

SAFETY DATA SHEET



1. Identification

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

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, dermal	Category 3
	Serious eye damage/eye irritation	Category 2A
	Reproductive toxicity	Category 1B
	Reproductive toxicity	Effects on or via lactation
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Causes serious eye irritation. May damage fertility or the unborn child. May cause harm to breast-fed children.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. 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.

Response	If exposed or concerned: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	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.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Benzethonium chloride		121-54-0	<5*
Butorphanol Tartrate		58786-99-5	2 mg/ml, 10 mg/ml
Citric acid		77-92-9	<5*
Sodium chloride		7647-14-5	<5*
Water for injection		7732-18-5	

Composition comments *Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician or poison control center immediately.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.

Eye contact 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.

Ingestion 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.

Most important symptoms/effects, acute and delayed 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.

Indication of immediate medical attention and special treatment needed opioid analgesic. Provide general supportive measures and treat symptomatically. Monitor respiratory, cardiac and central nervous system.

General information 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

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. 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. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions

7. Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in a well-ventilated place. @ 20 - 25C / 68 - 77F. Protect from sunlight. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Control banding approach

Butorphanol tartrate - Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Wear appropriate chemical resistant gloves. Impervious gloves.

Other

Wear appropriate chemical resistant clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection

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.

Thermal hazards

Not applicable.

General hygiene considerations

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

Appearance

Solution

Physical state

Liquid.

Form

Liquid.

Color	Clear, colorless
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known. May include products of carbon. nitrogen. May include hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.	
Skin contact	Causes mild skin irritation.	
Benzethonium chloride	Species: Rabbit	Severity: Mild
Citric acid	Species: Rabbit	Severity: Mild
Sodium chloride	Species: Rabbit	Severity: Mild
Eye contact	Causes serious eye irritation.	

Eye contact

Sodium chloride

Species: Rabbit
Severity: Moderate

Benzethonium chloride

Species: Rabbit
Severity: Severe

Citric acid

Species: Rabbit
Severity: Severe**Ingestion**

Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics

Mild skin irritation. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. 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.

Information on toxicological effects**Acute toxicity**

Product	Species	Test Results
Butorphanol Tartrate Injection		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg (Calculated ATE)
Components		
Species		
Test Results		
Benzethonium chloride (CAS 121-54-0)		
Acute		
Intravenous		
LD50	Rat	19 mg/kg
Oral		
LD50	Rat	368 mg/kg
Subcutaneous		
LD50	Rat	119 mg/kg
Butorphanol Tartrate (CAS 58786-99-5)		
Acute		
Oral		
LD50	Rat	315 mg/kg
Chronic		
Oral		
NOAEL	Mouse	60 mg/kg/day, 2 years Not carcinogenic
	Rat	60 mg/kg/day, 2 years Not carcinogenic
Citric acid (CAS 77-92-9)		
Acute		
Oral		
LD50	Mouse	5040 mg/kg
	Rat	3000 mg/kg
Sodium chloride (CAS 7647-14-5)		
Acute		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg

Skin corrosion/irritation
Serious eye damage/eye irritation

Prolonged skin contact may cause temporary irritation.

Causes serious eye irritation.

Eye Contact

Sodium chloride

Species: Rabbit
Severity: Moderate

Benzethonium chloride

Species: Rabbit
Severity: Severe

Citric acid

Species: Rabbit
Severity: Severe**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. coliUnscheduled 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 available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

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: Subcutaneous2.5 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** Prolonged inhalation may be harmful.**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.

Components	Species	Test Results
Benzethonium chloride (CAS 121-54-0)		
Aquatic		
Fish	LC50	Bluegill (<i>Lepomis macrochirus</i>) 1.4 mg/l, 96 hours
Sodium chloride (CAS 7647-14-5)		
Aquatic		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) 340.7 - 469.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>) 6020 - 7070 mg/l, 96 hours
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

Disposal instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	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).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations 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

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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)	Yes
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	Yes
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 10-30-2016
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.