

SAFETY DATA SHEET



Revision date: 17-Dec-2013

Version: 2.0

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

Product Identifier

Material Name: Butorphanol Tartrate Injection

Trade Name: TORBUTROL; TORBUGESIC

Chemical Family: Opioid analgesic

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

Intended Use: Pharmaceutical active 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 Control 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: Solution

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B
Effects on or via lactation

EU Classification:

EU Indication of danger: Toxic to reproduction, Category 2

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

Label Elements

Signal Word: Warning

Hazard Statements: H360D - May damage the unborn child
H362 - May cause harm to breast-fed children

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Precautionary Statements:

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- 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: 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.

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	0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium citrate	68-04-2	200-675-3	Not Listed	Not Listed	*
Citric Acid	77-92-9	201-069-1	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Benzethonium chloride	121-54-0	204-479-9	Not Listed	Not Listed	*

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Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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 spill with absorbent material. 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.

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7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. 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

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium chloride

Latvia OEL - TWA 5 mg/m³

Lithuania OEL - TWA 5 mg/m³

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/m³ to <10ug/m³)

Exposure Controls

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: 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:	Solution	Color:	No data available.
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility: No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility: No data available
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: The information included in this section describes the potential hazards of the individual ingredients.

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

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Benzethonium chloride

Rat Oral LD50 368mg/kg
Rat Subcutaneous LD50 119mg/kg
Rat IV LD50 19mg/kg

Butorphanol tartrate

Rat Oral LD50 315 mg/kg

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11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Citric Acid

Eye Irritation Rabbit Irritant
Skin Irritation Rabbit Non-irritating

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Benzethonium chloride

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties of the formulation have not been thoroughly 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.
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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:

D2a very toxic materials

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.



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15. REGULATORY INFORMATION

Sodium citrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-675-3

Citric Acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Butorphanol tartrate

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

Benzethonium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-479-9

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

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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 MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

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 10 - Stability and Reactivity. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis 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