

## **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

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Butorphanol Tartrate Tablets</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Torbutrol® * Torbutrol Tablets
<b>Recommended use</b>	Veterinary product used as opioid analgesic
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (US)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (EU)</b>	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	VMIPSrecords@zoetis.com

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Reproductive toxicity	Category 1B
	Reproductive toxicity	Effects on or via lactation
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	May damage fertility or the unborn child. May cause harm to breast-fed children.
<b>Precautionary statement</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	If exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Opioid analgesic.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Butorphanol Tartrate		58786-99-5	1, 5 or 10 mg***
Inert ingredients*		Mixture	

**Composition comments** \*\*\* per tablet/capsule/lozenge/suppository  
\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician or poison control center immediately.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
<b>Eye contact</b>	Do not rub eyes. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Continue rinsing. Get medical attention immediately.
<b>Ingestion</b>	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
<b>Most important symptoms/effects, acute and delayed</b>	opioid analgesic: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.
<b>Indication of immediate medical attention and special treatment needed</b>	opioid analgesic. Provide general supportive measures and treat symptomatically. Monitor respiratory, cardiac and central nervous system.
<b>General information</b>	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Ensure adequate ventilation. Remove sources of ignition.  Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.  Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.
<b>Conditions for safe storage, including any incompatibilities</b>	Store locked up. Keep tightly closed in a dry, cool and well-ventilated place. @ 15-30°C (59-86°F). Keep away from heat and sources of ignition. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Control banding approach</b>	Butorphanol tartrate - Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)
<b>Appropriate engineering controls</b>	Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate. Provide eyewash station.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves. Impervious gloves.
<b>Other</b>	Wear appropriate chemical resistant clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	Observe any medical surveillance requirements. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

<b>Appearance</b>	Tablet
<b>Physical state</b>	Solid.
<b>Form</b>	Solid.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.

Vapor density	Not available.
Relative density	Not available.
<b>Solubility(ies)</b>	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
<b>Other information</b>	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Sunlight. Keep away from heat, sparks and open flame.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known. May include products of carbon, nitrogen.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	No adverse effects due to inhalation are expected.
<b>Skin contact</b>	No adverse effects due to skin contact are expected.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.
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### Information on toxicological effects

<b>Acute toxicity</b>	Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May be harmful if swallowed.
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Product	Species	Test Results
Butorphanol Tartrate Tablets		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	> 3000 mg/kg (ATE)
<b>Components</b>		
<b>Species</b>		
<b>Test Results</b>		
Butorphanol Tartrate (CAS 58786-99-5)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	315 mg/kg
<b>Chronic</b>		
<b>Oral</b>		
NOAEL	Mouse	60 mg/kg/day, 2 years Not carcinogenic
	Rat	60 mg/kg/day, 2 years Not carcinogenic
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	

**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation.

**Respiratory or skin sensitization**

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Mutagenicity**  
Butorphanol Tartrate

Bacterial Mutagenicity (Ames)  
Result: Negative  
Species: Salmonella , E. coli

Unscheduled DNA Synthesis, (human fibroblast cells)  
Result: Negative  
Species: Human

**Carcinogenicity** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity** May cause harm to breastfed babies. May damage fertility or the unborn child.

**Developmental effects**  
Butorphanol Tartrate

Embryo / Fetal Development, Not Teratogenic (dose not specified)  
Result: NOAEL  
Species: Rat  
Organ: Oral

**Reproductivity**  
Butorphanol Tartrate

1 mg/kg/day Reproductive & Fertility, Fetal mortality  
Result: LOAEL  
Species: Rat  
Organ: Subcutaneous

2.5 mg/kg/day Reproductive & Fertility, Fertility  
Result: NOAEL  
Species: Rat  
Organ: Oral

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** None expected under normal and foreseeable conditions of use

**Further information** Caution - Pharmaceutical agent. opioid analgesic.

**12. Ecological information**

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

### 13. Disposal considerations

<b>Disposal instructions</b>	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	None known.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

### 15. Regulatory information

<b>US federal regulations</b>	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>SARA 304 Emergency release notification</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not regulated.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	Not listed.
<b>SARA 311/312 Hazardous chemical</b>	No
<b>SARA 313 (TRI reporting)</b>	Not regulated.
<b>Other federal regulations</b>	
<b>Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List</b>	Not regulated.
<b>Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)</b>	Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations** California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)  
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

**Issue date** 12-17-2013

**Revision date** 04-28-2017

**Version #** 03

**List of abbreviations** ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

**Disclaimer** 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. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information** This document has undergone significant changes and should be reviewed in its entirety.





# MATERIAL SAFETY DATA SHEET

Revision date: 29-Mar-2011

Version: 1.1

Page 1 of 6

## 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.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

# MATERIAL SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 29-Mar-2011

Page 2 of 6  
Version: 1.1

## 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.

## MATERIAL SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 29-Mar-2011

Page 3 of 6  
Version: 1.1

- 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  $>1\mu\text{g}/\text{m}^3$  to  $<10\mu\text{g}/\text{m}^3$ )

- 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.

# MATERIAL SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 29-Mar-2011

Page 4 of 6  
Version: 1.1

## 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)	<i>Salmonella</i> , <i>E. coli</i>	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.

## MATERIAL SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 29-Mar-2011

Page 5 of 6  
Version: 1.1

### 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

PZ01439

## MATERIAL SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 29-Mar-2011

Page 6 of 6  
Version: 1.1

### 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



Revision date: 27-May-2015

Version: 2.5

Page 1 of 8

## 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**  
**Contact E-Mail:** VMIPSrecords@zoetis.com

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

## 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

## SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 27-May-2015

Page 2 of 8  
Version: 2.5

**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:**  
**Long Term:**

### Known Clinical Effects:

May be harmful if swallowed.  
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. 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 overdose may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

**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	*



## SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 27-May-2015

Page 3 of 8  
Version: 2.5

**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 CO<sub>2</sub>, 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.

## SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 27-May-2015

Page 4 of 8  
Version: 2.5

**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<sup>3</sup> to <10ug/m<sup>3</sup>)

#### 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

<b>Physical State:</b>	Tablet	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

## SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 27-May-2015

Page 5 of 8  
Version: 2.5

### 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

#### Flammability:

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)

## SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 27-May-2015

Page 6 of 8  
Version: 2.5

### 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), >3000 mg/kg  
oral

### 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.

## SAFETY DATA SHEET

Material Name: Butorphanol Tartrate Tablets  
Revision date: 27-May-2015

Page 7 of 8  
Version: 2.5

### 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**

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

##### **Butorphanol tartrate**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	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.

PZ01439

## SAFETY DATA SHEET

**Material Name: Butorphanol Tartrate Tablets**  
**Revision date: 27-May-2015**

**Page 8 of 8**  
**Version: 2.5**

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**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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**End of Safety Data Sheet**