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels within the OEB range. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious, disposable gloves (double suggested) 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 disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	**Color:**	No data available.
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: None
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: skin contact

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

Butorphanol tartrate
Rat Oral LD50 315 mg/kg

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

Butorphanol tartrate
Reproductive & Fertility Rat Oral 2.5 mg/kg/day NOAEL Fertility
Embryo / Fetal Development Rat Oral Dose not specified NOAEL Not Teratogenic
Reproductive & Fertility Rat Subcutaneous 1 mg/kg/day LOAEL Fetal mortality

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

11. TOXICOLOGICAL INFORMATION

Butorphanol tartrate
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
Unscheduled DNA Synthesis Human fibroblast cells Negative

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

Butorphanol tartrate
2 Year(s) Rat Oral 60 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Mouse 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.

Product Level Toxicity Data
Acute Toxicity Estimate (ATE), oral >3000 mg/kg

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Inert ingredients

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Butorphanol tartrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	261-443-5

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Toxic to Reproduction: Category 2
Xn - Harmful

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

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this 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